HEALTH CARE FRAUD AND ABUSE

Kelly Knivila

Steven B. Ungar

Jeremy D. Sacks

Darin M. Sands

Oregon State Bar Legal Publications

Chapter 13

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KELLY KNIVILA, B.A., Western Oregon State College (1986); J.D., Georgetown University Law Center (1989); member of the Oregon State Bar since 1992; partner, Stoel Rives LLP, Portland.

STEVEN B. UNGAR, A.B., Washington University (1975); J.D., University of Missouri (1979); member of the Oregon State Bar since 1995, and the Washington State Bar Association since 2005; partner, Lane Powell, P.C., Portland.

JEREMY D. SACKS, B.A., Wesleyan University (1991); J.D., Georgetown University Law Center (1994); member of The State Bar of California since 1994, the District of Columbia Bar since 1996, the Oregon State Bar since 1999, and the Washington State Bar Association since 2006; partner, Stoel Rives LLP, Portland.

DARIN M. SANDS, B.A., Middlebury College (2000); J.D., Harvard Law School (2004); member of the Washington State Bar Association since 2004, The State Bar of California since 2008, and the Oregon State Bar since 2010; associate, Lane Powell, P.C., Portland.

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§13.1 SCOPE OF CHAPTER

This chapter seeks to familiarize the attorney with defending actions—and managing investigations—in which the putative defendant or target is alleged to have violated one or more of the many federal and state laws regulating the provision of health care services. Given the

wide-ranging nature of the regulations and laws, putative defendants include health care professionals, such as physicians, nurses, and the like; health care provider institutions, such as hospitals, clinics, and laboratories; long-term care facilities, such as skilled nursing homes and assisted living facilities; home health agencies; suppliers of durable medical equipment; pharmaceutical manufacturers and dispensaries; and health care insurers. The list of possible defendants includes most participants in the health care sector of the economy.

The complex landscape of health care fraud and abuse law has developed as government spending on health care has increased, and that spending has come with regulatory strings attached. In addition, common fraud, negligence, lack of internal controls, charting deficiencies, coding mistakes, and poor compliance with procedures and billing and reimbursement requirements all contribute to the increase in fraud and abuse cases over the last decade. This trend is likely to continue, with government and private plaintiffs seeking to enforce the laws that govern and regulate the provision and payment of health care in this country.

The stakes are high. On the civil side, sanctions may include monetary penalties, treble damages under the federal False Claims Act, exclusions, and debarment. Criminal sanctions may include significant jail time, restitution, and fines. It is critical that health care participants *and their lawyers* understand the laws and regulations that govern their business, and they must react quickly and seriously to defend against any potential liability.

§13.2 SURVEY OF RELEVANT FEDERAL LAWS

This chapter familiarizes the attorney with relevant Oregon laws and regulations the violation of which may give rise to health care fraud and abuse allegations. An in-depth analysis of relevant federal statutes, regulations, and case law bearing on these issues is beyond the scope of this chapter; there are a number of excellent sources counsel may consult that address federal issues in detail. Nevertheless, it is important for all attorneys to have a basic understanding of the federal scheme governing health care fraud and abuse matters.

§13.2-1 Kickbacks: The Federal Anti-Kickback Statute

§13.2-1(a) Overview and Definitions

The federal anti-kickback statute (AKS), 42 USC §1320a-7b(b), prohibits payment or remuneration to any person in return for the referral of patients participating in all "federal health care programs" (FHCPs) except the Federal Employees Health Benefit Program.

> NOTE: The term *federal health care program* is defined to include: (1) "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States government" (other than the Federal Employees Health Benefit Program), and (2) any state health care program, which includes state Medicaid plans and plans that receive money under Title V, the Social Security Act, Maternal and Child Health Block Grants, Title XX Social Service Block Grants, and Title XXI state child health plans. 42 USC §1320a-7(h), 42 USC §1320a-7b(f).

More specifically, the AKS prohibits:

- any knowing and willful offer, payment, solicitation, or receipt of any remuneration,
- in cash or in kind,
- overt or covert,
- in return for referring a person for any item or service,
- for which payment may be made under a "federal health care program" or in return for purchasing, leasing, ordering, or arranging for, or recommending purchasing, leasing, or ordering, any good, facility, service, or item for which payment may be made under an FHCP. 42 USC §1320a-7b(b).

Although the AKS has a broad reach—it addresses quid pro quos in purchasing, leasing, ordering, etc., as noted above—none of these terms has been defined by statute or regulation, and only a few cases address them. *See, e.g.*, *United States v. Bay State Ambulance and Hosp. Rental Serv.*, 874 F2d 20 (1st Cir 1989); *United States v. Adkins*, 683 F2d

1289, 1290 (9th Cir 1982); *United States v. Stewart Clinical Laboratory, Inc.*, 652 F2d 804 (9th Cir 1981). Nor is the term *remuneration* defined in the AKS. *But see* 42 USC §1320a-7a(i)(6) (defining *remuneration* under the civil money penalties law). Note, however, that the First Circuit has held in *Bay State Ambulance*, 874 F2d at 33–34, that remuneration need not involve funds or something purchased with funds derived from the Medicare program. *See also Hanlester Network v. Shalala*, 51 F3d 1390 (9th Cir 1995) (applying definition of remuneration from *Bay State Ambulance*).

§13.2-1(b) Intent

The anti-kickback statute (AKS) bars only certain actions that are undertaken "knowingly and willfully." 42 USC §1320a-7b(b). This standard applies not only to payments made solely in return for a referral, but also when the consideration at issue has both legitimate and prohibited purposes. In other words, the AKS prohibits remuneration even when only one purpose of the remuneration is to induce referrals. *United States v. Greber*, 760 F2d 68, 71 (3d Cir 1985); *United States v. Kats*, 871 F2d 105, 108 (9th Cir 1989); *see also United States v. Bay State Ambulance and Hosp. Rental Serv.*, 874 F2d 20, 30 (1st Cir 1989). Therefore, to pass muster under the AKS, payments must be attributable *exclusively* to the provision of goods or services.

Although the Ninth Circuit Court of Appeals considerably weakened the force of the AKS's intent requirement in *Hanlester Network v. Shalala*, 51 F3d 1390 (9th Cir 1995), by construing the term *knowing and willful* to hold that a violation occurs only if the participant (1) knows that the AKS prohibits the conduct, and (2) engages in the proscribed conduct with the specific intent to disobey the law, the Patient Protection and Affordable Care Act (HR 3590, 111th Cong (2010) §6402, Pub L No 111-148, 42 USC §§18001 et seq.), effectively overruled this holding. The act added language that states: "With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section." 42 USC §1320a-7b(h).

§13.2-1(c) Sanctions

Sanctions include fines of up to $25,000 for each violation as well as imprisonment for not more than five years or both. 42 USC §1320a-7b(b). The statute of limitations is five years. 18 USC §3282. In addition to these criminal penalties, the statute gives the U.S. Department of Health and Human Services authority to exclude from federal health care programs any individuals or organizations found in an administrative proceeding to have violated the statute. 42 USC §1320a-7a(f). The government also may impose civil money penalties of $50,000 for each prohibited act, plus damages of up to three times the amount of prohibited remuneration. 42 USC §1320a-7a(a)(7). Finally, all claims that include items or services that result from a violation of the anti-kickback statute are deemed to constitute false or fraudulent claims for purposes of the False Claims Act. 42 USC §1320a-7b(g).

§13.2-1(d) Safe Harbors

Federal "safe harbor" regulations describe various payment and business practices that arguably may violate the anti-kickback statute (AKS) but that are not treated as offenses under the law. The safe-harbor regulations can be found at 42 CFR §1001.952. Practices that fall within the safe harbors should not be prosecuted unless they are mere shams—such as when a contract formally meets the requirements of a safe harbor but does not reflect the parties' actual conduct. *See* 56 Fed Reg 35,972 (1991). If a practice does not squarely fall in a safe harbor, it does not necessarily violate the AKS. Rather, it still must be evaluated to determine whether the purpose was to induce referrals.

The safe-harbor rules and their preambles provide significant guidance with respect to a variety of business arrangements, although they leave many questions unanswered and should be reviewed and applied very carefully. Safe harbors include, but are not limited to, the following:

(1) Investment Interests;

(2) Space and Equipment Rentals;

(3) Contracts for Personal and Management Services;

(4) Sale of Practice;

(5) Referral Services;

(6) Warranties;

(7) Discounts;

(8) Employees;

(9) Group Purchasing Organizations;

(10) Waiver of Coinsurance and Deductibles;

(11) Managed-Care Safe Harbors;

(12) Practitioner Recruitment;

(13) Obstetrical Malpractice Insurance Subsidies;

(14) Investments in Group Practices;

(15) Cooperative Hospital Service Organizations;

(16) Return on Investment Interest by Ambulatory Surgical Centers;

(17) Referrals for Specialty Services;

(18) Ambulance Replenishing;

(19) Health Centers; and

(20) Electronic Prescribing and Electronic Health Records Items and Services.

42 CFR 1001.952.

§13.2-1(e) Enforcement Policies

The U.S. Department of Health and Human Services' Office of Inspector General (OIG) follows the enforcement policies listed in the preamble to the safe-harbor rules. Note that although the OIG declined to adopt a blanket policy on substantial compliance, the fact that a practice does not fall into a safe harbor does not mean that it violates the anti-kickback statute (AKS). 56 Fed Reg 35,954 (July 29, 1991). It is also important to remember that, when more than one safe harbor provision may apply, each practice at issue must fall within a specific safe harbor to

remove the practice from the reach of the AKS. For example, if only one purpose is served, such as compensation of an individual for services rendered, the parties need to comply with only one safe harbor provision (the employee or personal services safe harbor in this example). However, if two purposes are served by the practice at issue, such as the lease of equipment and the furnishing of technicians to operate it, the parties should comply with both applicable safe harbors to insulate the practice from prosecution (in this case, the equipment-rental and personal-services safe harbors). *See* 56 Fed Reg 35,957 (July 29, 1991).

The OIG's advisory opinions can offer additional guidance. The advisory opinions may be found online at <http://oig.hhs.gov/fraud/advisoryopinions.asp>, and providers may request an opinion if they like. Advisory opinions are legal opinions issued by the OIG to one or more requesting parties addressing the application of the OIG's fraud and abuse authorities to an existing or proposed business arrangement, but they are binding only on the requesting party or parties. A party that receives a favorable advisory opinion is protected from OIG administrative sanctions, as long as the arrangement at issue is conducted in accordance with the facts submitted to the OIG. Most attorneys view advisory opinions as instructive in advising clients how to structure their relationships that fall under the AKS's purview. Although preexisting advisory opinions can offer guidance, the OIG asserts that no person or entity may rely conclusively on an advisory opinion issued to another party.

§13.2-2 Regulation of Physician Self-Referrals

§13.2-2(a) The Stark Law: Regulation of Self-Referrals

Section 1877 of the Social Security Act (42 USC §1395nn) is known as the physician self-referral law and commonly called the "Stark Law" after the chief legislative sponsor of the initial bill. It prohibits physicians from referring Medicare (and to a lesser extent Medicaid) patients to an entity with which the physician or the physician's immediate family member has a financial relationship if such patients are receiving certain designated health services. The entity receiving the referral is barred from billing Medicare for the service provided as a

result of the prohibited referral. Violation can give rise to significant sanctions, including civil monetary penalties and fines. Unlike a number of other states, Oregon does not have a state law analogous to the Stark Law.

NOTE: The Stark Law's implementing regulations are found at 42 CFR §§411.350–411.389 and are extremely detailed. A thorough review of the Stark Law and its regulations is beyond the scope of this chapter. Instead, §13.2-2(b) to §13.2-2(f)(3) briefly analyzes potential issues arising under the Stark Law. For a more in-depth treatment of this topic, we recommend the following resources: W. BRADLEY TULLY & DAVID P. HENNINGER, FEDERAL SELF-REFERRAL LAW; BNA's Health Law & Business Series (No. 2400) (citation not verified by publisher); and CHARLES B. OPPENHEIM, STARK FINAL REGULATIONS: A COMPREHENSIVE ANALYSIS OF KEY ISSUES AND PRACTICAL GUIDE, AHLA HEALTH LAWYERS, EXPERT SERIES (4th ed 2008) (citation not verified by publisher). Careful lawyers also should consult the detailed Federal Register commentary (from 1992 to the present) for each of the many revisions of the Stark rules. A general discussion of the history of Stark Law rulemaking and publication may be found online at the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services' Web site, <www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html>.

§13.2-2(b) Elements of a Stark Violation; Intent; Sanctions

Unless the financial arrangement qualifies for an exception to the Stark statute (42 USC §1395nn) or a Stark rule (42 CFR §§411.350–411.389), a physician may not refer a patient to an entity that bills Medicare, and such entity is prohibited from billing Medicare for services provided pursuant to such referral, when (1) the referring physician (or an immediate family member of that physician) has a direct or indirect financial relationship with the entity, and (2) the referral is for the provision of certain designated health services. 42 USC §1395nn(a)(1); 42 CFR §411.353(a).

NOTE: Under the Stark Law, the term *physician* means not only a medical or osteopathic doctor, but also a dentist, oral surgeon, podiatrist, optometrist, or chiropractor. 42 USC §1395x(r); 42 CFR §411.351.

The Stark Law also prohibits the use of federal matching funds in a state Medicaid program to pay for services that violate the Stark Law. 42 USC §1396b(s). The "Stark II" proposed regulations include provisions for applying the Stark Law to the Medicaid program. 63 Fed Reg 1659, 1704, 1727 (1998). However, this proposed provision was never finalized. 66 Fed Reg 856, 911–912 (2001). Unlike most states, Oregon has not adopted legislation specifically prohibiting billing for services provided in violation of the Stark Law. Notwithstanding this gap, the discussion that follows treats the Stark Law as applicable to the Medicare and Medicaid programs.

