CHAPTER 5

KEY FEDERAL HEALTH CARE ENFORCEMENT LAWS, TRENDS, AND INVESTIGATORY TECHNIQUES

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§ 5.01 INTRODUCTION: ENFORCEMENT TRENDS AND RECOVERIES

In 1976, Congress directed the U.S. Department of Health and Human Services (HHS) to establish the Office of Inspector General (OIG) to identify and eliminate fraud, abuse, and waste in HHS programs and to promote efficiency and economy in its operations. As part of its mission, the OIG actively investigates fraud and abuse schemes to obtain money from the federally funded Medicare and Medicaid programs and, when appropriate, issues federal fraud alerts that identify segments of the health care industry that are particularly vulnerable to abuse. Importantly, OIG initiatives in the past have aggressively pursued numerous types of perceived fraud and abuse, including:

- Billing for services not actually rendered;
- Submitting claims for medically unnecessary services;
- Unbundling;
- Upcoding the types of services received in order to receive a higher payment rate;
- Duplicate billing of services or supplies;
- Routinely waiving deductibles and coinsurance;
- Misrepresenting of the types of services provided;
- Billing for services not covered under Medicare or Medicaid;
- Paying inappropriate remuneration to physicians in exchange for referrals;
- Leasing space or equipment to physicians without collecting fair market value rent;
- Providing interest-free loans to, or forgiving the debt of, physicians; and
- Overpaying for medical director services.

While the above are examples of practices that may be considered fraudulent, this list is not meant to be exhaustive. Indeed, fraud and abuse in the Medicare and Medicaid programs can take many forms, some more obvious than others. There is no doubt, however, that prosecution of fraud and abuse in the health care industry is reaping huge rewards for federal enforcement agencies. In 2006, the federal government won or negotiated more than $2.2 billion in judgments, settlements, and administrative impositions in health care fraud and abuse proceedings.[1] In addition to the approximately $1.5 billion added to the Medicare Trust Fund during 2006, an additional $177.1 million in federal Medicaid

[1] Annual Report of the Departments of Health and Human Services and Justice, Health Care Fraud and Abuse Control Program 2006 (Nov. 2007) (hereinafter HCFAC Report).

money also was recouped as a result of enforcement efforts.[2] Given this lucrative prosecutorial climate, it is not surprising that government support for health care fraud and abuse enforcement continues at the present time with full force and effect.

§ 5.02 AN OVERVIEW OF FEDERAL FRAUD AND ABUSE LAWS

The OIG uses a common set of enforcement tools in pursuing claims of fraud and abuse against health care providers. Primarily, these tools include the Medicare/Medicaid anti-kickback statute, the Stark Act and implementing regulations (collectively, the Stark law), and the False Claims Act. An important first step in defending against any fraud and abuse investigation is to analyze the arrangement or practice in question under these authorities and assess whether a potential violation is present.

[A] Anti-Kickback Statute

Whenever an arrangement involves a payment between health care referral sources (including referral sources other than physicians), it is necessary to analyze the arrangement under the federal anti-kickback statute to ascertain whether such payment could be construed as illegal remuneration in exchange for referrals.

[1] Prohibitions

The anti-kickback statute, originally established in 1972, prohibits anyone from knowingly and willfully soliciting or receiving, or offering or paying, any remuneration (including kickbacks, bribes, or rebates), directly or indirectly, overtly or covertly, in cash or in-kind, in return for or to induce either (1) the referral of an individual for any item or services for which payment may be made in whole or in part under Medicare and Medicaid or (2) the purchasing, leasing, ordering, or arranging or recommending the purchasing, leasing, or ordering of any good, facility, service, or item for which payment may be made in whole or in part under Medicare or Medicaid.[3] This statute is broadly written and has been broadly interpreted by the courts. While some courts have held that a specific intent to disobey the law must be shown to prove a violation,[4] others have ruled that "if one purpose of the payment was to induce future referrals, the [anti-kickback statute] has been violated."[5] As it currently stands, the latter standard is the benchmark used by the government to assess transactions under the anti-kickback statute.[6]

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[2] HCFAC Report.

[3] 42 U.S.C. § 1320a-7b(b) (2000).

[4] *See, e.g.* Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995).

[5] United States v. Greber, 760 F.2d 68, 69 (3d Cir. 1985). *See also* United States v. Kats, 871 F.2d 105 (9th Cir. 1989).

[6] *See* OIG Advisory Opinion No. 08-05 (Feb. 22, 2008).

Anyone who violates this provision will be guilty of a felony and may be fined up to $25,000 and imprisoned for up to 5 years, or both.[7] Violation of the anti-kickback statute also may result in exclusion from federal health care programs.

[2] Safe Harbors

Since the broad scope of the anti-kickback statute could implicate a number of innocuous commercial arrangements, Congress mandated that safe harbor regulations be issued to specify various payment and business practices that, although potentially capable of inducing referrals of health care business, would not be treated as a criminal offense. In turn, the OIG issued a series of safe harbor regulations that protect otherwise prohibited arrangements.

Specifically, the following payment practices have been identified as safe harbors, which shall not be treated as a violation of the anti-kickback statute:

- Investment interests;
- Space rental;
- Equipment rental;
- Personal services and management contracts;
- Sale of practice;
- Referral services;
- Warranties;
- Discounts;
- Employees;
- Group purchasing organizations;
- Waiver of beneficiary coinsurance and deductible amounts;
- Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans;
- Price reductions offered to health plans;
- Practitioner recruitment;
- Obstetrical malpractice insurance subsidies;
- Investments in group practices;
- Cooperative hospital services organizations;
- Ambulatory surgical centers;
- Referral agreements for specialty services;
- Price reductions offered to eligible managed care organizations; and

[7] 42 U.S.C. § 1320a-7b(b).

• Price reductions offered by contractors with substantial financial risk to managed care organizations.[8]

Of these safe harbors, the ones that often come into play with typical health care fraud and abuse investigations relate to space and equipment rentals, personal services and management contracts, employees, and practitioner recruitment. Any one of these safe harbors could be pertinent depending on the particular transaction under government scrutiny.

[a] Space and Equipment Rentals

The safe harbors for space and equipment rentals provide that prohibited remuneration does not include payments made by a lessee to a lessor for the use of premises or equipment where:

1. the lease agreement is in writing and signed by both parties;

2. the lease identifies and comprises all of the premises or equipment covered by the lease;

3. if the lease provides the lessee with access to the premises or equipment for periodic intervals of time rather than on a full-time basis, the lease specifies the exact schedule of such intervals, their precise length, and the exact rental payment for such intervals;

4. the term of the lease is for not less than one year; and

5. the aggregate rental charge is set in advance, is consistent with fair market value in arm's length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made under a federal health care program.[9]

[b] Personal Services and Management Contracts

Under the safe harbor for personal services and management contracts, remuneration from a principal to an agent as compensation for the services of the agent is not prohibited, provided that:

1. the agency agreement is set out in writing and signed by the parties;

2. the agency agreement covers and specifies all the services to be provided by the agent;

3. if the agency agreement provides for the services of the agent on other than a full-time basis, the agency agreement specifies the schedule for the agent's service intervals, the precise length of such intervals, and the exact charge for such intervals;

4. the term of the agreement is for not less than one year; and

[8] 42 C.F.R. § 1001.952.

[9] 42 C.F.R. §§ 1001.952(b), (c).

5. the aggregate compensation paid over the term of the agency agreement is set in advance, is consistent with fair market value in arm's length transactions, and is not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties reimbursed under a federal health care program.[10]

[c] Employees

Payment from an employer to an employee who has a bona fide employment relationship with the employer for the provision of items or services reimbursable by a federal health care program does not constitute prohibited remuneration under the employee safe harbor.[11]

[d] Practitioner Recruitment

Remuneration under the practitioner recruitment safe harbor does not include payment or other items of value from an entity to induce a practitioner (who has been practicing within his or her current specialty for less than one year) to locate, or to induce any other practitioner to relocate, his or her primary practice area into a health professional shortage area for his or her specialty area, so long as nine requirements are met:

1. the arrangement is in writing and signed by the parties;

2. if the practitioner is leaving an established practice, at least 75 percent of the revenues of the new practice must be from patients not previously seen in the practitioner's former practice;

3. the recruitment benefits are not provided for more than three years and are not renegotiated during this time period;

4. the practitioner is not required to make referrals or generate other business for the entity in order to receive recruitment benefits;

5. the practitioner is not restricted from establishing privileges or making referrals to any other entity;

6. the value or amount of benefits does not vary with the volume or value of referrals to the entity;

7. the practitioner agrees to provide services to Medicare or Medicaid patients in a nondiscriminatory manner;

8. at least 75 percent of revenues from the practitioner's new practice come from patients who are residing in a health professional shortage area or a medically underserved area, or who are part of a medically underserved population; and

[10] 42 C.F.R. § 1001.952(d).

[11] 42 C.F.R. § 1001.952(i).

