



BNA's

HEALTH CARE FRAUD REPORT



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Health Care Fraud Enforcement Priority for Public, Private Payers in Past 10 Years

In the past 10 years, health care fraud enforcement has emerged as a top priority for federal and state governments and private insurers as national health care costs have soared and concerns about quality of care for beneficiaries have garnered attention.

By many accounts, the past decade of health care program oversight was launched when Congress enacted the Health Care Insurance Portability and Accountability Act of 1996, which contained some of the broadest enforcement directives since the advent of the Medicare program as well as historic funding for enforcement activities.

Since then, stringent congressional oversight of federal health programs has increased as have new directives in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Deficit Reduction Act of 2005, and other statutes.

Federal initiatives have spilled over to private companies and have forced health care entities to develop comprehensive compliance programs to ensure their organizations are aligned with government expectations for health care providers serving beneficiaries of federal and state programs.

Officials from the Department of Health and Human Services Office of Inspector General, the Department of Justice, and the Centers of Medicare & Medicaid Services, as well as health care attorneys in private practice, share their insight and experiences from the past 10 years.

HHS OIG

In the 30-year history of the HHS OIG, the last 10 have marked some of its most substantial growth, including the amount of federal funding it receives for fighting fraud, the number of people hired to carry out OIG directives, and the level of results in terms of impositions, convictions, and exclusions.

Before Congress passed HIPAA, the OIG's activities were funded at less than \$80 million annually. By 2003, funding for the OIG doubled to \$160 million in mandatory funding from the Health Care Fraud and Abuse Account called for in HIPAA (HCFAC), plus additional money through discretionary funding.

The funding stream was capped in 2003, and in 2006 Congress authorized the first increase in funding since HIPAA. The Taxpayer Relief and Health Care Act of 2006 provides updates in funding over four years based on the Consumer Price Index through 2010.

Although the portability and privacy provisions in HIPAA garnered the most attention in 1997, Congress packed HIPAA with health care enforcement measures and a steady stream of funding for the OIG, DOJ, and other law enforcement agencies to combat fraud, waste, and abuse in federal programs. The statute even included language that urged the sharing of enforcement data with private payers.

Impositions (fines and penalties) resulting from OIG health care anti-fraud work since HIPAA enactment have gone from more than \$1.2 billion in 1997 to nearly \$1.6 billion in 2006, with a peak of \$1.9 billion in 2004. Convictions increased from 162 in 1997 to 310 in 2006, with the peak in 2005 at 384. Likewise, the number of providers excluded by the OIG from participating in federal health care programs increased from 2,719 in 1997 to 3,425 in 2006, with the peak in 2005 at 3,806.

All told, the OIG produced estimated cost savings of \$212 billion between 1997 and 2006 for all the programs for which it has oversight authority.

"HIPAA was truly a landmark for the OIG in our health care oversight efforts and significantly impacted how OIG addressed health care fraud issues," Inspector General Daniel R. Levinson told BNA. "HIPAA pro-

vided OIG with the infrastructure necessary to fight health care fraud in a comprehensive manner."

Industry Guidance. HIPAA also was the catalyst for OIG advisory opinions, which the industry has come to rely on for compliance resources but which both the OIG and DOJ initially opposed. The OIG's Industry Guidance Branch was established as a result of HIPAA.

"A hallmark of HIPAA related to fraud prevention is the establishment of a branch within OIG exclusively devoted to providing guidance to the health care industry," Levinson said.

"OIG issues a variety of guidance, including advisory opinions, fraud alerts, and special advisory bulletins," he said. "We have issued 20 fraud alerts and special advisory bulletins, which identify practices in the health care industry that are particularly vulnerable to abuse, and more than 150 advisory opinions to individuals and entities seeking advice on whether specific arrangements implicate the federal anti-kickback statute or other fraud and abuse laws" (see chart on this page).

Attorney Carolyn McElroy, Pacific Pulmonary Services, Novato, Calif., called the OIG's varied forms of guidance the "most important tools" developed in the past decade.

