27. Id. at § 10-16-121(1)(a).
29. See M. Conklin, "'Gag' Order Sparks Uproar: AMA Says Contract that
Prevents Doctors from Discussing How They're Paid is Illegal," Rocky Mountain
30. See "Denver Doctors: Protest Disclosure Clause in Contract," Health Line,
32. See, for example, Fla. S.B. 348 (1997); Minn. H.B. 354, § 2 (1997); Iowa
34. Id. at § 15(d).
35. Id. at § 20(b).
41. Id. at § 5.
42. See, for example, R.I. Gen. Laws § 23-17.13-3 (1996); and Me. Rev. Stat.
43. See, for example, Cal. Bus. & Prof. Code § 2056.1(c) (West 1996).
45. Id. at § 56-7-2349(c).
46. Id.
47. See Ill. H.B. 333, § 30(a)–(b) (1997).
52. See T. Precious, "Lawmakers Target HMOs' Gag Rules," Times Union,
53. See Adams, supra note 13.
54. See Hartnett-Barry, supra note 4.
55. See Adams, supra note 13.
56. See Conklin, supra note 29.
61. See id. at § 10-16-121(2)(b).
63. See id.
64. See N.Y. A.B. 8602, § 5 (1997).

**Fraud & Abuse: DOJ and Medicare and Medicaid Model Compliance Programs**

Medicaid and Medicare fraud and abuse has commanded the attention of the federal government in recent years due to its impact on escalating health care costs. Combating health care fraud is now one of the Department of Justice’s (DOJ) highest priorities, as evidenced by the extensive resources dedicated to investigating possible fraudulent activity. In this environment of active government enforcement, strict statutes proscribing health care fraud and abuse, and substantial penalties for violations, organizations are seeking to reduce their liability for acts of fraud and abuse by establishing compliance programs, requesting advisory opinions, and engaging in voluntary self-disclosure. On March 3, 1997, the Department of Health and Human Services (DHHS) Office of Inspector General (OIG) issued a model compliance plan for clinical laboratories in order to provide guidance to organizations interested in ensuring company compliance with federal law and reducing potential liability.

**Health care fraud and abuse statutes**

The government may prosecute health care fraud and abuse under various statutes, including the Antikickback Statute, Anti-Referral Statute (Stark II), and the recently enacted Health Insurance Portability and Accountability Act (HIPAA). Under the Anti-Kickback Statute, it is a felony to "knowingly and willfully" solicit, receive, pay, or offer any remuneration in return for referrals for services covered by Medicare or Medicaid. The statute provides for criminal penalties including fines of up to $25,000, imprisonment, and possible exclusion from the Medicare and/or Medicaid programs. The scope of the Anti-Kickback Statute is presently uncertain, pending U.S. Supreme Court review, due to different interpretations of the scienter requirement by the circuit courts of appeals. In response to the concern that certain relatively innocuous commercial arrangements may technically fall under the Anti-Kickback Statute, narrow "safe harbors" were created to designate those practices that would not be regarded as violations. HIPAA requires OIG annually to solicit and publish proposals regarding existing safe harbors and the potential creation of new safe harbors.

The Anti-Referral Statute is a civil statute that addresses a more limited class of conduct: physician self-referrals. The statute prohibits a physician, or any member of his immediate family, from making a referral to any entity with which he has a financial relationship, if the designated health services are covered under subchapter XVIII of the Social Security Act. The statute provides for substantial civil monetary penalties and possible program exclusion for acts that the "person knows or should know" would violate the statute.