9. the recruitment benefits cannot benefit any person other than the practitioner being recruited or any entity that is in a position to make referrals to the entity providing the recruitment benefits.[12]

Generally, an arrangement must meet each element of a safe harbor to be immune from investigation and prosecution under the anti-kickback statute. It is not necessary, however, to meet a safe harbor for an arrangement to be consistent with the anti-kickback statute. Indeed, the safe harbors are drafted narrowly and protect only a small subset of arrangements. Any arrangement that does not meet a safe harbor is judged on its own merits under the plain language of the anti-kickback statute itself, meaning that it will be scrutinized to determine whether there is the requisite "intent" to induce referrals. Establishing the requisite intent obviously can be a substantial burden on the government in any anti-kickback investigation.

Providers are free to seek advisory opinions from the OIG to confirm the appropriateness of an arrangement under the statute. Nonetheless, the safe harbors provide desired protection to health care providers and offer useful guidance in structuring arrangements that may fall outside a safe harbor but are not intended to be an inducement for referrals. Similarly, application of the pertinent safe harbor to arrangements under investigation is an integral component of the defense in any anti-kickback-related enforcement case.

[B] The Stark Law

Whenever an arrangement involves a physician and an entity to which the physician may refer, it is necessary to determine whether the Stark law applies to the arrangement and, if so, to ascertain whether an exception exists to permit otherwise prohibited referrals.

[1] Prohibitions

The federal Stark law prohibits a physician or an immediate family member of the physician from referring Medicare patients to an entity, including a hospital, that provides designated health services and with which the physician has a financial relationship.[13] The Stark law also prohibits the entity receiving the referral from filing a claim or billing Medicare or Medicaid for the designated health services arising out of the prohibited referral.[14] This prohibition applies regardless of the reasons for the financial relationship or the referral; that is, unlike the federal anti-kickback statute, no finding of intent to violate the law is required.

For purposes of the Stark law, "designated health services" mean the following items or services:

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[12] 42 C.F.R. § 1001.952(n).
[13] 42 U.S.C. § 1395nn.
[14] 42 U.S.C. § 1395nn.

- Clinical laboratory services;
- Physical therapy services, occupational therapy services, and speech-language pathology services;
- Radiology and certain other imaging services;
- Radiation therapy services and supplies;
- Durable medical equipment and supplies;
- Parenteral and enteral nutrients, equipment, and supplies;
- Prosthetics, orthotics, and prosthetic devices and supplies;
- Home health services;
- Outpatient prescription drugs; and
- Inpatient and outpatient hospital services.[15]

Further, a "financial relationship" exists when the physician has an ownership or investment interest in, or a compensation arrangement with, the entity, even if the financial relationship is wholly unrelated to the provision of designated health services payable by Medicare or Medicaid.[16] These financial relationships can be direct or indirect, meaning that the physician can have a financial relationship with the entity without any other person or entity interposed between them , or the physician can have a financial relationship with the entity when there is an intervening person between the physician and the entity.

Unlike the anti-kickback statute, the Stark law is not a criminal statute. Nevertheless, sanctions for violations of the Stark law are significant. The OIG may impose a civil monetary penalty of up to $15,000 against any person whom it determines has presented or caused to be presented a claim for a payment that such person knows, or should know, may not be made under Medicare or Medicaid; or against any person whom it determines has not refunded on a timely basis (i.e., within 60 days) amounts collected as a result of billing an individual, a third-party payor, or another entity for designated health services that were provided in accordance with a prohibited referral under the Stark law.[17] Stark law sanctions also may include exclusion from federal health care programs and fines of up to $100,000 for circumvention schemes.[18]

[2] Exceptions

Numerous exceptions exist to the proscriptions of the Stark law. The Stark law, however, is a strict liability statute, meaning that arrangements that fall under the Stark law must meet an exception under the law in order to protect the physician referrals and the entity's ensuing billing for such referrals. If an exception is not met, the referral violates the Stark law and can subject the parties to fraud and abuse liability, regardless of the intent of the parties. Based on the

[15] 42 C.F.R. § 411.351.
[16] 42 U.S.C. § 1395nn(1)(2).
[17] 42 U.S.C. § 1395nn(g).
[18] 42 U.S.C. § 1395nn(g).

"strict liability" nature of the Stark law, it is a favorite of the government in seeking to establish a prima facie fraud and abuse violation.

Stark law exceptions apply to:

1. either an ownership interest or a compensation arrangement;
2. only an ownership interest; or
3. only a compensation arrangement.

As such, when reviewing a given arrangement, it is imperative to identify the type of financial interest(s) involved so that the correct type of exception is used, since an exception for a compensation arrangement may not be applicable to protect a physician's ownership interest in an entity, and vice versa.

Exceptions that apply when the physician has either an ownership interest or a compensation arrangement include:

- Physician services;
- In-office ancillary services;
- Services furnished by an organization to its enrollees;
- Academic medical centers;
- Implants furnished by an ambulatory surgery center;
- Epoetin Alfa (EPO) and other dialysis-related drugs in or by an end-stage renal disease (ESRD) facility;
- Preventive screening tests, immunizations, and vaccines;
- Eyeglasses and contact lenses following cataract surgery; and
- Intra-family rural referrals.[19]

The exceptions that apply only to ownership interests are:

- Publicly traded securities;
- Mutual funds; and
- Specific providers (those that have ownership in a "whole hospital").[20]

Further, the following exceptions apply only to compensation arrangements:

- Rental of office space;
- Rental of equipment;
- Bona fide employment relationships;
- Personal service arrangements;
- Physician incentive plans;
- Physician recruitment;

[19] 42 C.F.R. § 411.355.

[20] 42 C.F.R. § 411.356.

- Isolated transactions (such as the one-time sale of a practice);
- Certain group practice arrangements with a hospital;
- Payments by a physician for items and services;
- Nonmonetary compensation up to $300;
- Fair market value compensation;
- Medical staff incidental benefits;
- Risk-sharing arrangements;
- Compliance training;
- Indirect compensation arrangements;
- Obstetrical malpractice insurance subsidies;
- Retention payments in underserved areas;
- Communitywide health information systems;
- Electronic prescribing items and services; and
- Electronic health records items and services.[21]

Similar to the anti-kickback statute safe harbors, the Stark law exceptions that commonly provide a defense to a typical fraud and abuse investigation relate to space and equipment rentals, personal service arrangements, bona fide employment relationships, and physician recruitment. Some of these Stark law exceptions, however, contain key differences from the related safe harbors.

[a] Space and Equipment Rentals

In addition to the requirements that any lease agreement for space or equipment be in writing; signed by the parties; for a term of no less than one year; with the aggregate rental charge set in advance, consistent with fair market value, and not taking into account the value or volume of referrals or other business generated by the parties, the Stark law exceptions for space and equipment rentals require that:

1. the space or equipment that is rented is limited to that which is reasonable and necessary for the legitimate business purposes of the rental;

2. the space or equipment rented be used exclusively by the lessee when being used by the lessee; and

3. the agreement is commercially reasonable, even if no referrals were made between the lessee and lessor.[22]

With hold-over situations, these conditions will be met in situations in which a lessee holds over on a month-to-month basis for up to six months immediately

[21] 42 C.F.R. § 411.357.

[22] 42 C.F.R. § 411.357(a), (b).

following an agreement to rent space or equipment for at least one year, as long as the hold-over rental is on the same terms and conditions as the previous agreement.[23]

[b] Personal Service Arrangements

For an arrangement to fall under the Stark law exception for personal service arrangements, the services contracted for cannot exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement and cannot involve the counseling or promotion of a business arrangement that violates any federal or state law.[24] These requirements are in addition to those that are nearly identical to the anti-kickback statute safe harbor for personal services and management contracts, namely that the agreement is in writing and signed by the parties; that it covers all of the services to be provided by the agent; that the term is for no less than one year; and that the aggregate compensation is set in advance, is consistent with fair market value, and is not determined in a manner that takes into account the volume or value of referrals or other business generated by the parties.[25]

[c] Bona Fide Employment Relationships

The Stark law exception for bona fide employment relationships requires that employment is for identifiable services and that compensation is consistent with fair market value, is reasonable under the circumstances, and does not take into account the volume or value of referrals by the physician.[26]

[d] Physician Recruitment

This Stark law exception is somewhat similar to the anti-kickback statute safe harbor for physician recruitment in that it requires that:

1. the arrangement is in writing and signed by the parties;

2. the physician is not required to refer patients to the hospital;

3. the amount of benefits are not based on the volume or value of actual or expected referrals by the physician; and

4. the physician is allowed to establish privileges and make referrals to any other entity.[27]

This, however, is where the safe harbor and Stark law exceptions for physician recruitment diverge. Importantly, under the Stark law, there is no requirement that the physician be recruited to locate or relocate his or her practice in a health professional shortage area. Instead, the physician must be recruited to locate or relocate his or her medical practice to the "geographic area served by the

[23] 42 C.F.R. § 411.357(a)(7), (b)(6).
[24] 42 C.F.R. § 411.357(d).
[25] 42 C.F.R. § 411.357(d).
[26] 42 C.F.R. § 411.357(c).
[27] 42 C.F.R. § 411.357(e).

hospital," defined as the "area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients."[28] Further, certain requirements must be met that are not required under the anti-kickback safe harbor, namely:

1. any payments made directly to the recruited physician, or indirectly to the physician through another physician or a group practice, must be passed directly to or remain with the recruited physician, except for actual costs incurred by the physician or group practice in recruiting the physician;

2. "in the case of an income guarantee made by the hospital to a recruited physician who joins [another] physician or a physician practice, the costs allocated by the [other] physician or physician practice do not exceed the actual additional incremental costs attributable to the recruited physician;"

3. records of actual costs and pass-through amounts are kept for five years;

4. remuneration from the hospital does not take into account the volume or value of actual or anticipated referrals from either the recruited physician or the physician practice receiving direct payments from the hospital;

5. there are no other practice restrictions, other than those relating to quality of care, imposed on the recruited physician by the physician practice; and

6. the arrangement does not violate the anti-kickback statute or any law relating to billing federal health care programs.[29]

Based on the strict liability nature of the Stark law, transactions subject to the statute must fall under one of the above or other exceptions, or they are subject to penalty.