Intent is not an element of a Stark Law offense, unlike alleged violations of the Medicare anti-kickback statute. Thus, a defendant's knowledge of the alleged wrongdoing is not necessary to demonstrate a prima facie violation. 42 USC §1395nn(g)(1). Penalties include nonpayment of claims, recovery of any payment already made for prohibited claims, civil money penalties of up to $15,000 per claim, exclusion from federal health care programs, and a fine of $100,000 for each arrangement found to be a scheme to circumvent the law. 42 USC §1395nn(g). However, before civil money penalties may be imposed, it must be proven that the defendant knew, or should have known, that the conduct was a violation. 42 USC §1395nn(g)(3). This penalty thus has a knowledge standard that is not required to establish the violation itself. Centers for Medicare and Medicaid Services (CMS) has taken the position that these penalties may apply to the referring physician as well as to the entity billing for the designated health service. 58 Fed Reg 54,097 n 1 (1993).

To date there have been only a few reported Stark Law enforcement actions or settlements. Summaries of recent settlement agreements can be found on the Office of Inspector General (OIG) Web site: <http://oig.hhs.gov/fraud/enforcement/cmp/kickback.asp>. More-

over, the Medicare Act was amended in 2010 to require the Secretary of the U.S. Department of Health and Human Services (HHS), in cooperation with the OIG, to adopt a voluntary Physician Self-Referral Disclosure Protocol, and, as a result, providers have self-disclosed Stark violations, resulting in settlements with HHS. The self-disclosure protocol, and summaries of the few Stark self-disclosure settlements that have resulted as a result of that protocol, can be found on CMS's Web site: <www.cms.gov/PhysicianSelfReferral/>. In addition, the facts causing violations of the Stark Law may give rise to liability under the federal civil False Claims Act, greatly increasing the likelihood of private enforcement by disgruntled employees and knowledgeable competitors. *U.S. ex rel Thompson v. Columbia/HCA*, 125 F3d 899 (5th Cir 1997) (remand of physician's False Claims Act *qui tam* allegations under Stark to determine whether they state claim).

§13.2-2(c) Referrals; Referring Physician

With certain exceptions described in the regulations, a referral includes either (1) any request by a physician for an item or service payable under Part B of Medicare or Medicaid, including a request for a consultation with another physician (and any test or procedure ordered by, or to be performed by, or under the supervision of, that other physician), or (2) any request or establishment of a plan of care by a physician that includes the provision of "designated health services." 42 USC §1395nn(h)(5); 42 CFR §411.351. Because referrals for Stark Law purposes are limited to designated health services payable by Medicare or Medicaid, the scope of the Stark Law is much narrower than that of the anti-kickback statute. However, violations of the Stark Law can affect a provider's participation in other federal health care programs (FHCPs); the exclusion authority for violations of the Stark Law includes the authority to exclude a violator from other FHCPs. As noted in §13.2-2(b), the term *physician* includes medical or osteopathic doctors, dentists, oral surgeons, podiatrists, optometrists, and chiropractors. 42 USC §1395x(r); 42 CFR §411.351.

§13.2-2(d) Designated Health Services

"Designated health services" include clinical laboratory services, physical therapy services, occupational therapy services, outpatient 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. 42 USC §1395nn(h)(6); 42 CFR §411.351. Some of these categories are further defined by lists of procedure codes published in the federal register and accessible on the Centers for Medicare and Medicaid Services Web site: <www.cms.gov/PhysicianSelfReferral/40_List_of_Codes.asp#TopOfPage>.

§13.2-2(e) Financial Relationships and Related Concepts

Financial relationships between a referring physician (or an "immediate family member" of a physician) and an entity fall into two categories: (1) direct or indirect investments or ownership interests, and (2) direct or indirect compensation arrangements. 42 USC §1395nn(a)(2); 42 CFR §411.354(a). The statute and regulations contain detailed definitions of each. The Stark Law also contains a list of relationships that are not considered compensation relations. 42 USC §1395nn(h)(1)(C). The precise interpretation of these definitions and exceptions is critical to avoid violating the Stark Law. Unfortunately, these rules are complicated, requiring a careful analysis of each arrangement.

> NOTE: The phrase *immediate family member* is defined as a "husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild." 42 CFR §411.351

§13.2-2(f) Exceptions to the Stark Self-Referral Prohibition

There are three types of exceptions to the Stark Law's (42 USC §1395nn) self-referral prohibition:

(1) Exceptions applicable to all financial relationships (*see* §13.2-2(f)(1));

(2) Exceptions applicable to ownership or investment interests (*see* §13.2-2(f)(2)); and

(3) Exceptions applicable to compensation arrangements (*see* §13.2-2(f)(3)).

Each exception contains multiple requirements that must be met for the exception to apply. In addition, many of the exceptions use defined terms that contain multiple requirements. For example, the exception for interoffice ancillary services contains at least seven elements and may apply only to a "group practice." To qualify as a "group practice," a group must meet nine requirements. All the Stark exceptions should be analyzed in conjunction with the corresponding anti-kickback safe harbors, because compliance with Stark does not guarantee compliance with the anti-kickback statute. A detailed discussion of the requirements of each safe harbor is beyond the scope of this chapter.

§13.2-2(f)(1) General Exceptions Applicable to All Financial Relationships

Exceptions to both compensation arrangements and ownership or investment interests include:

(1) Physician services provided personally by, or under the personal supervision of, other physicians in the same group practice, 42 CFR §411.355(a) and 42 CFR §411.351 (defining *group practice*);

(2) Certain in-office ancillary services, 42 CFR §411.355(b);

(3) Certain services furnished by prepaid health plans to enrollees, 42 CFR §411.355(c);

(4) Certain services provided by an academic medical center, 42 CFR §411.355(e);

(5) Certain implants furnished by an ambulatory surgical center, 42 CFR §411.355(f);

(6) Certain EPO and other dialysis-related drugs, 42 CFR §411.355(g);

(7) Certain preventive screening tests, immunizations, and vaccines, 42 CFR §411.355(h);

(8) Certain eyeglasses and contact lenses furnished to patients following cataract surgery, 42 CFR §11.355(i); and

(9) Certain intra-family rural referrals, 42 CFR §411.355(j).

§13.2-2(f)(2) Exceptions Related to Ownership Relationships

Exceptions to prohibited direct and indirect ownership relationships include:

(1) Certain publicly traded securities, 42 CFR §411.356(a);

(2) Mutual funds, 42 CFR §411.356(b); and

(3) Ownership or investment in certain specific providers, including rural providers, 42 CFR §411.356(c).

§13.2-2(f)(3) Exceptions Related to Compensation Relationships

Exceptions to prohibited direct and indirect compensation relationships include:

(1) Certain payments for the rental of office space and equipment, 42 CFR §411.357(a)–(b);

(2) Certain bona fide employment relationships, 42 CFR §411.357(c);

(3) Certain personal services arrangements, including certain payments under a valid physician incentive plan arrangement, 42 CFR §411.357(d);

(4) Remuneration provided by a hospital to a physician to induce the physician to relocate his or her practice to a location served by the hospital, 42 CFR §411.357(e), and, in certain payments by a hospital to a physician to retain the physician's practice in the geographic area, 42 CFR §411.357(t);

(5) Certain isolated transactions for fair market value, 42 CFR §411.357(f);

(6) Certain relationships with hospitals unrelated to the furnishing of designated health services, 42 CFR §411.357(g);

(7) Certain arrangements between a hospital and a group practice for designated health services furnished by the group but billed by the hospital, 42 CFR §411.357(h);

(8) Certain payments made by a physician to a clinical laboratory or other entity as compensation for items or services at fair market value, 42 CFR §411.357(i);

(9) Certain bona fide charitable donations by a physician, 42 CFR §411.357(j);

(10) Certain nonmonetary compensation not exceeding a specified amount each year, 42 CFR §411.357(k);

(11) Certain fair market value compensation, 42 CFR §411.357(*l*);

(12) Certain medical staff incidental benefits used on the hospital's campus, 42 CFR §411.357(m);

(13) Certain risk-sharing arrangements between a Managed Care Organization or Independent Physician Association and a physician for services provided to enrollees of a health plan, 42 CFR §411.357(n);

(14) Certain compliance training provided by an entity to physicians who practice in the area, 42 CFR §411.357(o);

(15) Certain indirect compensation arrangements, 42 CFR §411.357(p);

(16) Certain referral services, 42 CFR §411.357(q);

(17) Certain obstetrical malpractice insurance subsidies, 42 CFR §411.357(r);

(18) Under certain circumstances, health care offered at a free or discounted rate as a professional courtesy, 42 CFR §411.357(s); and

(19) Certain items or services related to electronic health records and information technology, 42 CFR §411.357(u)–(w).

§13.2-3 Fraud and False Statement Provisions

Certain provisions of the Social Security Act govern patient neglect and financial dealings with federal health care programs and private health plans. These provisions generally address allegedly fraudulent behavior on the part of health care providers. The statute of limitations for violations of these offenses is five years. *See* 18 USC §3282.

§13.2-3(a) False Statements Made in Connection with Payments by an FHCP: 42 USC §1320a-7b(a)

There are six false statement crimes contained at 42 USC §1320a-7b(a).

(1) It is a crime to knowingly and willfully make, or cause to be made, "any false statement or representation of a material fact *in any application* for any benefit or payment under a Federal health care program" (FHCP). 42 USC §1320a-7b(a)(1) (emphasis added). (Note that this prong generally is not an issue for providers. Note also that this crime exists in addition to the general federal false statements statute, 18 USC §1001, and the criminal False Claims Act.)

(2) It is a crime to knowingly and willfully make, or cause to be made, any "false statement or representation of a material fact for use in determining rights to such benefit or payment." 42 USC §1320a-7b(a)(2).

(3) It is a crime for an individual to conceal or fail to disclose an event that impacts either his own right to any benefit or payment or the rights of any other individual on whose behalf he has applied for benefits or payment, with "an intent fraudulently to secure such benefit or pay-

ment either in a greater amount or quantity than is due or when no such benefit or payment is authorized." 42 USC §1320a-7b(a)(3).

(4) It is a crime to knowingly and willfully convert any benefit or payment sought on behalf of another into a use other than for the use and benefit of the person of the intended beneficiary. 42 USC §1320a-7b(a)(4).

(5) It is a crime to present or cause to be presented a claim for payment by an FHCP for a physician's service knowing that the individual who furnished the service was not licensed as a physician. 42 USC §1320a-7b(a)(5).

(6) It is a crime to knowingly and willfully, and for a fee, assist an individual in disposing of assets to qualify for medical assistance under a state plan. 42 USC §1320a-7b(a)(6).

> PRACTICE TIP: Attorneys who counsel their clients to conceal, or not disclose, clear overpayments might also face personal liability under this statute. Self-disclosure, however, is a complex question.

The above conduct is punishable as a felony, with a fine of up to $25,000 or a five-year prison term, or both, if committed by a health care provider. The same conduct engaged in by a nonprovider is punishable as a misdemeanor, with a fine of up to $10,000 and a one-year prison sentence. 42 USC §1320a-7b(a)(6)(i)–(ii).

§13.2-3(b) False Statements Regarding Provider Certification: 42 USC §1320a-7b(c)

It is a crime under section 1320a-7b(c) to knowingly and willfully make or cause to be made, or induce or seek to induce, the making of any false statement or representation of material fact regarding the health care provider's conditions or operation so it can qualify for a listed benefit (i.e., certification). A violation is a felony and is punishable by a $25,000 fine, five years in prison, or both. 42 USC §1320a-7b(c).

§13.2-3(c) Charging Excess Rates or Improperly Preconditioning Admittance: 42 USC §1320a-7b(d)

Section 1320a-7b(d) prohibits charging excess rates or preconditioning either the admittance of a patient into a health care facility or the continued treatment of a patient, on the provision of a gift, donation, or other consideration. A violation is a felony and is punishable by a $25,000 fine, five years in prison, or both. 42 USC §1320a-7b(d).

§13.2-3(d) Violating Terms of Medicare Participation Agreement or Assignment: 42 USC §1320a-7b(e)

It is a crime for a provider who accepts assignment or agrees to be a participating provider under the Medicare program (as set forth in 42 USC §§1395u(b)(3)(B)(ii) and 1395u(h)(1)) to knowingly, willfully, and repeatedly violate the terms of assignment or the participation agreement. This offense is a misdemeanor punishable by a fine of $2,000, six months in prison, or both. 42 USC §1320a-7(e).

§13.2-3(e) Administrative Penalties Applicable to Beneficiaries Participating in Fraud; Provider Obligation to Report Overpayments: 42 USC §1320a-7k

Administrative penalties may be imposed on a beneficiary or recipient of Medicare, Medicaid, or Children's Health Insurance Program (CHIP) who knowingly participated in a fraud offense or a conspiracy to commit a fraud offense. Further, there is an affirmative obligation placed on "persons" (including providers of services, suppliers, Medicaid-managed care organizations, Medicare Advantage organizations, and Part D Plan sponsors) to report and return overpayments. Failure to do so can form the basis of a False Claims Act action and trigger fines and exclusion remedies. 42 USC §1320a-7k.

§13.2-4 Federal Health Care Offenses

The "Federal Health Care Offense" created by the Health Insurance Portability and Accountability Act (18 USC §24, 18 USC §1347), is defined as a violation of, or a criminal conspiracy to violate, certain enumerated provisions of federal criminal law if the violation or conspiracy relates to a public or private health care benefit plan. This

statute has been applied in a wide range of contexts. *See, e.g., United States v. Lucien*, 347 F3d 45 (2d Cir 2003) (holding that state no-fault automobile insurance program qualified as "health care benefit program" within meaning of 18 USC §24(b) and upholding convictions of participants in staged automobile accident scheme under federal health care fraud statute). These enumerated federal laws include, but are not limited to, the Food and Drug Act and Employee Retirement Income Security Act. A person need not have actual knowledge of the law or specific intent to be found guilty of a Federal Health Care Offense.