HIPAA establishes a new "health care fraud offense," which prohibits any attempt to defraud any health care benefit program. Penalties include fines under Title 18 of the United States Code and/or imprisonment of up to ten years. The term "health care benefit program" is broadly construed to mean "any public or private plan or contract, affecting commerce under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract." HIPAA's inclusion of private plans in its definition of programs falling under the statute greatly expands the government's authority in prosecuting health care fraud, which is usu-
Compliance programs and measures to prevent violations and to reduce liability

A compliance program is a "formal, ongoing program by which an organization seeks to ensure that all appropriate individuals within the organization understand applicable legal requirements and follow them." Courts often order companies that have violated the health care fraud and abuse statutes to create compliance programs as part of the legal settlement process. However, many companies also implement compliance programs on their own, to prevent violations and reduce possible liability for illegal activities. In a recent press conference, DHHS Inspector General (DHHS-IG) June Gibbs Brown explained that if a convicted "provider has an effective compliance plan in place, it is taken into account in determining the nature and level of sanctions, penalties, and/or exclusions to be imposed against the company."

OIG recently issued a model compliance plan for the clinical laboratory industry. The aim of the model is to provide the health care industry with guidelines regarding the necessary elements of a compliance program geared toward detecting and fighting Medicare and Medicaid fraud and abuse. The plan is a combination of elements from OIG investigations, the Federal Sentencing Guidelines, and policy recommendations issued in settlements with major independent clinical laboratories. In addition to recommending that laboratory compliance plans include training on the health care fraud and abuse statutes, the model also suggests that laboratories improve requisition forms and develop policies that encourage physicians only to order tests that are medically necessary. According to the OIG model compliance plan, a comprehensive plan must include, at the very least, the following eleven elements:

1. written standards of conduct for employees;
2. the development and distribution of written policies that promote the laboratory's commitment to compliance and that address specific areas of potential fraud, such as billing, marketing and claims processing;
3. the designation of a chief compliance officer or other appropriate high-level corporate structure or official who is charged with the responsibility of operating the compliance programs;
4. the development and offering of education and training programs to all employees;
5. the use of audits and/or other evaluation techniques to monitor compliance and ensure a reduction in identified problem areas;
6. the development of a code of improper/illegal activities and the use of disciplinary action against employees who have violated internal compliance policies or applicable laws or who have engaged in wrongdoing;
7. the investigation and remediation of identified systemic and personnel problems;
8. the promotion of and adherence to compliance as an element in evaluating supervisors and managers;
9. the development of policies addressing the nonemployment or retention of sanctioned individuals;
10. the maintenance of a hotline to receive complaints and the adoption of procedures to protect the anonymity of complainants; and
11. the adoption of requirements applicable to record creation and retention.

DHHS-OIG is currently working on several other model compliance programs for other industries, including the hospital and managed care industries.

In addition to developing compliance programs, health care companies may also seek advisory opinions under HIPAA on whether they can proceed with certain actions without violating federal law. HIPAA now requires OIG, in consultation with DOJ, to issue written advisory opinions with regard to: (1) what constitutes prohibited remuneration under the Anti-Kickback Statute; (2) what falls under one of the safe harbors; (3) what constitutes an inducement to limit services to Medicare and Medicaid recipients; and (4) which types of activity are subject to sanctions. OIG anticipates approximately 500 individuals and entities per year to request advisory opinions regarding the Medicare and Medicaid Anti-Kickback Statute. On February 19, 1997, OIG issued an interim final rule outlining the specific procedures to be followed in the advisory opinion process.

A less utilized means of mitigating liability for health care fraud and abuse is through the voluntary disclosure program instituted under Operation Restore Trust (ORT). ORT is a DHHS pilot program begun in 1995 operating in New York, California, Florida, Illinois, and Texas (the five states with the highest Medicare expenditures). Under ORT, federal and state investigators review the billing and service delivery practices of home health agencies, durable medical equipment suppliers, nursing facilities, and hospices in an attempt to both discover fraudulent activity and to alert the public and the health care industry to the fraud. As part of ORT, DHHS has established a toll-free hotline for the public to use to report fraud and abuse, as well as a voluntary self-disclosure program that can be utilized to reduce penalties for violations. For example, the False Claims Act allows courts to reduce fines to double, instead of triple, the amount of the fed-
eral government’s incurred damages, provided that the violation is disclosed within thirty days after it is discovered by the defendant.34 The health care industry has resisted the voluntary disclosure program.35 One of the most prevalent complaints revolves around the lack of immunity offered to companies taking advantage of the disclosure program. These companies receive no guarantee that the disclosed violation will not be prosecuted, which makes the industry wary of coming forward. Although statistics show that only 2 of 300 disclosures were prosecuted, displaying an apparent leniency to self-disclosing companies, individuals may still be criminally prosecuted.36 Due to the uncertain nature of prosecution, organizations are finding it necessary to err on the side of safety by establishing compliance programs.