[C] False Claims Act

[1] Elements of the False Claims Act

The federal False Claims Act, composed of criminal and civil provisions, prohibits a person from (1) knowingly and willfully making any materially false, fictitious, or fraudulent statements in connection with the delivery of or payment for health benefits[30] or (2) knowingly presenting to the U.S. government a false or fraudulent claim for payment.[31] For False Claims Act purposes, a person can act "knowingly" by acting with actual knowledge of the truth or falsity of the information, by acting in deliberate ignorance of the truth or falsity of the information, or by acting in reckless disregard of the truth or falsity of the

[28] 42 C.F.R. § 411.357(e)(2), (3).
[29] 42 C.F.R. § 411.357(e)(4).
[30] 18 U.S.C. § 1035.
[31] 31 U.S.C. § 3729.

information.[32] The latter two categories of knowledge generally address a situation in which the provider should have known that a claim was false, but chose not to, or simply was so reckless that the provider made no effort to determine whether claims were proper. In other words, a provider cannot shield itself from liability under the False Claims Act simply by ignoring the contents of a claim form or the rules governing payment and coverage.

Any person who violates the False Claims Act can be subject to severe penalties and fines. Not only may a person who violates the Act be subject to imprisonment for up to five years,[33] but civil penalties can range from $5,000 to $11,000 per false claim and include up to three times the government's damages.[34]

[2] Other Federal Statutes that Prohibit False Claims

Aside from the False Claims Act, numerous other federal statutes prohibit false claims. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) health care fraud statute, which applies to both governmental and private health care programs, provides that:

> whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice (1) to defraud any health care benefit program; or (2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property . . . under the control of, any health care benefit program, in connection with the delivery of or payment for health care benefits, items, or services, shall be fined . . . or imprisoned not more than ten (10) years or both.[35]

The False Statements Accountability Act of 1996 also imposes criminal penalties on those who knowingly and willfully falsify, conceal, or cover up any material fact or make any material false, fictitious, or fraudulent statements or representations to the federal government.[36]

Finally, regulatory agencies sometimes use the federal wire fraud statute[37] and federal mail fraud statute[38] to prosecute health care fraud when persons use wire, radio, or television communications, or the U.S. mail, in order to devise fraudulent schemes or to obtain money or property by fraudulent pretenses, representations, or promises.

[3] Bootstrapping Anti-Kickback Statute or Stark Law Violations into False Claims Act Cases

In some health care fraud and abuse cases, the federal government may seek additional charges against a provider by "bootstrapping" False Claims Act

[32] 31 U.S.C. § 3729.
[33] 18 U.S.C. § 1035.
[34] 31 U.S.C. § 3729.
[35] 18 U.S.C. § 1347.
[36] 18 U.S.C. § 1001(a).
[37] 18 U.S.C. § 1343.
[38] 18 U.S.C. § 1341.

charges onto those for violations of the anti-kickback statute or the Stark law. Essentially, bootstrapping means the government uses underlying anti-kickback statute or Stark law violations as grounds for False Claims Act charges. When a provider submits a claim for payment from the federal government, the provider impliedly certifies that the provider is in compliance with all Medicare and Medicaid rules of participation. If the provider is not in compliance with these laws, the claim is prohibited, and the government believes that the provider can be held liable under the False Claims Act on a bootstrapping theory.

Using the bootstrapping technique allows the government to substantially increase its potential recovery from providers who engage in fraud and abuse of the Medicare and Medicaid programs. Penalties of $5,000 to $11,000 per false claim and up to treble damages under the False Claims Act may be assessed, instead of only $25,000 or $15,000 in civil monetary penalties under the anti-kickback statute or Stark law, respectively. Invoking the False Claims Act in this fashion often provides the government considerable leverage to compel provider settlement of these cases.

§ 5.03 HOW FEDERAL COMPLIANCE INVESTIGATIONS ARISE

HIPAA established a National Health Care Fraud and Abuse Control Program (HCFAC), under the joint direction of the Attorney General and the Secretary of HHS, acting through the OIG.[39] HCFAC is designed to coordinate federal, state, and local law enforcement activities with respect to health care fraud and abuse. HCFAC is in its eleventh year of operation and has returned more than $10.4 billion to the Medicare Trust Fund since its inception in 1997.[40] The government believes the program's success confirms the soundness of a collaborative approach to identify and prosecute the most egregious cases of health care fraud and to prevent future fraud and abuse.

With these collaborative efforts among federal and state agencies, the number and scope of health care fraud and abuse investigations will only increase in the future. Recent settlements, including those involving hospitals, pharmaceutical companies, nursing homes, physicians, ambulance companies, hospices, durable medical equipment companies, and infusion therapy programs, provide evidence of the various provider/supplier types currently under scrutiny by the federal government.[41] Given the breadth, scope, and money involved, any health care

[39] Section 1128C(a) of the Social Security Act, as established by HIPAA, created HCFAC, a far-reaching program to combat fraud and abuse in health care, including both public and private health plans. The Act requires that an amount equaling recoveries for health care investigations (including criminal fines, forfeitures, civil settlements and judgments, and administrative penalties, but excluding restitution, compensation to the victim agency, and relators' shares) be deposited in the Medicare Trust Fund. All funds deposited into the Trust Fund as a result of HCFAC are available for the operations of the Trust Fund.

[40] HCFAC Report.

[41] During fiscal year (FY) 2006 (the most recent year for which published figures are available by the federal government), the OIG, the Department of Justice (DOJ), and their law enforcement partners brought to conclusion the investigation and prosecution of numerous health care fraud schemes. A limited sample of these "accomplishments" includes the following: a large Florida hospital chain

administrator will tell you that he or she fears investigation and scrutiny, regardless of who initiates the investigation. To better defend against a fraud and abuse investigation, providers should consider the source and impetus for the same.

[A] Internal Sources

[1] Current and Former Employees

A substantial number of fraud and abuse investigations begin as a result of whistleblower claims brought by current and former employees. For example, under the federal False Claims Act, a *qui tam* relator[42] is permitted to bring an action on behalf of the United States against any individual or corporation alleged to have filed a false claim against the government. A *qui tam* relator, also called a whistleblower, can be almost anyone. Whistleblowers include current or former employees and executives of the corporation that is allegedly committing the fraud; subcontractors; private citizens; government employees; and, in some instances, public interest groups. A whistleblower is entitled to receive 15 to 25 percent of the damages recovered by the government depending on the extent of the whistleblower's contribution to the case.[43] If the government does not go forward with a whistleblower's case, the whistleblower can proceed on his or her own and, if successful, receive 25 to 30 percent of the damages recovered.[44]

Providers receiving Medicaid reimbursement are required to train their employees on their ability to become whistleblowers. As of January 1, 2007, Section 6032 of the federal Deficit Reduction Act of 2005 (DRA) requires entities

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agreed to pay $900 million for billing practices that were alleged to be unlawful. In lawsuits filed by whistleblowers, this hospital chain also agreed to pay more than $46 million to resolve claims that it engaged in "upcoding," which refers to situations in which diagnosis codes that the hospital was unable to support, or that were otherwise improper, were assigned to patient records to increase reimbursement. The largest health care system in New Jersey paid $265 million to resolve allegations that nine of its hospitals fraudulently increased inpatient and outpatient care charges to elderly patients to obtain enhanced Medicare reimbursement for outlier claims. A large New York medical center also paid $73 million to resolve allegations that it submitted false claims for Medicare reimbursement in cost reports from 1992 to 2001. The New York hospital allegedly misrepresented information, including costs of private offices for faculty physicians, overhead for its methadone maintenance treatment program, and fundraising and marketing costs. More than $8 million was returned to the Medicare program by Pennsylvania hospitals, which submitted erroneous infusion therapy and/or blood transfusion claims. In one instance, a hospital improperly submitted infusion claims despite having been notified on five separate occasions that it was submitting bills for these services improperly. These represent only a handful of the hundreds of fraud and abuse investigations resolved each year in the health care industry.

[42] *Qui tam* is short for *"qui tam pro domino rege quam pro sic ipso in hoc parte sequitur"* meaning "who as well for the king as for himself sues in this matter." A relator is an individual plaintiff bringing suit, through a private right of action afforded by the False Claims Act, in the name of the United States. Such cases are captioned "United States *ex relatione* [Doe]," to indicate that the government is taking action on the relation (or *ex rel.*) of the individual plaintiff.

[43] 31 U.S.C. § 3730(d).