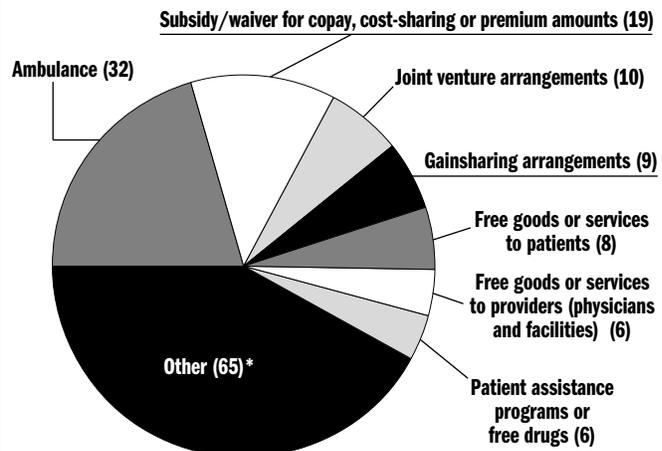
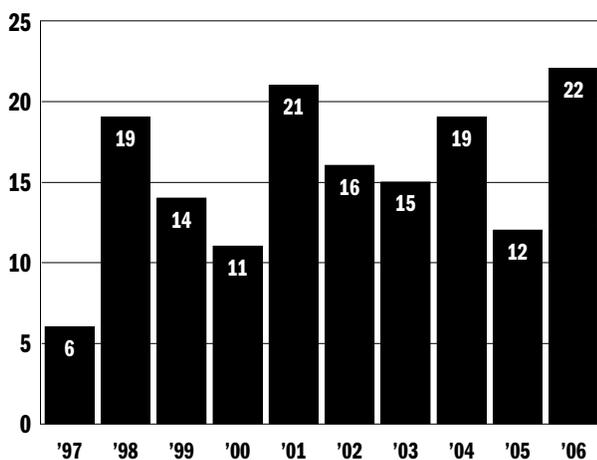
"An overwhelming majority of providers want to comply with the law and face investigation only when they do not understand the law, or they are seeking to meet the actions of a competitor who is engaging in aggressive marketing behaviors," McElroy said. "With the OIG's Web site, regulatory attorneys can provide more detailed advice, and have an archive of guidance to offer for discussion if the client says, 'But my competitor is doing it.'"

McElroy said the OIG's carefully crafted guidance "has done much to level the playing field" among health care providers.

Former IG Richard P. Kusserow told BNA that in the agency's earlier years, he found it difficult to impress on providers the threat of enforcement.

"One of the problems I had when I was IG was the industry seemed to be unclear about the kinds of issues that would cause problems with the government," he

Health and Human Services OIG Advisory Opinions Issued 1997-2006



Source: HHS OIG Web site

* Includes advisory opinions on the provision of malpractice subsidies to physicians, the leasing of equipment and space, and the provision of volunteer services and charitable donations.

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said, adding that even attorneys had trouble appreciating the risks. Kusserow now is chief executive officer of Strategic Management Systems Inc., a health care consulting firm in Alexandria, Va.

Media Attention. In addition to increased funding and enforcement tools brought by statute, Kusserow said that the health care bar increased in size and expertise and that health care fraud matters got more media attention during his tenure as IG.

“As IG, one of the things I did was institute an open door policy to the media to get the word out about education,” Kusserow said. “Years ago, there was lots of denial and there was so little information available that few people took fraud enforcement as a credible concern.”

Former chief counsel for the IG D. McCarty Thornton, now an attorney with Sonnenschein Nath & Rosenthal, Washington, agreed, saying OIG officials tried “mightily to get industry attention to fraud enforcement and compliance issues.” Media attention helped, he said, in “getting the word out” about the issues.

As media attention picked up through publications like BNA’s *Health Care Fraud Report*, Kusserow added, the OIG was better able to communicate fraud risks and the threat of enforcement. “It put a megaphone on the OIG,” he said.

In the years leading up to 1997, there also existed a “state of denial” about threats arising from failing to comply with health care laws and regulations, Kusserow said.

For example, he said, hospitals in rural areas or those who were not performing “as bad” as other competitor hospitals might have been under the government’s radar, but qui tam provisions and increasing use of data by government agencies puts every provider at the same level of scrutiny today. In that same vein, Kusserow said, qui tam provisions in the False Claims Act have had as significant an impact on health care enforcement as HIPAA has.