Conclusion

According to DOJ, the number of criminal health care fraud cases filed has increased over 200 percent and the number of civil cases filed has increased over 100 percent since 1992.17 In light of the high costs incurred due to violation of the anti-fraud statutes, health care institutions will have to take proactive measures to reduce liability. As the federal government cracks down on fraud and abuse, the health care industry will have to protect itself through careful documentation of practices and procedures and the establishment of compliance programs.

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References

2. There are coordinated criminal and civil enforcement teams for health care fraud in each of the ninety-four U.S. attorneys' offices, and approximately 450 full-time positions at the Federal Bureau of Investigation and the Office of the Inspector General (OIG) devoted to investigating health care fraud. “IG Estimates 500 Each Year Will Seek Advisory Opinions on Anti-Kickback Law,” Health Care Daily (BNA), at D-7 (Apr. 3, 1997); and O'Leary, supra note 1.
6. 42 U.S.C. § 1320a-7b(b).
7. See id. There are fourteen situations under which program exclusion is permissive (§ 1320a-7(b)) and two under which exclusion is mandatory (§ 1320a-7(a)).
8. Compare Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995) (finding thescienter requirement of Anti-Kickback Statute to require that the violator must (a) know that the statute prohibits the activity, and (b) act with specific intent to break the law) with U.S. v. Jain, 93 F.3d 436 (8th Cir. 1996) (upholding trial court's jury instructions defining “the word 'willfully' [to] mean ... unjustifiably and wrongfully, known to be such by the defendant...”).
11. HIPAA § 205, 42 U.S.C. § 1320a-7d.
13. See id. at § 1395nn(g)(3).
15. See id. at § 242(a), 18 U.S.C.A. § 1347. Violations resulting in serious bodily injury are punishable by fines under Title 18 and/or imprisonment of up to twenty years.
19. “HHS Issues Model Plan for Clinical Laboratories,” Health Care Daily (BNA), at D-3 (Feb. 25, 1997). See also “New Fraud, Abuse Law 'Real Sleeper'. Show Need for Good Compliance Plans,” Health Care Daily (BNA), at D-2 (Aug. 27, 1996). At an August 1996 conference on compliance programs for health care companies sponsored by the American Compliance Institute, Ilene Nagel, former commissioner of the U.S. Sentencing Commission from 1985-94, explained that convicted companies that already have a compliance program prior to the violation and report the violation to the U.S. Attorney's Office as soon as possible are awarded “substantial credit” under the sentencing guidelines.
21. See id. at 9435.
22. See id.
23. Id. at 9436.
24. See id.
25. This provision has been strongly opposed by the Clinton administration due to the fear that it will be difficult for OIG and DOJ to prosecute those who request advisory opinions and then later violate the Anti-Kickback Statute. “Administration to Propose Repeal of Some HIPAA Fraud, Abuse Provisions,” Health Care Daily (BNA), at D-3 (Mar. 7, 1997).
26. HIPAA § 205, 42 U.S.C.A. § 1320a-7d.
27. “IG Estimates 500 Each Year Will Seek Advisory Opinions on Anti-Kickback Law,” Health Care Daily (BNA), at D-7 (Apr. 3, 1997). This estimate is based on an average of six calls per day received by OIG over the past several years on topics that could be addressed by advisory opinions. It takes approximately two to forty hours to complete just one advisory opinion.
28. 62 Fed. Reg. 7350-01 (Feb. 19, 1997). This rule, established in accordance with section 205 of HIPAA, creates a new part 1008 in 42 C.F.R. chapter V.
29. “Health Care Fraud is High Pri-
Evidence: Oregon Court Excludes Expert Testimony in Breast Implant Litigation

On December 18, 1996, an Oregon federal district court granted numerous defense motions to exclude plaintiffs' expert testimony in *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387 (D. Or. 1996), a silicone breast implant case. The district court held that the bulk of the experts' conclusions failed the *Daubert* test for the admissibility of expert testimony (*Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)). The Oregon court's broad application of *Daubert*, if followed by other federal courts, suggests that breast implant litigation alleging systemic illness may face little success.