§13.2-5 General Criminal Statutes

A fraud allegation may trigger claims under a variety of federal laws, including the general criminal statutes in Title 18 of the U.S. Code. For example, health care fraud may be prosecuted under federal criminal false claims and false statement statutes, 18 USC §287 and 18 USC §1001, or as wire or mail fraud, 18 USC §1341, 18 USC §1343, racketeering (under the Racketeer Influence and Corrupt Organization (RICO) Act, 18 USC §§1961–1968), and related sections governing illegal predicate acts triggering RICO liability.

§13.2-6 Criminal and Civil False Claims Acts

The federal False Claims Act more properly consists of two statutory schemes—one criminal and one civil. Attorneys in the health care field should have a working knowledge of both.

§13.2-6(a) The Criminal False Claims Act and Conspiracy to Defraud: 18 USC §§286–287

Under the criminal False Claims Act, 18 USC §287, any kind of false claim submitted to the government, including claims for payment relating to Medicare and state health plans, may serve as the basis for a criminal violation. Criminal liability arises when an individual or entity submits any claim "upon or against the United States . . . knowing such claim to be false, fictitious, or fraudulent." 18 USC §287. Note that the intent standard to trigger liability under section 287 is lower than the standard included in 18 USC §1001, the federal false statements act.

Here, the defendant must only have acted "knowingly" rather than with the willfulness required by section 1001.

Section 286 of 18 USC, which criminalizes a conspiracy to defraud, amplifies the potential liability triggered by the criminal False Claims Act. Under section 286's expansive language, anyone who enters into an agreement, combination, or conspiracy to defraud the United States by "obtaining or aiding to obtain the payment . . . of any false, fictitious or fraudulent claim" is subject to additional criminal liability—separate and apart from any liability attaching under section 287.

§13.2-6(b) Civil False Claims Act: 31 USC §§3729–3733

§13.2-6(b)(1) Liability Triggers

Under the civil False Claims Act (FCA) and its recent amendments, a civil action may be brought against a defendant, including a health care provider, who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;
>
> (C) conspires to commit a violation of [the civil False Claims Act];
>
> (D) has possession, custody, or control of property or money used, or to be used, by the Government, and knowingly delivers, or causes to be delivered, less than all of that money or property;
>
> (E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;
>
> (F) knowingly buys, or receives a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or
>
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit

> money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government. . . . [This last prong is known as a "reverse false claim."].

31 USC §3729(a)(1). Of particular interest to health care providers are recent amendments that make all payments made by, through, or in connection with, a health care exchange subject to the FCA, and provide that items or services resulting from a bribe or kickback give rise to "false claims" under the FCA. *See* 42 USC §1320a-7b.

A "claim" is any request or demand, whether or not under contract, for money or property (whether or not the United States has title to the money or property) that is presented to an officer, employee, or agent of the United States or, in some cases, is made to a contractor, grantee, or other recipient spending money on the government's behalf. 31 USC §3729(b)(2). An "obligation" is an established duty arising from an "express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of an overpayment." 31 USC §3729(b)(3).

The intent standard woven throughout the FCA is a "knowing" act or acting "knowingly." This means that a defendant, with respect to the information at issue:

> (i) has actual knowledge of the information;
>
> (ii) acts in *deliberate ignorance of the truth or falsity* of the information; or
>
> (iii) acts in *reckless disregard of the truth or falsity* of the information.

31 USC §3729(b)(1)(A) (emphasis added).

Specific intent to defraud is not required. 31 USC §3729(b)(1)(B). The meaning of these standards is further defined in the case law; for example, in the Ninth Circuit, an innocent mistake or mere negligence is not actionable. *See, e.g., Wang v. FMC Corp.*, 975 F2d 1412, 1420–1421 (9th Cir 1992); *United States ex rel. Oliver v. Parsons Co.*, 195 F3d 457,

460, 464–465 (9th Cir 1999). A detailed discussion of this subject is beyond the scope of this chapter.

§13.2-6(b)(2) Penalties

False Claims Act (FCA) violations are punishable by a civil penalty of between $5,000 and $10,000 per false or fraudulent claim, as adjusted by 28 USC §2461 (the Civil Penalties Inflation Adjustment Act), plus three times the amount of damages incurred by the government. 31 USC §3729(a). Penalties may be reduced to double rather than treble damages if the defendant fully cooperates with the government investigation and meets certain other voluntary disclosure criteria. *See* 31 USC §3729(a)(2). A person who violates the statute is liable to the government for the costs of a civil action brought to recover such penalties or damages. 31 USC §3729(a)(3).

The statute of limitations under the FCA is six years after the date of violation or three years after the date when material facts are known, or should have been known, by the government, but no later than 10 years after the date on which the violation was committed. 31 USC §3731(b).

§13.2-6(b)(3) Prosecutions: Government or *Qui Tam* Relator?

Civil False Claims Act (FCA) actions may be brought by government prosecutors at the U.S. Department of Justice's Civil Division or the U.S. Attorney's office, or by private individuals or entities under the statute's *qui tam* provision.

Government prosecutions under the FCA are fairly straightforward; under 31 USC §3730(a), the U.S. Attorney General is required to "diligently" investigate a violation of 31 USC §3729, and if he or she finds a violation, a civil action may be brought.

The *qui tam* provision in section 3730(b) is more complicated. *Qui tam* actions are brought by private persons known as "relators" who seek to enforce the FCA through private actions in the name of the government. The *qui tam* complaint is filed under seal and is not served on the defendant until the court so orders. 31 USC §3730(b)(2). The

government may intervene in the case within 60 days (or more, because the government may obtain extensions) after it receives a copy of the complaint and the material evidence and information supporting it. 31 USC §3730(b)(2). The government can decide to officially intervene and take over the *qui tam* action filed by the relator, 31 USC §3730(b)(4), or it may decline, at which point the relator has the right to conduct the action. In any event, the action may be dismissed only if the court and the government give written consent and state their reasons for doing so in writing. 31 USC §3730(b)(1).

If the government takes over the action, the relator may be awarded at least 15 percent, but no more than 25 percent, of the proceeds from the claims. If the government declines to intervene and the action is pursued by the relator, he or she may be awarded between 25 percent and 30 percent of the proceeds, subject to court approval. 31 USC §3730(d)(1)–(2). Attorney fees are available if the relator prevails, but are not usually available if the relator does not. 31 USC §3730(d)(4). Because of this significant ability to obtain large awards and attorney fees, there is a cottage industry of law firms specializing in *qui tam* suits, actively seeking out employees who are willing to serve as relators.

Note, however, that the FCA bars certain actions that have particular resonance in the health care context. *Qui tam* actions may be dismissed if:

- They are based upon allegations or transactions that are already the subject of a civil suit or administrative civil monetary penalty hearing in which the government is a party. 31 USC §3730(e)(3);
- They are based on the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accountability Office (GAO) report, hearing, audit, or investigation, or from the news media—*unless* the action is brought by the United States or the relator is the "original source" of the information. 31 USC §3730(e)(4)(A). In *Rockwell International Corp. v. United States*, 549 US 457, 127 S Ct 1397, 167 L Ed2d 190 (2007), the United States Supreme Court narrowly interpreted the meaning of the term

original source. To be considered an "original source" and thereby avoid dismissal of an action based on the public disclosure exception, an individual must have "direct and independent" knowledge of the information in the original complaint *and* any amendments, and must voluntarily provide it to the government before bringing the claim. *Rockwell International Corp.*, 549 US at 473.

The FCA provides relief from an employer's retaliation related to an employee's efforts to stop an FCA violation. *See* 31 USC §3730(h). Employees, contractors, and agents are entitled to "all relief necessary" to make them "whole" if they are "discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms or conditions of employment" because of their efforts to stop FCA violations. 31 USC §3730(h)(1). Such relief includes reinstatement with the same seniority status that the employee would have had but for the discrimination, and two times the amount of backpay, interest, and compensation for special damages, including litigation costs and reasonable attorney fees to obtain such relief. 31 USC §3730(h)(2).

In the Ninth Circuit, the target of a *qui tam* suit may proceed with counterclaims for indemnification or contribution against the relator based on the relator's own participation in the wrongdoing when a *qui tam* defendant ultimately is found liable. *Mortgages, Inc. v. U.S. D. Ct. for D. of Nev.*, 934 F2d 209, 211–212, 214 (9th Cir 1991). Claims for "independent damages," that is, damages that do not only have the effect of offsetting the defendant's liability, may be brought against *qui tam* plaintiffs. *United States ex rel. Madden v. Gen. Dynamics Cor.*, 4 F3d 827, 830–831 (9th Cir 1993). The Ninth Circuit also has held that dependent counterclaims for contribution and indemnification may be advanced against the relator if a *qui tam* defendant is found not liable. *Madden*, 4 F3d at 831. *Qui tam* defendants also may seek indemnification and contribution from third parties even if they settle with the government. *See Cell Therapeutics Inc. v. Lash Group, Inc.*, 586 F3d 1204, 1212–1213 (9th Cir 2009).

§13.2-7 Administrative Sanctions

§13.2-7(a) Civil Monetary Penalties

In addition to statutory violations enforceable in court, providers may run afoul of federal laws and regulations enforceable through administrative action. Under the Social Security Act, the Secretary of Health and Human Services (HHS) may seek civil monetary penalties (CMPs) and assessments for a variety of conduct. The Secretary of HHS has delegated many of these CMPs to the Office of Inspector General (OIG), which also may seek exclusion from participation in all federal health care programs. The main authority for CMPs is found at 42 USC §1320a-7a. Implementing regulations are found at 42 CFR Part 1003. Prior to seeking formal penalties, the OIG generally tries to resolve matters through negotiation.

The CMP law penalizes knowingly presenting, or causing to be presented, a claim or cost report that:

(1) Is for an item or service that the health care service provider knew, or should have known, was not provided as claimed (including as part of a pattern or practice of using a higher-paying billing code than the applicable code);

(2) The provider knew, or should have known, was false;

(3) Is for a physician's or physician-related service that the provider knew, or should have known, was not provided by an appropriate person;

(4) Is for a period when the provider was excluded from billing the program; or

(5) Is for a pattern of items or services that the provider knew, or should have known, was not medically necessary. 42 USC §1320a-7a(1).

Other conduct that may be penalized under the civil monetary penalties provisions includes violating the anti-kickback statute (AKS), as discussed above, employing or entering into contracts for medical services with individuals who have been excluded from a federal health

care program (FHCP), violating the terms of an assignment or certain agreements, providing materially false or misleading information about a hospital inpatient, and offering inducements to individuals eligible for Medicare or Medicaid if the offeror knows or should know that the inducements will influence the patient to order or receive items or services from a particular provider, practitioner, or supplier. The Patient Protection and Affordable Care Act of 2010 added a number of new categories of conduct that will trigger civil monetary penalties, including failing to report or return an overpayment, ordering or prescribing items or services during a period when the prescriber was excluded from an FHCP, and failing to grant the OIG timely access for audits, investigations, and evaluations.

Violation of the CMP law can result in penalties that vary based on the type of violation at issue. *See* 42 CFR §1003.103. For example:

- If false or fraudulent claims are at issue, the OIG may seek a penalty of up to $10,000 for each item or service improperly claimed *and* an assessment of up to three times the amount improperly claimed. 42 USC §1320a-7a(a).
- In a kickback case, the OIG may seek up to $50,000 for each improper act *and* damages of up to three times the amount at issue (regardless of whether some of the remuneration was for a lawful purpose). *See* 42 USC §1320a-7a(a).
- Violation of the prohibition on providing misleading information is punishable by a $15,000 penalty for each individual misinformed by the health care provider. 42 USC §1320a-7a(a).
- Employment or engagement with individuals who have been excluded from an FHCP subjects individuals or entities to $10,000 per day in penalties for each day the improper relationship persists. 42 USC §1320a-7a(a).

Cases under the civil monetary penalties law are brought by the OIG and are heard by an administrative law judge (ALJ) at HHS. In determining the penalty, the ALJ must take into account: (1) the nature of the claims and the circumstances under which they were presented, (2)

the degree of culpability, (3) the history of prior offenses, (4) the financial condition of the person present in the claims, and (5) other matters as justice may require. 42 USC §1320a-7a(d). The statute of limitations for violations of the civil monetary penalties law is six years from the date the false claims were filed. 42 USC §1320a-7a(c)(1). Any person adversely affected by a determination of HHS may seek review by the United States Court of Appeals by filing a written petition for review within 60 days of receiving notice of the decision by HHS. 42 USC §1320a-7a(e).

§13.2-7(b) Program Exclusions

The U.S. Department of Health and Human Services (HHS) handles program exclusions at the federal level. It *must* exclude from federal health care programs (FHCPs) individuals and entities convicted of crimes related to the delivery of items and services under Medicare and state health care programs, patient abuse or neglect, or felony offenses involving state-controlled or federal-controlled substances. 42 USC §1320a-7. The mandatory exclusion from Medicare and Medicaid also extends to any felony conviction under federal or state law relating to health care fraud committed after August 21, 1996, even if federal programs were not involved. 42 USC §1320a-7(a)(3)–(4).

HHS also has the ability to exclude individuals and entities that:

(1) Have been convicted of certain other criminal offenses;

(2) Have had licenses revoked or suspended;

(3) Have been excluded or suspended from a federal or state health care program;

(4) Have submitted claims for excessive charges or medically unnecessary services;

(5) Have failed to provide medically necessary services;

(6) Have violated 42 USC §1320a (as described above); or

(7) Have failed to provide required information or access to records, as well as for other miscellaneous reasons. 42 USC §1320a-7(b).

