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The Expansion of Corporate Compliance: Guidance for Health Care Entities

Katheryn Ehler-Lejcher

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THE EXPANSION OF CORPORATE COMPLIANCE:
GUIDANCE FOR HEALTH CARE ENTITIES

Katheryn Ehler-Lejcher†

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I. INTRODUCTION

The health care fraud investigation of Columbia/HCA captured the attention of the media and the public.1 The attention given to health care fraud is not likely to subside; the press, politicians, and the public continue to keep it in the limelight.2 The government is aggressive in its regulation and investigation of health care fraud and abuse. It collects enormous fines for improper billing and other operational irregularities under the Medicare and Medicaid programs.3

1. See, e.g., CFO of Columbia/HCA Healthcare Resigns as Fraud Probe Continues, STAR TRIB. (Minneapolis-St. Paul), Aug. 9, 1997, at 3D.
3. Currently, the Department of Health and Human Services, Office of In-
Health care is a heavily regulated industry. The regulations governing the provision of health care are extremely complex. As a result, the health care industry often finds itself baffled in a quagmire of ambiguous legislation. In March of 1997, the federal government published corporate compliance program guidelines for clinical laboratories. This resulted in confusion about to what extent the clinical laboratory guidelines applied to other health care entities like hospitals. Other health care entities were unsure how to structure their corporate compliance programs. The Office of the Inspector General of the Department of Health and Human Services ("DHHS-OIG" or "OIG") tried to alleviate the confusion by publishing corporate compliance guidelines that applied to hospitals. The government structured these compliance program guidelines similar to those for clinical laboratories and the United States Sentencing Commission Guidelines.

Since health care fraud and abuse is a high priority for the federal government, health care corporations are taking a proactive approach by choosing to voluntarily implement a corporate compliance program before the federal government mandates one via a corporate integrity agreement. Even if a health care entity already has a compliance program, it should review the OIG model program to learn how the federal government determines the effectiveness of a compliance program.

Part II of this article provides information concerning recent actions taken by the government. Part III sets forth the legal issues involved in structuring a corporate compliance program. Part IV discusses the advantages and disadvantages of a compliance pro-

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4. See id.
8. See infra Part II and accompanying notes.
9. See infra Part III and accompanying notes.
Part V establishes the elements of a compliance program as promulgated by the DHHS-OIG. Finally, Part VI addresses the development and implementation of a corporate compliance program.

II. FEDERAL GOVERNMENT ACTION

In 1994, U.S. Attorney General Janet Reno proclaimed the investigation of health care fraud and abuse the number two priority of the Department of Justice. The government has been quite successful in its battle against health care fraud and abuse.

A. The Department of Justice

The Department of Justice ("DOJ") recouped $180 million in 1993 and $411 million through civil litigation in health care fraud cases in 1994. In 1994, the Federal Bureau of Investigation spent $37 million on health care fraud and abuse investigations, and collected more than $500 million in fines and assessments. In 1996, of the 333 qui tam suits brought under the False Claims Act, over one-half the suits alleged health care fraud.

The government recently increased its efforts. In 1997, the primary goal of the DOJ was to significantly increase the number of both civil and criminal prosecutors in charge of health care fraud cases. According to Debra Cohn, special counsel for health care to the deputy attorney general, the DOJ will place more health care fraud investigators in U.S. Attorneys' offices across the country.

10. See infra Part IV and accompanying notes.
11. See infra Part V and accompanying notes.
12. See infra Part VI and accompanying notes.
16. A qui tam action is an action brought by an informer under a statute which provides for a civil penalty for the commission or omission of a certain act, with part of the penalty going to the person who brought the suit and the remainder going to the state. See BLACK'S LAW DICTIONARY 867 (6th ed. 1991).
19. See id. at 9-10.
The DOJ will also make sure that there are comparable numbers of prosecutors available to follow through with each prosecution.20

In addition, the DOJ plans to have a "health care coordinator" in every U.S. Attorney's Office, as well as a "health care fraud working group" in each part of the country to process allegations of fraud and abuse with representatives from DOJ, Health and Human Services, the Federal Bureau of Investigation and other federal and state anti-fraud entities.21

B. The Department of Health & Human Services – Office of the Inspector General

DHHS-OIG has a similar goal. Its goal is to extend its investigative and audit staffs to cover all geographical areas in the country.22 In 1998, DHHS-OIG increased its staff levels from 1,126 to 1,258.23 DHHS/OIG also opened five new investigative offices.24 These actions increase the office's ability to conduct rapid national evaluations that provide policymakers with information, analysis and recommendations for improving DHHS programs.25

C. The Health Care Fraud & Abuse Control Program

The federal government combats health care fraud and abuse via the Health Care Fraud and Abuse Control Program. According to the 1998 Annual Report by the Health Care Fraud and Abuse Control Program,26 the federal government won or negotiated more than $480 million in judgements, settlements, and administrative impositions in health care fraud cases and proceedings.27 The federal government also collected $296 million from health care fraud and abuse cases.28

In 1998, the United State Attorneys' Offices ("USAOs") filed

20. See id. at 10.
21. See id.
23. See id.
24. See id.
25. See id.
27. See id. at 7.
28. See id. Of this amount, $271 million was returned to the Medicare Trust Fund, and $9 million was the federal share of Medicaid restitution. See id.
322 criminal health care fraud cases. This is a fourteen percent increase from 1997. There were 219 criminal health care fraud-related convictions, involving 326 defendants in 1998.

Civil enforcement action included the filing of 107 civil cases in 1998. This is an increase of twenty percent over 1997. By the end of 1998, 3,471 civil matters were still pending.

The number of individuals and entities excluded from the Medicare, Medicaid or other federally sponsored health care programs increased in 1998. In 1998, 3,021 individuals and entities were excluded. This represents an increase of eleven percent from the 2,700 exclusions in 1997. Many were excluded as a result of criminal convictions for program-related crimes and criminal convictions for patient abuse or neglect. Others were excluded based on licensure revocations or other professional misconduct.

III. LEGAL ISSUES AFFECTING A CORPORATE COMPLIANCE PROGRAM

It is important to understand that often health care fraud and abuse is not an intentional act by the health care entity. Some entities do not have sufficient infrastructure to determine if the organization is in compliance with the laws. As a result, employees may inadvertently make mistakes that could cost the health care entity millions. It has been estimated that losses resulting from fraud and abuse constitute ten percent of the total cost of health care.

Previously, instances of mispayment under the federal programs were resolved by negotiations with the Health Care Financing Agency ("HCFA") because of a mutual understanding that billing requirements and criteria were subject to various

29. See id. at 20.
30. See id.
31. See id.
32. See id. at 21.
33. See id.
34. See id. at 20.
35. See id. at 10.
36. See id.
37. See id. There were 584 excluded for program-related crimes and 302 excluded based on criminal conviction for patient abuse or neglect. See id.
38. See id. There were 1,251 excluded for licensure revocation or other professional misconduct. See id.
39. See JANET L. SHIKLES, GAO, HEALTH INSURANCE: LEGAL AND RESOURCE CONSTRAINTS COMPROMISE EFFORTS TO CURB FRAUD AND ABUSE 10 (1993). The cost of health care is approximately $800 billion a year. See id.
interpretations. However, the Office of the Inspector General and U.S. Attorney’s Offices now view this issue in more of a prosecutorial light. Fraud and abuse may result in prosecution under federal laws such as the False Claims Act, Anti-kickback Statute, Stark I and Stark II Laws, Racketeer Influenced and Corrupt Organizations Act (“RICO”), wire fraud and mail fraud laws, federal antitrust laws and other federal, state, and local laws.

Health care fraud and abuse involve activities such as improper billing, kickbacks for patient referrals, financial incentives and financial arrangements. A majority of the fraud and abuse activity occurs within the Medicare and Medicaid programs. Health care entities may be reimbursed for services that are covered by these programs. If a health care entity submits an improper claim for payment under either program, then the Anti-kickback Statute, Stark Law, and the False Claims Act may have been violated. Violations can result in substantial penalties. Penalties may be in the form of civil monetary penalties, criminal monetary penalties, or even exclusion from the Medicare and Medicaid programs.

A health care entity should consider federal, state, and local law when structuring a corporate compliance program. A compliance program should detect fraud and abuse and implement corrective action that demonstrates a good faith attempt to comply with the law.

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40. See Karen S. Boxer & Helaine Gregory, Compliance is Good for Your Corporate Health, 943 PLI/CORP. 353, 359 (1996).
41. See id.
42. See id.
43. See discussion infra Part III.B.
44. See Health Care Fraud Annual Report, supra note 22, at 14. The annual audit report of HCFA’s financial statement estimated that improper Medicare fee-for-service payment in 1997 were $20 billion, or about 11% of the total $177.4 billion in fee-for-service payments. See id. Many improper payments were the result of insufficient or no medical documentation of services, lack of medical necessity, improper coding, and unallowable services. See id. The audit did not conclude what payments were attributable to fraud. See id. See generally GAO Official Says Program Fraud Could be as High as $20 Billion, 3 Health Care Daily (BNA), at 2, Mar. 5, 1997 (stating that fraud and waste for the Medicare program ranges from $6 billion to $20 billion per year).
A. The Anti-kickback Statute

1. The Law

The Anti-kickback law prohibits referrals by a provider of a federally financed health care service that are made for personal economic benefit.46 The Anti-kickback Statute prohibits an individual from “knowingly and willfully solicit[ing] or receiv[ing] any remuneration . . . directly or indirectly, overtly or covertly, in cash or in kind . . . in return for referring [or inducing to refer] an individual” for services payable under the Medicare or Medicaid programs.47 The DHHS-OIG has interpreted a referral to include any action taken by physicians, hospitals, and other health care providers to influence a patient’s decision in the use of health care services.48 Remuneration has been broadly defined to include anything of value. The statute also prohibits remuneration in “return for purchasing, leasing, ordering, or arranging for or recommending [or inducing the same] [of] any good, facility, service, or item for which payment may be made . . .” under these programs.49

The Anti-kickback Statute requires an intentional act by establishing that payments be made “knowingly and willfully.”50 Courts apply the “primary purpose” or the stricter “one purpose” test to determine whether a payment violates the Anti-kickback Statute. If either the primary purpose or one purpose of the payment is to induce a prohibited referral, then the entire payment is deemed illegal.51 Furthermore, if a payment exceeds fair market value, then the government may presume that the payment was to induce a re-

46. See id.
47. Id. §§ 1320a-7b(b) (1)(A), (2)(A).
49. 42 U.S.C. §§ 1320a-7b(b) (1)(B), (2)(B) (Supp. III 1997).
50. See id. §§ 1320a-7b(b)(1)(A), (2)(A); see also Eiland, supra note 48, at 14-15.
51. See, e.g., United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20, 29-30 (1st Cir. 1989) (noting that a jury instruction employing “primary purpose” standard at a minimum was consistent with congressional intent); United States v. Greber, 760 F.2d 68, 71-72 (3d Cir. 1985) (adopting “one purpose” test and explaining it is consistent with the intent of the legislation). The primary purpose or one purpose test does not consider whether another legitimate service was rendered. See Greber, 760 F.2d at 72.
2. Exemptions Under the Anti-kickback Statute

There are exceptions to the Anti-kickback Statute. Excepted activities include:

- Disclosed and reflected discounts;
- Payments to employees;
- Payments to purchasing agents in certain group purchasing arrangements;
- Waiver of Part B coinsurance for patients qualifying for subsidized services;
- Safe harbors created by regulation; and
- New exceptions for risk-sharing organizations.

Congress developed these exceptions and requires the Secretary of Health and Human Services to issue safe harbors. According to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Secretary must now establish a procedure to annually solicit recommendations, publish proposals to modify existing and add new safe harbors under the Anti-kickback Statute.

52. See Eiland, supra note 48, at 15.
54. See id. § 1320a-7b(b)(3)(B).
55. See id. § 1320a-7b(b)(3)(C).
56. See id. § 1320a-7b(b)(3)(D).
57. See id. § 1320a-7b(b)(3)(E).
58. See id. § 1320a-7b(b)(3)(F).
60. See 42 U.S.C. § 1320a-7d (Supp. III 1997). On July 29, 1991, the OIG issued safe harbors for activities that would not be subject to the Anti-kickback Statute. These safe harbors include the following activities:

- investment interests;
- space rental;
- equipment rental;
- personal services and management contracts;
- sale of a practice;
- referral services;
- warranties;
- discounts;
- payments to employees;
- group purchasing organizations;
- price reductions offered to health plans;
3. **Penalties for Violation of the Anti-kickback Statute**

There are severe penalties for violation of the Anti-kickback Statute. Civil monetary penalties are imposed against a health care entity that submits a false claim to the government under either the Medicare or Medicaid program.\(^{61}\) Violation of the statute is a felony punishable by not more than five years in prison and/or a fine

- waiver of beneficiary coinsurance/deductible; and
- increased coverage, reduced cost sharing amounts, or reduced premium amounts offered by health plans.

42 C.F.R. § 1001.952(a)-(m) (1994).

Recently, the OIG issued the widely anticipated eight new safe harbors to the Federal Anti-kickback Statute. These new safe harbors include:

- investments in underserved areas;
- practitioner recruitment in underserved areas
- obstetrical malpractice insurance subsidies for underserved areas;
- sales of physician practices to hospitals in underserved areas;
- investments in ambulatory surgical centers;
- investment in group practices;
- referral arrangements for specialty services; and
- cooperative hospital service organizations.

64 Fed. Reg. 63,518 (Nov. 19, 1999). In addition to establishing these eight new safe harbors, the final rule also clarifies six of the original eleven safe harbors published in 1991, and two new interim final safe harbors implementing the statutory exception to the Anti-kickback Statute for risk arrangements. See id. This makes a total of twenty-three regulatory safe harbors.

The two risk-sharing exceptions, which implement the shared risk exception created by HIPPA, address:

- price reductions offered to eligible managed care organizations; and
- price reductions offered by contractors with substantial financial risk to managed care organizations.

See 64 Fed. Reg. 63,518 (Nov. 19, 1999); HIPAA § 216 (to be codified at 42 U.S.C. § 1320a-7b(b)(3)(F)). An arrangement for items or services between a Medicare HMO or Competitive Medical Plan and an individual or entity does not result in an illegal remuneration if the arrangement is pursuant to a written agreement. See Colleen M. Faddick, *Health Care Fraud and Abuse: New Weapons, New Penalties, and New Fears for Providers Created by the Health Insurance Portability and Accountability Act of 1996 (HIPAA)*, 6 ANNALS HEALTH L. 77, 84 (1997) (citing Peter A. Pavarini, *Physician Networks & Other Organization Models for Managed Care Contracting*, in NATIONAL HEALTH LAWYERS ASS'N, ALIGNING THE NEW HEALTH CARE SYSTEM (Mar. 13-15, 1997)). Arrangement for items or services, if in writing, that the individual or entity is obligated to provide are not considered illegal remuneration under the Anti-kickback Statute. See id.

of $50,000 per act plus three times the remuneration offered.\footnote{62} The government can exclude the health care entity from participation in the Medicare and/or Medicaid programs.\footnote{63} Under the Balanced Budget Act of 1997, the government issued new program exclusion provisions. One provision is the “Three Strikes and You’re Out” provision.\footnote{64} This provides mandatory lifetime program exclusion for any provider convicted of defrauding the Medicare/Medicaid program on two or more occasions.\footnote{65} The second provision is called the “One Strike and You’re Out” provision.\footnote{66} This establishes a ten year program exclusion for any provider convicted of defrauding the Medicare/Medicaid program.\footnote{67}

In addition, under the Balanced Budget Act of 1997,\footnote{68} the Secretary of Health and Human Services is authorized to refuse to enter into, renew, or terminate an agreement with a health care provider convicted of a felony under federal or state law. The provider must be convicted of an offense which the Secretary determines is “detrimental to the best interests of the program or program beneficiaries.”\footnote{69} Furthermore, civil penalties of $50,000 per act are imposed against individuals who contract with an excluded provider.\footnote{70}

\textbf{B. The Stark Law}

The Stark Law evolved through the passage and amendment of several legislative bills introduced by U.S. Representative Fortney “Pete” Stark (R-Cal.).\footnote{71} The initial Stark law was introduced under the title of Ethics in Patient Referrals Act (“Stark I”).\footnote{72} It was ini-

\footnote{62. See Eiland, supra note 48, at 3 (discussing the new civil monetary penalties for violations of the Anti-kickback law passed under the Balanced Budget Act of 1997). These penalties are effective for arrangements entered into after August 5, 1997. See id.}

\footnote{63. See 42 U.S.C. § 1320a-7a(a)(7) (Supp. III 1997).