[44] 31 U.S.C. § 3730(d).

that receive at least $5 million in Medicaid payments annually to (1) establish written policies for all its employees, contractors, and agents providing detailed information about the False Claims Act and any state laws that pertain to (a) civil or criminal penalties for making false claims and statements and (b) whistleblower protections under federal and state laws; and (2) include in the entity's employee handbook specific discussion about the laws described in the written policies, the rights of employees to be protected as whistleblowers, and information regarding the entity's compliance policies in place to detect and prevent fraud, waste, and abuse.

When the relator is a current or former employee, confrontation between the employer, employee, or former employee has the potential to develop into allegations of fraud and abuse. Employees who repeatedly have brought their business and billing concerns to management, only to be ignored or punished, are potential whistleblowers. With the potential for substantial rewards, these current and former employees may decide to use their knowledge of internal business and billing practices against an employer when their repeated complaints are mishandled by management. Of course, any retaliation against an employee whistleblower only leads to additional exposure for the provider under the False Claims Act.[45] Both federal and state enforcement agencies recognize the value of disgruntled current and former employees to the government's investigation and will make every attempt to locate and contact potential witnesses who may be able to assist with the investigation.

[2] Other Internal Sources

An organization may be at risk of the government initiating a fraud and abuse investigation as a result of a current or former employee becoming a relator (or whistleblower). Another internal source of fraud and abuse allegations also may surface from medical staff physicians and their office staff. Disputes between a hospital and its employed physicians over treatment, coding, and billing practices may open up additional potential areas of fraud and abuse allegations.

Another potentially significant internal source of fraud and abuse allegations comes from the auditors and consultants hired to help the organization identify and correct irregularities in its business and billing practices. When an internal auditor becomes a *qui tam* relator, audit reports and the organization's internal response, or nonresponse for that matter, could become a significant aspect of the government's case and ongoing investigation.

[B] External Sources

[1] Patients

With escalating health care costs, providers find that patients scrutinize their medical bills very closely and do not hesitate to complain, not only about the

[45] 31 U.S.C. § 3730(h).

quality of their care but also about perceived fraud and abuse. With the population of Medicare beneficiaries increasing, the government is also appealing directly to Medicare beneficiaries in its attempt to educate the public about fraud and abuse reporting. Publications distributed by HHS advise Medicare beneficiaries that they are the most important link in ferreting out Medicare fraud. One such recent publication, titled "How to Report Medicare Fraud," provides beneficiaries with a step-by-step process for reporting claims in writing and by telephone.[46] The publication also provides Medicare beneficiaries with the OIG's hot line for confidential reporting of potential fraud and abuse.

Although many reports made by Medicare beneficiaries are a result of a misunderstanding on the beneficiaries' part, or a simple mistake on behalf of the provider, it is important that providers recognize that this external source of fraud and abuse reporting will only increase as a result of escalating health care costs and the government's increased outreach efforts and education of the public.

[2] Fiscal Intermediaries, Carriers, and Program Safeguard Contractors

Medicare fiscal intermediaries and carriers[47] have become an important external source of information for health care fraud and abuse investigations. The Centers for Medicare & Medicaid Services (CMS) requires fiscal intermediaries and carriers to have distinct units to detect and deter fraud and abuse. These units are part of CMS's overall Medicare Integrity Program and are monitored by the CMS regional offices.

The fraud and abuse specialists at the fiscal intermediary and carrier level may best be characterized as the front line of defense in detecting fraudulent activity. It is important to note that this front line of defense may be less inclined to accept "misunderstanding" of Medicare policy as an option available to forgive providers. As a result, fiscal intermediaries and carriers may not show the same leniency in working with providers as they have in the past to resolve billing and payment errors.

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[46] *Available at* <http://www.medicare.gov/FraudAbuse/HowToReport.asp> (last visited Mar. 31, 2008).

[47] Currently, fiscal intermediaries and carriers perform Medicare Fee-for-Service claims processing activities for Medicare Part A and Part B, respectively. However, Section 911 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires CMS to transition by 2011 all claims processing activities from the fiscal intermediaries and carriers to new Medicare Administrative Contractors (MACs), who will then be responsible for administering all of Medicare's Fee-for-Service programs. In total, after engaging in a competitive bidding process, CMS will award 23 MAC contracts, including 15 contracts with Primary A/B MACs servicing Part A and Part B providers, 4 contracts with specialty MACs servicing home health and hospice providers, and 4 contracts with specialty MACs servicing durable medical equipment suppliers. CMS, *Fact Sheet Report to Congress* (Aug. 2005), *available at* <http://www.cms.hhs.gov/MedicareContractingReform/Downloads/rtc_fact_sheet.pdf> (last visited July 29, 2008).

In addition to working with the fiscal intermediaries and carriers, CMS also contracts with program safeguard contractors (PSCs) to detect and deter Medicare fraud and abuse.[48] As of 2006, PSCs were established nationwide across all provider and supplier types in the Medicare fee-for-service (FFS) program. The PSCs perform data analysis to identify potential problem areas, investigate possible fraud, develop cases for referral to law enforcement, and assist with active investigations.[49] Although many of the PSC's anti-fraud functions are not new, the structure of PSCs allows for a more streamlined and aggressive campaign to detect and prevent fraud and abuse activities.

[3] Recovery Audit Contractors

Section 306 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) directed HHS to conduct a three-year demonstration program using recovery audit contractors (RACs) to detect and correct improper payment in the Medicare FFS program.[50] Section 302 of the Tax Relief and Health Care Act of 2006 required HHS to make the RAC program permanent and nationwide no later than January 1, 2010. The three-year demonstration requires RACs to (1) detect Medicare improper payment, including both underpayments and overpayments, and (2) correct Medicare improper payments (i.e., repay money to a provider who was underpaid or collect money from a provider who was overpaid).[51]

In fiscal year 2007, RACs identified and corrected $371 million in Medicare improper payments.[52] Over 96 percent of these improper payments were overpayments collected from providers, and the remaining 4 percent were underpayments repaid to providers.[53] Taking into consideration the amount repaid to providers for underpayments, monies overturned on appeal, and the costs of operating the RAC program, during 2007 the RACs returned approximately $247.4 million to the Medicare Trust Fund, with the majority of overpayments collected from inpatient hospitals. Provider education about RAC-identified problem areas is a critical component of CMS's strategy to prevent future improper payments. As the RAC program sweeps into additional states in the

[48] *Budgeting to Fight Waste, Fraud and Abuse: Hearing Before the H. Comm. on the Budget*, 110th Cong. (2007) (statement of Timothy B. Hill, chief financial officer, CMS) (hereinafter Budget Hearing Testimony), *available at* <http://www.house.gov/budget_democrats/hearings.htm> (last visited Mar. 31, 2008).

[49] Budget Hearing Testimony.

[50] CMS, *RAC Status Document FY 2007: Status Report on the Use of RACs in the Medicare Program* (2008) (hereinafter RAC Status Report), *available at* <http://www.cms.hhs.gov/RAC/> (last visited Mar. 31, 2008).

[51] RAC Status Report.

[52] RAC Status Report.

[53] RAC Status Report. Two factors appear to explain why only 4 percent of the improper payments identified were underpayments. First, although RACs have extensive past experience identifying overpayments, the RACs did not have past experience identifying underpayments before the start of the program. Second, the government apparently expects a lower percentage of underpayment identification. The improper Medicare FFS payment report estimates that only 9 percent of Medicare improper payments are underpayments.

future, providers in those jurisdictions may encounter a corresponding increase in fraud and abuse investigations.

In sum, with the financial returns the federal government is reaping through investment in fraud and abuse enforcement, coupled with the many internal and external sources of these investigations, the health care industry can only expect more of the same in years to come.

§ 5.04 ENFORCEMENT AGENCIES

In fiscal year 2006, the United States Attorney's Offices (USAOs) opened 836 new criminal health care fraud investigations involving 1,448 potential defendants. Federal prosecutors had 1,677 health care fraud criminal investigations pending, involving 2,713 potential defendants, and filed criminal charges in 355 cases, involving 579 defendants.[54] A total of 547 defendants were convicted for health care fraud–related crimes during the year. Also in fiscal year 2006, the DOJ opened 915 new civil health care fraud investigations and had 2,016 civil health care fraud investigations pending at the end of the fiscal year.[55] Many of these cases were the direct result of whistleblower input. This level of enforcement activity demands involvement and cooperation among a variety of federal and state agencies.[56] In the event of an investigation, it is important to identify the agency or agencies involved in the investigation.

[A] Office of Inspector General

The OIG has primary authority for enforcing health care fraud and abuse laws throughout the United States. The OIG also conducts investigations on behalf of the DOJ and other federal agencies. In addition, the OIG participates in investigations, audits, and evaluations to identify, assess, and address vulnerabilities in government health care programs. The OIG has the authority to exclude individuals and entities from participation in Medicare, Medicaid, and other federal health care programs. The OIG also has the authority to impose civil monetary penalties against providers and suppliers who knowingly submit false claims to the government, who participate in unlawful patient referral or kickback schemes, who fail to appropriately treat or refer patients who present at hospital emergency rooms, or who engage in other activities proscribed by statute.[57]

[B] Department of Justice

The DOJ also has criminal and civil health care fraud units. The USAOs within the DOJ support both civil and criminal health care fraud and abuse litigation. The USAOs are the principal prosecutors of federal crimes, and each district has designated both a criminal and a civil health care fraud control coordinator. Civil cases also are obtained from *qui tam* complaints. Under the False Claims Act, a *qui tam* relator must file his or her complaint under seal in a

[54] HCFAC Report.
[55] HCFAC Report.
[56] HCFAC Report.
[57] HCFAC Report.