In addition, the Office of Inspector General (OIG) is authorized to initiate permissive exclusion against any person or entity making false statements or misrepresentations of material fact on an application, agreement, bid, or contract in order to prevent enrollment as a provider or supplier. 42 USC §1320a-7(b). The OIG has published nonbinding guidelines to be used to determine whether to impose a permissive exclusion. 62 Fed Reg 55,410 (1997). *See also Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act* (October 20, 2010) (available at <http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf>). The administrative procedure for exclusions is outlined at 42 USC §1320a-7(c)–(h). No limitations period is specified. Regulations implementing the OIG's exclusion authority are set forth in 42 CFR §1001.

Exclusions last a specified length of time, depending on the reason for the exclusion. 42 USC §1320a-7(c)(3). For example, in convictions relating to health care fraud, the exclusion term is five years. 42 USC §1320a-7(c)(3)(B). There is a one-year minimum exclusion for individuals or entities that have submitted or caused to be submitted claims for excessive charges or that have furnished unnecessary items or services, or for health maintenance organizations or entities that have failed to provide medically necessary services and items. 42 USC §1320a-7(c)(3)(F). A detailed discussion of the lengths of the various exclusions is beyond the scope of this chapter.

Exclusions also may reach to individuals. Individuals may be excluded who: (1) have a direct or indirect ownership or control interest in a sanctioned entity and knew, or should have known, of the action constituting the basis for exclusion, or (2) are officers or managing employees of the entity, if the entity has been convicted of health care fraud or has been excluded from Medicare or Medicaid for any reason, even if the individual did not participate in the wrongdoing. 42 USC §1320a-7(b)(8). Failure of the excluded individual to divest his or her interests in the sanctioned entity can result in civil fines of $10,000 per

day for each day the prohibited relationship between the excluded individual and sanctioned entity continues. 42 USC §1320a-7a(a)(4).

Individuals or entities seeking to enroll or revalidate their enrollment in the Medicare or Medicaid programs must disclose current or previous direct or indirect affiliations with individuals or entities who: (1) have been excluded from participation in Medicare, Medicaid, or the Children's Health Insurance Program (CHIP); (2) have uncollected debts or have been subject to a payment suspension under an FHCP; or (3) have had billing privileges revoked or denied. 42 USC §1395cc(j)(5). If such an affiliation is found by the Secretary of HHS to pose an undue risk of fraud, waste, or abuse, the secretary shall deny the application to enroll or revalidate enrollment.

§13.2-8 Federal Patient Abuse and Neglect Laws

Unlike Oregon statutes, federal criminal or civil statutes do not directly address abuse or neglect of residents or patients. Federal prosecutors must use other statutes to punish abuse and neglect. In *United States v. GMS Management-Tucker*, No. 96-127 (ED Pa Feb. 21, 1996), *reported in Philadelphia Nursing Home Owner Settles First Nutrition, Wound Care Claims Case*, 5 Health L Rep (BNA) 10–11 (Mar 7, 1996), the government prosecuted a neglect case under the federal False Claims Act (FCA); the defendant settled for $600,000. Likewise, in *United States v. Chester Care Center, el al.*, Case No. 98-CV-139 (ED Pa 1998), the government prosecuted another neglect case against three nursing homes and their corporate owner under the federal FCA, which settled for $500,000. In 2005, the Department of Justice reached a $2.5 million settlement with a Georgia nursing home after prosecuting it for deficient care under the FCA, *reported in the Department of Health and Human Services and the Department of Justice Health Care Fraud and Abuse Control Program Annual Report for FY 2006*, at 13 (available at <http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2006.pdf>). *But see United States ex rel. Swan et al. v. Covenant Care, Inc.*, 279 F Supp 2d 1212 (ED Cal 2002) (summary judgment opinion questioning viability of prosecuting *qui tam* quality of care claims under FCA).

Nor does the civil monetary penalties law, 42 USC §1320a-7(a), directly authorize administrative penalties for abuse or neglect, although it can be used to penalize a provider who *knew or should have known* that an item or service was not provided as claimed. For example, a nursing facility may be penalized if it reports costs sufficient to meet state or federal licensing and certification standards, when in fact *less* money than reported has been spent on food, staffing, or medical care, resulting in the neglect of residents. Similarly, the federal exclusion statute, 42 USC §1320a-7(a)(2), addresses neglect and abuse only obliquely, requiring exclusion of: (1) an individual or entity convicted of a criminal offense relating to the neglect or abuse of residents or patients, and (2) practitioners who are sanctioned for failure to comply with professionally recognized standards. 42 USC §1320c-5(b).

§13.3 SURVEY OF RELEVANT STATE LAWS

§13.3-1 Fraud: State False Claims Act and Other Civil Statutes/Proceedings

§13.3-1(a) State False Claims Act: ORS 180.750-180.785

In 2009, Oregon adopted a False Claims Act (the "Oregon FCA"). ORS 180.750–180.785. The statute is similar to the federal FCA, with some key differences. First, the Oregon FCA does not include *qui tam* provisions allowing a private individual to sue in the place of the government. Only the Oregon Attorney General's office may do so. ORS 180.760(1). Second, and perhaps most important for health care attorneys, the Oregon FCA mandates distribution of recoveries from an action under the statute in a manner that would violate federal law if applied to Medicaid claims. The Oregon FCA requires that any recovery be distributed to reimburse the state for its costs in pursuing the recovery, and then to reimburse the state or federal agency for its loss. All remaining amounts (including any award of penalties above single damages) must be paid to the Department of Justice Protection and Education Revolving Account. ORS 180.780. But Centers for Medicare and Medicaid Services has interpreted the federal Medicaid statute to require any amounts recovered by a state through a state FCA, including any

penalties, to be divided between the state and federal governments according to the federal financial participation percentage. *Letter from Herb B. Kuhn, Acting Director, CMS, to State Health Official* (Oct 28, 2008). Because of this conflict, it is unlikely that the Oregon Attorney General will pursue false Medicaid claims under the Oregon FCA.

§13.3-1(b) Other Civil Recovery Statutes

ORS 411.675 prohibits the submission of wrongful claims for any payment for furnishing a service to a recipient of public assistance, including any Medicaid recipient.

> NOTE: 2013 HB 2859 amends ORS 411.675 but has not been signed by the governor as of July 2013.

Violation gives rise to relief in the amount of the payment plus the Medicaid agency's costs and disbursements in pursuing the action. However, the statute provides that the Medicaid agency can recover treble damages against a person who violates ORS 411.675(1) if the violation occurs after the person has been afforded an opportunity for a contested case hearing. ORS 411.690(2); OAR 407-120-1505(18)(g) (providers previously warned in writing by the Department of Human Services, Oregon Health Authority, or the Oregon Department of Justice about improper billing practices will be liable to the Provider Audit Unit for triple the amount of any overpayment).

The Oregon Department of Justice also relies on the following civil statutes and rules in Medicaid fraud cases, depending on the factual circumstances: ORS 646.515–646.545 (unfair trade practices), ORS 166.715–166.735 (civil racketeering), ORS 659A.200–659A.233 (whistleblowing), OAR 410-120-1395 to 410-120-1510.

§13.3-1(c) Administrative Proceedings

Oregon's Medicaid agency, the Oregon Health Authority, Division of Medical Assistance Programs, has a multitude of sanctions available to address fraudulent billing practices. Sanctions may include, for example: (1) assessing overpayments, often based on statistical samples of a provider's records; (2) assessing treble damages if there is a prior warning; (3) withholding future payments; (4) terminating, suspending,

or excluding the provider from participating in the Medicaid program; (5) requiring the provider to attend education classes; (6) suspending billing privileges; and (8) recovering investigative and legal costs. OAR 410-120-1560; OAR 410-120-1580. A provider who receives a notice of proposed sanction will be entitled to a contested case hearing or administrative review. The rules governing these proceedings are found at OAR 4078-120-1560 and OAR 410-120-1580 to 410-120-1875. *See also* OAR ch 407, div 120.

§13.3-2 Oregon Criminal Fraud Statutes

Oregon has its own criminal Medicaid fraud statute: ORS 411.675. It is a Class C felony to knowingly submit, or cause to be submitted: (1) a false claim, (2) a claim that has already been submitted for payment (unless the subsequent claim is clearly labeled as a duplicate), or (3) a claim on which payment has already been made by Medicaid or any other source (unless the claim clearly so indicates). It also is a crime to accept Medicaid payments for work not performed or a service not provided. ORS 411.675. The ordinary statute of limitations for ORS 411.675 is three years from the date of the act alleged in the indictment (e.g., the submission of a wrongful claim). ORS 131.125(7)(a). However, the statute of limitations may be extended by an additional three years if fraud or the breach of a fiduciary obligation is pleaded and proved as a material element. ORS 131.125(8)(a).

False claims submitted for health care payments are criminalized by ORS 165.690–165.698. It is a Class C felony to knowingly: (1) make, or cause to be made, a claim for health care payment that contains any false statement or false representation of a material fact in order to receive payment, or (2) conceal or fail to disclose an event or other information with the intent to obtain or retain greater payment than that to which the health care provider is entitled. ORS 165.690–165.692.

Other generic state criminal statutes can be used against health care providers who steal from clients, breach their fiduciary duty, make false insurance claims, or take charge of dependent or elderly persons in the interest of committing fraud. If a nonhealth, care-specific felony statute is used, the ordinary statute of limitations is three years, which can be

extended by up to three years if fraud or breach of a fiduciary obligation is pleaded and proved as a material element. ORS 131.125(7)(a), (8). If a nonhealth care misdemeanor statute is used, the ordinary time limitation is two years under ORS 131.125(7)(b). The misdemeanor statute's limitations period also can be extended by up to three years in the case of fraud or breach of fiduciary duty. ORS 131.125(8).

§13.3-3 State Patient Neglect and Abuse Provisions

§13.3-3(a) Oregon Criminal Statutes

Oregon's criminal mistreatment statute, ORS 163.205, applies to all health care providers that have a legal duty to provide care for another person, as well as to providers that have assumed permanent or temporary care, custody, or responsibility for such a person. Under this statute, a provider that intentionally or knowingly withholds necessary and adequate physical care, food, or medical attention from such a person is guilty of a felony. The same conduct, performed with a criminally negligent state of mind, constitutes a misdemeanor under ORS 163.200. It is also a felony to: (1) cause physical injury to such a person, or (2) leave him or her unattended in circumstances likely to endanger his or her health or welfare if the person is 65 years old or older or dependent for physical care because of age or physical or mental disability. ORS 163.205(1).

Abuse and neglect also may be charged under other general-jurisdiction criminal statutes, such as assault, harassment, and sex offenses.

Public and private officials (as defined by ORS 124.050(9), including physicians, nurses, counselors, and psychologists) having reasonable cause to believe that anyone over 65 years old has suffered abuse have a duty to report such abuse to the Department of Human Services or law enforcement authorities. ORS 125.060, ORS 125.065. A person who is obligated to report abuse under ORS 125.060 and fails to do so commits a Class A violation. ORS 125.990.

Police agencies have jurisdiction to investigate any criminal allegation made against a health care provider. The Oregon Department

of Justice's Medicaid Fraud Control Unit also has jurisdiction to investigate and prosecute abuse and neglect that occurs in any health care facility that receives Medicaid money, regardless of whether the abused or neglected patients or residents are Medicaid recipients. The statute of limitations for ORS 163.205 is two years, and for ORS 163.200, it is three years. *See* ORS 131.125(7)(a)–(b).

§13.3-3(b) Civil Statutes

Health care providers may be sued civilly for inadequate, neglectful, or abusive patient care. Potential actions include private wrongful death suits; actions brought privately or by the Oregon Department of Justice under the Unlawful Trade Practices Act for failure to provide services as represented; and actions under ORS 124.100 (civil action for abuse of elderly, financially incapable, or incapacitated person) if the provider is covered by the law. A plaintiff who successfully brings suit under ORS 124.100 is entitled to recover three times the economic and noneconomic damages, plus attorney fees and guardian ad litem fees. ORS 124.100(2)(a)–(d). ORS 124.100 does not generally apply to surgical centers or hospitals; residential, intermediate, skilled, or other nursing care facilities; foster homes; hospices; or certain other nonhealth care entities. ORS 124.115. The statute of limitations for ORS 124.100 is seven years after the conduct is discovered. ORS 124.130.

§13.4 STATE AND FEDERAL ENFORCEMENT

The Oregon Department of Justice enforces state and related federal health care fraud laws through a specialized group of investigators, including CPAs, medical records reviewers, and prosecutors, appointed by the Oregon Attorney General and certified by federal authorities. Together, they comprise the Medicaid Fraud Control Unit. This office is empowered to commence investigations and prosecutions on its own initiative or on referrals from other agencies and the public (e.g., complaints initiated by relatives of residents of assisted living or long-term care facilities). Federal enforcement is handled by white-collar prosecutors with the U.S. Attorney's office, in collaboration with the Office of Inspector General (OIG) (acting on referral from the U.S.

Department of Health and Human Services (HHS)), the FBI, and increasingly, IRS special agents who investigate tax and money laundering aspects of the investigation.

With growing frequency, fraud auditors with fiscal intermediaries under contract to HHS (such as BlueCross/BlueShield) refer health care fraud cases to state and federal authorities, which coordinate their efforts as a joint federal-state task force. This approach allows the government the ability to attack Medicare and Medicaid abuse allegations in combination. It has proven highly effective and presents a distinct challenge to providers.