About the same time that whistleblower cases began increasing in the health care fraud industry, Kusserow said, the OIG began promoting compliance programs as a way to head off employees becoming relators.

In addition, Kusserow said electronic health care claims data is one of the most important oversight and enforcement tools for the OIG today. The federal government has more sophisticated mechanisms for managing claims data than in the past, he said, making volumes of data easily accessible by law enforcers.

CMS has billions of records in which the government can look for inappropriate billing, he said, meaning the nature of enforcement has changed from the OIG waiting for someone to knock on the door with a fraud problem to being able to detect them through aberrances in data.

While waste, fraud, and abuse in the health care industry had long been an area of focus for the HHS OIG, HIPAA went a long way toward raising the level of importance of such cases for other law enforcement agencies, including DOJ and the Federal Bureau of Investigation.

The HCFAC account established funding streams for those agencies, and established program integrity efforts within CMS.

“Although it may seem commonplace today, HIPAA institutionalized cooperation among law enforcement agencies,” Levinson said. “We also expanded our presence throughout the country and launched nationwide initiatives that resulted in increased savings and recoveries returned to taxpayers. Through myriad activities, HIPAA helped OIG and our law enforcement partners to strengthen the fight against health care fraud.”

Department of Justice

DOJ has and continues to play a pivotal role in fighting health care fraud, and over the last 10 years has seen a steady funding stream from the HCFAC account, which operates under the joint direction of the attorney general and the secretary of health and human services.

The resources dedicated to the account from the Medicare Trust Fund were designed to provide dedicated annual appropriations for HHS and DOJ to prevent, investigate, and prosecute health care fraud.

In fiscal 1997, HIPAA authorized up to \$104 million for HHS and DOJ health care fraud enforcement and prevention efforts, and allowed OIG and DOJ to increase that appropriated amount by up to 15 percent annually until 2003, DOJ said. That year, the FBI got \$47 million in dedicated funding for its health care fraud investigations.

DOJ said its funding peaked at \$55.2 million in 2002, and since 2003, when HCFAC funds reached their statutory cap, DOJ received \$49.4 million annually through fiscal 2006. Such funding for the FBI peaked at \$114 million in 2003.

Recovery Rates. A look at HCFAC funding and returns shows that recovery rates associated with the program generally have increased with the growth in annual allocations from the HCFAC account (*see chart on next page*).

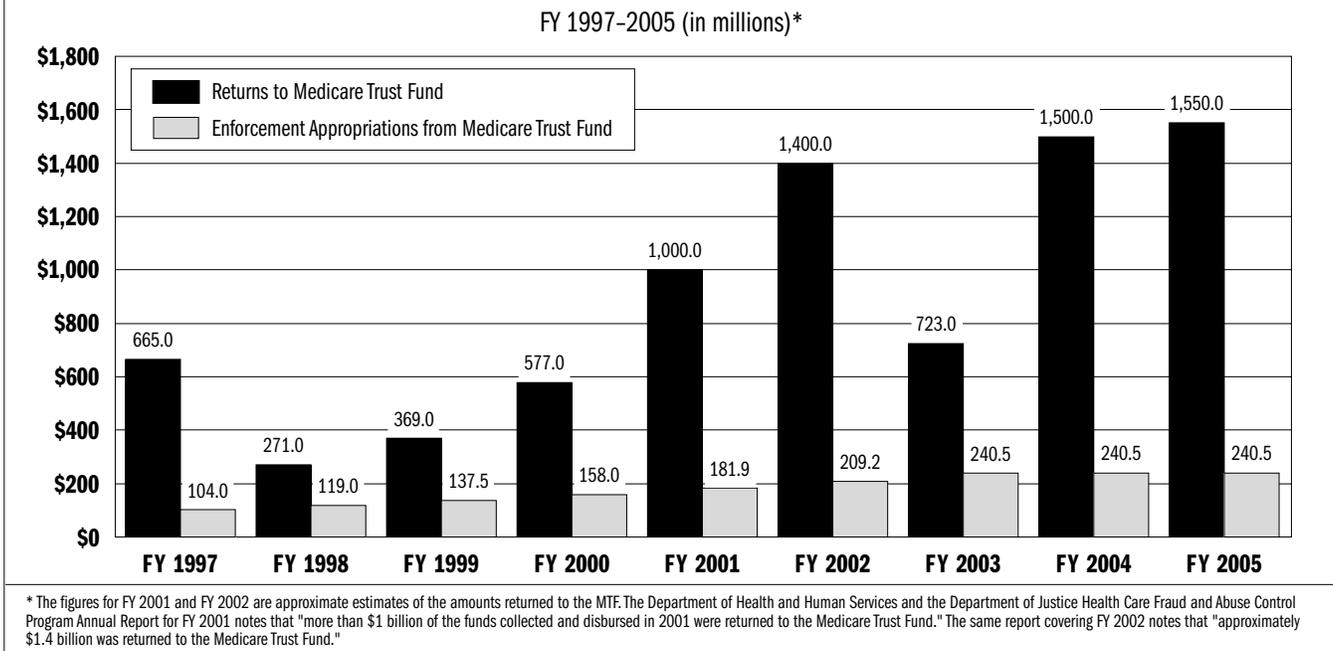
Since 1998, health care fraud-related collections, returns, and transfers to the Medicare Trust Fund generally have increased during most years along with HIPAA annual dedicated appropriations for federal law enforcement efforts, DOJ told BNA. The “return on investment” or “recovery rate” to the Medicare Trust Fund for every dollar of HCFAC funding allocated for federal law enforcement has increased from less than \$2 in 1998 to nearly \$5 in 2004 and 2005.