64. See Eiland, supra note 48, at 2.


\footnote{66. See Eiland, supra note 48, at 2.

67. See 42 U.S.C. § 1320a-7a(a) (1994 & Supp. III 1997). This is applicable to convictions occurring on or after August 5, 1997. See id.


70. See id. (discussing the Balanced Budget Act of 1997). This penalty is also effective for contracts entered on or after August 5, 1997. See id.


72. See Theodore N. McDowell, Jr., \textit{Physician Self Referral Arrangements: Legiti-
tionally passed as part of the Omnibus Budget Reconciliation Act of 1989 ("OBRA") and became effective January 1, 1992. The statute prohibits physicians from referring Medicare patients to a clinical laboratory in which that physician or a member of that physician's immediate family has a financial relationship. Stark I further provides that an entity that has a financial relationship with a physician may not submit or cause to be submitted, a claim for reimbursement for services provided pursuant to a prohibited referral, unless there is an exception.

In 1993, the Omnibus Budget Reconciliation Act expanded Stark law. This became known as Stark II. The subsequent law expanded the referral prohibition of Stark I to include other designated health services. It also broadened the self-referral prohibition to include the Medicaid program. Stark II became effective on January 1, 1995.

Recently, HCFA proposed rules to enforce Stark II. As of the date of this article, the proposed rules have not been adopted. When adopted, these regulations will greatly impact the enforcement of the Stark II. These proposed rules should be considered when implementing a compliance program and will be discussed below.


75. See id. § 1395nn(a)(1)(A).
76. See id.
78. See Wachler & Avery, supra note 77, at 1274.
79. See 42 U.S.C. § 1395nn(h)(6)(A)-(K) (1994). Designated health services are defined in the statute as: clinical laboratory services; occupational therapy services; radiation therapy services; parenteral and enteral nutrients, equipment, and suppliers; prosthetics, orthotics and prosthetic devices; physician therapy services; radiology services; durable medical equipment; outpatient prescription drugs; home health care services; and inpatient/outpatient hospital services. See id.
81. See id.
82. See 63 Fed. Reg. 1659 (1998) (to be codified at 42 C.F.R. pts. 411, 424, 435, 455) (proposed Jan. 9, 1998). Due to the complexity of the proposed rule and the numerous requests for more time to analyze potential ramifications of rule, the comment time for the proposed Stark II regulations was extended to May 11, 1998. See id. at 1649.
83. This article will discuss the effects the proposed rules would have on the enforcement of the Stark II if adopted in their current form.
1. The Elements of the Stark Law

To establish a Stark violation, the following elements must be present: (1) a "financial relationship" between a health care entity and physician; (2) a "referral" by the physician to the entity for "designated health services" and the submission of a claim for the services; and 3) the absence of an exception. Unlike the Anti-kickback Statute, Stark law does not require an intentional act for a violation to occur.

a. A Financial Relationship

A financial relationship between a health care entity and a physician can be in the form of an ownership interest, investment interest, or a compensation arrangement with the health care entity. An ownership or investment interest may be through equity, debt, or other means. It also includes an interest in an entity that holds an ownership or investment interest in another health care entity.

84. The proposed rules may affect several definitions under Stark. The proposed regulations define the designated health services added by Stark II. See 63 Fed. Reg. at 1673. First, when the definition of a designated health service differs under a state Medicaid plan from the definition under Medicare, HCFA will assume the services under the state plan govern even if the definition includes services that are not covered by Medicare. See id. at 1673. Second, the proposed rules exclude invasive radiology from the designated health service of "radiology services." See id. at 1676. The rationale is that such services are incidental, secondary or "merely peripheral" to another procedure, so that abuse via overutilization is unlikely. See id. Third, the proposed rules consider the exclusion of surgically implanted devices from the definition of prosthetic devices. See id. at 1678-79. HCFA is concerned about situations in which a physician has a financial interest with a device manufacturer. See id. at 1678. The physician may choose a device based on financial reasons rather than considering what is best for the patient. See id. at 1679. Such a physician may be in a position to manipulate the hospital's choice of prosthetic device. See id. While this may not result in an overutilization of services, it may increase costs of services that are not subject to a fee schedule. See id. Finally, the proposed rules define inpatient and outpatient hospital services. See id. at 1681-84. HCFA borrowed the definition for inpatient hospital services from Medicare Part A. See id. at 1681. However, HCFA includes lithotripsy under this definition. See id. at 1682. Although there is little risk of overutilization, abuse may occur if a physician uses certain equipment because of a financial incentive rather than considering what is best for the patient. See id. The definition of outpatient services includes services furnished by a psychiatric hospital and a rural primary care hospital covered under Medicare Part B. See id. at 1683. The proposed definition includes outpatient hospital services incident to physician services, diagnostic outpatient hospital services, and partial hospitalization services. See id. at 1683-84.


entity that provides a designated health service.87

The regulations proposed by HCFA redefine the phrase “financial relationship.”88 Under the proposed rules, stock options and nonvested interests constitute an ownership interest.89 Thus, if stock options are given as part of compensation, then an illegal ownership interest and a compensation arrangement is created unless a Stark law exception applies.90

The proposed rules seek to establish two situations in which an ownership interest is created via debt. First, the rules assert that an ownership interest is created when the physician91 loans money or other valuable consideration to a health care entity and the debt is secured by the property or assets of the entity.92 Second, the rules propose an ownership interest in a creditor-debtor relationship that has an indicia of ownership. An example of this is when the creditor participates in revenue, profits, or ownership of bonds that can be converted into the common stock of the issuer.93

Finally, the proposed regulations establish that a financial relationship exists through an indirect ownership or investment interest, regardless of how many times it is removed from the direct interest.84 This proposed rule requires a health care entity to identify financial relationships with physicians and their immediate family members all the way down the chain of ownership and investment.95 If this regulation is adopted, it will create an enormous burden for large managed care companies.96

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87. See id.
89. See id. at 1708.
90. See id.
91. See id. This includes the immediate family member of the physician as well. See id. at 1686, 1708. The proposed rules provide that loans to physicians or their family members from the entity do not create an ownership interest, but do create a compensation arrangement. See id. at 1707.
92. See id. at 1707.
93. See id.
94. See id. at 1686.
95. See id. at 1703. The definition of an immediate family member includes in-laws and the spouses of grandchildren. See id. at 1672.
96. See id. at 1703. “A number of entities have pointed out to us that the amounts of data they are required to report under the statute will, in some circumstances, be overwhelming.” Id.
b. Compensation Arrangements

A compensation arrangement is defined under Stark II as any arrangement involving remuneration, direct or indirect, between a physician and the health care entity. It includes any payment, discount, forgiveness of debt or other benefit made directly or indirectly, overtly or covertly, in cash or in kind. The proposed rules do not change this definition, but recognize that payments resulting from an ownership or investment interest are not compensation. For example, dividends or other returns on an investment would not be considered compensation.

c. Referrals

The proposed rules try to clarify what constitutes a referral. Stark I broadly defined a referral as "the request by a physician for any item or service for which payment may be made under Medicare Part B . . ." The proposed regulation narrows this by limiting a referral to instances in which a physician requests, orders, certifies, or recertifies the need for, or establishes a plan of care that includes, designated health services covered by Medicare Part A or Part B. The proposed rules recognize that a consultation occurs when a physician requests that the patient see a specialist, but still maintains control over the care of the patient. A consultation does not occur when the specialist takes over the care of the patient.

The preamble to the proposed rules sets forth that creating a plan of care that results in a patient receiving a designated health service from a health care entity with which a physician has a permissible financial relationship. This is true as long as the physi-
cian does not control or influence the decision to refer the patient.\textsuperscript{103} If it is unclear who referred a patient and the patient’s physician has a financial relationship with the entity that provided the designated health care services, then HCFA will presume that the physician made an illegal referral and may impose sanctions.\textsuperscript{104}

2. \textit{Exceptions to the Stark Law}

The Stark law has a number of exceptions. These exceptions may be organized into three broad categories: (1) exceptions applicable to both ownership interests and compensation arrangements; (2) exceptions applicable to ownership interests; and (3) exceptions applicable to compensation arrangements.

\begin{itemize}
\item \textit{a. Exceptions to Both Ownership Interests and Compensation Arrangements}
\item \textit{i. The Physician Services Exception}

Three exceptions apply to both ownership interests and compensation arrangements. The first exception pertains to physician services. This exception permits physician services\textsuperscript{105} and some designated health services to be performed or directly supervised by the physician who is not making the referral if the referring physician is a member of the same group practice.\textsuperscript{106}

\item \textit{ii. The In-house Ancillary Service Exception}

Another exception pertains to in-house ancillary services. This exception permits a referral when services are:

\begin{enumerate}
\item provided personally by the referring physician, a member of his or her group practice, or an individual who is directly supervised\textsuperscript{107} by either the referring physician or
\end{enumerate}

\begin{flushright}
\textsuperscript{103} \textit{See id. at 1711.}
\textsuperscript{104} \textit{See id.} This presumption may be rebutted with contrary evidence presented by the physician. \textit{See id.}
\textsuperscript{105} The proposed regulations make clear that this exception does not include “incident to” services. \textit{See id.} at 1695. Under this exception, personal supervision is interpreted to mean that the supervising physician is legally responsible for monitoring the results of the designated health service and is accessible to assist the non-member physician. \textit{See id.}
\textsuperscript{106} \textit{See 42 U.S.C. \S 1395nn(b)(1) (1994).}
\textsuperscript{107} \textit{See 63 Fed. Reg. 1659, 1684 (to be codified at 42 C.F.R. pts. 411, 424, 435, 1999).}
\end{flushright}
a member of the group practice;
(2) furnished in the building in which the referring physician or group practice furnishes physicians' services that are unrelated to the providing of designated health services; and
(3) billed by the physician performing or supervising the services, the group practice of which the physician is a member, or an entity that is wholly owned by such physician or such group practice.

iii. Effect of the Proposed Rules on the Physician Services and In-house Ancillary Services Exceptions

Both the physician services and in-office ancillary services exceptions permit referrals among members of the same group practice. The proposed regulations impact the group practice aspect of these exceptions.

(a) Definition of Group Practice

Currently, the law defines a group practice as a practice consisting of two or more physicians who have formed a partnership, separate professional corporation, foundation, not-for-profit cor-

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455) (proposed Jan. 9, 1998). The proposed regulations interpret direct supervision as including "brief unexpected absences as well as . . . routine absences of a short duration (such as during a lunch break), provided the absences occur during time periods in which the physician is otherwise scheduled and ordinarily expected to be present . . . ." Id.

108. See id. at 1695. The proposed regulations clarify this requirement by stating that "the same building" is a single physical structure but does not include a mobile x-ray unit parked in the building's garage. Id. In addition, the same location test may be fulfilled by group practice providing services in a building used for the "centralized provision" of the group's designated health services. See id. at 1696. This standard is met if it "services more than one of a group's offices and if it furnishes one or any combination of designated health services." Id. Therefore, a group practice may have several "centralized" locations, but the direct supervision test must be satisfied at each location. See id.

109. See 42 U.S.C. § 1395nn(b)(2) (1994). This exception does not apply to durable medical equipment (excluding infusion pumps) or parenteral and enteral nutrients, equipment, and supplies. See id. Alternatively, the group may furnish the services in a building that is used to provide either some or all of the group's clinical laboratory services. See id. The proposed rules also allow group practices to bill under any assigned number to the group. See 63 Fed. Reg. 1659, 1696 (to be codified at 42 C.F.R. pts. 411, 424, 435, 455) (proposed Jan. 9, 1998).

poration, faculty practice plan, or similar association. Stark I did not acknowledge a practice as a group practice if it was comprised of two or more separate legal entities.

The proposed rules also require that a group practice be one legal entity. However, the proposed rules interpret “one legal entity” to include owners who are individual professional corporations or owned by physicians who are individually incorporated. Thus, a physician who is a sole member or shareholder of his or her own entity may contract with the group practice without affecting the group’s status as one legal entity. These physicians also qualify as members of the group and may supervise services for the group practice.

(b) Independent Contractor Physicians and the “75% Requirement”

Under Stark I, independent contractor physicians were considered members of a group practice. As a result, many group practices employed independent contractor physicians to perform and/or supervise designated health services. The rules proposed by the HCFA, however, modify the definition of group practice to exclude independent contractor physicians. An independent contractor would not be permitted to directly supervise or render a designated health service under this proposed definition.

The proposed rule will make it easier for group practices with part-time contractors to fulfill the “75% requirement.” The 75% requirement mandates that substantially all (interpreted by the proposed rules to mean at least seventy-five percent) of the patient care services of group member physicians are furnished and

112. See id.
113. See id.
114. See id.
115. See id.
116. See id. The proposed regulations redefine “members of a group” as physician partners, other physician owners (including individual professional corporations), and full-time and part-time physician employees. Id. at 1689. These physicians are members of the group while furnishing patient care services. See id.
117. See id. at 1687.
118. See id. at 1689-90.
119. See id. at 1689.
120. See id.
121. See id. at 1688.
billed through the group. Patient care services are measured by the total patient care time each group member spends on these services. Thus, if a physician works forty hours per week and thirty hours are attributable to patient care services, the physician has spent 75% of his or her time rendering countable patient care services.

Stark I defined patient care services as tasks performed by a group practice member that pertain to the medical need of specific patients. The proposed rules expand this definition by adding "tasks that generally benefit a particular practice." This would include things like staff training, arranging for equipment, and administrative or managerial tasks. HCFA is recognizing the fact that a physician functions as a group member by providing administrative service.

The 75% requirement is key to enforcement of the Stark law. This standard requires a group practice to annually file an attestation which demonstrates that the group fulfilled the 75% requirement during the most recent twelve month period. If a group practice fails to satisfy this requirement, Medicare payments may be considered overpayments. The proposed regulations expand this provision by requiring that the attestation be signed by a knowledgeable group representative. This notifies representatives that false statements submitted to the Medicare program will be subject to criminal and civil sanctions.

iv. The Prepaid Health Plan Exception

The final exception applicable to both ownership interests and compensation arrangements applies when designated health services are provided by certain prepaid health plans to enrolled individuals. This exception is limited because it applies only to health

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122. See id. at 1687-88.
123. See id. at 1688-89.
124. See id. at 1687-88.
125. Id.
126. See id. This provision also requires that 75% of the patient care services be billed under a billing number given to the group. See id. at 1689. The proposed regulations interpret this to allow a group or a wholly-owned subsidiary of the group to possess more than one billing number. See id. at 1689, 1696.
127. See id. at 1670.
128. See id. at 1671.
129. See id.
130. See id.
services provided by specific prepaid plans.\textsuperscript{131} The proposed rules retain this exception, but interpret it to include services furnished by the organizations and services furnished to the organization's enrollees by contracted physicians, providers, or suppliers.\textsuperscript{132} The extension to outside contractors is helpful because most prepaid health plans do not actually furnish services, but do contract for services with outside personnel.\textsuperscript{133}

\textit{b. Ownership Interests Exceptions}

There are five ownership interest exceptions under Stark law. The first exception states that this law does not apply to ownership of investment securities that:

1. May be purchased on terms generally available to the public;\textsuperscript{134}
2. Are publicly traded; and
3. Were issued by a corporation which had a minimum of $75 million in shareholder equity (or for securities purchased before January 1, 1995, with assets exceeding $100 million) on average over the last three fiscal years or at the end of the most recent fiscal year.\textsuperscript{135}

The proposed regulations modify this exception so that it applies to investment securities "that, at the time they [were obtained] could be purchased on the open market ..."\textsuperscript{136} If adopted, this regulation will greatly impact physician practice management companies that acquire physician practices for cash and stock, and then later go public. A physician receiving stock as payment will not fit within this exception because the stock may not be publicly traded at the time of sale. As a result, physician practice

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\textsuperscript{133} See id. at 1696-97.
\textsuperscript{134} See id. at 1698. The proposed rules establish similar provisions to Stark I. The rules clarify this section by establishing that investments be in securities "which may be purchased on terms generally available to the public." Id. The proposed regulations will cover only investment securities on the open market. See id.
\textsuperscript{135} 42 U.S.C. § 1395nn(c) (1994).
\textsuperscript{136} 63 Fed. Reg. at 1698.
management companies may not provide designated health services based on referrals made by physician investors.