Enforcement of laws related to health care fraud is likely to intensify in the coming years. In May 2009, HHS and the U.S. Department of Justice announced the creation of the Health Care Fraud Prevention and Enforcement Action Team (HEAT), a federal interagency effort. A key component of HEAT is the expansion of Medicare Fraud Strike Force operations, which are active in Baton Rouge, Brooklyn, Detroit, Houston, Los Angeles, Miami, and Tampa. In the first 30 months of the Strike Force program, prosecutors filed 244 cases charging 456 defendants involving over $900 million in improperly billed Medicare payments. U.S. Department of Health and Human Services and Department of Justice, *Health Care Fraud and Abuse Control Program, Annual Report for Fiscal Year 2009*, at 11 (May 2010), *available at* <http://oig.hhs.gov/publications/hcfac.asp>.

To support Strike Force operations, OIG has organized the Advanced Data Intelligence and Analytics team (the "Data Team"). Composed of OIG special agents, statisticians, programmers, auditors, and analysts, the Data Team integrates intelligence gathered by agents with data analysis to identify health care fraud schemes, trends, and geographic "hot spots." *See* Testimony of Daniel R. Levinson to House Subcommittee on Health, Inspector General of U.S. Department of Health and Human Services, September 22, 2010, *available at* <http://oig.hhs.gov/testimony/docs/2010/testimony_levinson_09222010.pdf>.

In this climate, reimbursement and billing problems arising from "routine" audits by Medicare contractors (e.g., fiscal intermediaries) must be addressed promptly. If such problems are not resolved to the intermediary's satisfaction, the matter may be referred to a joint task force. In the Northwest, common causes for such referrals include the provider's failure to produce documents, to cooperate with intermediary auditors, and to respond in a timely and cooperative manner to billing inquiries. Provider cooperation should be the rule and is required under provider contracts with state and federal health care programs. However, an exception to this rule may arise when a provider—based on an outside internal investigation, perhaps by criminal defense counsel—discovers a high probability of health care fraud and is advised to assume a defensive posture.

> NOTE: Durable Medical Equipment (DME) fraud has become an increasing focus of federal and state enforcement authorities. *See* Testimony of Daniel R. Levinson to House Subcommittee on Health, Inspector General of U.S. Department of Health and Human Services, September 15, 2010, *available at* <http://oig.hhs.gov/testimony/docs/2010/testimony_levinson_09152010.pdf> (explaining OIG past efforts and future strategies for combating DME fraud); *see also Health Care Fraud and Abuse Control Program, Annual Report for Fiscal Year 2009*, *supra*, at 24–25 (highlighting successful prosecutions of DME fraud in 2009). The Patient Protection and Affordable Care Act of 2010 (PPACA) requires that certifications and written orders for DME be made only by Medicare enrolled physicians and other professionals. Under section 6406(a) of the PPACA, HHS may revoke enrollment of physicians or suppliers for up to a year if they fail to maintain and provide access to documentation relating to written orders or requests for payment of DME. Title VI to the PPACA amends various regulations to require a face-to-face encounter between the patient and a physician or a qualified individual under the supervision of a physician 90 days before certification for a DME purchase is granted. OIG has indicated that pursuit of DME fraud will be an ongoing focus of investigative

efforts in the coming years. Other new provisions contained in the PPACA have also expanded efforts to impose competitive bidding programs on DME purchases. The act also permits the Centers for Medicare and Medicaid Services to withhold funding for new DME providers for up to 90 days if a significant risk of fraud is found.

An effective way to avoid liability under the health care fraud laws is to catch problems in their infancy. Provider compliance programs are an indispensable tool in this regard; providers with compliance programs are more likely to avoid criminal investigations. Furthermore, in many cases, having a compliance program in place when alleged misconduct occurs will improve the provider's position in negotiating with government investigators. The OIG has promulgated model compliance programs, characterized as "guidance" to certain providers, such as hospitals, laboratories, nursing homes, and physician practices. Guidelines for additional types of providers are expected in the future.

PRACTICE TIP: The OIG's Web site, <http://oig.hhs.gov>, also contains an excellent repository of forms, advisory opinions, and other invaluable information for the provider's corporate or criminal defense counsel. Model plans can be downloaded in digital form; recent commentary and developments are set forth; and reports of settlements and investigations are available, subject to certain confidentiality constraints.

Under section 6401(a)(3) of the Patient Protection and Affordable Care Act of 2010, the Secretary of HHS will soon begin mandating that certain categories of providers enrolling in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) establish a compliance program. 42 USC §1395cc(j)(8)(A). The Secretary of HHS will establish a time line for implementation for each category of provider. 42 USC §1395cc(j)(8)(C). The statute further provides that the Secretary of HHS, in consultation with the Inspector General of HHS, will establish core elements for the compliance program, as well as its implementation. 42 USC §1395cc(j)(8)(B). Guidelines for additional types of providers are expected in the future.

§13.5 THE PROVIDER'S RESPONSE TO A CRIMINAL INVESTIGATION OR INDICTMENT

§13.5-1 Investigation by Governmental Officials

Investigations into alleged health care abuse originate from numerous potential sources, including complaints of abuse or neglect to an ombudsman or state agency, intermediary auditors, pharmacy audits, and Medicaid referrals to or coordination with the Office of Inspector General. Official investigations most commonly focus on the following categories of provider misconduct:

(1) Filing fraudulent claims for services or items not rendered, as well as for durable medical equipment;

(2) Filing claims that misrepresent the services or items rendered (e.g., upcoding or billing for six visits when there were only four);

(3) Patterns of waiving copayments, leading to falsely stated claims;

(4) Filing claims for services that were "not medically necessary";

(5) Using incorrect diagnosis codes;

(6) Engaging in deceptive practices referred to as "unbundling," or improperly fragmenting claims that should be billed as a "global package";

(7) Filing cost reports claiming items that are unrelated to patient care or that contain figures reflecting improper allocations or expenses;

(8) Accepting kickbacks, that is, consideration for referring business in violation of the anti-kickback statute, 42 USC §1320a-7b(b);

(9) Self-referral, that is, physicians ordering that their patients receive items or services to be delivered by entities in which the ordering physician has a financial interest, 42 USC §1395nn; 42 CFR §§411.350–411.408; and

(10) Quality-of-care issues.

§13.5-2 Responding to a Government Investigation

At the commencement of an investigation, the provider and its counsel must react swiftly and cautiously, balancing a number of competing factors:

(1) The employer's financial interests;

(2) The exposure of employees and management to personal criminal liability;

(3) Confidentiality issues and privileges that may or may not attach to certain documents and other information;

(4) Potential conflicts of interest between the provider and its employees (or the provider and its officers or directors in the case of larger corporations); and

(5) Cooperation with government agencies to ensure the provider's ongoing ability to serve residents or patients and to receive reimbursement from Medicare, Medicaid, HMOs, or private insurers.

> CAVEAT: As a general rule, because the provider's contracts with Medicare and Medicaid contain extensive recordkeeping and reporting requirements, nearly all provider records are available to the government on demand. A provider's failure to comply with requests for records may result in exclusion from the program. For example, HCFA Form 1500, a standardized claim form, indicates that by applying for payment for services, the beneficiary authorizes the U.S. government to have access to the patient's medical records for verification purposes. The penalties for refusing to provide such access range from nonpayment of the claim to exclusion of the provider entirely.

PRACTICE TIP: The severity of this potential sanction often weighs heavily in favor of disclosure to the government of the requested documents. The analysis may be affected by the nature of the provider, however; if it is an individual or a closely held entity, the potential of personal liability may counsel against disclosure, despite the threat of exclusion. In either event, counsel should evaluate the benefits of cooperation, including the Office of Inspector General's Voluntary Self-Disclosure Protocol, as well as the provider's obligations to self-disclose any overpayments. Exclusion is a formidable weapon, as are the potentially high civil monetary penalties and exposure to enhanced sentencing. Together, they convince most providers to settle institutional health care fraud investigations rather than litigate them.

COMMENT: In the final analysis, the provider may be faced with an election of risks: staying in business, at least temporarily, versus suffering the consequences of a criminal conviction.

NOTE: Section 6402 of the Patient Protection and Affordable Care Act of 2010 has given the United States Department of Health and Human Services (HHS) power to suspend Medicare and Medicaid payments to providers or suppliers if "credible allegations of fraud" have been made against the provider. Section 6402 allows for the suspension of Medicare and Medicaid payments to providers. The Secretary of HHS must determine if "good cause" exists to order such a suspension. 42 USC §1396(i)(2)(C).

§13.5-3 Subpoenas for Documents or Testimony

Investigators may initiate or follow up fiscal intermediaries' requests for documents by subpoena duces tecum pursuant to FRCP 17, administrative subpoena from the Office of Inspector General (OIG), or a sitting grand jury.

If a provider (or its employee) receives a subpoena, the provider should follow these general guidelines:

(1) Retain and coordinate an appropriate legal counsel team, including a criminal defense attorney if warranted, and consider whether any individual subpoena recipients or targets require separate counsel. A litigation hold notice should be sent to relevant recipients, preferably by in-house counsel.

(2) Examine the subpoena, determine whether it meets constitutional and statutory criteria, and challenge it as appropriate, given both legal and strategic considerations.

(3) Promptly contact the investigatory agencies and prosecutors involved to determine, if possible, the scope and basis of the investigation.

(4) To the extent possible, discover the identity of "targets" and "subjects" of the investigation.

> NOTE: These terms are defined in the UNITED STATES ATTORNEYS' MANUAL §9-11.151 (1997), found at <www.justice.gov/usao/eousa/foia_reading_room/usam/title9/11mcrm.htm#9-11.151> as follows:
>
> A *target*
>
> > is a person as to whom the prosecutor or the grand jury has substantial evidence linking him or her to the commission of a crime and who, in the judgment of the prosecutor, is a putative defendant. An officer or employee of an organization that is a target is not automatically considered a target even if such officer's or employee's conduct contributed to the commission of the crime by the target organization. The same lack of automatic target status holds true for organizations that employ, or employed, an officer or employee who is a target.
>
> A *subject* of an investigation "is a person whose conduct is within the scope of the grand jury's investigation."

Note that the government must respond to a proper request for disclosure from defense counsel inquiring on behalf of an individual or entity under investigation, whether the client is currently a target, a subject, a witness, or none of the foregoing.

(5) Evaluate privileges (work product, attorney-client, patient confidentiality).

(6) Negotiate modifications based on any possible defenses if a motion to quash was filed, including overbreadth regarding the number of patient/resident files, the period of time involved, the degree of interference with ongoing operations, and additional time in which to respond.

(7) After documents are identified for production, and before producing them (the government will demand all originals): (a) prepare a log of all documents produced and those withheld based on privilege (although time-consuming, this is invaluable if an investigation turns into a prosecution); (b) agree on a method of sequencing documents, such as Bates stamping; and (c) make a copy for the provider, replacing the originals turned over, and a copy for all counsel. As part of document production, the provider should come to an agreement with the government on the scope and format of production for electronic documents as well.

(8) Advise the provider's president and board of directors, consistent with company protocol.

> CAVEAT: Careful handling of documents at the provider's facility and offices is essential, as is maintaining ongoing communications between all counsel and government investigators. If document production is delegated to paralegals or the provider's employees, these persons should be carefully supervised. Every effort should be made to ensure that documents (both physical and electronic) are not misplaced, lost, or inadvertently destroyed. If, despite these efforts, documents are missing, the surrounding circumstances will affect (a) charging decisions, (b) the scope or necessity of future investigations, (c) proof of mental state and other elements of health care fraud crimes if there is a trial, and (d) whether obstruction-of-justice charges will be filed. The importance of gaining and maintaining firm control over the provider's documents once an investigation is commenced cannot be overstated.

NOTE: When a specific employee of the provider receives a subpoena, the employee is free to, and should, obtain separate counsel and take appropriate measures to comply with the law and to safeguard constitutional rights (e.g., the Fifth Amendment) if testimony is also sought. The employee may seek indemnification for attorney fees. The corporate provider may be obligated to reimburse or to pay for the fees incurred by the employee in this context; the provider's business counsel should be involved in evaluating applicable statutes, the entity's organizational documents, and employment agreements.

NOTE: Section 6402 of the Patient Protection and Affordable Care Act of 2010 extends the Secretary of the U.S. Department of Health and Human Services' investigative subpoena powers (described at 42 USC §205(d) and (e)) to program exclusion investigations undertaken pursuant to 42 USC §1320a-7(f). This authority can be delegated to the OIG.

§13.6 SEARCH WARRANTS

Search warrants are a more invasive tool than subpoenas to combat health care fraud and abuse. They carry the element of surprise, remove the possibility that documents will be destroyed or misplaced (innocently or otherwise), and avoid Fifth Amendment privilege arguments that may be raised in response to subpoenas. Search warrants are governed by the Fourth Amendment to the United States Constitution, which has been interpreted strongly in favor of the government over the past few decades. Search warrants must be supported by a sworn affidavit of probable cause. Although the affidavit would be extremely valuable to the provider's counsel in assessing how the investigation originated and where it may be headed, it is customarily filed under seal (to provide confidentiality of witnesses and the investigation generally) and is not disclosed (if at all) unless or until criminal charges are filed and a party with standing moves to challenge the warrant.

CAVEAT: Because of adverse publicity that may ensue, it may not be in a party's interest to have an affidavit unsealed. The

provider's counsel should carefully balance the pros and cons before filing such a motion.

A provider should have an established procedure for responding to a search warrant, drafted in conjunction with counsel. Ideally, legal counsel should be contacted to intervene the moment a search is underway. Because this is not often logistically feasible—and the government may be unwilling to delay its search and seizure of evidence until such counsel arrives—the following steps will help preserve the provider's rights:

(1) Determine who is the lead agent and ask to speak with him or her. Obtain the agent's name and phone number. Request the name of the prosecutor who authorized the warrant and inquire about the nature of the suspected wrongful activity.