DOJ Targets. Throughout the last 10 years, all segments of the health care industry have been subject to DOJ scrutiny, and the agency has obtained civil recoveries or criminal pleas and fines from the hospital industry, pharmaceutical manufacturers, nursing home chains, and prescription drug retailers, as well as smaller entities such as durable medical equipment suppliers and individual providers, such as physicians, DOJ said.

To some extent, the department’s enforcement efforts are driven by matters brought to its attention by whistleblowers filing qui tam actions under the False Claims Act. The recent spate of large settlements with pharmaceutical manufacturers has prompted various filings by whistleblowers that allege fraud in that industry, which DOJ said are being pursued.

Also, with large federal expenditures expected as a result of the new Medicare prescription drug program, DOJ said it fully expects issues pertaining to pharmaceutical pricing to remain a priority.

Total Funds Returned to the Medicare Trust Fund (MTF) versus Total Funds Appropriated from the MTF for Health Care Fraud Enforcement



Source: The Department of Health and Human Services and the Department of Justice Health Care Fraud and Abuse Control Program. Annual Reports for FY 1997-2005, as compiled in reports by Taxpayers Against Fraud.

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Insurance Schemes. During the past 10 years, there also has been an increase in federal prosecution of corrupt private insurance schemes, DOJ said. These schemes may involve entities that offer and sell health benefit plans by means of misrepresentations and false promises that leave employees and their families without insurance and personally responsible for unpaid medical bills.

For example, DOJ said, to avoid state insurance regulation, corrupt insurers may falsely claim they are employee health benefit plans, which are exempted from state insurance regulation by the Employee Retirement Income Security Act (ERISA) and therefore not required to maintain claim reserves or pay premium taxes for state guaranty funds. Federal criminal prosecution physically removes the insurers from the health insurance industry and deters others who would engage in similar schemes from following their example, DOJ said.

The department cited one insurer, Employers Mutual, that operated in all 50 states. The collapse of its scheme left participating individuals, who thought they were insured, with more than \$20 million in unpaid medical claims. The operator of the company was sentenced to 25 years in jail and ordered to pay \$20 million in restitution (11 HFRA 116, 2/14/07).

Medical Privacy Issues. One area where there is enforcement authority that did not exist 10 years ago is medical privacy, DOJ said. HIPAA's medical record privacy rules became fully enforceable in April 2004.

In 2005, DOJ publicly announced that the technical language of HIPAA permitted prosecution of health care providers and health plans for privacy violations. It

also provided prosecution of certain individuals who might be liable under principles of corporate liability, who conspire with a covered entity or who under the commonly known "aiding and abetting" statute effectively cause a "covered" entity to violate the criminal HIPAA statute.

DOJ told BNA it has pursued select targeted prosecutions of egregious medical record theft undertaken for purposes ranging from identity and credit theft to fraudulent health care billing and attempts to identify federal law enforcement agents.