The second ownership interest exception provides an exception for a physician who owns shares in an investment company. According to this exception, a physician may own shares in a regulated investment company whose total assets exceeded $75 million at the end of the company’s most recent fiscal year or on average for the previous three fiscal years.\textsuperscript{137}

The third exception pertains to a physician who has an ownership or investment interest in an entity that provides designated health services. This exception requires that the entity be located in a rural area.\textsuperscript{138} The entity must also render substantially all of its services in the same rural area.\textsuperscript{139}

The fourth ownership interest exception applies when a physician makes a referral within a hospital in which he or she holds an ownership interest.\textsuperscript{140} Referrals are permitted if the “physician is authorized to perform services at the hospital,” and the “ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital).”\textsuperscript{141} This is known as the “whole hospital” exception.\textsuperscript{142} According to the proposed rules, this provision pertains to designated health services that are furnished by a hospital, and not to services furnished by other health care providers that are owned by the hospital, such as a home health agency or skilled nursing facility.\textsuperscript{143}

Finally, the fifth exception that applies to an ownership interest pertains to hospitals located in Puerto Rico that render designated health services.\textsuperscript{144} According to this provision, the ownership interest does not have to be in the entire hospital.\textsuperscript{145}

\begin{enumerate}
\item See 42 U.S.C. § 1395nn(c)(2) (1994).
\item See id. § 1395nn(d)(2).
\item See id.
\item See id. § 1395nn(d)(3).
\item Id.
\item See ASPEN HEALTH LAW CENTER, HEALTH CARE FRAUD AND ABUSE COMPLIANCE MANUAL 4:14 (1997).
\end{enumerate}
c. Compensation Arrangement Exceptions

The Stark law provides five exceptions for physicians who have compensation arrangements with a health care entity. Under these exceptions, a physician must have a compensation arrangement with the facility to which he or she refers patients for designated health services. Those services must be subject to reimbursement under the Medicare and/or Medicaid programs.

i. Rental of Office Space and Equipment

The first exception applies to rental of office space and/or equipment. Payments made for the rental of office space or equipment are not prohibited under the Stark law if:

1. the lease is in writing, signed by the parties, and specifies the leased premises or equipment;
2. the space or equipment rented does not exceed what is reasonable or necessary for its legitimate business purpose and it is used exclusively by the lessee;
3. the lease is for at least one year;
4. the rent charged is established in advance, consistent with fair market value, and is not determined in a manner that considers the volume or value of any referral or other business generated.

146. See 42 U.S.C. § 1395nn(e).
147. See id.
149. Id. §§ 1395nn(e)(1)(A)(ii), (e)(1)(B)(ii).
150. Id. §§ 1395nn(e)(1)(A)(iii), (e)(1)(B)(iii). The proposed rules seek to clarify the meaning of several key terms found in the Compensation Arrangement Exceptions. This provision relates to the one year requirement that is found in several of the compensation-related exception. The rules clarify that a clause that allows the parties to terminate the agreement for good cause will not disqualify the arrangement from satisfying the one-year requirement. See 63 Fed. Reg. 1698 (to be codified at 42 C.F.R. pts. 411, 424, 435, 455) (proposed Jan. 9, 1998). However, the parties may not terminate the agreement and enter into a new arrangement within the initial one year period. See id.
151. Under the proposed rules, the HCFA “defines fair market value as the value in arm’s-length transactions, consistent with the general market value . . . .” 63 Fed. Reg. at 1686. The HCFA suggests that the bone fide sales price may be indicative of the general market value. See id. The fair market value of rentals and leases means the value of rental property for general commercial purposes (not considering its intended use or proximity to the source of patient referrals). See id.
(5) the lease would be commercially reasonable even if no referral were made between the parties, and

(6) the lease meets any other requirements that may be imposed by the Secretary of Health and Human Services.

A health care entity must meet all these requirements to qualify for this exception. The proposed regulations recognize that this exception does not apply to a capital lease because such a lease is more like an installment sale than a rental agreement.

ii. Bona Fide Employment Relationships

The second compensation exception to the Stark law pertains to a bona fide employment relationship. Any payment "by an employer to a physician (or an immediate family member of such physician) who has a bona fide employment relationship with the employer" does not create a prohibited "financial relationship." In order to fit within this exception, the following conditions must be met:

(A) the employment is for identifiable services;
(B) the amount of remuneration under the employment is:
   (i) consistent with the fair market value of the services; and
   (ii) is not determined in a manner that takes into account the volume or value of any referrals;
(C) the remuneration provided pursuant to an agreement must be for designated health services. See 63 Fed. Reg. at 1700. The proposed rules explain that a compensation arrangement may fail to meet this standard even when a physician's payments from an entity are always the same. See id. For example, if a hospital requires a physician to refer only within network, then that physician's compensation would reflect the volume or value of the referrals. See id.

153. 42 U.S.C. §§ 1395nn(e)(1) (A) (v), (e) (1) (B) (v) (1994). This commercial reasonableness standard is found in several provisions of the compensation-related exceptions. The proposed rules interpret commercial reasonableness as an arrangement that seems to be a "sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals." 63 Fed. Reg. at 1700.


157. See supra note 151 (defining fair market value).

158. See supra note 152 (defining volume or value of referrals).
would be commercially reasonable even if no referrals were made to the employer; and
(D) the employment meets any other requirements that may be imposed by the Secretary of Health and Human Services.

According to Stark II, a person is an employee if the individual satisfies the definition of an employee under the usual common law rule as required by section 3121(d)(2) of the Internal Revenue Code. This definition is favorable because it presumes that an individual who works full-time in the facility of another is the employee of that facility, unless the individual can prove otherwise.

Under the bona fide employment relationship exception, the proposed regulations specifically limit productivity bonuses. Productivity bonuses may be paid based on services personally performed by the physician. Under this compensation exception, a physician may receive payment for designated health services that the physician referred to himself. The proposed rule attempts to remedy this by allowing "group practices to pay members a productivity bonus only if the bonus is not directly related to the volume or value of the physician's own referrals."

iii. Personal Service Arrangements

If a physician receives payment pursuant to a personal service arrangement, it may fit within an exception under the Stark law. Such payment will not be considered remuneration if the following elements are satisfied:

(i) the arrangement is in writing, signed by the parties;

159. See supra note 153 (defining commercially reasonable).
164. See id.
165. Id. at 1700-01. This employee exception under the proposed rule differs from the group practice exception. The group practice definition permits bonuses based on services personally performed furnished and incident to physicians services. See id. at 1701. The group practice exception also permits profit sharing among group members as long as a physician's share is not based on referrals. See id.
(ii) the arrangement covers all of the services to be provided by the physician to the entity;

(iii) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;\(^{166}\)

(iv) the arrangement is for at least one year;\(^{167}\)

(v) the compensation to be paid is set in advance and does not exceed fair market value,\(^{168}\) and except in the case of a physician incentive plan is not determined in a manner that takes into account the volume or value of any referrals\(^{169}\) or other business generated between the parties;

(vi) the services to be performed under the arrangement do not involve the counseling or promotion or a business arrangement or other activity that violates any State or Federal law; and

(vii) the arrangement meets such other requirements as may be imposed by the Secretary of Health and Human Services.\(^{170}\)

This exception is designed to protect arrangements in which providers of designated health services obtain "personal services" from independent contractor physicians who are not employees.\(^{171}\) Arrangements that involve any service that a physician may render, including administrative service and patient care services, are permitted if the requirements of this exception are satisfied.

In the proposed rules, HCFA recognizes that it may not be logical for all physician personal service contracts to be contained in one agreement. Thus, the proposed rules allow multiple contracts.\(^{172}\) Each contract must meet all of the requirements of the exception, and incorporate each other by reference.\(^{173}\)

\(^{166}\) See supra note 153 (defining commercially reasonable).

\(^{167}\) See supra note 150 (discussing the one-year requirement).

\(^{168}\) See supra note 151 (defining fair market value).

\(^{169}\) See supra note 152 (discussing volume or value of referrals).


\(^{171}\) See MANGINO, supra note 162, at 59.


\(^{173}\) See id.
iv. Physician Incentive Plan

One would think that a physician incentive plan would be prohibited under the Stark laws. Surprisingly, this is not the case. Payments made pursuant to a physician incentive plan may take into account the volume or value of referrals in some circumstances. This is achieved by withholding, capitation, or bonuses. A physician incentive plan is permissible if:

(1) no payment is made to induce the reducing or limiting of medically necessary services to individuals who are enrolled with the entity;

(2) the plan places the physician or a physician group in some sort of financial risk as determined by the Secretary of Health and Human Services, the plan must meet any additional requirements that may be imposed by the Secretary; and

(3) the entity provides the Secretary of Health and Human Services with access to any requested information about the plan.

v. Physician Recruitment

The final exception pertains to physician recruitment. Remuneration may be given to induce a physician to relocate to the geographic area served by a hospital. A compensation arrangement for recruitment is permitted if: (1) the physician is not required to refer patients to the hospital; (2) the remuneration to be paid does not consider referrals; and (3) the arrangement meets any other requirements that might be imposed by the Secretary of Health and Human Services. If a hospital makes recruitment

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174. Physician incentive plan is defined by the exception to the Stark law as "any compensation arrangement between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the entity." 42 U.S.C. § 1395nn(e)(3)(B)(ii) (1994).
176. See id.
177. Id.
180. See id.
payments to a physician within the hospital's geographic area, or to a group practice that intends to employ the relocating physician and contract with the hospital, then payments may fit within the compensation arrangement exception.\textsuperscript{181}

\textit{vi. New Compensation Arrangement Exceptions}

The proposed regulations issued by HCFA create several new compensation arrangement exceptions.\textsuperscript{182}

\textbf{(a) The Fair Market Value Exception}

The Fair Market Value Exception would protect arrangements between a physician, or group of physicians, and a health care entity if the arrangement satisfies the following conditions:

(1) the arrangement is in writing, signed by all the parties, and covers only identifiable items or services specified in the agreement. The arrangement must also cover all of the items and services that will be provided by the physician or immediate family member to the entity or, cross-reference any other agreements for items or services between any of the parties;

(2) the arrangement must set forth a time frame for any period of time and contain a termination clause, provided the parties enter into only one arrangement covering the same items or services during the course of a year. If the arrangement is for less than one year, it may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change;

(3) the arrangement must specify the compensation that will be provided under the arrangement. The method for determining the compensation must be established in advance. Compensation must be consistent with fair market value, and may not be determined in a manner that takes into account the volume or value of any referrals; payment for referral of medical services that are not covered under Medicare or Medicaid; or other business generated between the parties; and

\textsuperscript{181} See 63 Fed. Reg. at 1702.

\textsuperscript{182} See id. at 1699.
(4) the arrangement must involve a transaction that is commercially reasonable and furthers the legitimate business purposes of the parties and must satisfy the conditions of a safe harbor under the anti-kickback statute or otherwise be in compliance with the Medicare/Medicaid anti-kickback provisions.\textsuperscript{183}

This proposed regulation acts as a catch-all to cover the more common compensation arrangements that are based on fair market value or are otherwise commercially reasonable, and does not reflect the volume or value of a physician’s referral.\textsuperscript{184} This exception is used if there is doubt about whether the arrangement meets the requirements under another Stark II exception.\textsuperscript{185}

\textit{(b) Discounts}

The proposed regulations also provide a compensation arrangement exception relating to discounts.\textsuperscript{186} Any discount given to a physician must be passed on in full to either the patient or the patient’s insurers and may not inure to the benefit of the referring physician.\textsuperscript{187} The discount is exempt if it meets the following requirements:

\begin{itemize}
  \item[(1)] the discount is offered to all similarly situated individuals, regardless of whether they make referrals to the entity;
  \item[(2)] it doesn’t reflect the volume or value of referrals the physician has made or will make to the entity; and
  \item[(3)] the discount is passed on to Medicare or other insurers.\textsuperscript{188}
\end{itemize}

The proposed regulation establishes that when a physician fails to pass on a discount to a patient, Stark II is violated. For example, sanctions may be imposed if a physician receives a discount from a drug manufacturer on a drug and fails to pass that discount to the Medicare program and to patients. The proposed rule assumes

\begin{footnotes}
183. \textit{Id.} at 1699.
184. \textit{See id.} at 1699.
185. \textit{See id.}
186. \textit{See id.} at 1694.
187. \textit{See id.}
188. \textit{Id.}
\end{footnotes}
that drug manufacturers and medical product suppliers furnish designated health services as defined by Stark. 189

(c) The De Minimis Exception

The proposed rules provide an exception for compensation arrangements that involve de minimis remuneration. 190 HCFA recognizes that physicians or their immediate family members acquire compensation in the form of incidental benefits that are not part of a formal, written agreement. 191 This includes items like free drug samples; staff training sessions prior to entering into a contract with a facility that provides designated health services; training sessions that are not considered part of the agreement; coffee mugs; or note pads. 192

The proposed exception applies to compensation from an entity in the form of items or services, other than cash or cash equivalents, that do not exceed $50 per payment and an aggregate of $300 per year. 193 The following must be satisfied:

(a) the entity providing the compensation makes it available to all similarly situated individuals, regardless of whether these individuals refer patients to the entity for services; and

(b) the compensation is not determined in a way that takes into account the volume or value of the physician's referrals to the entity; 194 and

(c) the arrangement meets other requirements as may be imposed by the Secretary of Health and Human Services as needed to protect against program or patient abuse. 195

The proposed exception applies only to noncash items or services and would not apply to gift certificates, stocks or bonds, or discounted airline frequent flier miles. 196

Free parking has been debated as de minimis remuneration in

189. See id.
190. See id. at 1699.
191. See id.
192. See id.
193. See id.
194. Id.
195. Id. at 1700.
196. See id. at 1699.
some parts of the country. The proposed rules clarify that while a physician is making rounds, free parking benefits both the hospital and its patients and is not a personal benefit to the physician. Thus, free parking in this case would not constitute a compensation arrangement. However, if a hospital does provide parking to physicians at times, which do not coincide with the physician's rounds, sanctions may be imposed for a Stark violation.

(d) Other Exceptions

Finally, Stark law provides for other situations that do not qualify under the enumerated ownership interest or compensation arrangement exceptions. These other exceptions address isolated transactions and group practice arrangements in which the hospital bills for services rendered. The proposed rules do not affect these exceptions.

(1) Isolated Transaction Exception

This exception considers payments received by a physician in an isolated transaction, such as a one time sale of a medical practice. An isolated transaction is an acceptable compensation arrangement under the Stark laws if:

(1) the remuneration involved in the transaction is in accordance with the fair market value of the services, and does not take into account the volume or value of referrals made to the entity by the physician;
(2) the remuneration provided pursuant to an agreement is commercially reasonable even if no referrals were made between the parties; and
(3) the transaction meets any other requirements that may be imposed by the Secretary of Health and Human Services.

In addition, there can be no transactions between the physician and provider of designated health services for six months after

197. See id. at 1713-14.
198. See id. at 1714.
199. See id.
201. See id. § 1395nn(e)(2).
the isolated transaction, unless specifically excepted under other Stark provisions.\(^{202}\)

(2) Group Practice Exception

The Stark law also provides an exception for group practice arrangements between a hospital and a group practice.\(^{203}\) The exception applies if the group provides designated health services, but the services are billed by the hospital.\(^{204}\) This is permitted if the following requirements are satisfied:

1. the arrangement is in compliance with the provision of inpatient hospital services;
2. the arrangement began prior to December 19, 1989, and has continued without interruption since that day;\(^{205}\)
3. under the arrangement, the group furnishes substantially all of the designated health services to patients of the hospital;
4. the arrangement is written and specifies the services covered;
5. the compensation is fixed in advance and is consistent with fair market value.\(^{206}\)

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202. See 42 C.F.R. § 411.357 (1997). For example, upon the purchase of a physician’s practice, installment payments for that purchase would create significant exposure to liability under Stark laws. In the preamble to the Stark I proposed regulations, concerns were raised about installment payment arrangement. See MANCINO, supra note 162, at 64. The Department of Health and Human Services stated that installment payment arrangement would not qualify for the isolated transaction exception and that the former owners would be prohibited from referring patients to the entity until all the payments were made. See id. It may be asserted that it is a contractual right to receive a deferred payment and the payment is considered an investment in that entity. See id. at 13. Furthermore, this provision may be circumvented by either making the payments within a time frame of six months or by placing the amount paid in a trust. A trust would permit the trust to make the payment of both the principal and the interest and, arguably, would remove the possibility of the intention to induce a prohibited referral.