(2) If counsel is not present at the search site, counsel should ask the agent to read the warrant over the phone.

(3) The provider's top-level supervisor or manager should direct full cooperation in showing agents the location of documents, assisting with computer searches, and identifying files, disks, and other material listed in the warrant. The provider should create a list of materials seized during the search.

NOTE: If counsel cannot be present at the search site or cannot arrange for criminal defense counsel to arrive there in a timely fashion, the recommendations that follow should be delegated to a single supervisory employee or handled by counsel via telephone during the search.

(4) Obtain a copy of the warrant—including the list of items to be seized—and (later) a receipt of property seized. (Although the affidavit should also be requested, it is normally filed under seal and not produced.)

(5) Request that agents not interview employees, but if they do, unless criminal defense counsel is present and properly intervenes, do not interfere. A facility representative should always request to be present at

interviews and should take complete notes of the interview. Better yet, request that any interviews take place only in the presence of counsel.

(6) Warn employees not to interfere in any way with the search.

(7) Request that employees make written notes of where the agents searched and what the agents said.

(8) Advise agents, respectfully, that employees do not have the authority to consent to any search or seizure, and request that agents not seek consent from employees.

(9) Urge employees to stay calm. Reassure them that the company will be doing everything possible to resolve the situation. Ask them to respectfully decline making any comments or statements to agents (aside from showing the agents where certain specified materials are, e.g., computer disks, which may prevent the computers from being seized). In this regard, advise employees that they have no obligation to answer any questions; however, emphasize that this is a decision that only they can make. Advise employees that they have the right to an attorney if an agent begins to focus specific questions on a specific employee.

> NOTE: This issue requires far greater legal and ethical analysis, which is beyond the scope of this chapter. The provider will have to make decisions about whether to defend and indemnify an employee, to take a neutral position, or even to terminate an employee whose misconduct is first discovered as a result of a subpoena or search warrant. Each of these decisions involves an intensive factual and legal analysis, which should be assessed by the provider's counsel.

(10) Do not destroy any documents left behind after the search, and suspend any regularly scheduled shredding, removal, or destruction procedures. A formal litigation hold notice should be issued.

(11) Counsel or management accompanying the agents during the search should take notes of questions and responses, as well as of items or files seized.

(12) Request to make copies of documents that are essential for the running of the business. Because this may constitute 90 percent or more of the documents seized, make this request early and, if allowed, make copies as the documents are being logged.

(13) After the search and seizure, the agents will submit an inventory list for signature by the provider. Counsel or an employee who has observed the search should sign it. Review the inventory list carefully to ensure that it describes the seized property as specifically as possible to avoid subsequent disputes.

(14) As soon as practicable after the search, debrief all employees who interacted with the agents outside the presence of counsel. Immediately transcribe a summary of any conversations or interviews for criminal defense counsel.

> PRACTICE TIP: Depending on the nature of the investigation and the level of trust between counsel and the agents, before or even during the search, it may be possible to negotiate suspension of or limitations on the search, subject to counsel's promise to provide certain documents by subpoena, accompanied by sworn statements from the facility's recordkeepers.

> PRACTICE TIP: Although searches are disruptive and stressful for all involved, they also provide counsel with an opportunity to gain insight into the investigation and to establish the best rapport possible with the agents. Given the threats of criminal prosecution and program exclusion, counsel must make every effort to preserve negotiating options and actual defenses.

§13.7 GRAND JURY PROCESS

The federal grand jury is the most likely place where a health care fraud investigation will reside following a criminal referral.

> NOTE: Because federal funds are primarily involved, the Office of Inspector General and federal prosecutors have the "first option" regarding whether to seek an indictment. If they decline to do so, the Oregon Department of Justice may decide to present

Medicaid fraud or evidence of other state law violations to a state grand jury. Both federal and state investigations can be maintained simultaneously, although this is the exception more than the rule.

The grand jury's proceedings are entirely secret. However, the prosecutor must advise subpoenaed persons whether they are targets, subjects, or only witnesses.

PRACTICE TIP: Persons identified as targets or subjects should retain counsel to review their rights, to determine whether they should testify, to determine whether they should seek immunity, and to consider all other options available.

Grand jury proceedings are transcribed, and witnesses are sworn under oath. Penalties for perjury and obstruction of justice apply. Although grand jurors and government representatives may not disclose what occurred before the grand jury, witnesses may disclose the questions asked and their own testimony provided in response. Providers whose employees, contractors, suppliers, or others give grand jury testimony should bear this in mind.

COMMENT: Defense counsel is not allowed in the grand jury room and cannot monitor the proceedings. However, counsel may remain outside the grand jury room, and witnesses are permitted to consult with counsel there. The grand jury is a hostile and risky environment for targets, subjects, and witnesses. Agency and law enforcement officers will present testimony outlining the results of their investigations; lay and expert witnesses will be subpoenaed to testify. Some witnesses may appear voluntarily and without counsel (e.g., a record custodian who does not fear prosecution). As noted in §13.8, because of the Fifth Amendment protection against self-incrimination, an individual target (but not a corporation) may refuse to testify before a grand jury; most refuse to do so absent a negotiated plea or immunity agreement. Corporate and individual subjects and witnesses who are uncertain about their exposure should retain experienced counsel to assess their risk of prosecution and to explore other options.

§13.8 PRIVILEGES: FIFTH AMENDMENT, ATTORNEY-CLIENT, AND WORK PRODUCT

The Fifth Amendment to the United States Constitution may play an important role in the provider's analysis of its options in the wake of a criminal investigation and grand jury proceedings. An individual has an absolute Fifth Amendment right against self-incrimination and cannot be compelled to testify before a grand jury. A corporation has no such right, and certain corporate employees (e.g., records custodians) can be compelled to testify. With limited exceptions, neither an individual nor a corporation has a Fifth Amendment right to resist production of documents; the right extends only to testimony, not to things.

> NOTE: The Fourth Amendment to the United States Constitution may apply to certain documentary evidence seized by the government.

> CAVEAT: To a limited extent, there exists an "act of production" Fifth Amendment privilege to resist turning over records subpoenaed. This exception is based on the premise that, in certain contexts, the production of documents itself would effectively incriminate the individual producing the records and is therefore constitutionally impermissible. The complexity of this doctrine precludes a full discussion in this chapter. *See United States v. Doe*, 465 US 605, 104 S Ct 1237, 79 L Ed2d 552 (1984).

The attorney-client doctrine and work-product privilege may allow a witness to resist disclosure of certain information or material in a grand jury proceeding. These privileges are subject to many exceptions and rigorous interpretation in this context; counsel must therefore carefully assess their applicability and determine the relative disadvantages in asserting them.

> NOTE: Providers are encouraged, and in some circumstances required, to furnish potentially incriminating information to the authorities. Remember, however, that the Fifth Amendment's guarantee against self-incrimination extends to individuals arrested as well as those being investigated for other transgressions that

might have criminal implications. The privilege has been held to override an individual's statutory reporting obligations to the extent the reporting obligations are penal rather than regulatory in nature. *Whiteside and Co. v. SEC,* 883 F2d 7 (5th Cir 1989).

Potential waivers of privilege, both intentional and inadvertent, are ordinarily considered by both prosecution and defense counsel. Often the provider will find waiver and disclosure to be consistent with its commitment to cooperate in the investigation and to comply with its obligations under contracts with Medicare and Medicaid. In many circumstances, the provider will have little choice but to produce documents and offer testimony under threat of exclusion. Even if the provider is prosecuted, there are significant financial incentives under the federal sentencing guidelines to cooperate early and to comply prospectively after health care abuse is disclosed. *See* USSG §8C2.5(g).

PRACTICE TIP: Counsel must be extremely guarded against inadvertent waivers of the privilege. For example, disclosures of a provider or its counsel to the government pursuant to obligations to cooperate, to respond to a subpoena, or to self-disclose may constitute such a waiver of the attorney-client privilege or protections of the work-product doctrine. Careful review of documents or information produced is necessary. *See Westinghouse v. Republic of the Philippines*, 951 F2d 1414 (3d Cir 1991).

The attorney-client privilege and work-product doctrine are subject to a "crime/fraud exception." OEC 503(4)(a). The government may view counsel as a potential participant in criminal schemes under investigation. Although case law in this area is still developing, the attorney-client doctrine and work-product privilege may be lost if a showing is made that counsel is implicated. Communications may be subject to in camera review if the government presses the issue. *See, e.g., In re Grand Jury Investigation*, 974 F2d 1068 (9th Cir 1992) (upholding district court's ruling preventing prosecution's attacks on attorney-client privilege asserted by defendant laboratory in Medicare fraud case; case discusses threshold showing required for in camera review).

Providers may find that certain confidential communications with outside business counsel or general counsel are not privileged. Only communications made in the context of legal representation are protected. Communications made in connection with the rendering of business advice are not. (Communications and work papers of outside consultants, accountants, and investigators retained directly by counsel will, in most instances, be protected as privileged communications, as long as legal and not business advice is being rendered.) A detailed discussion of privilege is beyond the scope of this chapter. However, attorneys should be well versed in these issues when dealing with the government in the health care law context.

§13.9 IMMUNITY

Grants of immunity to a grand jury witness (or to an individual or a corporation involved in an ongoing prosecution) must be negotiated through the prosecutor, not through a government agency or an investigating officer. The agreement must be recorded in an official letter from the U.S. Attorney or corresponding authority within the Oregon Department of Justice. "Use and derivative use immunity" in the federal system may be obtained only through application of the U.S. Attorney to the Attorney General pursuant to a statutory procedure, the mechanics of which must be carefully followed. 18 USC §§6001–6005. When a witness asserts the Fifth Amendment's protection against self-incrimination, prosecutors often offer immunity in exchange for full cooperation and debriefing by investigators, with a promise from the witness to testify in all future proceedings. In this situation, the testimony or other information given by the witness cannot be used against the witness in any criminal case.

> COMMENT: The government does not forgo prosecution absent valuable consideration. Immunity deals are contracts, enforceable by either party based on traditional contract principles. The government will demand that the witness's cooperation extend to "naming names" and explaining why certain medical, billing, reporting, or reimbursement procedures occurred, and who was

responsible for the practices or procedures under investigation—all of which could lead to the further prosecution of other individuals, or even the provider. The interests of the provider and certain employees, management, and even high-level executives may diverge. Counsel for the provider must ensure that clear lines are drawn between advising the provider-corporation and individuals who may face personal exposure, and who should retain separate counsel.

§13.10 REPRESENTATION AND INDEMNIFICATION

Once an investigation, a grand jury proceeding, or an indictment commences, the provider must decide whether to provide legal representation for all or only selected employees. The issues underlying the decision are complex and fact-dependent.

Some of the considerations bearing on a provider's decision to provide counsel to its employees include the following:

(1) Counsel for the provider should not represent individual employees of the provider. Potential conflicts make joint representation unwise and often ethically untenable. *See* Oregon RPC 1.7(a); *see also In re Jeffrey*, 321 Or 360, 898 P2d 752 (1995). Although certain conflicts can be waived, joint representation is extremely risky in this context. *See* Oregon RPC 1.7(b). Among other consequences, if a conflict arises, the provider's counsel may be disqualified from representing both parties—the provider and the individual.

(2) A critical decision for the provider is whether it should provide (i.e., pay for) independent legal representation for employees whose testimony is sought by the government in interviews, before the grand jury, or at a trial (as either a witness or a defendant). High-level employees, officers, and directors may be entitled to representation as a matter of contract, pursuant to governing documents, articles of incorporation, or bylaws, or by statute.

NOTE: With full disclosure to the client, an attorney representing corporate employees may accept payment of fees

from the provider as long as there is no interference with the lawyer's independent professional judgment. Oregon RPC 1.8(f). Even if an employer is not legally obligated to provide defense costs of an employee, it may nevertheless determine that it is in the employer's and employees' common interest to do so. Among other things, such collaboration may increase employee morale and facilitate receipt of information about the matter under investigation, both of which may justify the cost involved.

NOTE: Although employees who are acting in good faith and for the benefit of the corporation may therefore be entitled to payment of attorney fees, their actions in good faith and for the benefit of the corporation may subject the corporation to liability for that employee's conduct.

§13.11 INTERNAL INVESTIGATIONS

§13.11-1 Developing a Plan for Conducting the Investigation

Providers should have an established procedure for conducting an independent internal investigation when health care fraud is suspected or when governmental action is underway. Such facts or allegations could come to the provider's attention through a number of channels, including an employee, contractor, counsel, CPA, intermediary, patient or resident, state or federal investigator, subpoena, search warrant, or criminal indictment.

To avoid conflicts of interest and to comport with the seriousness of the potential consequences, the board of directors (or similar governing body) or a compliance officer designated by the board should formally initiate and supervise the investigation, often working with outside counsel. If the provider has a compliance program and a compliance officer is designated, the compliance officer should implement the plan and report to the board the results of the investigation and recommendations for corrective actions.

Management's involvement in the alleged wrongdoing must be assessed quickly. If the board believes that management participated in or

had actual or constructive knowledge of the questionable practices, the board is well advised to retain independent counsel to direct the internal investigation. Depending on the composition of the board and the potential magnitude of the problem, the provider may wish to establish a special committee, composed of independent, outside directors, to oversee the investigation and to make recommendations. These actions should be reflected in special resolutions. The resolutions should be stated in general terms because they may be discoverable or subject to subpoena.

To preserve confidentiality as much as possible, the committee's reports to the board should be oral, not written, and outside counsel (not the provider) should retain experts (such as fraud auditors or CPAs) to preserve the attorney-client privilege and the protections of the work-product doctrine. These legitimate safeguards will provide a substantial shield against discovery of employee interviews, analysis of documents, evaluation of criminal exposure, and advice ultimately given to the provider.