Rise in Qui Tam Cases. According to DOJ, the numbers of both civil and criminal health care fraud cases have increased substantially since the inception of HCFA. The number of civil health care fraud cases in which the department filed complaints or intervened nearly tripled between 1997 and 2004.

Health care continues to be the chief area of DOJ's FCA qui tam litigation, accounting for more than 53 percent of the 5,643 qui tam cases filed since 1986 overall. The percentage of qui tam cases involving health care was 61 percent in fiscal 2002, 65 percent in fiscal 2003, 66 percent in fiscal 2004, 68 percent in fiscal 2005, and 57 percent in fiscal 2006, DOJ said. Since fiscal 2000, an average of 225 health care related FCA qui tam cases per year have been filed.

Civil recoveries reflect this activity, DOJ said, and since 1986, a total of \$11.5 billion of the \$18.1 billion recovered under the False Claims Act has been for health cases, or about 64 percent. In addition, of that \$11.5 billion since 1986, \$8.06 billion represents federal recoveries in cases brought by qui tam plaintiffs (69 percent).

In the past three years, health care recoveries have averaged 74 percent of DOJ's total FCA recoveries.

DOJ told BNA that the number of criminal convictions for health care fraud offenses reached an all time high in 2006. Since the first year of the HCFAC program, health care fraud convictions have increased by more than 50 percent from 363 to 547 last year.

The department said it found no appreciable trend from trials toward negotiated settlements in its health care fraud cases over the past 10 years, saying the overwhelming percentage of both civil and criminal matters continue to be resolved prior to trial.

DOJ Priorities. Over the course of 10 years, DOJ enforcement priorities shifted, especially right after the 9/11 terrorist attacks. Resources that were devoted to health care fraud enforcement and other priorities were diverted temporarily to address more pressing and immediate needs. Since then, DOJ said resources devoted to health care fraud enforcement efforts have returned to, or now exceed, their pre-Sept. 11 levels.

Other legislative actions that affected DOJ in its pursuit of health fraud enforcement and prevention include MMA, which established the Medicare prescription drug benefit, and the Deficit Reduction Act of 2005, which established several new streams of Medicaid anti-fraud funding for HHS agencies and will lead to more health care fraud referrals to DOJ for investigation and prosecution, DOJ said.

The department said DRA will provide HHS agencies with \$99 million in new anti-fraud resources in 2007, and \$660 million over the five-year period of 2006-2010. The administration, recognizing DOJ's needs for additional health care fraud litigation resources to address pending cases, as well as new Medicare and Medicaid workload demands, has requested \$17.5 million in enhanced discretionary funding for DOJ and the FBI in the president's FY 2008 budget request.

FBI Priorities. The FBI today fights health care fraud through the 56 health care fraud task forces across the country, which vary in size and member composition based on available resources and the crime problem in each jurisdiction, Angela L. Byers, supervisory special agent at FBI's Health Care Fraud Unit, Washington, told BNA.

For example, the western New York health care fraud task force was formed in 1998, special agents William Martin Fallon and Marc Falconett in FBI's Buffalo, N.Y. office, told BNA. Previously, the health care task force was made up of an ad hoc group consisting of FBI and HHS OIG officials, Fallon said.

"The OIG cofounded the task force with the FBI," Fallon said. "Our task force has been identified as a model in forming other task forces, and they have been up and running because of our success."

The task forces now often include members of federal law enforcement agencies and state and local law enforcement and regulatory agencies. The vast majority of recoveries by the health care task force in New York is for the Medicare program—FBI works with HHS on almost all cases that focus on Medicare and Medicaid, Fallon said.

The health care task forces were formed to combat the ever increasing problem of health care fraud in both the government and private sectors, Byers said. The FBI health care fraud investigators rely upon their relation-

ship with other agencies, groups, and the public to identify and prosecute health care fraud, she said.

As quality-of-care cases have increased, Fallon said, the New York health care task force has investigated clinics, pharmacies, hospitals, physicians, durable medical equipment suppliers, laboratories, mental health facilities, ambulances, and home health care agencies.