204. See id.
205. See id. § 1395nn(e) (7) (A). The proposed rules recognize that this requirement is still satisfied even if the contract between the parties has changed so that it covers different services, or the services are provided by different individuals within the same group practice. See 63 Fed. Reg. 1659, 1702 (to be codified at 42 C.F.R. pts. 411, 424, 435, 455) (proposed Jan. 9, 1998).
206. See supra note 151 (defining fair market value).
(6) the arrangement is commercially reasonably;\textsuperscript{207} and
(7) the arrangement meets any other requirements that the Secretary of Health and Human Services may im-
pose.\textsuperscript{208}

The Stark law truly is a law of exceptions. There are many ex-
ceptions and proposed exceptions to physician self-referrals. Physi-
cians and entities providing designated health services who create
ownership interests or compensation relationships should review
the manner in which profits are shared, and compensation is paid,
to determine if these relationships comply with Stark law. The dif-
ficulty of the Stark law is in understanding its intent and excep-
tions. Failure to comprehend the intricacies of Stark law when es-
tablishing a corporate compliance program may result in
substantial penalties.

3. Penalties for Violating the Stark Law

The penalties under the Stark law are significant. First, if a vio-
lation is found, payment for the provided service may be denied.\textsuperscript{209} Second, the government may require repayment of the claims
billed in violation of the law.\textsuperscript{210} Third, any person who presents or
causes to be presented a bill or claim for services that the individual
knows or should know is for a service for which payment may not
be made, or for which a refund has not been made, shall be subject
to a civil money penalty of not more than $15,000 for each serv-
ice.\textsuperscript{211} Fourth, any physician or health care entity that enters into
an arrangement or scheme that the physician or entity knows or
should know has the principal purpose of circumventing the law, is
subject to a civil money penalty of not more than $100,000 for each
arrangement or scheme; and/or exclusion from the Medicare and
Medicaid programs.\textsuperscript{212} Finally, any person who is subject to, but
fails to meet, a reporting requirement may be assessed a civil
money penalty of not more than $10,000 for each day the reporting
was required.\textsuperscript{213}

\textsuperscript{207. See supra note 153 (discussing commercial reasonableness).
210. See id. § 1395nn(g)(2).
211. See id. § 1395nn(g)(3).
212. See id. § 1395nn(g)(4).
213. See id. § 1395nn(g)(5).}
C. The False Claims Act

1. The Law

The False Claims Act ("FCA") was originally enacted in 1863 to rid the defense industry of fraud. The FCA resurfaced in 1986 to combat all forms of government procurement and contracting fraud, including fraud in the Medicare and Medicaid programs. Currently, the FCA requires those who do business with the federal government to deal with the government in an honest fashion. It imposes liability on persons or health care entities who:

(1) knowingly present or cause to be presented a false or fraudulent claim for payment to the United States;

(2) knowingly use a false record or statement to obtain payment on a false or fraudulent claim paid by the United States; or

(3) engage in a conspiracy to defraud the United States to obtain allowance for payment of a false or fraudulent claim.

The term "knowingly" means having actual knowledge, or acting with deliberate ignorance of the truth or falsity of the information, or acting with reckless disregard for the truth or falsity of the information. Specific intent is not required by the FCA. The intent behind the FCA was to stop "ostrich head in the sand" behavior that happens when a person fails to make any inquiry for fear that it would reveal the false claim.

217. Id. § 3729(a)(1).
218. Id. § 3729(a)(2).
219. Id. § 3729(a)(3).
220. See id. § 3729(b)(1)-(3).
221. See id. § 3729(b).
2. Violations of the False Claims Act

Violations of the FCA can result in the assessment of civil monetary penalties of $5,000 to $10,000 for each false claim filed, plus treble damages. The government does not have to prove actual damages to recover under the FCA. The government must only prove that the defendant health care entity acted with "deliberate ignorance" or "reckless disregard" of the truth or falsity of the information. It appears that the only real defenses to an FCA claim are negligence and inadvertent mistake that the claims against the government were false.

The court may reduce the penalties. This reduction is permitted if: (1) full disclosure of all known information is made within thirty days after the defendant obtains the information; (2) the entity fully cooperates with the government investigation; (3) and no action had commenced under the FCA and the defendant had no actual knowledge of the existence of a government investigation of such violation when the information was given.

Finally, the FCA has a six-year statute of limitations. However, this time may be tallied three years from the point at which the government or qui tam relator knew, or reasonably should have known, of the alleged fraud.


_226._ _See_ United States _ex rel_. Hagood v. Sonoma County Water Agency, 929 F.2d 1416, 1421 (9th Cir. 1991).


_228._ _See id._

_229._ _See id_. § 3731(b)(1).

_230._ _See id_. § 3731(b)(2); _see also_ United States _ex rel_. Hyatt v. Northrop Corp., 91 F.3d 1211, 1216-17 (9th Cir. 1996).
3. **Qui Tam Actions**

A qui tam suit is an action under the FCA that is brought on behalf of the federal government by a private individual, known as a "qui tam plaintiff," "relator," or "whistle-blower." These individuals may be past or current hospital employees, patients, or anyone who knows that an organization or individual has committed fraud.

Filing a qui tam complaint is the first step. The only requirements for bringing a qui tam action are that the qui tam relator is the original source of the false claim information, and that the individual has direct and independent knowledge of the information that is the basis for the allegations. The qui tam complaint must be filed in camera, and is automatically sealed for sixty days, pending a government investigation and a decision to intervene.

Government involvement with the action will affect the amount of recovery for the qui tam relator. A qui tam relator may receive a percentage of the government's recovery, twenty-five to thirty percent if the government does not intervene in the action or fifteen to twenty-five percent if the government does intervene. Given the potential for large recoveries, a qui tam relator may earn a substantial amount of money. However, if the information was not a substantial contribution to the case, then the qui tam relator may only receive a maximum of ten percent of the recovery. In addition, the qui tam relator may recover reasonable attorney fees and costs. If the qui tam relator is criminally convicted for activity that gave rise to the FCA violation, then the qui tam relator is dismissed from the civil action and is not entitled to receive any share of the recovery.

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233. See id. § 3730(b)(2). Among other extensions, the government may chose to extend the 60-day period to investigate the matter if good cause is found. See id. § 3730 (b)(4).

234. See id. § 3730(d)(1)-(2).

235. See id. § 3730(d)(1).

236. See id. § 3730(d)(1)-(2).

237. See id. § 3730(d)(3).
Qui tam actions have been extremely successful. In 1987, only $200,000 was recovered by qui tam actions. In 1994, the government recovered $1.09 billion from civil fraud cases, with $411 million attributable to health care providers. Of the $1.09 billion, $378 million was obtained via qui tam litigation. Qui tam relators in these cases received a total of $70 million. Qui tam litigation has become such a lucrative area that some private law firms solicit qui tam relators via web sites on the Internet. In addition, the DHHS-OIG has a whistle-blower web site on the Internet as well as an e-mail address for reporting fraud and abuse.

Since the potential for qui tam actions is so significant, a health care entity must consider them when structuring its corporate compliance program. The compliance program should be structured in a way that encourages employees to report violations to the organization rather than immediately seeking to bring a qui tam action with the hopes of obtaining personal wealth.

D. The Health Insurance Portability and Accountability Act of 1996 ("HIPAA")

Recently, the federal government increased the tools available for investigating and prosecuting instances of health care fraud and abuse when it adopted the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). HIPAA establishes four new programs to assist in eradicating health care fraud and abuse which include: Fraud and Abuse Control Program, Medical Integrity Program, Beneficiary Incentive Program, Beneficiary Incentive Program, Fraud and Abuse

238. See West, supra note 224, at 16 (citing Government Recovers $800 Million Through Whistleblower Litigation, 5 Medicare Rep. (BNA), at 1291-92 (Nov. 18, 1994)).
240. See West, supra note 224, at 16.
245. See id. § 201.
246. See id. § 1983.
247. See id. § 203(a).
Data Collection Program.\(^{248}\)

First, the Fraud and Abuse Control Program coordinates federal, state, and local health care anti-fraud enforcement programs.\(^{249}\) This program is jointly administered by the Attorney General and the Secretary of Health and Human Services, acting through the OIG.\(^{250}\) The Administration awarded $2.25 million in grants to nine state agencies and the District of Columbia, the Department of Defense, and the IRS to cover costs of audits, prosecuting, and consumer education.\(^{251}\) Fifteen grants valued at $750,000 were awarded by the HHS Administration on Aging to expand Operation Restore Trust in twelve new states.\(^{252}\)

Next, the Medicare Integrity Program authorizes HCFA to contract with private companies to conduct fraud and abuse detection, cost report audits, utilization review, provider payment determinations, provider education, and the development of a list of durable medical equipment ("DME") subject to prior Health and Human Services payment authorization.\(^{253}\) This program is administered by the Secretary of Health and Human Services and funded by money appropriated from the Medicare Part A Trust fund.\(^{254}\)

The Beneficiary Incentive Program is another program established by HIPAA. This program enlists Medicare beneficiaries and others to assist in identifying health care fraud and abuse. Whistleblowers may be paid a portion of the fines collected by the DOJ or HHS if the information given leads to the recovery of at least $100 by the federal government.\(^{255}\) The process requires the Secretary of

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\(^{248}\) See id. § 203(b).

\(^{249}\) See id. § 201(a) (to be codified at 42 U.S.C. § 1320a-7c).


\(^{251}\) See id.

\(^{252}\) See Eiland, supra note 48, at 4. This program is funded by the Medicare Hospital Insurance Part A Trust Fund. Fines, penalties and other fraud and abuse recoveries will also contribute to funding. Appropriations for the first fiscal year of 1997 may not exceed $104 million and may be increased by 15% for each year thereafter through fiscal year 2003. See HIPAA § 201(b), 42 U.S.C. § 1395i (1994 & Supp. III 1997).

\(^{253}\) See HIPAA § 202(a), 42 U.S.C. § 1395ddd.

\(^{254}\) See id. § 201(a), 42 U.S.C. § 1320a-7c and § 201(b), 42 U.S.C. 1395i. The program will be generously funded receiving in 1997 between $430 million and $440 million and increasing up to the amount of $720 million for each year after 2002. See id.

\(^{255}\) See id. § 203(b) (2), 42 U.S.C. § 1395b-5.
Health and Human Services to: (1) provide an explanation of benefits to Medicare beneficiaries for each item or service that is covered under the program;\(^{256}\) (2) establish new programs to encourage individuals to report suspected incidents of Medicare fraud and abuse;\(^{257}\) and (3) solicit feedback from beneficiaries on ways to improve the program.\(^{258}\)

Finally, HIPAA requires the Secretary of Health and Human Services to establish the Fraud and Abuse Data Collection Program.\(^{259}\) This program operates in coordination with the National Practitioner Data Bank.\(^{260}\) It provides for a monthly reporting of final adverse actions\(^{262}\) taken against a health care practitioner, provider, or supplier by federal and state government agencies and health plans.\(^{253}\) A description of the acts or omissions and injuries upon which final adverse action is based must accompany the report.\(^{264}\) The description must also include whether or not the action is on appeal.\(^{265}\) Malpractice claims and settlements where no liability was found do not have to be reported.\(^{266}\)

Federal and state government agencies, as well as health plans, may obtain information from the database for a reasonable fee.\(^{267}\) Providers, suppliers, and licensed practitioners may get a report on themselves and may dispute the accuracy of the information in the

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256. See id. § 203(a), 42 U.S.C. § 1395b-5.
257. See id. § 203(b) (1), 42 U.S.C. § 1395b-5.
258. See id. § 203(c) (1), 42 U.S.C. § 1395b-5.
259. See Eiland, supra note 48, at 4-5.
260. See id.
261. See HIPAA § 221 (b) (4).
262. HIPAA defines a final adverse actions as the following:

(1) civil judgments;
(2) federal or state criminal convictions;
(3) revocation or suspension of licensure;
(4) reprimand, censure, or probation;
(5) exclusion from participation in any federal or state health program;
(6) any other negative action or finding by such federal or state agency that is publicly available; and
(7) any other adjudicated decisions that HHS identifies by regulation.

HIPAA § 221(a), 42 U.S.C. § 1320a-7e(g)(1)(A)(i)-(v).
263. See id. § 221(b)(1).
264. See id. § 221(b) (2)(D).
265. See id. § 221(b) (2)(C).
266. See Eiland, supra note 48, at 5.
267. See HIPAA § 221(a), 42 U.S.C. § 1320a-7e(d) (Supp. III 1997).
Health and Human Services has been authorized to develop procedures to deal with disputes and corrections of the reports. Civil liability occurs if a person or entity knowingly submitted false information. The enactment of HIPAA demonstrates that health care fraud and abuse remains a high priority for the federal government. The cost to fight health care fraud and abuse under these new programs is substantial. The budget for health care fraud fighting programs is expected to reach $310 million by the year 2002, and then plateau without a sunset provision. Settlements, criminal fines, civil monetary penalties, and other penalties or damages recovered from individuals and entities involved in health care fraud and abuse will also support these programs.

IV. REASONS FOR STRUCTURING A CORPORATE COMPLIANCE PROGRAM: THE ADVANTAGES AND DISADVANTAGES

Corporate compliance "efforts are designed to establish a culture within a hospital that promotes prevention, detection and resolution of instances of conduct that do not conform to federal and state law, and federal, state and private payor health care program requirements, as well as the hospital's ethical and business policies." The DHHS-OIG developed compliance program guidance for hospitals to assist hospitals and their agents and sub-providers in developing effective internal controls and infrastructure as well as to advance the prevention of fraud, abuse, and waste. Most importantly, these guidelines further the mission of hospitals, which is to provide patients quality health care.

A. Advantages of a Corporate Compliance Program

1. Identify and Prevent Criminal and Unethical Conduct

The primary goal of a corporate compliance program is to prevent violations of the law. Thus, a compliance program must

268. See id. § 221(c)(1)(A).
269. See id. § 1320(a)-7c(e).
271. See id. § 201(b), 42 U.S.C. § 1395i(k).
272. OFFICE OF INSPECTOR GENERAL, supra note 5, at 1.
273. See id. at 2.
determine areas of the health care entity that pose potential legal risks. A compliance program develops procedures that permit "the prompt, thorough investigation of alleged misconduct by corporate officers, managers, employees, independent contractors, physicians, [and] other health care professionals and consultants." Compliance programs benefit a corporation by providing a more accurate view of employee and contractor behavior.

If a health care entity has any effective corporate compliance program, it will learn about wrongful conduct before criminal charges are brought. The health care entity may modify the behavior of the employee and reduce the potential for liability. Early detection may prevent qui tam or other whistleblower suits and permit an entity to decide whether to voluntarily disclose the misconduct to the government.

2. Decrease Exposure to Civil Damages and Penalties, Criminal Sanctions, Administrative Remedies and Reduce Legal Costs

According to the Federal Sentencing Guidelines, if an effective corporate compliance program has been implemented, then the fine imposed for the criminal violation may be reduced. The fine


275. OFFICE OF INSPECTOR GENERAL, supra note 5, at 3.

276. See id.

277. See id. at 3-4. The compliance program guidelines for hospitals list as a benefit of a compliance program the ability to initiate immediate and appropriate corrective action; and early detection and reporting to minimize the loss to the government from false claims which would reduce a hospital's exposure to civil damages and penalties, criminal sanctions, and administrative remedies, such as program exclusion. See id.


279. See 31 U.S.C. § 3729(a) (1994). The OIG will consider the existence of an effective compliance plan that pre-dated any governmental investigation when determining administrative penalties. See id. Additionally, the False Claim Act, 31 U.S.C. §§ 3729-3733, provides that a person in violation of the Act, who discloses the violation will, in some situations, be subject to not less than double, as opposed to treble damages. See id.; see also U.S. SENTENCING COMMISSION, GUIDELINES MANUAL, § 8C2.5(f) (1994) ("U.S.S.G."). If an effective corporate compliance program is in place, the Sentencing Guidelines reduce a convicted organization's "culpability score" by three points. See id. This deduction may reduce the fine range by as much as 80%, which could save a corporation millions of dollars. See DAN K. WEBB ET AL., CORPORATE INTERNAL INVESTIGATION: AVOIDING CRIMINAL LIABILITY § 16.03[2][a] (1993). This reduction is not available, however, if a "high level individual" or an "individual responsible for administration or enforcement"
will be reduced if two conditions are met: (1) the compliance program must be implemented prior to the violation; and (2) the compliance program must contain all necessary elements.  