Subject to the above-stated concerns regarding confidentiality and conflicts of interest, an independent internal investigation should be coordinated with management, the compliance officer, or the provider's general counsel because their familiarity with the provider's operations, employees, and regulatory matters and their relationship with executive management and the board will be critical in assessing the problem under investigation.

The internal investigation should have some combination of the following elements:

(1) Counsel must review all documents known to be at issue (e.g., copies of documents seized or under subpoena) and gather additional documents from within the provider's offices or facilities.

> PRACTICE TIP: Counsel should distribute to appropriate employees a memorandum outlining the procedures to be followed in assembling documents and directing that no documents should be destroyed or discarded. A formal litigation hold notice should

be issued immediately to relevant recipients, preferably by in-house counsel, and regular document destruction policies should be suspended.

A responsible employee of the provider should be designated to coordinate efforts between the provider and outside counsel. Confidential documents should be segregated or marked as privileged. Documents from third parties (e.g., pharmacy or medical supply companies) should be requested.

(2) Counsel must review applicable federal and state health care laws concerning both criminal liability and related civil or administrative exposures.

(3) Counsel should interview appropriate current and former management and employees. An associate counsel or a paralegal should be present to take notes; that person may be asked to testify if facts learned in the interviews are later disputed. Counsel should advise each employee that counsel represents the provider and not the employee, that the content of the interview should be kept confidential, and that the content of the interview is protected by the attorney-client privilege, provided, however, that the provider must reserve the right to waive the privilege and to disclose certain information if deemed necessary (e.g., in voluntary disclosures to, or cooperation with, the government). Counsel should identify quickly the employees who may later require separate representation.

(4) Counsel should interview company auditors (CPAs and bookkeepers).

(5) Counsel should interview investigating agents and prosecutors, if possible.

(6) Counsel should retain outside experts, such as accountants, reimbursement experts, and medical records reviewers, and obtain their analyses of the relevant issues to gain as accurate a picture as possible of the provider's criminal exposure. (Counsel's direct retention of experts will preserve the relevant privileges.)

(7) On completion of document analyses, interviews, and audits, counsel should prepare confidential memoranda, together with counsel's opinions and impressions, to qualify for protection as attorney work product.

(8) Counsel should prepare interim reports as well as a final report of the internal investigation, containing findings, conclusions, and recommendations to the provider. Even if the report qualifies as work product or is protected by the attorney-client privilege, it could be disclosed to the provider's auditors, to government regulators, in criminal law discovery, or pursuant to a voluntary disclosure to the government. Counsel must take great care in preparing these reports and in determining whether to disseminate them. Electing not to do so, or providing the board of directors with only oral reports, may expose counsel to significant risk if the provider or the provider's officers or directors later face criminal exposure and claim that counsel did not fully apprise the provider of matters at hand. On the other end of the spectrum, if the reports are overly candid and are later disclosed, criminal exposure may increase.

§13.11-2 Benefits of Retaining Outside (Independent) Counsel

Outside counsel often is retained to conduct an internal investigation when wrongdoing is suspected or irregularities are discovered. This approach may bolster the protection of the attorney-client privilege and work-product doctrine. As noted above, outside counsel also is well advised to retain independent investigators (e.g., fraud auditors), CPAs, and other experts to ensure that sensitive communications, which may include employee interviews, are confidential among the defense team and (absent an agreement with the government) are protected from discovery.

Other reasons to engage outside counsel include protection against inadvertent obstruction-of-justice, perjury, or witness-tampering charges; preparation of witnesses who may be called to testify before a grand jury; negotiation of delicate issues between separate counsel for the entity and for its officers, directors, and employees; handling negotiations involving indemnification claims against the corporation for payment of attorney

fees; added credibility in dealing with prosecutors and agency investigators, as well as the potential for averting prosecution; working with other counsel for the provider (if such exist) and administrative personnel to ensure full cooperation, preservation of evidence, and orderly and proper handling of documents, with the least possible disruption of day-to-day operations.

§13.12 DEFENSES COMMONLY RAISED BY THE PROVIDER

Many of the same defenses employed in other white-collar criminal prosecutions are used in the defense of health care prosecutions as well. For example, counsel may attack circumstantial evidence used to prove the necessary mental state, impeach witnesses who received plea agreements in exchange for testimony against the provider or one of its officers or directors, and identify inconsistencies in the government's presentation of documents or theory of the case.

The following defenses are especially applicable in health care fraud and abuse cases. This list is by no means comprehensive. There are myriad defenses specific to each health care fraud and abuse statute.

(1) Lack of federal agency jurisdiction. This defense may succeed, for example, when a false claim is made to an intermediary or HMO (health maintenance organization).

(2) Inadequate proof that the provider "caused" a false claim to be filed.

(3) Inadequate proof of the requisite intent or mental state, especially regarding the provider's (or a key employee's) limited knowledge of complex or technical regulatory statutes. This defense has become increasingly difficult to establish under recent case law. Nevertheless, juries and some judges may sympathize with a provider who can show good-faith efforts to comply with overly burdensome laws or overaggressive regulators.

(4) Inadequate proof that a claim or statement is "material."

(5) The government's failure—through an intermediary before trial or by its experts at trial—to consider reasonable interpretations of the charged false claim or statement.

(6) Certain violations of Medicare manuals are insufficient evidence of fraud.

(7) Insufficient proof of an illegal agreement, direct or circumstantial, or lack of proof of improper means of accomplishing an allegedly wrongful act, necessary for a conspiracy conviction.

(8) Good-faith reliance on counsel remains a viable defense in limited circumstances, although the courts have carved out multiple exceptions.

(9) When prosecutions are based on both traditional and recently enacted health care abuse laws, defenses based on multiplicity of counts and vagueness may be successful.

(10) When the intermediary (e.g., a Medicare contractor) has through oral or written communications approved (or at least not disapproved) practices or transactions that later are alleged as crimes, the defense of estoppel based on reasonable reliance on governmental advice may apply.

(11) Legal, accounting, and reimbursement experts may negate governmental evidence of the requisite criminal intent.

§13.13 ORGANIZATION (CORPORATE) CRIMINAL LIABILITY

§13.13-1 Exposure to Liability

Health care providers that are organizations, such as corporations or limited liability companies, may be held liable for the acts of their employees under any of the criminal laws mentioned in this chapter, if the government can prove that (1) the employee acted (at least in part) for the benefit of the provider and (2) the act was within the scope of the employee's employment. The provider can be held responsible even if

the wrongful act was unauthorized or against corporate policy, pursuant to customary respondeat superior analysis.

Generally, judicial interpretations of requisite criminal intent in the health care abuse context have been unfavorable to providers, particularly when the provider's defense centers on a lack of actual knowledge of the wrongful act, policy, or practice. However, the *Bank of New England* doctrine allows the government to prove criminal intent through "collective knowledge" or "flagrant organizational indifference" to applicable statutes. *U.S. v. Bank of New England N.A.*, 821 F2d 844, 855 (1st Cir 1987). (The Ninth Circuit has also expressed this doctrine by holding that the corporation cannot avoid liability by "burying its head in the sand" vis-à-vis compliance.) On the conviction of a provider or its employees, the federal sentencing guidelines allow judicial imposition of financial penalties and compliance obligations that have the potential to cause substantial damage to the provider. Collateral consequences, including program or provider exclusion, lender defaults, and repetitive and costly audits, can have enormous impact. Given these potentially significant sanctions, cooperation often may provide the best avenue of damage control for a corporate provider.

§13.13-2 Defenses Available to Provider Organizations

Several defenses are available to providers, including the following:

(1) Although the employee acted criminally, he or she did not act for the benefit of the corporation. This defense can be especially effective when the employee was trained in compliance prevention and was instructed about the substantial and damaging effects of noncompliance on the provider. There are of course limits to this—the mere existence of a corporate compliance program does not eliminate the potential for corporate liability under the doctrine of respondeat superior. *See United States v. Beusch*, 596 F2d 871, 878 (9th Cir 1979) ("[A] corporation may be liable for acts of its employees done contrary to express instructions and policies, but . . . the existence of such instructions and policies may be considered in determining whether the employee in fact acted to benefit the corporation."); *United States v.*

Potter, 463 F3d 9, 26 (1st Cir 2006) ("although not mechanically exculpatory of corporate liability, [corporate compliance programs] may well bear upon what is or is not within the scope of the agent's duties"); *see generally* UNITED STATES ATTORNEYS' MANUAL §9-28.800 (1997), *available at* <www.justice.gov/usao/eousa/foia_reading_room/usam/title9/28mcrm.htm>.

(2) Large companies cannot reasonably be expected to monitor each piece of information processed in government health care programs, which have become increasingly burdened with complex and ever-changing paperwork. Combining the knowledge of multiple employees in this context falls short of the scienter necessary to convict. Moreover, to do so would penalize well-meaning corporations that have taken reasonable measures to prevent health care abuse (assuming that such measures have been taken). This defense will trigger an analysis of the provider's compliance program.

(3) In a case involving criminal liability for fraud, no proof exists that at least one corporate employee had the specific intent to defraud. *See U.S. v. LBS Bank-New York, Inc.*, 757 F Supp 496 (ED Pa 1990) (requiring such proof).

(4) Fraud crimes are distinguishable from regulatory violations. Regulatory violations give rise to civil remedies, not criminal sanctions. (Note, however, that civil sanctions can carry equal or more harsh consequences for a provider, such as program exclusion or civil monetary penalties, trebled in some circumstances.)

§13.14 PERSONAL LIABILITY OF INDIVIDUALS

Personal exposure to criminal liability is perhaps the most serious issue a provider and its personnel will face. Although a health care organization (such as a corporation) cannot be sentenced to jail, its officers, directors, and employees may face criminal exposure, including incarceration, under all state and federal statutes discussed in this chapter. Personal criminal liability can be based on conspiracy, aiding and abetting, or actual commission of proscribed conduct.

§13.14-1 Requisite Intent

The standard for imposing personal criminal liability differs depending on the crime involved. Knowledge (actual or circumstantial) is required in most cases (e.g., to prove a crime under the False Claims Act in the Ninth Circuit), *Hanlester Network v. Shalala*, 51 F3d 1390, 1400 (9th Cir 1995); proscribed conduct under certain provisions of the Health Insurance Portability and Accountability Act requires proof that the defendant "willfully and knowingly" committed fraud, embezzlement, etc., 18 USC §1347. Defenses available under USC Title 18, so-called white-collar crime prosecutions (e.g., mail or wire fraud), will apply. Attorneys should consult the statutes in question and case law interpretation for a more detailed look at intent standards.

The government generally need not prove actual, wrongful knowledge that a crime was being committed. Conscious or deliberate avoidance of relevant information, or a reckless disregard that certain violations are occurring, may suffice as proof of the requisite level of intent. The doctrine of constructive knowledge is applied by courts in health care fraud cases, consistent with congressional intent to reach what it perceives to be pervasive fraud in the administration of health care reimbursement programs. *U.S. v. Gay*, 967 F2d 322, 326 (9th Cir 1992); *U.S. v. Beecroft*, 608 F2d 753, 757 (9th Cir 1979); *U.S. v. Price*, 623 F2d 587, 591 (9th Cir 1980), *overruled on other grounds*, 730 F2d 1255 (9th Cir 1984). Providers are expected to know the health care laws and regulations relating to the segment of health care in which they operate. This underscores the necessity for compliance programs, employee training, and comprehensive documentation.

§13.14-2 Corporate Versus Personal Representation

If an officer, director, or employee of the corporate provider contacts counsel seeking advice on potential health care fraud and abuse, it should be immediately established who counsel represents: the provider or an individual employee, officer, or director who may be personally targeted for prosecution. If counsel represents the provider entity, information disclosed to counsel or shared by such individual targets cannot be held confidential, as is often requested. Rather, the

provider's counsel is obligated to promptly disclose all material information to the board and to recommend appropriate action. This issue becomes increasingly problematic when the contact and request for confidentiality are made by employees who are also high-level officers or directors of the provider entity.

COMMENT: Defense counsel representing an individual prosecuted personally will approach precharge, pretrial, trial, and sentencing strategies from a different perspective, because the risks of facing a potential jail term on conviction are fundamentally different from risks related to assessing financial sanctions on the organization. The implications will have a significant effect on the dynamics between defense counsel for multiple parties and counsel for the provider.

§13.15 ALTERNATIVES TO LITIGATION

In an investigation, the provider's main concern is to avoid exclusion from participation in the Medicare and Medicaid programs under 42 USC §1320a-7(a)(3)–(4) and (c)–(h) and 42 CFR §1001. If the government prevails in a prosecution against the provider and secures a felony conviction under one or more of several broad categories of offenses, the provider faces mandatory exclusion from federal health care programs for a minimum of five years. 42 USC §1320a-7(a)(3)–(4), (c)–(h); 42 CFR §1001.101. Offenses requiring mandatory exclusion include those: (1) relating to the delivery of an item or a service under Medicare or Medicaid; (2) occurring after the enactment of the Health Insurance Portability and Accountability Act in 1996, with respect to delivery of an item or a service, although not under the Medicare or Medicaid program, but constituting a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct; and (3) involving abuse or neglect of residents.

Hence, the threat of criminal conviction and the financial penalties that may be imposed on the corporate provider may well be less onerous and play a subordinate role in the combined decision-making process of

corporate and criminal defense counsel when a government or internal investigation reveals facts that may support exclusion as a remedy.

> COMMENT: Investigators (and, in particular, the Office of Inspector General) often signal whether the government's intention is to put the provider out of business. Unless the violations under investigation reflect repetitive conduct or are highly egregious, the practical problems of closing a facility and causing the displacement of patients or residents compel the government and the provider to consider settlement alternatives carefully. (Note that the same reasoning rarely would apply in the case of an individual professional or small group practice.)