Byers said that FBI priorities have changed over the last 10 years based on the evolving threats to the nation. The number one priority for the FBI is protecting against terrorist threats, but investigating and prosecuting health care fraud "has been, and will continue to be, important to the FBI," she said. Current FBI health care fraud initiatives involve outpatient surgery fraud, Internet pharmacy fraud, auto accident insurance fraud, and durable medical equipment fraud.

CMS Program Integrity

CMS has been on the forefront of health care fraud enforcement and program oversight for the Medicare and Medicaid programs over the past 10 years. Historically, the so-called pay-and-chase model of enforcement was how the CMS Program Integrity Group approached its role in the cadre of oversight efforts for the largest federal health care programs.

However, since the 1996 enactment of HIPAA—which created the largest funding stream for CMS's program integrity efforts—the agency has become proactive in heading off fraud and abuse before it gets out of hand, CMS Program Integrity Group Director Kimberly L. Brandt told BNA.

The turning point, Brandt said, came in 2003 when CMS and OIG became aware of rampant fraud in the durable medical equipment industry, where some suppliers were grossly overcharging Medicare for power wheelchairs. This led to the launch of "Operation Wheeler Dealer," a joint initiative by CMS and the OIG to curb fraud and abuse in the power wheelchair market.

Brandt said program integrity officials saw an opportunity to get ahead of problems before they "got big" and attracted congressional attention—and before money was paid out for fraudulent claims.

Today, Brandt describes CMS's program integrity efforts as more of a compliance program that is part of the day-to-day operations of Medicare and Medicaid.

"It's part of our culture," she said.

System More Data-Driven. Perhaps the greatest driver, though, for improved program integrity efforts at CMS is the use of claims data to detect aberrances and potential fraud trends, Brandt said.

For example, she explained, CMS uses the Comprehensive Error Rate Testing (CERT) program as a diagnostic tool to detect areas of fraud and abuse concerns. Furthermore, CMS gleans data from program safeguard contractors that is used by agency analysts to oversee program performance.

"We never had that ability before," Brandt said. "It's a huge step forward."

William J. Mahon, a health policy consultant in Washington, and former president of the National Health Care Anti-Fraud Association, recalled a time when program integrity at CMS took a back seat operationally and culturally to other priorities.

Over time, the agency has increased its role in fighting against fraud and abuse in federal programs, which he credited to the work of past administrator Nancy Ann DeParle, Brandt, and strong field offices. DeParle served during the Clinton administration, when the agency was named the Health Care Financing Administration.

"[CMS's] Los Angeles PI Branch is a model of how effective an anti-fraud partner the agency can be in the field," Mahon said (9 HFRA 557, 7/6/05).

Brandt said she does not see CMS's program integrity efforts as duplicating those of the OIG and DOJ in health care fraud enforcement. Instead, she described the agencies as having complementary relationships, adding that CMS's goal is to ensure program effectiveness, while OIG and DOJ have a greater impact in the area of overall law enforcement.

"CMS can take administrative actions," she said, "but, in some cases, ultimately, nothing is as effective as a criminal conviction or settlement."

CMS's program integrity efforts are funded largely with money made available through HIPAA in the Medicare Integrity Program fund, just as it is with OIG's and DOJ's funding. Also, as with the OIG and DOJ, annual funding flat-lined five years ago, meaning that resources must be stretched farther, Brandt said.

Even with all its growth and impact, Brandt said more needs to be done. She said CMS's oversight and enforcement efforts will be vastly improved by integrating claims data from all aspects of the Medicare program.

Right now, Part A, Part B, Part D, and Durable Medical Equipment data are separate because different contractors are responsible for claims processing. Contractor reform will help drive data integration so that aberrances can be detected across all parts of the Medicare program.

Private Payers

As the federal government began ramping up health care fraud enforcement efforts 10 years ago, the private payer community reaped the benefits of HIPAA enactment, in which Congress called for the coordination of oversight efforts between the government and private sector.

Mahon said the move to include language in HIPAA about the "coordination and sharing of fraud-related data with health plans," reflected an understanding among lawmakers that health care fraud was an "all payer problem."

Furthermore, Mahon said, the statute "acknowledged the practical need for private-public information sharing as an essential aspect of addressing fraud effectively."

Also helpful to insurers was the OIG's 1998 implementation guidelines for the fraud and abuse control program that provided specific details for enacting HIPAA and included recommendations that health plans and law enforcement agencies designate someone to coordinate information sharing among plans as well as between plans and federal law enforcers.