A corporate compliance program may reduce legal costs by encouraging employees to report potential problems. A compliance program may detect litigation risks before they develop into a cause of action. It may also improve the speed and quality of responses to lawsuits, investigations, and other emergencies that may arise.

Government prosecutors have substantial discretion in deciding whether to indict a health care entity based on the unlawful conduct of its employees. The main factor prosecutors consider when determining whether to bring an indictment is whether the corporation acted to avoid the criminal conduct. Prosecutors often determine this by analyzing the quality of the compliance program. The government may not prosecute if the corporation made a good faith effort to avoid wrongful conduct or the problem is properly resolved. If litigation occurs, penalties may be significantly reduced if the entity has an effective corporate compliance program in place.

of the corporate compliance program participated, condoned or remain willfully ignorant of the unlawful conduct. Webb & Molo, supra note 278, at 379.

280. See U.S.S.G. § 8C2.5(f); U.S.S.G. § 8A1.2, cmt. n.3(k).

281. See OFFICE OF INSPECTOR GENERAL, supra note 5, at 3-4.

282. See Webb & Molo, supra note 278, at 377.

283. See id. at 378.

284. See id. at 377-78 (citing DAN K. WEBB ET AL., CORPORATE INTERNAL INVESTIGATIONS: AVOIDING CRIMINAL LIABILITY § 16.03[2][a] (1993)).

285. See Webb & Molo, supra note 278; see also Davis & McFarland, supra note 274, at 70 (citing Charles J. Walsh & Alissa Pyrick, Corporate Compliance Programs as a Defense to Criminal Liability: Can a Corporation Save Its Soul?, 47 RUTGERS L. REV. 605, 666-67 (1995)).

286. According to the U.S.S.G., if a corporation is convicted, the penalty is imposed by multiplying a "base fine" by a multiplier. Note, Growing the Carrot: Encouraging Effective Corporate Compliance, 109 HARV. L. REV. 1783, 1785 (1996). This multiplier is determined by a "culpability score." Id. The base fine is set at the largest of either the standard fine for that specific violation, the financial gain to the offender, or the financial harm caused by the violation. See id. Each entity begins with a culpability score of five. See id. Judges may add points to the culpability score for aggravating factors, such as the involvement in the unlawful activity by upper-management; if the crime is a repeat offense or a violation of probation or a judicial order; or the organization is uncooperative during the investigation, prosecution, or sentencing. See id. Judges may also subtract points from the culpability score if mitigating factors exist. See id. at 1785-86. Mitigating factors include the existence of an "effective" compliance program; the corporation admitting responsibility for the unlawful conduct; cooperation of an entity during the
In addition, the creation and operation of a corporate compliance program is tax deductible. Legal costs are generally reimbursable as part of a Medicare cost report. Penalties imposed against a health care entity without a corporate compliance program are not reimbursable or tax deductible.

3. A Corporate Public Relations and Employee Morale Tool

A corporate compliance program may improve employee morale, as well as the public image of the health care entity. Implementation of a corporate compliance program demonstrates to employees, and the community, that the hospital has a strong commitment to honest and responsible corporate conduct. The health care entity should convey the corporate attitude that compliance with the law is important by demanding ethical conduct from all its employees. The public image of a health care entity may be enhanced if it seeks to uphold ethical business practices.

287. David D. Queen, Corporate Compliance Programs, An Overview, Presentation at the Illinois Association of Healthcare Attorneys Fifteenth Annual Health Law Symposium (Oct. 17, 1997). The current HCFA reimbursement process permits some of the costs associated with the creation of a voluntarily established compliance program may be allowable costs on certain types of hospitals' cost reports. See OFFICE OF INSPECTOR GENERAL, supra note 5, at 7 n.7 (citing 42 U.S.C. § 1395x(v)(1)(A) (defining reasonable cost); 42 C.F.R. §§ 413.9(a), (b)(2) (costs related to patient care)). These costs must be reasonable and related to patient care. See id. However, costs from the implementation of a corporate compliance program imposed by the government as a result of a civil or criminal judgment or settlement are not reimbursable. See id.

288. See OFFICE OF INSPECTOR GENERAL, supra note 5, at 3.

289. See Davis & McFarland, supra note 274, at 34 (citing Lynn Sharp Paine, Managing for Organizational Integrity, 72 HARV. BUS. REV. 106, 111 (Mar./Apr. 1994)).
The corporate compliance program may bolster morale. A positive corporate attitude can remedy problems associated with employee misconduct. Misconduct can cause poor employee productivity and disrupt business operations. A corporate compliance program may increase employee productivity by improving employee morale. Furthermore, corporate compliance training will make employees feel appreciated, valued and a part of the success of the health care entity.

4. Improvement in Corporate Communications

A corporate compliance program establishes infrastructure necessary to effectively communicate changes in corporate policy. A compliance program creates a centralized source for distributing information pertaining to health care statutes, regulations and other program directives related to fraud and abuse. Corporate policy may be quickly distributed beyond upper level management to all employees.

B. Disadvantages of a Corporate Compliance Program

1. Documentation May Be Subject to Discovery

An effective corporate compliance program cannot be a few pages in an employee handbook. It must be proactive in the detection and investigation of fraud and abuse. The primary disadvantage of a corporate compliance program is that communication and documentation generated by it may be subject to discovery. The attorney-client privilege and work product doctrine, however, may protect the communications from discovery if litigation arises.

290. See Webb & Molo, supra note 278, at 377; see also Davis & McFarland, supra note 274, at 34.
291. See id.
292. See Office of Inspector General, supra note 5, at 3.
294. See Davis & McFarland, supra note 274, at 34-35.
295. See id. at 35.
a. The Attorney-Client Privilege

One way of preventing disclosure of documentation generated by internal investigations of a corporate compliance program is to invoke the attorney-client privilege. This privilege encourages full and frank communication between attorneys and their clients. The privilege recognizes that sound legal advice or advocacy serves a public end and that such advice or advocacy depends upon the lawyer's being fully informed by the client. In the case of Upjohn Co. v. United States, the Supreme Court upheld the attorney-client privilege in a healthcare compliance setting. The Court considered the following factors:

- communications were made by Upjohn employees;
- employees communicated with attorneys for Upjohn;
- employees communicated with the attorney at the direction of corporate superiors;
- employee communications were made in order to obtain legal advice;
- information was needed to supply a basis for legal advice concerning compliance with various laws, duties to shareholders, and potential litigation;
- this information was not available from upper level management;
- employee communications concerned matters within the scope of the employees' corporate duties;
- employees knew that they were being questioned so the corporation could acquire legal advice;
- pursuant to instruction of the chairman of the board, the communications were considered "highly" confidential when made; and
- communications have been kept confidential by the corporation.

If any of these elements are missing, a court may determine that the attorney-client privilege does not apply and the documentation is subject to discovery. Information received as a result of

296. See id.
300. See id. at 394-95.
301. See id. at 389.
an internal investigation or monitoring should significantly involve
an attorney so that this information may be protected by the attor-
ney-client privilege.\textsuperscript{302} Although the attorney-client privilege is ap-
plicable to communications between a corporation's employee and
its in-house counsel, an attorney independent of the corporation
may be used because it eliminates questions about whether the in-
vestigation is truly for legal advice.\textsuperscript{303} Any communications between
in-house counsel and employees for other than obtaining legal ad-
dvice do not fall under the protection of the attorney-client privi-
lege.\textsuperscript{304} If corporate documents are created because of the need for
legal advice, the privilege should protect the documents from dis-
covery.\textsuperscript{305}

It is unclear whether communications between the investigat-
ing attorney and a former corporate employee are protected by the
attorney-client privilege. Some courts have decided that the attor-
ney-client privilege applies as long as the communications pertain
to the former employment and are needed to render legal advice
to the former employer.\textsuperscript{306} Other courts have rejected this notion
and have decided that the work product doctrine may protect this
type of communication.\textsuperscript{307} An attorney should exercise caution
when communicating with former employees of the health care en-
tity.

If any information received via the internal investigation is re-
vealed to a third party (other than outside counsel), the attorney-
client privilege is waived.\textsuperscript{308} According to the U.S. Sentencing

\textsuperscript{302} See Davis & McFarland, supra note 274, at 35. The attorney-client privilege
may not apply if in-house counsel participated in the internal investigation. See,
ext. g., General Counsel v. United States, 599 F.2d 504, 510-11 (2d Cir. 1979) (stating
that to claim the attorney-client privilege a corporation has the burden to show
the communication was made to secure legal advice in contemplation of future
action by the attorney).

\textsuperscript{303} See Davis & McFarland, supra note 274, at 35.

\textsuperscript{304} See id.

\textsuperscript{305} See First Chicago Int'l v. United Exch. Co. Ltd., 125 F.R.D. 55, 57-58
(S.D.N.Y. 1989) (finding that documents created at counsel's request for assis-
tance in providing a legal opinion were privileged).

\textsuperscript{306} See, e.g., Admiral Ins. Co. v. United States Dist. Court, 881 F.2d 1486, 1493
(9th Cir. 1989) (holding that former employee's interview with corporate counsel
was protected by the attorney-client privilege); City of Long Beach v. Standard Oil
Co., 658 F.2d 1355, 1361 n.7 (9th Cir. 1981) (stating that conversations between
attorney and client remain privileged after the employee leaves).

\textsuperscript{307} See In re Grand Jury Subpoena, 478 F. Supp. 368, 374 (E.D. Wis. 1979)
(stating that the documents arising from interviews with former employees fall
under the work product doctrine rather than the attorney-client privilege).

\textsuperscript{308} See Davis & McFarland, supra note 274, at 35.
Guidelines, a corporation may have to turn over the investigative report to the government in order to receive benefits under the Corporate Compliance Guidelines. The power to waive the attorney-client privilege is a decision that is often made by the officers or directors of the corporation. The corporation is in a difficult position because in order to defend itself it must waive the privilege, but doing so may increase the potential for other litigation.

Waiver of the attorney-client privilege as to one party may imply a waiver as to another party. In the case of Permian Corp. v. United States, the court determined that one cannot waive the attorney-client privilege from some and invoke it for others. The U.S. Court of Appeals for the D.C. Circuit expanded Permian doctrine and decided if information is disclosed to a federal agency, the attorney-client privilege is waived for discovery requests made by third parties.

However, the U.S. Court of Appeals for the Eighth Circuit, in Diversified Industries, Inc. v. Meredith, decided that a privilege is not waived as to third parties. The court's rationale was that a total waiver creates a disincentive to voluntarily report corporate misconduct, which directly conflicts with the objectives of a corporate compliance program. Thus, a health care entity should determine the risk before making any communications to third parties.

In addition, waiver about a specific topic may result in a waiver

309. See U.S.S.G. § 8C2.5(g).
310. See In re Grand Jury Investigation, 599 F.2d 1224, 1236 (3d Cir. 1979). "If the employees had engaged in questionable activity, the corporation clearly would have the power to waive the privilege and to turn the employees' statements over to law enforcement officials." Id.
312. See id. at 1221 (finding that where a corporation has been willing to sacrifice confidentiality of document in order to expedite approval of an offer, the corporation could not invoke attorney-client privilege to prevent the Securities and Exchange Commission from providing access to those documents to the Department of Energy).
313. In re Subpoenas Duces Tecum, 738 F.2d 1367, 1369-70 (D.C. Cir. 1984) ("For the purposes of the attorney-client privilege, there is nothing special about another federal agency in the role of potential adversary as compared to private party litigants acting as adversaries.").
314. 572 F.2d 596 (8th Cir. 1977).
315. See id. at 611.
316. See id. The court held that the voluntary disclosure of attorney-client communications to the Securities Exchange Commission was a limited waiver of the privilege. See id.
of all privileged communications concerning the same topic. Currently, jurisdictions are split with regard to this type of waiver. In the case of United States v. Pollard, the U.S. Court of Appeals for the Fourth Circuit held that disclosure of a final report of an investigation waives the privilege with respect to all other documents. However, in the case of Von Bulow v. Von Bulow, the U.S. Court of Appeals for the Second Circuit determined that no waiver exists as to other privileged communications if the disclosure of privilege material would not prejudice the adversary in a judicial proceeding.

Finally, as for partial disclosures, the U.S. Court of Appeals for the Third Circuit determined that "[w]hen a party discloses a portion of otherwise privileged materials while withholding the rest, the privilege is waived only as to those communications actually disclosed, unless a partial waiver would be unfair to the party's adversary." A solution to this waiver dilemma may be in adopting a bifurcated approach to the investigative process. The health care entity may employ an independent investigator to conduct a factual investigation and compose a factual report that does not contain any opinions or conclusions. This report could then be given to the attorney for the entity who would use it as a basis of rendering legal advice. If the corporation has to disclose information to the government, it may satisfy the government by disclosing only the factual investigation. The attorney's legal conclusion and advice may only be relevant to the extent that they support the government's claim. A health care entity may successfully claim the attorney-client privilege or work product doctrine if the attorney's opinions and advice are not mixed with discoverable facts.

318. Id.
319. See id. at 622-24.
320. 828 F.2d 94 (2d Cir. 1987).
321. See id. at 102.
b. *The Work Product Doctrine*

The work product doctrine protects from discovery documents and "tangible things" that are prepared in anticipation of litigation or for trial.\(^{324}\) The doctrine protects the mental impressions and legal analysis of an attorney.\(^{325}\) It applies to both documents prepared by an attorney as well as other materials prepared by agents of the attorney.\(^{326}\)

Materials may be discoverable, however, if the opposing party can show a "substantial need" for the information.\(^{327}\) This exception permits disclosure of non-opinion work product such as witness interview notes that do not contain the mental impression of the attorney.\(^{328}\) Disclosure of interview notes is permissible when the witness is no longer available for questioning.\(^{329}\)

Work product containing the mental impressions, opinions and legal theories of an attorney are rarely discoverable.\(^{330}\) Rule 26(b)(3) of the Federal Rules of Civil Procedure states that a "court shall protect against disclosure of the mental impressions, conclusions, opinions, or legal theories of an attorney or other representative of a party concerning the litigation."\(^{331}\) This has been interpreted to mean that opinion work product cannot be discovered even if there is a substantial need or when failing to reveal the information would cause undue hardship to the party seeking discovery.\(^{332}\)

In the context of a corporate compliance program, documentation created as part of an internal investigation may not be protected by the work product doctrine. Documentation created in

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324. *FED. R. CIV. P.* 26 (b)(3). The work product doctrine was first established by the case of *Hickman v. Taylor*, 329 U.S. 495 (1947) and was later codified by the Federal Rules of Civil Procedure.

325. *See* *FED. R. CIV. P.* 26(b)(3).

326. *See id*.

327. *See id*.

328. *See id*.

329. *See id* (stating that the work product is only available upon a showing that the party seeking discovery has substantial need of the materials in the preparation of the party's case and that the party cannot obtain the "substantial equivalent" of the materials in another way).

330. *See, e.g.*, United States v. Pollard (*In re* Martin Marietta Corp.), 856 F.2d 619, 626 (2d Cir. 1988) (finding that opinion work product is to be afforded great protection by courts); United States v. Rosenthal, 142 F.R.D. 389, 394 (S.D.N.Y. 1992) (opining that courts should go to great lengths to protect work product).


332. *See* *Duplan Corp. v. Moulinage et Retorderie de Chavanoz*, 509 F.2d 730, 734 (4th Cir. 1974).
conjunction with an internal investigation is only protected by the work product doctrine if it is prepared in anticipation of litigation and litigation was a possibility when it was created. A health care entity must be prepared to prove that at the time the internal investigation documentation was created, litigation was possible.

The work product doctrine may be waived. Partial disclosure of internal investigations can create difficulties, when disclosure is to a government agency. Partial disclosure of investigation documentation creates a waiver of the work product doctrine. As a result, potential third-party claimants can get the documentation through discovery. The U.S. Court of Appeals for the Eighth Circuit is the only court that recognizes selective waiver. The court decided that the work product doctrine may be waived with respect to the government agency, but not with respect to third parties.