U.S. district court and serve a copy on the USAO for that judicial district.[58] The complaint remains under seal for at least 60 days and is not served on the defendant until the court so orders.[59]

[C] Office of General Counsel

The Office of General Counsel (OGC) is active in supporting Medicare and Medicaid program integrity activities and provides legal support within the statutory authority of the HCFAC program. The OGC assists the DOJ in negotiating corporate integrity agreements, which are often required as part of the resolution of a fraud and abuse investigation. In 2006, the OGC provided support to the DOJ in actions relating to Medicare and Medicaid fraud under the False Claims Act and assisted the USAOs in criminal prosecution of Medicare providers. Additional support activities of the OGC also include the following:

- Suspensions and revocations;
- Assisting the USAOs in the criminal prosecution of Medicare providers;
- Assessment of civil monetary penalties;
- Enforcement of the Clinical Laboratory Improvement Amendments;
- Affirmative overpayment litigation; and
- Medicaid enforcement.[60]

[D] Federal Bureau of Investigations

The Federal Bureau of Investigation (FBI) has been actively investigating health care fraud for many years. The FBI has become one of the primary investigative agencies with jurisdiction over federal health care programs and private insurance programs. The FBI's mission in this area is to oversee health care fraud initiatives by providing national guidance and assistance to support health care fraud investigations targeted at individuals and organizations.[61]

The FBI works closely with its federal, state, and local law enforcement partners, CMS, and other government and privately sponsored organizations to address vulnerabilities, fraud, and abuse in the governmental programs. The FBI often is involved as the fact-finding agency working with the DOJ and often collaborates on investigations with the OIG. Health care fraud investigations are currently among the highest priority investigative activities within the FBI's white collar crime program.[62] The FBI also works with the DOJ and various USAOs to pursue offenders through parallel criminal and civil enforcement activities.[63]

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[58] 31 U.S.C. § 3730(b)(2).
[59] 31 U.S.C. § 3730(b)(2).
[60] HCFAC Report.
[61] Federal Bureau of Investigation, Criminal Investigation Division, Financial Crimes Report to the Public (2007) (hereinafter Financial Crimes Report), a*vailable at* <http://www.fbi.gov/publications/financial/fcs_report2006/financial_crime_2006.htm#Health>.
[62] Financial Crimes Report.
[63] Financial Crimes Report.

[E] Other Enforcement Agencies

Many states have their own versions of the federal anti-kickback statute, Stark law, and False Claims Act, along with general fraud statutes and consumer protection laws designed to prevent health care fraud and abuse and protect the states' Medicaid programs. While Medicare is wholly controlled by the federal government, Medicaid is a combined federal and state health care and social services program administered by the individual state's Medicaid agency. As a result of the states' authority to administer the Medicaid program, the enforcement of health care fraud and abuse in the Medicaid program most often lies with each state's Medicaid fraud control unit and the state Attorney General's office. Most Medicaid fraud control units rely on referrals from Medicaid agencies and/or the Surveillance and Utilization Review Subsystem of the Medicaid Management Information System to initiate many of their case investigations.[64]

The investigatory roles of other federal agencies with enforcement divisions, such as the Drug Enforcement Administration, Internal Revenue Service, or the United States Postal Service, are beyond the scope of this chapter.

§ 5.05 FEDERAL INVESTIGATORY STRATEGIES

As the number of fraud and abuse investigations continues to rise, health care providers need to be aware of the investigatory strategies typically employed by government investigators. The type of investigatory strategy varies according to the type and severity of the suspected fraud and abuse under investigation. Although each investigation is unique, there are some common strategies employed in many health care fraud investigations.

[A] Contact Letters

It is quite common for state and federal investigators to send a contact letter to a provider identifying alleged misconduct and speculating on the potential monetary damages associated with such misconduct. The contact letter typically cites to the law, or laws, allegedly violated and requests that the provider respond, in writing, to the allegations. The contact letter most often is sent to the provider by the USAO and invites some level of negotiation or self-analysis on the part of the provider within a prescribed time frame.

The contact letter should be read very carefully to determine precisely what the investigating agency is requesting. It is critical to secure documents and ensure that there is no destruction of any records, documents, or communications regarding the issue identified in the contact letter. Document destruction once the provider is put on notice regarding a potential regulatory and compliance matter could result in a claim of obstruction of justice, which is a separate, actionable offense.

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[64] Financial Crimes Report.

The provider may wish to confer with legal counsel in order to assist in coordinating and responding to a contact letter. As in most regulatory and compliance matters, it is important to identify deadlines and promptly request an extension from the investigating authority, if one is needed. It is not unusual for a provider to require some additional time to gather the necessary documents and complete its own internal review and investigation in order to adequately respond to the government's allegations and alleged monetary damages. Such extensions should be requested as early as practicable and certainly not on the stated deadline date.

[B] Entity Visits and Interviews

Federal investigators also commonly present to a health care facility or provider's office during normal business hours and undertake an unannounced, onsite visit that includes a request to review documents and informally interview employees. A number of issues may arise as to counsel's role in such visits and interviews. For example, since government payors require providers to make records and documents available to the government as a condition of program participation, providers may be asked immediately to produce documents. Although cooperation is critical, the provider may wish to consult with legal counsel and consider whether to request a subpoena compelling production prior to producing documents. Such a request may offer a more coordinated and complete response to the investigator's request.

In addition to reviewing documents, investigators also may request to speak with specific employees by name, individuals who hold certain positions within the organization, and those individuals with knowledge regarding the documents requested. Similar to a request for production, when a request for an interview or interviews is made by the investigator, it is important to cooperate; however, it is also important to remember that employees have a right to consult with legal counsel before participating in such an interview. A provider should not direct employees not to participate in interviews, as this could be interpreted as an obstruction of justice. In this instance, providers should consider whether to have a representative, such as legal counsel, participate in these interviews on behalf of the provider. Because it is often difficult to recall the specific discussions that occur during each separate employee interview, the provider representative should take notes during the original interview, which may prove helpful to the provider as the investigation unfolds. Providers should also verify the credentials of the agents requesting information and/or interviews to verify their identity and authority.

Investigators also may wish to speak to former employees. Because these individuals are no longer under the provider's employment, counsel may not always be present during such interviews. Nonattendance during these interviews is, of course, a disadvantage for the provider as the entity under investigation will not know the substantive discussion that occurred or any claims made against the provider.

In any witness interview situation, it is essential that witnesses respond truthfully and to the best of their knowledge. Speculation is usually unnecessary in this context. The enforcement agent's assessment of the credibility of the provider witnesses during these initial interviews can have a dramatic impact on further case developments. Legal counsel's involvement in coordinating and preparing witnesses for these interviews usually is beneficial for the provider under investigation.

[C] Subpoenas

A subpoena is an order directing a person to appear at a particular location on an appointed date and time to testify regarding information and subject matter requested by the subpoena. A subpoena *duces tecum* requires an individual or entity, typically the chief executive officer or the chief records custodian of the provider, to bring certain documents to a particular location on an appointed date and time, as opposed to testifying. Subpoenas may be issued and used as part of a criminal, civil, or administrative proceeding. Many regulatory agencies have the authority to issue subpoenas for testimony of witnesses and/or discovery of documents.

Subpoenas have the authority of either a statute or court behind them and carry severe sanctions, including fines and imprisonment, for noncompliance. Subpoenas usually are served by sending the subpoena by registered or certified mail to the last known address, or principal place of business, of the entity. Service also may occur personally by local agents. The subpoena will contain a general description of the subject matter under investigation, as well as a limited timeline to produce the requested records or prepare for testimony. Providers often request additional time to comply with a subpoena, especially when the request for documents is extensive and burdensome. As with contact letters, it is critical that the provider not destroy any documents related to the investigation, as document destruction could result in separate charges of obstruction of justice.

If an individual or entity is served with a subpoena, consider the following recommended action plan for complying:

1. Determine when and by whom the subpoena was received;

2. Carefully read the content of the subpoena and determine its scope and breadth;

3. Promptly contact the entity's compliance officer and legal counsel to begin the process of complying with the subpoena;

4. Identify the court, agency, or other entity who has issued the subpoena;

5. Identify the date and location for responding and complying with the terms of the subpoena;

6. Assign responsibility among provider staff regarding all aspects of the documents subject to the subpoena;

7. Make a timely assessment as to whether additional time may be necessary for production, and if necessary, request an extension from the designated contact person;

8. If an extension is requested and granted, memorialize the same in written correspondence to the designated contact;

9. If possible, determine whether the subpoena is part of a larger investigation;

10. Determine whether any responsive documents may be subject to the attorney-client privilege or some other applicable protection; and

11. Make a timely and complete production to the government representative or office location specified in the subpoena.

[1] Document Production

It is important that document production be coordinated with the organization's compliance officer and legal counsel. The compliance officer may wish to appoint individual(s) responsible for gathering and producing the requested information. To successfully manage the process, it is helpful to:

1. keep the number of individuals responding to the subpoena limited;
2. have individuals respond directly to the compliance officer; and
3. provide concrete timelines in which individuals must respond.