The federal movement had spurred the same growth in anti-fraud efforts for private payers who are subject to the same schemes as were federal programs.

Among the resulting changes, Mahon explained, was a greater willingness among payers to publicize their

anti-fraud efforts and results because of the cost-savings those efforts have for their premium-paying customers. That disclosure, he added, was something most payers were "culturally loathe to do."

Nevertheless, Mahon said some still question the deterrent effect of anti-fraud efforts in light of the endless parade of health care-related false claims cases so many years after some of the most notable schemes and settlements, including the so-called California rent-a-patient center schemes in which health individuals were recruited from around the country for unnecessary surgeries (10 HFRA 8, 1/4/06).

False Claims Act Enforcement

Perhaps playing the biggest role in the fight against health care fraud in federal programs over the last 10 years is the False Claims Act, under which health care cases have grown exponentially.

During the past 10 years, health care FCA cases surpassed military contractor FCA cases as the greatest source of financial recoveries, Lynn Shapiro Snyder, an attorney at Epstein Becker & Green PC, Washington, told BNA. After all, there are a lot of companies that do business directly with the federal health care programs or have products covered by federal health care programs, she said.

"Indeed, I have seen every segment of the health care industry now touched by the whistleblower provisions of the FCA—the predominant source of the health care fraud enforcement today," Snyder said. "I have seen the clinical labs get hit, then the hospital industry, the [durable medical equipment] suppliers, the CMS contract administrator sector, and, more recently, the manufacturers of pharmaceuticals and medical devices."

The assistant U.S. attorneys now are addressing many of these cases, and prosecutors usually come to the case with some familiarity about the possible health regulatory issues at stake, Snyder said.

"I have seen cases that years ago were settled for smaller dollar amounts now being settled for much greater dollar amounts," Snyder said. "I have seen cases that would have been prosecuted as civil fraud matters now being opened as criminal cases both as to the company and as to the relevant individuals."

The government—and the whistleblowers and their bar—clearly are more aggressive, Snyder said. In terms of outcomes other than the settlement amounts, it used to be the case that the OIG's integrity obligations for the waiver of its permissive exclusion authority were inside the DOJ settlement agreement because they were just a few paragraphs, she said.

Later, they were spun out into a separate corporate integrity agreement. These CIAs are more comprehensive in their requirements even if the scope of the underlying alleged misconduct is significantly different from case to case, Snyder said.

TAF Weighs In on FCA. Commenting on the growth of the use of the False Claims Act in the health care arena, Joseph E.B. White, legal education director for the Taxpayers Against Fraud Education Fund, Washington, told BNA that law enforcement agencies, with the help of whistleblowers, have recovered nearly \$11 billion in stolen health care funds.

With government spending on health care programs escalating and fraud often masked by seemingly innocuous business transactions, U.S. attorneys and the OIG have come to rely more on whistleblowers uncovering fraudulent activities, he said.

In 1987, not a single stolen health care dollar was recovered through qui tam lawsuits, White said. He added that in 2005, more than 50 percent of the health care dollars returned to the federal government originated from such cases, and by 2006, that number reached nearly 80 percent.

Even more impressive than the growing role of whistleblowers, White said, is the resulting efficiency whistleblowers have brought to the overall fraud enforcement system.

Health care fraud settlements have become the main source of FCA settlement dollars, accounting for more than 70 percent of the returned dollars over the last 10 years, White said. He noted that a recent TAF Education Fund study showed the federal government is recovering \$15 in returned dollars for every \$1 spent investigating and prosecuting FCA whistleblower actions involving health care fraud. In 2001, a TAF study showed the ratio was \$8 to \$1.

Recently, however, Congress sought to remedy this situation through provisions of DRA that offer incentives to states to pass their own FCAs and to use them to go after Medicaid fraud dollars, White said.