One way to address this dilemma outside of the Eighth Circuit is to enter into an agreement with the government. The agreement should provide that the disclosure is confidential and does not constitute a waiver. The agreement should also refer to any parallel or subsequent litigation and forbid disclosure to a third party. This agreement may not withstand the scrutiny of the courts, but may persuade the court that the health care entity was acting reasonably in the face of a government enforcement action.

c. The Self-Evaluative Privilege

The self-evaluative privilege is recognized by only a few jurisdictions. Currently, federal agencies do not recognize this privilege, and federal courts construe it narrowly. This privilege protects materials related to an internal investigation and audit. The self-evaluative privilege is more expansive than the attorney-client privilege and work product doctrine by protecting the efforts of management independent of any attorney involvement.

Self-evaluation by a health care entity assists in promoting an

333. See, e.g., In re Grand Jury Investigation, 599 F.2d 1224, 1229 (3d Cir. 1979) ("Some possibility of litigation must exist."); Duffy v. United States (In re Grand Jury Proceedings), 473 F.2d 840, 847 (8th Cir. 1973) ("The test of whether the work product doctrine applies is not whether litigation has begun but whether documents were prepared or obtained in anticipation of litigation.").

334. See Diversified Indus., Inc. v. Meredith, 572 F.2d 596, 611 (8th Cir. 1977).

335. See id.

336. See Note, supra note 286, at 1797; see also Joseph E. Murphy & Roselee M. Oyer, The Self-Evaluative Privilege and Beyond, INSIGHTS, Mar. 1993, at 11, 12.

337. See Note, supra note 286, at 1797.
effective corporate compliance program. Results of an audit must be available to all employees. If results are not disclosed to employees, the compliance program may be ineffective because employees will not be informed and able to modify their conduct to avoid future violations.

The self-evaluative privilege may not always prevent discovery of internal materials. A health care entity should assign the responsibility of performing an internal investigation to an internal or independent corporate attorney. This will increase the likelihood that the attorney-client privilege or work product doctrine will provide protection for the results of an internal investigation.

2. Implementation of an Ineffective Compliance Program is Harmful

Another disadvantage of a corporate compliance program is that the failure to implement an "effective" program may harm the health care entity. "[Compliance] programs hastily constructed and implemented without appropriate ongoing monitoring will likely be ineffective and could result in greater harm or liability to the hospital than no program at all." The OIG knows that even an effective compliance program may not eliminate all instances of fraud, abuse and waste. The government will consider whether the entity has made a sincere effort to adhere to federal and state standards as well as the requirements of private health care programs. The OIG considers the effectiveness of a compliance program when selecting an appropriate penalty. Severe penalties will be imposed if the government deems the compliance program ineffective, or recklessly implemented.

3. Mandatory Duty to Respond

Health care entities that implement a corporate compliance program have an affirmative duty to respond to the unlawful and unethical conduct of their employees. This is a disadvantage for health care entities because it increases litigation with disgruntled

338. See id. at 1797-98.
339. See id. at 1798.
342. See id. at 4.
343. See id.
344. See id. at 4 n.2.
employees. An effective corporate compliance program may remedy unlawful or unethical conduct by taking disciplinary action. If prompt corrective action is taken, then a health care entity may receive a reduced penalty. An inappropriate response may increase civil damages and may also result in punitive damages.

Disciplinary action, such as termination of employment, may create litigation. Legal counsel should be consulted when disciplinary action is taken. The health care entity must be able to justify the termination under the compliance program. The compliance program may be modified if the employee conduct resulted from a systemic problem.

4. Negative Publicity

Another disadvantage of a corporate compliance program is that the discovery of unlawful and/or unethical employee conduct may become public knowledge and result in negative publicity. Negative publicity may harm the business operations of the health care entity. Patients may hesitate to seek treatment at a hospital that has been negatively portrayed in the media. If the entity does not have a compliance program, the government may require the corporation publish the violation. The health care entity may avoid negative press by establishing sound confidentiality policies and procedures.

345. See U.S.S.G. § 8C2.5(f). An element of a compliance program for hospitals is the development of a system to respond to allegations of improper and/or illegal activities and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations or federal health care program requirements. See Office of Inspector General, supra note 5, at 8.

346. See Davis & McFarland, supra note 274, at 36.

347. A compliance program must use audits and/or other evaluation techniques to monitor compliance efforts and aid in the reduction of identified problem areas. "Detected but uncorrected misconduct can seriously endanger the mission, reputation, and legal status of the hospital." Office of Inspector General, supra note 5, at 45.

V. THE NECESSARY ELEMENTS OF CORPORATE COMPLIANCE FOR A HEALTH CARE ENTITY

There is no cookie cutter answer on how to structure a corporate compliance program. Each health care entity is unique, whether it be a large urban medical center or a small rural hospital. Each entity should tailor its compliance program to set up the necessary internal controls and monitoring systems needed to prevent and correct unlawful conduct. The DHHS-OIG has suggested elements that can be incorporated into the managerial structure of multi-hospital and integrated delivery systems.

These necessary elements include:

1. The development and distribution of written standards of conduct, as well as written policies and procedures that promote the hospital’s commitment to compliance (for example, by including adherence to compliance as an element in evaluating managers and employees) and that address specific areas of potential fraud, such as claims development and submission processes, code gaming, and financial relationships with physicians and other health care professionals;

2. The designation of a chief compliance officer and other appropriate bodies, for example, a corporate compliance committee, charged with the responsibility of operating and monitoring the compliance program, and who report directly to the CEO and the governing body;

3. The development and implementation of regular, effective education and training programs for all affected employees;

4. The maintenance of a process, such as a hotline, to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation;

5. The development of a system to respond to allegations.

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349. The compliance program guidelines were published to promote voluntarily developed and implemented compliance programs for the health care industry. The guidelines are not limited to hospitals, but also include the agents of the hospital and subproviders develop infrastructure to ensure compliance with the laws. See Office of Inspector General, supra note 5, at 1.

350. These elements are based on the seven steps of the Federal Sentencing Guidelines. See U.S.S.G. § 8A1.2, cmt. n.3(k).
of improper/illegal activities and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations or federal health care program requirements;

(6) the use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas; and

(7) the investigation and remediation of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals.\textsuperscript{351}

The OIG understands that all elements may not be implemented at first, but suggests that the governing body and CEO make a good faith commitment to ensure that a compliance program is successful.\textsuperscript{352}

A. Establishing Written Compliance Policies and Procedures

Written policies and procedures must be developed and distributed when implementing a corporate compliance program. These policies and procedures should be created by the compliance officer and/or compliance committee. Policies and procedures should be distributed to all affected employees. The policies and procedures should establish criteria for how employees should conduct themselves in all business relationships.

1. Standard of Conduct Policy

A health care entity should adopt a standard of conduct for its employees. The standard of conduct should set forth a commitment to the corporate compliance program by upper level management. The standard should establish the health care entity's commitment to comply with all federal and state standards and emphasize the prevention of fraud and abuse. The standard should also state the mission, goals, and ethical requirements of the corporate compliance program. Employees should understand the standard of conduct policy. Therefore, the health care entity should provide alternate versions of the policy, including a version

\textsuperscript{351} Office of Inspector General, supra note 5, at 7-8.
\textsuperscript{352} See id. at 6-7.
in large print and versions in foreign languages. The policy should also be written at an appropriate reading level.  

2. Special Risk Areas

The written policies and procedures should analyze the potential liability for each function or department of the health care entity. Corporate compliance policies should be tailored to specific risk areas. For example, a staff nurse does not need to learn about all the intricacies of the billing process but may benefit from a more general discussion about billing and the compliance program. The OIG suggests that policies and procedures coordinate with training and educational programs with emphasis on the following areas:

(1) Billing for items or services not actually rendered;
(2) Providing medically unnecessary services;
(3) Upcoding;
(4) "DRG creep;"
(5) Outpatient services rendered in connection with inpatient stays;
(6) Teaching physician and resident requirements for

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353. See id. at 8-9.
354. See id. at 11.
355. See id.
356. See id. at 12.
357. See id. at 13. Intentionally seeking reimbursement for a service rendered that is not warranted by the patient's current and documented medical condition. See id. at 14 (citing 42 U.S.C. § 1395y(a)(1)(A) (1994)).
358. See id. Upcoding is the use of a billing code that provides a higher payment than the billing code that properly reflects the health care service rendered. See id. at 14 n.15. The HIPAA established an additional civil monetary penalty to the OIG's sanction authorities for upcoding violations. See 42 U.S.C. § 1320a-7a(a)(1)(A) (Supp. III 1997).
359. Office of Inspector General, supra note 5, at 14. "DRG Creep" is the practice of billing using a Diagnosis Related Group ("DRG") that provides a higher payment than the DRG code that properly reflects the health care service rendered. See id. at 14 n.16.
360. See id. This is known as the 72-hour window investigation. Under Medicare billing rules, tests performed within 72 hours of an admission to a facility are considered part of the inpatient stay and are reimbursed under the hospital's DRG payment. However, hospitals have billed separately for these tests which has resulted in double payment. See id.
teaching hospitals; 361
(7) Duplicate billing; 362
(8) False cost reports; 363
(9) Unbundling; 364
(10) Billing for discharge in lieu of transfer; 365
(11) Patients' freedom of choice; 366
(12) Credit balances - failure to refund; 367
(13) Hospital incentives that violate the Anti-kickback statute or other similar federal or state statute or regulation; 368
(14) Joint ventures; 369
(15) Financial arrangements between hospitals and hospital-based physicians; 370
(16) Stark physician self-referral law; 371
(17) Knowing failure to provide covered services or necessary care to members of a health maintenance organization; 372 and
(18) "Patient Dumping." 373

361. See id.
362. See id.
363. See id.
364. See id. at 16. Unbundling occurs when bills for medical treatment are submitted in a fragmented fashion to maximize the reimbursement for various tests or procedures that are required to be billed together at a reduced cost. See id. at 16 n.20.
365. See id. According to Medicare laws, when a prospective payment system ("PPS") hospital transfers a patient to another PPS facility, the hospital to which the patient is transferred may charge the full DRG. See id. at 16 n.21. The transferring hospital may only charge Medicare for costs per diem. See id.
366. See id.
367. See id.
368. See id. at 17.
369. See id. at 18.
370. See id.
371. See id. at 19.
372. See id.
373. Id. at 20. "Patient Dumping" is addressed by the Emergency Medical Treatment and Active Labor Act ("EMTALA"), which requires that hospitals that operate an emergency department that participate in the Medicare program that: (1) provide appropriate medical screening examination upon request to determine whether an individual has an emergency medical condition; and (2) if the person has such a condition, (a) stabilize that condition; or (b) appropriately transfer the patient to another hospital. See 42 U.S.C. § 1395dd(b)(1)(A)-(B)
These are only some of the areas of risk. These areas of concern have been compiled as a result of the recent investigative and audit efforts of the OIG. These areas should be part of the compliance program by incorporating them into the written policies and procedures, as well as employee training.

3. Establishing a Claim Development and Submission Process

The Compliance Program Guidance for Hospitals sets forth recommendations for structuring a billing process. Often a corporate compliance program is imposed by a settlement agreement between the OIG and various health care entities. Thus, the OIG is in a better position to render advice about what are acceptable processes to ensure compliance with federal and state laws and program requirements. The written policies and procedures of the health care entity should reflect and reinforce current federal and state law with regard to the submission of claims and Medicare cost reports. Written policies and procedures should:

(1) provide for proper and timely documentation of all physician and other professional services prior to billing to ensure that only accurate and properly documented services are billed;

(2) emphasize that claims should be submitted only when appropriate documentation supports the claims and only when such documentation is maintained and available for audit and review. The documentation which may include patient records, should record the length of time spent in conducting the activity leading to the record entry, and the identity of the individual providing the service. The hospital should consult with its medical staff to establish other appropriate documentation guidelines;

(3) state that, consistent with appropriate guidance from medical staff, physician and hospital records and medical

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374. See Office of Inspector General, supra note 5, at 20. When the Government imposes a corporate compliance program against a corporation, it is termed a “corporate integrity” agreement. See id. Such agreements were often required in addition to the payment of civil damages and/or criminal fines and penalties. See id.

375. See id.

376. See id.
notes used as a basis for a claim submission should be appropriately organized in a legible form so they can be audited and reviewed;

(4) indicate that the diagnosis and procedures reported on the reimbursement claim should be based on the medical record and other documentation, and that the documentation necessary for accurate code assignment should be available to coding staff; and

(5) provide that the compensation for billing department coders and billing consultants should not provide any financial incentives to improperly upcode claims.\footnote{\textit{Id.} at 21.}

Written policies and procedures about coding should reflect current reimbursement standards as established by applicable regulations and should be developed along with private payor and organizational standards.\footnote{\textit{See id.}}

4. Records Retention Policy

\hspace{1em} a. General Policy

A corporate compliance program should create a records management and retention policy.\footnote{\textit{Id.} at 29.} Policies and procedures should be developed with regards to the creation, distribution, retention, storage retrieval and destruction of documents.\footnote{\textit{See id.}} Health care entities should develop a records retention policy that considers the use of the records for patient care, adherence to state and federal law, accreditation requirements, possible government or internal investigations, and state and federal statutes of limitations.

A records retention policy should start with an inventory of all records created and received by each department of the health care entity. This may be accomplished by a facility-wide written survey. The survey should ask what documents exist in each de-

\textit{Regulations include the official coding guidelines created by HCFA, the National Center for Health Statistics, the American Medical Association and the American Health Information Management Association, International Classification of Diseases, 9th Revision, Clinical Modification ("ICD-CM"); 1998 Health Care Financing Administration Common Procedure Coding System ("HCPCS"); and Physicians' Current Procedural Terminology ("CPT"). \textit{See id.} at 21 n.27.}

\textit{See id. at 29.}

\textit{See id. at 30.}
department and whether the department has a record retention policy. This survey should be followed up with an in-person interview with a staff member from each department. The interview should determine if other documents exist that were not mentioned on the survey.

The policy should set forth what records are and are not created by each department. These requirements should be included in employment policies and procedures. It should also establish employee disciplinary procedures for failure to comply with the records retention policy.

The records policy must identify how each record created or received is distributed both within and outside the facility. Distribution should be limited and monitored. The policy should contain a strict provision pertaining to document reproduction. The provision should set forth whether a document may be copied and to whom it may be distributed. Distribution beyond the policy must be prohibited.

The record policy must also set forth schedules for the destruction of documents as well as the method of destruction. Schedules should be created for all records authorized to be preserved, along with retention dates for each category of records. Destruction methods should be designed to ensure total destruction of the documents. Document destruction should be complete and conducted in a way that maintains the confidentiality of the

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382. See id.
383. See id. Guarino notes:

Often forgotten documents include inter or intra office memoranda (both written or electronic mail), construction records, plant and property records (including maintenance and repair reports for both buildings and equipment), ethics committee records, market research data, consultant reports, certificates of insurance, real and personal property records, internal audit reports, employment inquiries, grant applications and reports and accountings, plant safety and technology records, and training manuals.

Id. at 15.

384. See id. at 15.
385. See id. Reproduction may include microfilm. Microfilming may have to be performing in accordance with an approved procedure for the records to be admissible in court and acceptable to government agencies. See id.
386. See id.
documents. A procedure must be developed for the storage of records. Storage must permit or restrict access as needed. For example, access to substance abuse, mental health and employee health records should be restricted because of heightened confidentiality requirements. Finally, the records retention program should institute management procedures that ensure compliance with the laws. This should include monitoring the creation of paper and electronic records, distribution, duplication, storage, retention, and destruction.

b. Specific Requirement of Medicare for Record Retention

The Medicare program has many requirements for the retention of records. The Medicare program has different periods of retention for different types of records. The Medicare program requires hospitals to retain medical records in their original or legally reproduced form for a period of at least five years in order to participate in the program. Records for specific health care services must be retained for various periods of time as a condition for participation in the Medicare program. Radiological records, including copies of printouts, reports, films, scans and other image records must be kept for five years. Laboratory test requisitions and records of patient testing, including the original report must be retained for a minimum of two years after the date of reporting. Immunohematology records must be retained for no less than five years. Pathology test reports must be kept for ten years from the date of the reporting.

Medicare requires health care providers to retain and make available records and documents pertinent to the amount of Medi-
care payments due. Hospitals must retain clinical and other medical records relating to Medicare claims for five years after the month the Medicare cost report is filed. If the health care provider appeals a reimbursement decision, relevant records should be kept until the decision at the appellate level is obtained.