It is critical that all individuals with a "need to know" are informed to not alter, destroy, or tamper with any documents or files, including all communications sent by electronic mail. The destruction of records following receipt of a subpoena will cause irreparable harm to the organization and may result in a *per se* finding of misconduct or violation of particular fraud and abuse laws. It is also important for the organization to secure all files, documents, and information responsive to the subpoena and designate a secure location to store the materials in preparation for responding to the subpoena. Limiting access to the documents and the secure location where they are stored also is advised to maintain the integrity of the materials.

It is important to only provide information that is requested by the subpoena. Those responding to subpoenas should not speculate or add information that they "think" may be responsive to the subpoena. Instead, if questions arise as to the scope and breadth of the subpoena, those responding should rely on guidance from legal counsel who may contact the subpoenaing agency for clarification on the entity's behalf. Legal counsel also may provide valuable assistance by requesting that the government narrow its request for documents, both as to the categories and types of documents requested and the time period covered by the subpoena. If clarification is obtained, it is recommended to remind the subpoenaing agency of this clarification, in writing, at the time the documents are produced. It is important to remember that there is no obligation to give more documents than what is demanded specifically by the terms of the subpoena.

As for the actual production, unless specifically demanded by the agency serving the subpoena, an entity should not supply original documents, but rather, verify that copies or computer discs are acceptable for production. Electronic document production is becoming more common; however, it is imperative that the production conform to the agency's very detailed requests. All documents being produced also should be consecutively numbered, or "Bates stamped." This will make it easy for the entity to maintain a detailed, internal inventory of the types of documents produced, as well as any documents that may be inflammatory or potentially damaging to the organization. It is also helpful to catalogue documents produced and to make and keep a complete copy of the document production.

A letter accompanying responsive documents should indicate which subpoena specifications are being responded to and provide a general catalogue of documents being produced. If the entity does not have any documents responsive to a particular specification in the subpoena, this should be specifically stated in the accompanying transmittal letter so there is no confusion or assumption that the entity's production is somehow incomplete. The submission to the subpoenaing agency also should include a "privilege log" identifying all responsive documents that are being withheld from production based on privilege grounds. It is recommended that the entity tender responsive documents and all lists under the direction of counsel, or through counsel. The entity also may wish to leave open the possibility that other documents, if found, will be produced in a timely manner. Every effort should be made to make a timely and complete document production to the pertinent enforcement agency.

[D] Search Warrants

Although not commonly used for investigating health care fraud and abuse at this time, a search warrant is a written court order allowing law enforcement to search an organization's premises. Search warrants are used for the investigation of criminal activity, and require a court order issued by a judge who is satisfied that sufficient "probable cause" exists.[65] Probable cause requires that those requesting the search warrant's issuance demonstrate by oath or affirmation that evidence of a crime exists at a specified location.[66]

There are a number of reasons that federal enforcement agencies may prefer to use a search warrant when investigating criminal fraud:

- The element of surprise ensures integrity of the evidence;
- The government is able to seize the evidence before it is destroyed or no longer available;

[65] Fed. R. Crim. P. 41.

[66] Fed. R. Crim. P. 41.

- It provides the investigators an opportunity to confront witnesses; and
- It allows investigators to discover additional evidence in "plain view."

The execution of a search warrant at the provider's offices is a true emergency and can result not only in disruption of daily business but also adverse publicity. As a result, it is essential to maintain professionalism and contact counsel immediately.

When a search warrant is executed, it is typical for multiple FBI agents to descend upon the premises with an agent-in-charge directing other agents and the organization's own employees on what to do. Agents will attempt to talk to employees, to obtain documents, and to secure the premises. It is critical that employees do not refuse the agents' entry or act in any manner to obstruct access to materials subject to the search warrant.

When confronted with a search warrant, it is important to ask to review the search warrant and also request to see the affidavit of probable cause, if available, to ensure that the scope of the search is limited by the warrant. There is no obligation to consent to a search beyond the scope of the warrant. To the contrary, the provider may object if the agents attempt to search beyond the scope of the warrant. While the agents may do so anyway, objecting to the search obviates the agents' argument that the entity consented to a broader search. Objecting also may preserve legal arguments that the expanded search was unlawful.

In the event of a search, employees should be informed that they have certain rights if the agents should request an interview:

- Employees have no duty or obligation to speak to the agents;
- Likewise, employees can speak to the agents if they choose to do so;
- If an employee talks with an agent, the employee has a right to have counsel present; and
- The employee has the right to consent to where the interview will occur.

With any interview, the provider and its legal counsel should attempt to debrief employees as soon as possible following the departure of the investigators, particularly if no provider representative, other than the employee, participated in the interview.

§ 5.06 INTERNAL INVESTIGATION RESPONSE TO FEDERAL INVESTIGATIONS

Given the current climate of aggressively uncovering and prosecuting potential health care fraud and abuse, as well as the intense scrutiny health care organizations are receiving from the federal government, an organization should not be surprised if at some point it finds itself in the middle of a federal investigation or inquiry. It is important for the organization to be prepared for

such an event and understand how to conduct its own investigation into the alleged misconduct. A provider's failure to understand its options when an investigation occurs can put the provider at a serious disadvantage even before the investigation hits full stride.

[A] Maintaining the Attorney-Client Privilege and the Work Product Doctrine

When participating in a federal compliance investigation, agents and representatives of an entity must understand how to preserve the entity's legal rights with respect to confidential matters so as to safeguard the entity's interests. The attorney-client privilege and work product doctrine may help providers maintain confidentiality during investigations. Indeed, to conduct a meaningful internal investigation of the conduct in question, providers should be able to have candid discussions without fear of later disclosure as to the underlying facts, and how to best position the organization for an appropriate defense.

[1] Attorney-Client Privilege

The attorney-client privilege is an evidentiary privilege that protects against disclosure to third parties of confidential communications between an attorney and a client seeking legal advice, often as part of an investigation, audit, or litigation. In federal courts, this privilege is "governed by the principles of common law as . . . interpreted by the courts of the United States in light of reason and experience."[67] The purpose of this privilege is to "encourage full and frank communication between attorneys and their clients," based on the premise that an attorney cannot provide sound legal advice without being fully informed by his or her client.[68]

The attorney-client privilege applies to both individuals and corporations as clients.[69] Applying the privilege in the corporate context, however, presents difficulties when determining which of the corporation's confidential communications fall under the attorney-client privilege. Some state jurisdictions apply a narrow "control group test" whereby communications with a corporate client (including corporate employees) are privileged only when made by employees who are in positions to control or make substantial decisions regarding corporate actions.[70] The Supreme Court, however, in the case *Upjohn Co. v. United States,* expressly rejected the "control group test" and adopted a more flexible "subject matter test" that protects from disclosure communications with corporate clients and their employees when:

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[67] Fed. R. Evid. 501.

[68] Upjohn Co. v. United States, 449 U.S. 383, 389 (1981).

[69] *Upjohn,* 449 U.S. 383, 390 (citing United States v. Louisville & Nashville R. Co., 236 U.S. 318, 336 (1915)).

[70] *Upjohn,* 449 U.S. 383, 390 (citing Philadelphia v. Westinghouse Elec. Corp., 210 F. Supp. 483, 485 (E.D. Pa. 1962)).

1. the communication was made for the purpose of securing legal advice;

2. the employee making the communication did so at the direction of his or her corporate superior;

3. the superior made the request so that the corporation could secure legal advice;

4. the subject matter of the communication was within the scope of the employee's corporate duties; and

5. the communication was not disseminated beyond those persons who, because of the corporate structure, need to know its contents.[71]

By adopting the more lenient "subject matter test," the Supreme Court acknowledged that numerous employees within a corporation, even nonexecutive employees, may have relevant information that counsel needs in order to adequately represent the corporate client.[72] As such, confidential communications between anyone within the corporation and corporate counsel are privileged so long as the communications meet the requirements of the "subject matter test" and no waiver of the privilege occurred.

The "subject matter test" applies to confidential communications with in-house counsel as well as external counsel, provided that in-house counsel is in a position to provide legal advice to the company with respect to the matter at hand.[73] In other words, the communication cannot be made to in-house counsel merely to cloak the communication under the attorney-client privilege. If, however, in-house counsel is legitimately in a position to render legal advice to the corporation, the attorney-client privilege may apply.