§13.15-1 Settlement Through Negotiation and Compromise

Potentially severe penalties under the federal sentencing guidelines provide the government with substantial leverage in negotiating a plea agreement in all criminal cases. Health care providers have additional motivations for seeking to resolve an investigation or a prosecution through compromise. These include the avoidance of personal liability of officers and directors, exclusion from federal health care programs, and forfeiture of valuable assets, including the real estate housing the facility. As one leading commentator notes: "Negotiate early and often." *Health Care Fraud and Abuse: Enforcement and Compliance*, Health L & Bus Series (BNA) 2600:0701 (rev 1999). The potential exposure compels the provider's counsel to maintain open lines of communication with investigators, the intermediary, and prosecutors. Tactics that might work in other criminal cases must be carefully reconsidered in the health care context. Even the most aggressive and competent counsel for a provider, declaring total innocence in the face of a criminal investigation, is obligated to explore settlement options, optimally on a global basis. Counsel representing the provider should be encouraged to plan and coordinate negotiations; there is a significant benefit for the provider who enters into one agreement addressing criminal, civil, and administrative liability.

The Office of Inspector General (OIG) customarily works hand in hand with an assistant U.S. Attorney, the FBI, and their Oregon counter-

parts. A provider should determine whether one official (or agency) can speak or act for the others. Similarly, a provider should take care not to inadvertently exclude any governmental official from the negotiation process. One agency is not legally obligated to follow the recommendations or agreements of another. Therefore, as discussions move forward, it may be advisable to fashion a strategy whereby all officials are participating in the negotiation as they desire.

Because of the disparity of power existing between the provider and the government agencies, the provider must be respectful in plea negotiations. However, this does not mean that the provider should just "roll over" in every criminal investigation simply to avoid heavier penalties or to thwart exclusion. The provider and the provider's counsel must rigorously analyze the case. The government has been known to overreach in the scope of its investigations, to make errors in analyzing documents reviewed, to misapply the law, or to otherwise subject providers to greater exposure than is warranted. For these reasons, a thorough investigation using qualified experts is critical to preserve as much balance as possible on behalf of a provider. Defense counsel should be sensitive to the inherent power differential in this equation but should strike an aggressive posture when a strong position is factually justified and approved by the client.

Factors to consider in negotiations include the following:

(1) If a *qui tam* "whistleblower" complaint is involved, the provider's potential financial exposure will weigh heavily in the settlement negotiations. Sizeable fines in the form of civil monetary penalties may be demanded by the government as part of the plea agreement.

(2) In cases in which a global settlement includes criminal, administrative, and civil resolution, the OIG will propose and direct negotiation of a final agreement, called a corporate integrity agreement (CIA). This document will have significant and continuing consequences for the facility, including strict compliance obligations for a period of at least five years; adjustments or reimbursements to the U.S. Department of Health and Human Services in the form of civil monetary penalties;

responsibility for paying all necessary audits or other compliance requisites; and strict reporting and disclosure obligations. If the government is considering exclusion as a possible remedy in the negotiation process, some providers may consent to onerous terms and conditions simply to stay in business. Counsel should make it a priority to press for the most reasonable terms and conditions possible with regard to a CIA. Counsel's best defense may be to impress on the government that unduly onerous conditions would result in financial distress or, in the case of a facility closure, a counterproductive and ultimately harmful result for patients.

(3) Prosecutors will seek larger financial penalties as part of a plea bargain (or a global settlement with the OIG) in lieu of forgoing convictions that would lead to exclusion. Under the exclusion statute, however, certain health care fraud convictions cause the imposition of mandatory exclusion. Counsel handling the plea bargaining process must be cognizant of these pitfalls.

(4) As in other criminal contexts, the targeted facility or individual providers will be presented with an alternative rewarding their full cooperation in assisting the government to identify, prove, or prosecute other health care abuses (or to disclose additional information about their own or their employer's conduct). The rewards may include avoiding exclusion, reducing fines, or reducing charges to be admitted.

(5) Before indictment, counsel should thoroughly explore alternatives to avert prosecution. The subject or target of the investigation may seek pretrial diversion, in which offenders are accepted into an officially sanctioned program and pay restitution, perform community service, undergo counseling, and sign an agreement outlining future obligations monitored by the probation office and U.S. Attorney's Office. UNITED STATES ATTORNEYS' MANUAL §§9-22.010 to 9-22.200 (1997), *available at* <www.justice.gov/usao/eousa/foia_reading_room/usam/title9/title9.htm>. This alternative is seldom used by prosecutors in cases involving extensive losses. However, the benefit of a diversion program is well worth the time spent seeking it. This option is particularly suited to individual providers whose violations are not egregious.

(6) Any settlement should be carefully reviewed to ensure that the provider's payments to the government in settlement of the investigation or prosecution receive as favorable tax treatment as possible.

(7) To avoid collateral consequences, the CIA should include standard release language (e.g., that the agreement is made in compromise of disputed claims, that the provider does not admit or deny liability, and that the agreement is not an admission). This result may be difficult, if not impossible, to achieve if the plea requires the defendant to accept responsibility, in which case counsel should otherwise attempt to negotiate the best deal possible with the U.S. Attorney's Office, given sentencing guidelines.

(8) The law requires that CIAs contain specific compliance program requirements, to be imposed on the provider for a period that is sufficient for the government to ensure that remedial actions have been taken and that old patterns have not recurred. The OIG's Web site, <http://oig.hhs.gov>, has several model CIA formats that are strongly recommended for review. These documents express the culmination of a health care fraud investigation, prosecution, and settlement. Counsel and the provider's other professional experts will gain invaluable insight into the components that enforcement officials value by reviewing the model CIAs.

(9) The government's position is that the CIA is not confidential. This may cause adverse ancillary effects (e.g., bankers calling loans, IRS audits, collateral licensing proceedings, suits by families or private payors). These ancillary effects must be considered in the negotiations to mitigate their consequences, if possible. Well-planned, tactical negotiations are indispensable to the criminal defense strategy when health care fraud has occurred and damage control is a primary focus. Providers should be especially wary of attorneys whose language is confined to "winning" or "losing" at trial. Cases rarely go to trial, and then only after all reasonable attempts at negotiation and settlement have been made. This is consistent with the reality that health care providers

must remain in business and participate in government programs irrespective of regulatory setbacks.

§13.15-2 Voluntary Self-Disclosure Protocol

Although the federal law enforcement arsenal is formidable and results in the prosecution of many health care fraud schemes, the government has long recognized that effective across-the-board enforcement requires that the health care industry actively police itself. To this end, the Office of Inspector General (OIG) initiated voluntary self-disclosure rules in 1995, as part of Operation Restore Trust. This program enjoyed limited success and was replaced by the current Voluntary Self-Disclosure Protocol (the "Protocol"), designed to overcome some of the uncertainties and deficiencies of the prior law. 63 Fed Reg 58,399 (1998). The OIG has provided supplemental guidance to health care providers periodically since the adoption of the Protocol. *See* <http://oig.hhs.gov/fraud/selfdisclosure.asp>. In addition, and as noted in §13.2-2(b), many providers have self-disclosed Stark Law violations resulting in repayments.

§13.15-2(a) Advantages

(1) Providers may participate in the Voluntary Self-Disclosure Protocol (Protocol) even if they did not initially discover the fraud or irregularities under consideration. This affords Protocol protections to providers who may have been subject to *qui tam* actions, or whose practices prompted an investigation at the behest of an intermediary or a state agency. Note that such providers are not really "volunteers" as that term is used in parallel contexts before certain agencies such as the Internal Revenue Service. The Protocol allows participation even when an official investigation or audit is ongoing and the disclosures are in effect made by the government. The provider is able to "adopt" these disclosures.

(2) The provider need not make any specific commitments when making the self-disclosures. (By the same token, the government will make no commitments to the provider.)

(3) By its own terms and based on the Office of Inspector General's (OIG's) track record, the new Protocol is more flexible and affords the provider greater latitude in working through the investigation and implementing corrective action to right any wrongs that are disclosed by either the provider or the government.

(4) There are no absolute time frames in the Protocol, affording the provider the opportunity to carefully evaluate and negotiate a settlement or to proceed to trial if no reasonable settlement is possible.

(5) The provider should make its disclosure decision only after a thorough internal investigation. Such an investigation will apprise the provider of any threatened or potential allegations by the government, whether problems are more pervasive than alleged, and whether exposure may extend to personal liability on the part of officers, directors, and employees.

(6) If the OIG's investigation was on the right track, but an internal investigation exposed a larger-scale scheme or practice, the provider will reap rewards in exchange for reacting swiftly to impose corrective measures, such as implementing accounting and personnel changes, disclosing the fraud to the OIG, and coordinating the official and internal investigations along agreed guidelines (e.g., employee interviews, review of personnel files, and meetings with intermediaries to explain irregularities and abuse). This ordinarily assures a more lenient sentence at the federal level under the sentencing guidelines, reduces the possibility of multiple prosecutions by state and federal officials, reduces civil monetary penalties, produces less onerous corporate integrity agreement audits and ongoing compliance terms, and results in other benefits too lengthy to enumerate here. *See* Health L & Bus Series (BNA) 2600:09, *et seq.* (rev 1999). *See also* <http://oig.hhs.gov>.

§13.15-2(b) Disadvantages

(1) Uncertainty is the primary disadvantage in self-disclosing under the Office of Inspector General's (OIG's) program. The government is not obligated to promise leniency to the self-disclosing provider who embraces the Voluntary Self-Disclosure Protocol (Pro-

tocol). There is no assurance that by self-policing and revealing incriminating information, the provider can negotiate guaranteed, specified protection.

Although there is no guarantee of a reward for self-disclosure, experience shared by practitioners nationwide reveals that the government routinely rewards self-disclosure. It is often—though not always—the best course of action.

> NOTE: Cases in which the provider discloses incriminating information as part of a proffer, in a formal plea negotiation context, whereby the provider will likely be offered a plea agreement requiring full, ongoing cooperation in exposing the fraud and in identifying any other persons who may be involved in criminal activity are an exception to this general rule. Such individuals (or businesses) would receive a somewhat more concrete blueprint of their exposure and obligations.

(2) From the OIG's point of view, irrespective of the Protocol, the provider has the ongoing duty to audit books and records and to police the facility or office in question as part of the benefit program contract. Because the program (manifest through the intermediary or carrier, among others) has the right to audit all program-related documents at any time, it could be argued that the government is not really withholding rewards from candid providers who self-disclose.

(3) If the disclosure reveals a crime, past or ongoing, the OIG must make a criminal referral to the Attorney General's Office.

(4) An authorized representative of the provider must certify that all information contained in the Protocol submission is true and based on good-faith efforts to assist the OIG in its investigatory and oversight role.

(5) Voluntary disclosure, once discovered by others in the facility, may trigger *qui tam* actions on behalf of disgruntled employees.

§13.15-3 Mandatory Self-Disclosure of Overpayments

The recently enacted health care reform bill imposes new obligations on Medicare and Medicaid providers, suppliers, and plans to report and return overpayments within the later of 60 days of the date the overpayment was identified or the date any corresponding cost report is due, if applicable. 42 USC §§1301 et seq. In addition, the statute requires the provider, supplier, or plan to notify the entity to whom the overpayment is returned, in writing, of the reason for the overpayment. An overpayment is defined as "any funds that a person receives or retains under [the Medicare or Medicaid Act] to which the person, after applicable reconciliation, is not entitled under such title." 42 USC §1320a-7k(d)(4)(B).

In addition, the failure to report and return an overpayment within the specified deadlines becomes an "obligation." 42 USC §1320a-7k(d)(3). Under the False Claims Act (FCA), "knowingly and improperly avoid[ing] or decreas[ing]" an obligation to repay Medicare or Medicaid monies can form the basis for a claim under the FCA. 31 USC §3729(a)(1)(G). The FCA penalties are potentially severe and include triple the amount of the "damage" to the government, plus significant penalties. 31 USC §3729(a)(1)**.** In addition, a failure to repay an overpayment can be grounds for exclusion from the Medicaid program for certain providers. This specific link to the FCA and to program exclusion makes it vitally important that providers, suppliers, and plans develop a system for quickly and appropriately responding to any identified overpayments.

In addition, voluntary disclosure of known overpayments can reduce the damages under the FCA if done quickly enough. It also provides mitigation credits under the U.S. Sentencing Guidelines, §8C2.5(g) (potential of up to five mitigation points). Moreover, failure to voluntarily reveal known wrongdoing or overpayments is a factor the Office of Inspector General (OIG) intends to consider in determining whether to impose a permissive exclusion. Proposed Criteria C.2, C.3.B, 62 Fed Reg 55,412 (1997). It could also color the interpretation of the individual's or entity's original intent in the eyes of enforcement

officials and the trier of fact, leading to criminal, rather than just civil, liability. Even when not compelled, voluntary disclosure allows the discloser to frame the issues and explain the context in the best light, enhances the discloser's credibility, and may allow the discloser to avoid or negotiate subpoenas.

The risks of voluntary disclosure include alerting the government to matters it might not discover on its own; the possibility that the government will view the conduct more harshly than the discloser; the possible imposition of a more burdensome corporate compliance plan than the entity otherwise would have adopted voluntarily; the potential waiver of certain defenses inherent in characterizing the conduct as unjustified when making the disclosure; and the possibility that the government will detect additional wrongdoing if it conducts its own investigation. Moreover, voluntary disclosure does not lead to immunity from either government or private enforcement.

If the decision to disclose is made, the discloser must decide to which agency the disclosure will be made: the fiscal intermediary or carrier, the OIG, the U.S. Attorney, or state agencies. Neither the decision to disclose nor the decision where to disclose should be made without consulting counsel who is knowledgeable about fraud and abuse.