In addition, Medicare also has specific retention requirements for long-term care facilities, home health agencies, comprehensive outpatient rehabilitation facilities, clinics and rehabilitation agencies which provide outpatient physical therapy and/or speech pathology services, and for end-stage renal disease services.

B. Compliance Oversight Responsibilities

The demand for corporate compliance in the health care industry has resulted in the creation of new lucrative positions as compliance officers. The salary for a compliance officer ranges from $50,000 for $200,000. There are no statistics available on the number of hospitals and health systems with compliance officers, but industry experts estimate that about five percent of hospitals have compliance officers.

The DHHS-OIG recommends that a hospital appoint both a

395. See id. at 16 (citing PROVIDER REIMBURSEMENT MANUAL, PRM-1, § 2304.1).
396. See id. (citing MEDICARE HOSPITAL MANUAL, HIM-10, §§ 413, 413.1).
397. See id. at 8.
398. The retention period is often required by state law, but if a state requirement does not exist, then for five years for the date of discharge for adults and for a minor for three years after the resident reaches a legal age as set forth by state law. See id. (citing 42 C.F.R. § 483.75(1) (1998)).
399. See id. (citing 42 C.F.R. § 484.38 (1998)). Records must be retained for five years after the month that the relevant cost report is filed. See id.
400. See id. (citing 42 C.F.R. § 485.60(c) (1998)). Records must be retained for five years after patient discharge. See id.
401. See id. (citing 42 C.F.R. § 405.1722(d) (1998)). The period of record retention is determined by the state. See id. If there is no state provision, then the retention period is for five years after the date of discharge for adults and, for minors, three years after the patient becomes of age under state law or five years after discharge, whichever is longer. See id.
402. See id. (citing 42 C.F.R. § 2139(e) (1998)). The state usually sets forth the record retention requirement. See id. However, if no state provision exists, then the records should be retained for five years from the date of discharge, for minors, for three years after the patient reaches the age of majority. See id.
403. Deanna Bellandi, Rolling Out the Red Carpet, MOD. HEALTHCARE, Sept. 29, 1997, at 28, 32.
404. See id.
405. See id. (quoting Lori Walters, administrator of the American Compliance Institute).
compliance officer and a compliance committee to oversee the compliance efforts of the health care entity.406 The corporate compliance program may be the sole duty or added to other management responsibilities of an individual so long as the compliance function is not neglected or tainted by the individual’s management perspective.407 A separate compliance function may ensure independent and objective legal review and financial analysis of the health care entity’s compliance efforts.408 A corporate compliance officer should be a high-level employee with direct access to the governing body and the chief executive officer (“CEO”) of the health care entity.409 In addition, the OIG suggests that a multi-hospital organization coordinate with each hospital owned by the corporation or foundation via a headquarter-based compliance officer who works with parallel positions at each facility or regional office.410

The OIG recommends that responsibilities of a corporate compliance officer include the following:

(1) overseeing and monitoring the implementation of the compliance program;

(2) reporting on a regular basis to the hospital’s governing body, CEO and compliance committee on the progress of implementation, and assisting these components in establishing methods to improve the hospital’s efficiency and quality of services, and to reduce the hospital’s vulnerability to fraud, abuse and waste;

(3) periodically revising the program in light of changes in the needs of the organization, and in the law and policies and procedures of government and private payor health plans;

(4) developing, coordinating, and participating in a multifaceted educational and training program that focuses on the elements of the compliance program, and seeds to ensure that all appropriate employees and management are knowledgeable of, and comply with, pertinent federal and

406. See Office of Inspector General, supra note 5, at 31 n.35.
407. See id. at 31.
408. See id. at 31 n.35. The OIG will consider the size and resources of each health care entity and understands that smaller facilities may not be able to establish a compliance officer whose sole duty is a compliance function. See id.
409. See id.
410. See id. at 31 n.36.
state standards;
(5) ensuring that independent contractors and agents who furnish medical services to the hospital are aware of the requirements of the hospital’s compliance program with respect to coding, billing, and marketing, among other things;
(6) coordinating personnel issues with the hospital’s Human Resources office (or its equivalent) to ensure that the National Practitioner Data Bank and Cumulative Sanction Report have been checked with respect to all employees, medical staff and independent contractors;
(7) assisting the hospital’s financial management in coordinating internal compliance review and monitoring activities, including annual or periodic reviews of departments;
(8) independently investigating and acting on matters related to compliance, including the flexibility to design and coordinate internal investigations (e.g., responding to reports of problems or suspected violations) and any resulting corrective action with all hospital departments, providers and sub-providers, agents and, independent contractors; and
(9) developing policies and programs that encourage managers and employees to report suspected fraud and other improprieties without fear of retaliation.\(^\text{411}\)

The health care entity must use due care and not assign oversight responsibilities to individuals with the propensity to engage in illegal activities.\(^\text{412}\) The compliance officer is a very prominent position that requires access to all documents and information related to compliance activities, which may include patient records, billing records, marketing strategies, employment and other contracts.\(^\text{413}\)

The OIG suggests that a compliance committee be established to advise and assist the corporate compliance officer.\(^\text{414}\) Members of the compliance committee should include the corporate compliance officer and other high-level employees with executive or

\(^{411}\) See id. at 31-32.
\(^{412}\) See Webb & Molo, supra note 278, at 375.
\(^{413}\) See OFFICE OF INSPECTOR GENERAL, supra note 5, at 33.
\(^{414}\) See id. at 34.
The corporate compliance committee should furnish various perspectives by including committee members who represent different operations within the corporation such as finance, audit, human resources, utilization review, social work, discharge planning, medicine, coding and legal as well as other key operating departments.

The DHHS-OIG recommends the following compliance committee functions:

(1) analyzing the organizations' industry environment, the legal requirements with which it must comply, and specific risk areas;

(2) assessing existing policies and procedures that address these areas for possible incorporation into the compliance program;

(3) working with appropriate hospital departments to develop standards of conduct and policies and procedures to promote compliance with the institution’s program;

(4) recommending and monitoring, in conjunction with the relevant departments, the development of internal systems and controls to carry out the organization’s standards, policies and procedures as part of its daily operations;

(5) determining the appropriate strategy/approach to promote compliance with the program and detection of any potential violations, such as through hotlines and other fraud reporting mechanisms; and

(6) developing a system to solicit, evaluate and respond to complaints and problems.  

Depending on the size and resources of a health care entity,

415. See Webb & Molo, supra note 278, at 382 (citing U.S.S.G. § 8A1.2 cmt. n.3 (b)).
416. See OFFICE OF INSPECTOR GENERAL, supra note 5, at 30 n.34. The OIG suggests that its Management Advisory Report entitled “Financial Arrangements between Hospitals and Hospital-Based Physicians,” Special Fraud Alerts, audit and inspection reports, and advisory opinions, as well as the annual OIG work plan may be the basis for standard, educational courses and programs for appropriate hospital employees. See id. at 35 n.40.
417. Id. at 34.
the compliance committee may address other functions. The compliance committee may issue an annual report to demonstrate their effectiveness. In addition, the committee and/or compliance officer should be evaluated regularly but not less than once per year.

C. Employee Training

Corporate officers, managers, employees, physicians, and other health care professionals should receive corporate compliance training. The OIG suggests that a health care entity communicate its standards and procedures to all affected employees, physicians, independent contractors and other significant agents.

The best way to communicate compliance program standards and procedures to employees depends on the type of health care entity, procedures, and the composition of the work force. A single training program may not be sufficient for the entire work force. A health care entity should train employees in accordance with their responsibilities, educational backgrounds, and the impact of the compliance program on them.

Health care entities may train employees by using written materials, seminars, videos, computer software programs, and vignettes. Interactive training is more effective than lectures and presentations that do not involve audience participation. Training in different languages may be necessary for health care entities with a culturally diverse staff. Targeted compliance training should be provided to corporate officers, managers and employees whose actions affect the accuracy of the claims submitted to the government, such as those involved in coding, billing, cost reporting and marketing processes.

The OIG recommends that employee training should include the following areas:

418. See id.
419. See id. at 35.
420. See id.
421. See Webb & Molo, supra note 278, at 394.
422. See id.
423. See id.
424. See Office of Inspector General, supra note 5, at 35.
425. See id.
426. See id.
(1) government and private payor reimbursement principles;  
(2) general prohibitions on paying or receiving remuneration to induce referrals; 
(3) proper confirmation of diagnoses;  
(4) submitting a claim for physician services when rendered by a non-physician (i.e., the "incident to" rule and the physician physical presence requirement);  
(5) signing a form for a physician without the physician's authorization;  
(6) alterations to medical records; 
(7) prescribing medications and procedures without proper authorization;  
(8) proper documentation of services rendered; and 
(9) duty to report misconduct.\footnote{427}

Educating employees about these areas of concerns may clarify whether an activity is prohibited by the compliance program.\footnote{428}

Participation in a training program should be mandatory.\footnote{429}
The corporate compliance program should require employees to have a minimum number of educational hours per year.\footnote{430} New employees should receive compliance training early in their employment but training should be ongoing.\footnote{431} Compliance program refresher training should be regularly offered.\footnote{432} Corporate compliance training may be made a condition of employment. A health care entity may provide that failure to comply with training program requirements will result in disciplinary action or termination.\footnote{433} Completion of training requirements should also be considered in the employee’s annual evaluation.\footnote{434}
The health care entity must be able to demonstrate to the government that employees were properly trained. Employees should certify they received the training materials and participated in a training program. Attendance at all compliance program employee training should be documented in the employee's personnel file.

D. Reporting Unlawful/Unethical Conduct: Establishing the Lines of Communication

The compliance officer must be accessible to hospital personnel in order for a compliance program to be successful. Policies regarding confidentiality of communication and non-retaliation should be developed and distributed to all employees to encourage communication and reporting of unlawful and unethical conduct. The compliance committee should structure several ways to report fraud, waste, or abuse so that such reports cannot be diverted by supervisors or other personnel.

The OIG also recommends that a health care entity establish a procedure for hospital personnel to seek clarification from the compliance officer or members of the committee if any confusion or questions arise about the compliance policy or procedure. Inquiries and answers should be documented and, if appropriate, shared with others so that standards, policies and procedures may be updated and/or clarified.

The OIG suggests using hotlines, e-mails, written memoranda, newsletters, and other forms of information exchange to maintain open lines of communication. If a hotline is established, the telephone number should be available to employees and posted in common work areas. Health care entities should also post the Health and Human Services, Office of Inspector General Hotline telephone number along side the organization's hotline number.

435. See id. (recommending that hospital retain records of training including attendance logs and copies of materials distributed).
436. See id. at 38.
437. See id.
438. See id.
439. See id.
440. See id.
441. See id. at 39.
442. See id.
443. See id. at 39 n.46. The DHHS-OIG Hotline number is 1-800-HHS-TIPS. See Department of Health and Human Services, Office of the Inspector General
The compliance program should be structured so that employees have the option to anonymously submit fraud, abuse and waste reports.\textsuperscript{444} Reports of unlawful or unethical conduct should be documented and promptly investigated.\textsuperscript{445} The compliance officer should maintain documentation that track reports and telephone calls, the nature of any internal investigation and the results.\textsuperscript{446} The compliance program should establish infrastructure to maintain the confidentiality of an employee's identity.\textsuperscript{447} However, employees should be informed that their identities may be revealed if government authorities become involved in the investigation.\textsuperscript{448}

\textbf{E. Compliance Program Disciplinary Action}

Failure to comply with the compliance program should result in disciplinary action.\textsuperscript{449} Noncompliance with hospital standards of conduct, policies and procedures, or federal and state laws may damage the reputation of the entity as a reliable, honest and trustworthy health care provider.\textsuperscript{450} A health care entity's commitment to corporate compliance may be demonstrated by the strength and severity of its disciplinary efforts.

The OIG recommends that a written disciplinary policy be distributed to all employees.\textsuperscript{451} This policy should clearly establish the degrees of disciplinary actions.\textsuperscript{452} There should be significant sanctions for intentional or reckless noncompliance.\textsuperscript{453} These sanctions may include oral warnings, suspension, privilege revocation, termination of employment, and/or financial penalties.\textsuperscript{454} The policy should set forth procedures for handling disciplinary problems.\textsuperscript{455} Discipline may be addressed by managers or senior administra-

\begin{itemize}
\item \textsuperscript{444} See \textsc{Office of Inspector General}, \textit{supra} note 5, at 39.
\item \textsuperscript{445} See \textit{id}.
\item \textsuperscript{446} See \textit{id}.
\item \textsuperscript{447} See \textit{id}.
\item \textsuperscript{448} See \textit{id}.
\item \textsuperscript{449} See \textit{id} at 40.
\item \textsuperscript{450} See \textit{id} at 59.
\item \textsuperscript{451} See \textit{id} at 40.
\item \textsuperscript{452} See \textit{id}.
\item \textsuperscript{453} See \textit{id}.
\item \textsuperscript{454} See \textit{id}.
\item \textsuperscript{455} See \textit{id}.
\end{itemize}
tors. Managers and supervisors should discipline employees in an appropriate and consistent manner. All employees should be subject to the same disciplinary action regardless of their status within the health care entity. Management may be held responsible for the foreseeable noncompliant behavior of their subordinates. Furthermore, to increase the deterrent effect, the health care entity may consider disclosure of the disciplinary action imposed on an employee to other similarly situated employees to the extent legally possible. This may motivate other employees to avoid misconduct.

A health care entity should avoid hiring individuals who are inclined to behave in an unlawful and/or unethical manner. This may be accomplished by conducting a background investigation that includes a reference check. The employment application should specifically ask the applicant to disclose any criminal conviction or exclusion from any health care reimbursement program like Medicare.

The health care entity should establish a policy that prohibits the employment of individuals who have been convicted of a criminal offense related to health care or who are debarred, excluded or otherwise ineligible for participation in federal health care programs. A policy should also be established to prohibit contracting with independent contractors or other agents who also have a criminal conviction related to health care or have been debarred, excluded or are ineligible for participation in federal health care programs. If criminal charges are alleged or debarment or exclusion is sought, that employee should be relieved of all responsibility for, or involvement in, any federal health care program until the matter is resolved. If a conviction,

456. See id.
457. See id.
458. See id.
459. See id.
460. See Webb & Molo, supra note 278, at 395.
461. See id.
462. See OFFICE OF INSPECTOR GENERAL, supra note 5, at 40-41.
463. See id. at 41. "Criminal conviction" is defined by statute. 42 U.S.C. § 1320a-7(i) (1994).
464. See OFFICE OF INSPECTOR GENERAL, supra note 5, at 41.
466. See OFFICE OF INSPECTOR GENERAL, supra note 5, at 41 n.48.
467. See id. at 41.
debarment, or exclusion results then employment should be terminated. 468

F. Monitoring and Auditing

Reasonable steps should be taken to ensure that employees abide with the standards established under the compliance program. 469 Therefore, the compliance program should have a monitoring and auditing feature. This may be conducted by inside employees or outside consultants. 470

Periodic audits may ensure compliance with the policies and procedures of the health care entity as well as federal, state, and local laws and regulations. The audit at a minimum should address Anti-kickback laws, 471 illegal physician self-referrals under Stark law, 472 International Classification of Diseases, 9th Revision, Clinical Modification ("ICD-CM"), 1998 Health Care Financing Administration Common Procedure Coding System ("HCPCS") and Physicians' Current Procedural Terminology ("CPT") coding, claim development and submission, reimbursement, cost reporting and marketing. 473 Individuals performing the audits should have access to all information, personnel, areas of operations, and existing corporate auditing resources. The audit should address hospital relationships with third-party contractors. 474 The audit should also inquire into compliance with specific rules and policies that have

468. See id.
469. See id. at 42.
470. See id.; see generally George M. Burditt, Corporate Compliance Audits, 51 FOOD & DRUG L.J. 217 (1996) (discussing corporate compliance monitoring and audits for FDA-regulated industries). The OIG suggests that the auditor or monitoring reviewer should:

(1) be independent of physicians and line management;
(2) have access to existing audit and health care resources, relevant personnel and all relevant areas of operation;
(3) present written evaluative reports on compliance activities to the CEO, governing body and members of the compliance committee on a regular basis, but not less than annually; and
(4) specifically identify areas where corrective actions are needed.