This particular case was transferred for pretrial purposes with other breast implant litigation to a multi-district litigation panel supervised by Judge Pointer in Alabama and was subsequently remanded to the Oregon district court for trial. Plaintiffs sought product liability damages for systemic illnesses allegedly caused by silicone breast implants. Under Oregon law relating to toxic tort actions, plaintiffs must prove a medical probability of causal connection between the alleged harm and the resultant injury. To prove causation, plaintiffs called numerous experts in epidemiology, immunology, rheumatology, and chemistry to testify that silicone can cause a particular constellation of symptoms labeled "atypical connective tissue disorder" (ACTD). The court held that the experts failed to meet the twin requirements of *Daubert* that scientific testimony must (1) reflect "scientific knowledge" and be grounded "in the methods and procedures of science" and (2) "fit" and be "relevant to the task at hand" (947 F. Supp. at 1396).

On the first requirement, the court held that the existence of ACTD lacked sufficient proof to constitute "scientific knowledge." Quoting testimony from plaintiffs' epidemiologist that researchers "are back at the beginning of formulating studiable hypotheses to test," the court ruled that ACTD was an untested hypothesis and excluded all ACTD epidemiology. Moreover, alluding to the traditional *Frye* test for determining the admissibility of scientific evidence, the court consistently noted that because most of the plaintiffs' conclusions were not widely held in the scientific community, judges should be skeptical of views held by a small minority of researchers (*Frye v. United States*, 293 F. 1013 (D.C.Cir. 1923)). (*Daubert* makes the "widely held" test one of several criteria to be considered in determining admissibility.) Having excluded testimony supporting the existence of ACTD, the court then used the "fit" requirement to reject all testimony from other fields of study that would lend collateral support to the ACTD theory. Without epidemiological testimony about ACTD, the rheumatology no longer "fit."

Significant to both the present case and the *Daubert* line of cases in general is the court's assertion that there is no useful distinction between scientific methodology and the conclusions it generates. Prior to *Daubert*, the *Frye* test provided that an expert's conclusion was not assessed by the court if he could demonstrate that his methods were "generally accepted." The Oregon court, however, held that judges should exercise a gatekeeping function on the process and logic by which the expert reached his conclusions. Admitting the difficulty of exercising such review in technical areas, the court appointed neutral experts in each of the major relevant scientific fields to assist the court pursuant to the Federal Rules of Evidence 104(a). Courts have interpreted this rule to provide that the judge may summon assistance in deciding preliminary issues related to the admissibility of evidence. The use of Rule 104 enabled the court to consult with expert advisors not retained by any litigant; here, the judge gave a number of questions to the advisors concerning the methodological foundations and ultimate conclusions of the proposed testimony.

In its broadest terms, *Hall* raises major questions about the judge's role in controlling the entrance of scientific data into the trial. By shifting focus from the methodology itself to the appropriateness of a proffered conclusion, the court firmly limits the kind of testimony that will survive a *Daubert* inquiry. Although the methodology question has usually been recognized as a primarily mechanical inquiry appropriate for the judge, it is unclear if the conclusion question extends the judge's gatekeeping function to issues of credibility, usually reserved for juries. On the other hand, an attempt to make the conclusion question more mechanical could require the judge to look increasingly to the opinions of other experts in the field. Such a standard may tacitly resurrect the *Frye* "general acceptance" test, albeit in a less potent form. Further cases may better resolve these issues.

R.W.G.