To gain protection under the attorney-client privilege, confidential communications also can be in any form, including verbal discussions, written correspondence, hand-written notes, email messages, and audio and video recordings. This is not to say, however, that the privilege is without limits. Underlying facts about a case are never protected from disclosure; only confidential communications related to those facts are privileged.[74]

Further, certain categories of information are not considered confidential communications, and thus are not protected by the attorney-client privilege. These categories include, among others, the existence of an attorney-client relationship and the identity of a client,[75] the general purpose for which an attorney is retained,[76] fee arrangements with clients,[77] and foundational issues

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[71] *Upjohn*, 449 U.S. 383, 394-395.
[72] *Upjohn*, 449 U.S. 383, 391.
[73] *Upjohn*, 449 U.S. 383, 394.
[74] *Upjohn*, 449 U.S. 383, 395.
[75] *See, e.g.*, United States v. Horn, 976 F.2d 1314, 1317 (9th Cir. 1992).
[76] *See, e.g.*, In re Grand Jury Subpoena, 204 F.3d 516, 520 (4th Cir. 2000).
[77] *See, e.g.*, In re Grand Jury Subpoenas, 906 F.2d 1485, 1492 (10th Cir. 1990).

such as the date, time, and location of a meeting between an attorney and his or her client or who was present when a confidential communication was made.[78] The attorney-client privilege also cannot be invoked retroactively, so counsel must be engaged before a communication is made for the communication to be protected from disclosure.

[2] Work Product Doctrine

Communications not protected by the attorney-client privilege could, nevertheless, be protected from disclosure under the work product doctrine. The work product doctrine protects from discovery documents and tangible materials that a party, or a party's representative, such as an attorney or a consultant, prepares in anticipation of litigation or for trial.[79] This evidentiary shield is both broader and narrower than the attorney-client privilege. It is broader because anyone can create work product, even without an attorney's direct involvement. Conversely, it is narrower because the work product doctrine applies only to materials created during or in anticipation of litigation. "In anticipation of litigation" has been broadly interpreted such that even materials prepared by a corporation while internally investigating corporate wrongdoing may be protected as work product.[80]

It is important to understand that the work product doctrine is not a privilege that provides absolute protection from disclosure. Instead, the work product doctrine provides a qualified immunity from disclosure that may be overcome if an adversary can show substantial need for the materials in the preparation of the adversary's case and that the adversary cannot, without undue hardship, obtain the materials, or the substantial equivalent of the materials, by other means.[81] Regardless of an adversary's need for the information, work product containing the mental impressions, opinions, conclusions, or legal theories of an attorney or an attorney's representative is never discoverable.[82]

[3] Waiver of the Privilege or the Work Product Doctrine

Though related, the attorney-client privilege and the work product doctrine are two separate legal theories whose protections can arise in different circumstances and be eliminated separately. As a result, it is necessary to analyze each theory individually to determine whether one or the other has been waived, either purposefully or unintentionally.

Generally, disclosure of privileged materials to *any* third parties will result in a waiver of the privilege's protection. This is true even if the disclosure was inadvertent or the client failed to understand that his or her actions would result in a forfeiture of the privilege.[83] Conversely, waiver of the work product doctrine

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[78] *See e.g.,* Refuse & Envtl. Sys., Inc. v. Indus. Serv. of Am., 120 F.R.D. 8, 10 (D. Mass. 1988).
[79] Fed. R. Civ. P. 26(b)(3).
[80] *See Upjohn,* 449 U.S. 383.
[81] Fed. R. Civ. P. 26(b)(3).
[82] Fed. R. Civ. P. 26(b)(3).
[83] *See, e.g.,* In re Grand Jury Proceedings, 727 F.2d 1352 (4th Cir. 1984).

generally occurs only when disclosure is made to an adversary. As a result, even if a client cannot assert the attorney-client privilege because confidential information was disclosed to an outside party (i.e., an independent auditor), the client may in some cases still be able to protect the information by arguing that disclosure was not made to an adversary.

While waiver of the attorney-client privilege and the work product doctrine can occur under different circumstances, it is important to understand that selective waiver generally is not allowed in either situation. In other words, one usually cannot waive the privilege or the work product doctrine as to one party but attempt to assert the privilege or work product doctrine as to another party.[84] This is the case in most jurisdictions even if the parties enter into a confidentiality agreement as a means of protection. While the use of a confidentiality agreement will provide the disclosing party a contract remedy if the recipient of the disclosed information fails to maintain confidentiality, the attorney-client privilege and work product doctrine will in most jurisdictions still be waived as a result of the disclosure even if a valid confidentiality agreement is in place.[85]

Although some government agencies support the concept of selective waiver by suggesting that voluntary production of privileged material to the government in the course of an investigation does not waive the privilege as to nongovernmental parties,[86] the DOJ announced in December 2006 that government prosecutors were restricted in their ability to seek waivers of the privilege in the context of these investigations.[87] Indeed, Deputy Attorney General Paul McNulty, in a memorandum to United States Attorneys (the McNulty Memorandum), laid out a detailed process that prosecutors must follow in the event they actively seek a waiver of the attorney-client privilege from the entity being investigated.[88] This process requires the prosecutors to show a legitimate need for the privileged information and to obtain written authorization from the U.S. attorney or the deputy attorney general before requesting the entity waive the privilege.[89] The McNulty Memorandum also clarified that an entity's refusal to waive the privilege and disclose confidential communications to the government may not

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[84] *See, e.g.,* In re Columbia/HCA Healthcare Corp. Billing Practices Litig., 293 F.3d 289 (6th Cir. 2002).

[85] *See, e.g., In re Columbia/HCA,* 293 F.3d 289, 303.

[86] In May 2006, the Advisory Committee on Evidence Rules proposed revisions to Federal Rule of Evidence 502 which would provide for selective waiver of the attorney-client privilege to government agencies in the exercise of the agencies' regulatory, investigative, or enforcement activities. Memorandum from Honorable Jerry E. Smith, Chair of the Advisory Committee on Evidence Rules to Honorable David F. Levi, Chair of the Standing Committee on Rules of Practice and Procedure (May 2006), *available at* <www.uscourts.gov/rules/Reports/EV05-2006.pdf> (last visited Apr. 7, 2008). Ultimately, this proposed rule proved controversial and was not recommended for adoption by the advisory committee. Legislative efforts to provide for selective waiver to government agencies, however, continue.

[87] Memorandum from Paul McNulty, Deputy Attorney General, DOJ to Heads of Department Components, United States Attorneys (December 2006) (hereinafter McNulty Memorandum), *available at* <www.usdoj.gov/dag/speeches/2006/mcnulty_memo.pdf> (last visited Apr. 7, 2008).

[88] McNulty Memorandum.

[89] McNulty Memorandum.

be considered by the government when making a charging decision against the entity. Thus, while prosecutors may favorably consider an entity's acquiescence to a waiver request, waiver is not required in order for the entity to be considered to have cooperated in the government's investigation.[90]

[4] Maintaining the Attorney-Client Privilege when Retaining Consultants

While disclosure of communications to any third parties generally will waive the attorney-client privilege with respect to those communications, the privilege may not be waived if the disclosure was made to the third party so that the third party could assist the attorney in rendering legal advice.[91] For instance, disclosure made to an external consultant performing an audit of an organization's billing practices may not result in a privilege waiver if the consultant is performing the audit so that counsel can provide legal advice to the organization in relation to the organization's billing practices. It is important to note though that if a reviewing court were later to conclude that the consultant was actually working at the direction of the client and that counsel was only involved to cloak the review from discovery, no privilege may apply.[92]

To protect confidential communications with a consultant under the attorney-client privilege, legal counsel, not the organization, should formally engage the consultant and direct the engagement. An engagement letter between legal counsel and the consultant, at a minimum, should specify:

- that legal counsel is engaging the consultant to assist counsel in rendering legal advice to the organization;
- that legal counsel is directing the engagement and instructing the consultant on performance of the requested tasks;
- that the consultant will deliver the consultant's findings, conclusions, and recommendations (if any) directly to legal counsel;
- that all information and documents received, gathered, and created by the consultant pursuant to the engagement shall remain the work product of legal counsel;
- the prohibition against disclosure to any third parties absent legal counsel's written consent of any information related to the engagement; and
- the safeguards to employ to protect the confidentiality of all communications related to the engagement, including designating on all written communications between and among legal counsel, the organization, and the consultant that the communications are "Attorney-Client Privileged/ Attorney Work Product/Confidential."

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[90] McNulty Memorandum.

[91] *See* United States v. Kovel, 296 F.2d 918 (2d Cir. 1961).

[92] *See Kovel*, 296 F.2d 918.

After the consultant is formally engaged, other practices should be followed to ensure the privilege is preserved. For example, it is imperative that the consultant act only at the direction of legal counsel and submit any interim and final reports to counsel. All communications with the consultant should be limited to those matters within the scope of the consultant's duties. Any meetings with the consultant should be directed by legal counsel and should be properly documented and state the legal purpose of the meeting. Finally, counsel should apply the consultant's report and recommendations in rendering legal advice to the provider. When engaged properly, consultants with technical expertise often can play a valuable role in assisting counsel in preparing the provider's defense to a fraud and abuse investigation.

[B] Conducting the Parallel Internal Investigation

As the phrase suggests, a parallel internal investigation is one that occurs by the organization itself when it first discovers it is subject to a government investigation. Conducting a parallel internal investigation allows the organization to gain accurate and timely information regarding potential misconduct. Oftentimes, the government's investigation will take significant time to unfold and evolve. An internal investigation that occurs as the government's investigation is underway allows the organization to gain insight and information as to whether the allegations of misconduct are accurate. In the event the allegations of misconduct, or aspects of the allegations, are found to be true, the internal investigation affords the organization an opportunity to evaluate the potential regulatory, civil, and criminal exposure and develop and implement a plan for responding to the inquiry, as well as to correct any systemic failures that may have contributed to the incident. In these situations, it is essential for the provider to gather as much information as possible regarding the alleged misconduct or the provider will be at a distinct disadvantage in trying to respond to the investigation.