OFFICE OF INSPECTOR GENERAL, supra note 5, at 44.
471. See id. at 42. See generally supra Part III.A and accompanying notes.
472. These are known as the Stark Laws. See supra Part III.B and accompanying notes.
473. OFFICE OF INSPECTOR GENERAL, supra note 5, at 42.
474. See id.
been focused on by Medicare fiscal intermediaries or carriers and law enforcement, as demonstrated by OIG Special Fraud Alerts, OIG audits and evaluations, and law enforcement’s initiatives.\footnote{See id.}

A comprehensive internal audit should first be conducted when the compliance program is developed and repeated on a regular periodic basis thereafter.\footnote{See id. at 42-43.} This provides a “snapshot” of operations from a compliance perspective.\footnote{See id. at 43 n.51.} The snapshot establishes a baseline for the compliance activities, which assists the compliance officer and others in identifying and reviewing deviations therefrom.\footnote{See id.} If the deviation is for a legitimate reason, the compliance officer, hospital administrator, or manager may take limited or no disciplinary action.\footnote{See id.} If the deviation occurred because of an improper procedure or misinterpretation of policy, corrective action should be taken.\footnote{See id.} Any resulting overpayments should be paid back to the affected payor.\footnote{See id.} The health care entity should report to the government deviations that are the result of fraud or systemic problems.\footnote{See id. at 43 n.52.}

The monitoring process should determine whether the elements of the compliance program have been satisfied.\footnote{See id. at 43.} This will determine the conformity of all departments with the compliance program.\footnote{See id.} This review may provide evidence that the appropriate documentation has been created and maintained as part of the implementation of an effective compliance program.\footnote{See id.}

The OIG recommends the techniques that should be utilized as part of the monitoring and auditing process as follows:

(1) on-site visits;

\footnote{See id. at 42-43.} \footnote{See id. at 43 n.51.} \footnote{See id.} \footnote{See id. at 43.} \footnote{See id.} \footnote{See id.} \footnote{See id. at 43 n.52.} \footnote{See id. at 44.} \footnote{See id.} \footnote{See id.}
(2) interviews with personnel involved in management, operations, coding, claim development and submission, patient care, and other related activities;
(3) questionnaires developed to solicit impressions of a broad cross-section of the hospital's employees and staff;
(4) reviews of medical and financial records and other source documents that support claims for reimbursement and Medicare cost reports;
(5) reviews of written materials and documentation prepared by the different divisions of a hospital; and
(6) trend analyses, or longitudinal studies, that seek deviations, positive or negative, in specific areas over a given period.

Use of these techniques may generate reports that permit corrective action for past conduct and prevent reoccurrence of the same difficulty. Subsequent reviews should be conducted to ensure that the corrective action was actually taken and it ameliorated the problem.

G. Modification of the Compliance Program: Responses to Internal and External Investigations

The OIG has made specific recommendations with regard to modifications of a compliance program in response to an investigation. Upon a report or other indication of noncompliance, an internal investigation should be immediately conducted to determine whether federal, state or local law, or the compliance program requirements have been violated. If a violation has occurred, the health care entity may seek the advice of an attorney to plan an appropriate response.

486. Id.
487. See id. at 45.
488. See id.
489. See id.
490. See id.
491. See id. at 45-46. An appropriate response may include the internal development of a corrective action plan, referral to criminal and/or civil law enforcement, reporting to the government and repayment of any overpayments. See id. at 46.
1. General Reporting to the Government and the Operation Restore Trust Program

An appropriate response may include making a report to the appropriate federal and state government officials. An adequate response requires reporting misconduct within a reasonable period of time, but no longer than sixty days after determining whether a violation has occurred. Serious violations may require immediate reporting prior to, or simultaneously with, the commencement of an internal investigation. In instances where fraud and abuse are involved, the government has established a voluntary disclosure program that is referred to as Operation Restore Trust. This voluntary disclosure program was created because the government realized that it cannot maintain the integrity of Medicare and other federal health care programs without the assistance of health care providers by way of their self-policing efforts.

492. See id. at 50 n.60. "Appropriate federal and state authorities" include the Criminal and Civil Divisions of the Department of Justice, the U.S. Attorney in the hospital’s district, and the investigative arms for the agencies administering the affected federal or state health care programs, such as the state Medicaid Fraud Control Unit, the Defense Criminal Investigative Service, and the Offices of Inspector General of the Department of Health and Human Services, the Department of Veterans Affairs and the Office of Personnel Management (which administers the Federal Employee Health Benefits Program).

493. See id. at 47-48.

494. See id. at 48 n.58. Immediate notification to governmental authorities is required if the conduct:

(1) is a clear violation of criminal law;
(2) has a significant adverse effect on the quality of care provided to program beneficiaries (in addition to any other legal obligations regarding quality of care); or
(3) indicates evidence of a systemic failure to comply with applicable laws, and existing corporate integrity agreement, or other standards of conduct, regardless of the financial impact on federal health care programs.

Id.

495. See Eiland, supra note 48, at 40. Operation Restore Trust began as a two-year federal project that focused its efforts on home health agencies, nursing homes, durable medical equipment suppliers, and hospices in the states of New York, Illinois, California, Florida, and Texas. See id. These states were chosen because they accounted for one-half of all of the nation’s Medicare beneficiaries and Medicaid recipients. See id. This project initially resulted in 50 criminal convictions, 48 civil judgments and 149 exclusions. See Barbara J. Youngberg et al., The Risk Manager’s Desk Reference 109-10 (2d ed. 1998).

496. See Office of Inspector General, supra note 5, at 46 n.55.
Trust has the following requirements:

(1) the disclosure must be on behalf of an entity and not an individual;
(2) the disclosure must be truly voluntary with no pending proceeding or governmental investigation;
(3) the entity must disclose the nature of the wrongdoing and resulting harm to the federal programs; and
(4) the entity must not be the subject of bankruptcy proceeding before or after the self-disclosure. 497

Operation Restore Trust is applicable to home health agencies, nursing homes, durable medical equipment companies ("DME"), clinical laboratories, long-term care, inpatient psychiatric, rural health clinics, and community mental health centers. 498 Currently, Operation Trust is applicable only in the states of California, Florida, New York, Texas, Illinois, Arizona, Colorado, Georgia, Louisiana, Massachusetts, Missouri, New Jersey, Ohio, Pennsylvania, Tennessee, Virginia, and Washington. 499

In a May 1997 press release, the federal government announced that Operation Restore Trust recovered $187.5 million in overpayments, restitution, fines and settlements owed to the government. 500 It also resulted in seventy-four criminal convictions and 218 provider exclusions for inappropriately billed or medically unnecessary services. 501 The OIG indicates that false claims were as high as sixty-six percent in some the nursing homes investigated under this program. 502

In general, a health care entity should voluntarily disclose the unlawful and/or unethical conduct, so that the penalties imposed for the violation may be reduced. 503 It is better for a health care en-

497. Id.
498. See Eiland, supra note 48, at 40. The OIG issued a report on July 28, 1997 which states that one-fourth of the providers in the initial five states of California, Florida, New York, Texas, and Illinois, were "problem" providers who defrauded the program. See id.
499. See id.
500. See id.
501. See id.
502. See id.
503. See U.S.S.G. § 8C4.1 (1994). The United States Sentencing Guidelines provide a reduction in fines for entities that self-report, or assist the Government in its investigation and recognize and accept responsibility for the unlawful or un-
tity to voluntarily disclose the improper conduct than to be caught up in a cover-up by the government or by employees who may bring a qui tam action.

2. Internal Investigation Responses

An internal investigation is a proper response to misconduct within the health care entity. As stated previously, internal investigations may include interviews, on-site visits, access and review of all relevant documentation, development of questionnaires and/or surveys, audits and possibly the involvement of an independent attorney outside of the entity. The compliance office should take steps to ensure that all relevant documentation or other evidence is not destroyed pending the investigation.

Additionally, if it is determined that the integrity of the internal investigation is at stake because of the employees under investigation, those individuals should be relieved from their work responsibilities until the investigation is complete. However, if an internal or government undercover operation is implemented as a part of an investigation, then the individual should still perform their assigned work activities.

ethical conduct. Section 8C4.1 of the Sentencing Guidelines provides:

Substantial Assistance to Authorities—Organizations (Policy Statement)
(a) Upon motion of the government stating that the defendant has provided substantial assistance in the investigation or prosecution of another organization that has committed an offense, or in the investigation of prosecution of an individual not directly affiliated with the defendant who has committed an offense, the court may depart from the guidelines.
(b) The appropriate reduction shall be determined by the court for reasons stated on the record that may include, but are not limited to, consideration of the following:
   (1) the court's evaluation of the significance and usefulness of the organization's assistance, taking into consideration the government's evaluation of the assistance rendered;
   (2) the nature and extent of the organization's assistance; and
   (3) the timeliness of the organization's assistance.

504. See supra Part V.F and accompanying notes.
505. OFFICE OF INSPECTOR GENERAL, supra note 5, at 41.
506. See id. at 47.
507. See id.
Finally, the corporate compliance officer should review the events that gave rise to the investigation and determine whether similar problems have been uncovered.\(^{508}\)

The final response to a detected offense is the identification and restitution of any overpayment to the affected payor and the imposition of appropriate disciplinary action.\(^{509}\) Failure to do so in a timely manner can be viewed as an attempt to hide the overpayment from the government. This provides an independent ground for a criminal violation.\(^{510}\)

VI. DEVELOPMENT AND IMPLEMENTATION OF A COMPLIANCE PROGRAM

Given the elements and recommendations of a corporate compliance program, the next question is how does a health care entity develop and adopt a corporate compliance program? First, it is important to note that failure to implement an effective corporate compliance program may result in liability under the responsible officer doctrine. In the case of In re Caremark International Inc.,\(^{511}\) the court stated the following:

[A] director's obligation includes a duty to attempt in good faith to assure that a corporate information and reporting system, which the board concludes is adequate, exists, and that failure to do so under some circumstances may... render a director liable for losses caused by non-compliance with applicable legal standards.\(^{512}\)

This statement exemplifies the "responsible corporate officer" doctrine. This doctrine imposes criminal punishment for an officer's failure to fulfill his corporate duties.\(^{513}\) A corporate official with authority over matters that are regulated by criminal statutes may be prosecuted for failing to act to remedy problems that de-
developed even before they assumed their positions of responsibility. Therefore, a successful corporate compliance program must elicit the support of the board of directors ("Board") and CEO. The Board and upper-level management must make corporate compliance a priority. First, the Board should adopt a resolution authorizing the creation of a corporate compliance program. The resolution should record the date on which the health care entity made a commitment to corporate compliance. After creation of the compliance program, the Board should adopt another resolution that officially approves and adopts the compliance program.

The Board must delegate oversight of the compliance program. An audit committee and/or a compliance committee may be formed. These committees may be given implementation, enforcement, and investigative powers. If the Board also retains some oversight power, it should require regular reporting from the program administrator and should consider significant compliance policy matters as agenda items when appropriate.

Most importantly, the CEO's involvement in the program sets the tone for the compliance program. A CEO may demonstrate his commitment to the health care entity's compliance efforts by distributing a code of conduct under his signature, by emphasizing the importance of compliance efforts during meetings, and by meeting with employees who are responsible for administering the compliance program. These actions will show that the health care entity takes corporate compliance seriously.

Next, as stated previously, the health care entity must determine the areas of risk that the compliance program must address. This may be accomplished by conducting an internal audit, which includes interviewing management and employees, as well as examining the practices and standards within its own industry, and should involve an attorney to have a legitimate argument for the attorney-client privilege. The audit process to determine the ar-

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514. See id. at 748-49.
515. See YOUNGBERG ET AL., supra note 495, at 112. This may also extend the attorney-client privilege to the design of the compliance program. See id.
516. See id. at 114.
517. See Webb & Molo, supra note 278, at 384.
518. See id.
519. See id. at 384-85.
520. See id.
521. See Davis & McFarland, supra note 274, at 36.
areas of risk should be as extensive as the intended compliance program. The audit may include a review of the company’s existing and contemplated business activities, operations that pose a high risk of litigation, past legal or ethical programs, current policies, procedures, and compliance efforts. The health care entity should also consider federal, state, and local law and regulation that may impose criminal or civil liability. The health care entity may prioritize its compliance efforts by first applying the corporate compliance program to areas with the greatest legal risk. Other risk areas may be added to the compliance program later when time and money permit.

Next, the health care entity should decide what policies to implement. The entity should consider “the size and bureaucracy of the organization, the commitment of the officers and the board of directors, and the financial and personnel resources available to implement the compliance program.” The health care entity

522. See YOUNGBERG ET AL., supra note 495, at 113.
523. See id. at 112. Such regulations and laws may include:

- False Claims Act and state or local counterparts;
- Anti-kickback Statute and state or local counterparts;
- Stark Law and state or local counterparts;
- Antitrust laws including but not limited to price information, referral, and discriminatory pricing;
- Tax laws;
- Civil monetary penalties;
- Racketeering Influence and Corrupt Organization Act (“RICO”);
- Mail Fraud Statute;
- Wire Fraud Act;
- Government ethics, lobbying, and campaign finance statues and ordinances;
- Medical waste management;
- Employment discrimination and other employment-related laws such as the Family Medical Leave Act, the American with Disabilities Act, Compensation, leave time, harassment, Fair Labor Standards Act;
- Patient confidentiality statutes;
- Data transmission statutes;
- Billing standards;
- Patient Self-determination Act;
- Emergency Medical Treatment and Active Labor Act (“EMTALA”);
- Medicare/Medicaid patient program and protection acts;
- Health Insurance Portability and Accountability Act of 1996;
- Safe Medical Device Act.

Id. at 111 (compiling a list in Exhibit 10-2).
524. See Davis & McFarland, supra note 274, at 36.
525. YOUNGBERG ET AL., supra note 495, at 113.
must also establish the infrastructure to articulate its policies to its employees and agents. Codes of conduct are a starting point, but policies should also include employee training and procedures for reporting violations. 526 Employee handbooks should contain the policies. Again, these policies and handbooks should be easy to read and understandable for employees of all reading levels. 527

The organization must implement a compliance program by creating the necessary infrastructure. The personalities of the employee as well as their roles within the organization should be considered. Audit and/or corporate compliance committees may be created. Compliance committees are the first tier of the structure while managers and employees work to carry out the program. 528 Infrastructure must be established to enforce the compliance plan. The compliance program must be flexible enough to permit the adoption of new policies. The health care entity must be able to change the compliance program if a new risk area develops. The adaptability of the compliance program demonstrates that the health care entity is making a sincere effort to comply with the law. 529

VII. CONCLUSION

Those working in the health care industry must be mindful of ongoing investigations and settlements that competitors reach with the government. Review of investigations and settlements may be beneficial because they may indicate the future of health care corporate compliance. Since so much attention has been given to corporate compliance, there should be several negotiations and settlements available for review.

Future areas of corporate compliance programs may include issues pertaining to:

(1) quality of care;
(2) denial of services by HMOs;
(3) HMO loss or denial of claims for necessary treatment

526. See Davis & McFarland, supra note 274, at 36.
527. See YOUNGBERG ET AL., supra note 495, at 112.
528. See id. at 113.
529. See Davis & McFarland, supra note 274, at 36. The health care entity should document all attempts, successes, and failures at engaging in a corporate compliance program. See YOUNGBERG ET AL., supra note 495, at 114.
including EMTALA violations and last-day denials;
(4) HMO denial of access to treatment;
(5) health system control of referrals;
(6) physician incentive plans; and
(7) research-related activities including experimental services/clinical trials.

Unlike prior compliance guidelines that pertained solely to clinical laboratories, the government has given the health care industry compliance a solid beginning by setting forth guidelines that establish the federal government's expectations when structuring and implementing a corporate compliance program.

Corporate compliance cannot be viewed by the health care entity as only a billing problem. Health care entities must acknowledge that corporate compliance is an operational problem that requires the implementation of sufficient internal infrastructure. Ultimately, the health care entity must tailor the compliance program to its individual needs. Adopting a corporate compliance program is not enough. Knowledgeable individuals must be recruited to oversee and enforce the adopted compliance plan. Corporate compliance is the responsibility of every employee. The key to a successful corporate compliance program is not the documents creating the program, but the manner in which the program is carried out.

530. James Sheehan, Presentation at the Association of American Medical Colleges (Sept. 24, 1997).
531. See Youngberg et al., supra note 495, at 118.