The organization may wish to consider coordinating the internal investigation with the assistance of counsel before beginning any investigation to protect the communications under the attorney-client privilege and/or work product doctrine, to the extent possible and desirable. This determination may be based on the seriousness of the allegations, as well as the past compliance history of the organization.

[1] Interviewing Witnesses

As part of the internal investigation, the compliance officer may, with the assistance of counsel, wish to interview witnesses to learn as much as possible regarding the underlying facts of the alleged misconduct. By coordinating the interviews at the direction of counsel, witnesses avoid unprivileged conversations that potentially could place the organization at risk.

Witness interviews should be structured and designed to learn as much as possible about a particular witness's knowledge related to the alleged misconduct. Careful consideration should be given to the order of the witness interviews to ensure that the order allows the organization the best opportunity to gather as much information from each witness as possible, as well as build off earlier interviews. It also may be helpful to develop a basic chronology of the facts to guide the interview process. This chronology may change over time as the organization learns additional details and facts as a result of the witness interviews.

Ultimately, each witness interview has the potential to add important information to the existing chronology, uncover additional facts (both favorable and unfavorable) pertinent to the particular compliance matter, identify gaps and raise questions regarding the matter at issue, and also identify additional witnesses and interviews that may need to be completed. If legal counsel is involved with these interviews, it also may be necessary to remind the witness that counsel represents the organization and also remind the witness of the privileged nature of the discussion.

[2] Maintaining and Reviewing Records

During the internal investigation, it is important to maintain the integrity of all pertinent documents and also maintain a complete copy of all documents and materials responsive to the government's investigation. Any pertinent documents must be retained and not purged, altered, destroyed, hidden, or withheld. The organization will want to know, at minimum, as much as the government does regarding the organization's own documents. To gain an understanding of the contents of the documents, the organization likely will need to complete a thorough review of all such documents. This comprehensive document review will help the organization determine whether there are any vulnerabilities that may be present given information contained in these materials.

[3] Keeping Senior Management Advised

Keeping senior management advised of the status of the internal investigation, as well as the status of the government's investigation, is critical. Senior management, including an organization's board of directors or board of trustees, often is charged with protecting the best interests of the organization with respect to compliance matters. As such, their oversight over corporate integrity matters is a part of doing business and signifies a provider's commitment to being a good corporate citizen.

With increasing frequency, key organizational leaders are being held accountable for the conduct of the organization. Updating senior management on the status and findings of an internal investigation helps build a record that the organization's leaders take compliance seriously and will do what is necessary to conform practice to the pertinent legal standards. While senior management and board members do not need to know every factual detail involving an internal

investigation, it is critical that these individuals receive timely and accurate information about important compliance investigations and are made aware of potentially significant compliance findings, especially those that may require their direct input and guidance.

Senior management and board members should not be shy about asking questions and requesting additional information about particular compliance matters, suspicious conduct, or the potential risks associated with the organization's investigative findings. Senior management and the board have a duty to inquire about the status of the organization's compliance program and should do so regularly. Ultimately, the government will be interested in learning whether or not senior management fostered a culture of compliance at the highest levels and extending throughout the organization.[93]

[C] Corrective Actions

Once an internal investigation has revealed or confirmed errors, particularly errors that have resulted in the government making overpayments to the organization, the organization's corporate responsibility program must respond quickly and effectively. While remedial corrective action taken as a result of a government investigation may vary, it is imperative that the organization consider, at minimum, the following potential responses:

- The organization has identified and corrected the actions and/or processes in place that caused the misconduct;
- The organization has developed new or revised existing written policies and protocols to prevent similar behavior from recurring in the future;
- The organization has trained pertinent staff regarding these revised policies and protocols;
- The organization has appropriately disciplined any staff member who may be individually culpable for the particular wrongful practices under investigation;
- The organization has implemented ongoing audits of the services and processes involved in the misconduct so as to confirm that the corrections put into place are working properly and any errors are promptly identified;
- For billing and payment issues, the organization has accurately calculated an error rate for the alleged misconduct and extrapolated the error rate to the potential population of affected claims;
- With the assistance of counsel, the organization has considered various options and strategies for refunding any overpayments; and

[93] OIG Supplemental Program Guidance for Hospitals, 70 Fed. Reg. 4874 (Jan. 31, 2005).

- The organization has upgraded its compliance program to better address any shortcomings revealed from the investigation.

Clearly, a risk/benefit analysis of the specific issues and fact situations is critical as the organization evaluates its potential responses. Moreover, even if corrective actions are viewed as coming too late based on the ongoing government investigation, it is usually still preferable for the provider to take some appropriate action at such time rather than stand idly by while the investigation progresses.

[D] Communicating with Agents and Attorneys

At times, it may be prudent for the organization, or its legal counsel, to personally contact the investigating agent and/or the assistant U.S. attorney (AUSA) handling a particular compliance matter. Communicating with agents and government attorneys offers an organization the opportunity to clarify any questions it has regarding the scope of an investigation. It also may reflect well on an organization's commitment to compliant practices as part of its participation in federal health care programs. This also may present an opportunity to discuss possible explanations for the conduct in question once more background information is learned from the organization's own internal review of the matter.

If an organization would like to move forward in resolving a particular compliance matter, it should be prepared to cooperate with the agent and AUSA. The level of cooperation may take a variety of forms depending on the particular facts and circumstances involved. Maintaining credibility is vital during these discussions, and provider representatives should be conscientious about the accuracy of their stated positions.

[1] Position Papers

An organization may wish to consider using a position paper as a means of communicating with and educating the investigating governmental agency regarding the matter at issue. A position paper offers the organization the opportunity to outline for the investigating agent or the AUSA the organization's position on several matters, including, for example, the following:

1. The organization's interpretation of regulatory guidance;
2. How that guidance has evolved over time; and
3. How it impacts transactions similar to the one subject to investigation.

While the enforcement agencies usually are well versed in the underlying regulatory authorities, a position paper can often provide an effective starting point to frame these authorities for purposes of the present case.

[2] Negotiating Settlements

In most instances, negotiating a settlement of a compliance investigation likely will involve legal counsel. Some of these investigations are resolved quickly, without the need for face-to-face meetings between provider and government

representatives. In other cases, counsel can be integral in coordinating personal meetings between key individuals within the organization and the government's investigatory team, which may include the investigating agent, the AUSA, and various other individuals and agencies assisting in the review and prosecution of a particular compliance matter.

The course of the settlement discussions, as well as the potential benefits to the organization in coordinating a face-to-face meeting with the government, depends on the nature and circumstances of each enforcement case. An in-person meeting provides the organization with the opportunity to review and highlight key components of any earlier written submission. The meeting also offers the organization the opportunity to speak directly to its compliance program and its efforts at improving its compliance practices. From the government's standpoint, a face-to-face meeting with organization leadership can provide an opportunity for clarification, questioning, and a direct request for additional information.

One factor that is critical during negotiations, as well as in the outcome of most enforcement actions, is the nature of the existing compliance efforts of the organization under investigation. Generally, if the government is unimpressed with the organization's compliance program, the government may require a corporate integrity agreement with the organization to resolve the case and to prevent the conduct from recurring. On the other hand, a corporate integrity agreement may not be necessary in the government's view if the government is satisfied that the organization has sufficient compliance programming already in place to make recurrence of the behavior in question unlikely. For these reasons, organizations should remain committed to maintaining an effective compliance program before, during, and after any government investigation.[94]

§ 5.07 SUMMARY

Prosecuting health care fraud and abuse is big business. The lucrative awards and settlements the government has received are fueling this prosecutorial climate, and there is no end in sight. Although one might think that health care fraud and abuse is increasing, it is more likely that the various government agencies are simply more active in investigating individuals and organizations and have a lower tolerance for errors and "misunderstandings" of federal policies.

In an effort to prevent fraudulent or abusive practices, or the appearance of such conduct, it is critical that organizations understand the enforcement tools the government will use in pursuing claims of fraud and abuse. A basic, fundamental knowledge of the anti-kickback statute, the Stark law, and the False Claims Act is an organization's first step in preventing inappropriate conduct, relationships,

[94] Under the federal sentencing guidelines, the existence of an effective compliance program is a mitigating factor for the government to consider in how to charge a corporation subject to prosecution. Federal Sentencing Guideline Manual § 8C2.5(f) (2004).

and arrangements. Organizations also should regularly reevaluate their own compliance programs to ensure that these programs are effective to proactively identify potential problem areas and respond timely and effectively to any compliance concerns. In this regard, effective provider compliance programs should be viewed as the best "preventive medicine" to keep a government investigation from hitting the provider's doorsteps.

Finally, in the event an organization becomes the target of a federal compliance investigation, it is critical that the organization understand how to respond. A failure to understand the process could subject the organization to increased liability and damages. Providers do have options in these difficult situations, and it remains vital that they know how to use them.