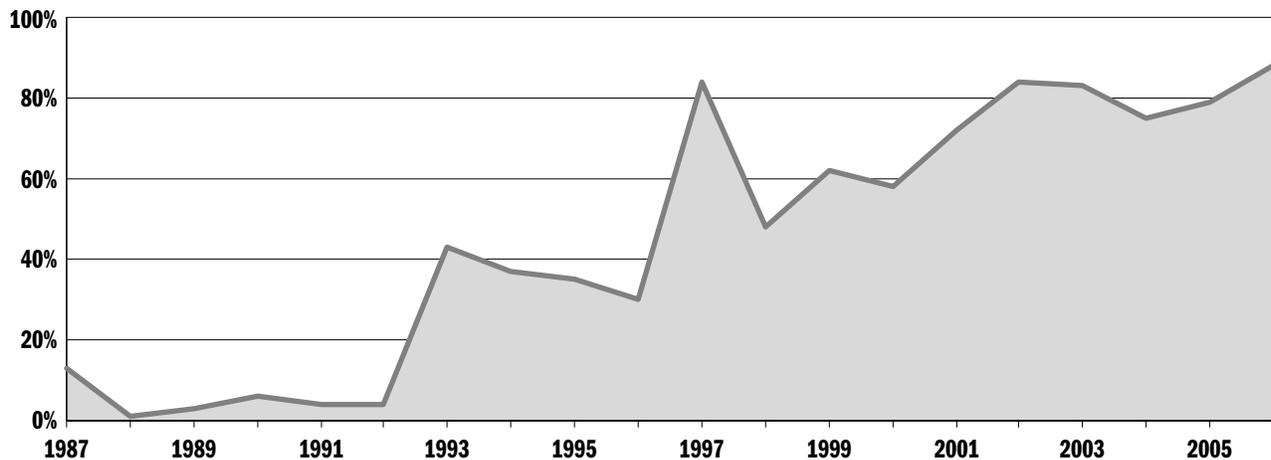
“Hopefully all states will enact FCAs that comply with the requirements of the DRA, solidifying effective fraud fighting,” White said.

Nursing Home Quality Cases. One of the significant trends involving the False Claims Act, according to Stuart I. Silverman, an attorney with the District of Columbia Office of Inspector General’s Medicaid Fraud Control Unit, has been the continued push by federal prosecutors to use the federal law as a tool to encourage greater quality of care at nursing homes.

The Nursing Home Reform Act, enacted by Congress in 1987, provided the basic building blocks for allegations of substandard care at nursing homes in federal prosecutions, Silverman said, while the U.S. Attorney’s Office for the Eastern District of Pennsylvania has taken a leadership role in using FCA as an enforcement mechanism.

Generally, courts have come to recognize both the implied and express certification theories as viable

Percent of Total FCA Settlement Amounts that Derive from Health Care Fraud Cases



Source: Taxpayers Against Fraud Education Fund

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The federal FCA has proven so effective, he said, that 16 states, the District of Columbia, and the cities of New York and Chicago have enacted their own versions.

“Thankfully for the public fisc, it appears that the trend of increased reliance on whistleblower initiated cases is continuing and spreading,” White said.

“False Claims Acts have been enacted in traditionally Republican states, such as Texas and Tennessee, to traditionally Democrat states, like California and Massachusetts,” he said. “When it comes to fighting health care fraud in America, both sides of the aisle have truly embraced False Claims Act legislation.”

While the federal False Claims Act has been quite successful in fighting Medicare fraud, there has been, until recently, a significant lack of success in fighting Medicaid fraud, White said, explaining that the difference derived from several problems, most of which were rooted in the complications of the joint federal-state nature of the Medicaid program.

touchstones to allow causes of action to be pressed under the FCA, Silverman said. This development has led to the use of those theories in FCA cases pressed against nursing home for substandard care.

Another significant development has been the use of the False Claims Act as a tool to redress fraud in drug expenditures, and marketing practices, under the Medicare and Medicaid programs, most notably in cases brought against drug manufacturers for violation of the Medicaid Drug Rebate Program and best price rules, Silverman said.

Other cases in this area that have Medicare and Medicaid aspects (as well as private third-party payers), are those brought against drug manufacturers for illegally inflating the reported sales price, and thus the average wholesale price, so that windfall reimbursements are made to providers of those drugs, Silverman said. He called the practice “marketing the spread.”

In addition, he said, FCA is being used more often to address illegal “off-label” marketing of drugs.

FCA and Behavioral Change. John T. Brennan Jr., an attorney at Crowell & Moring LLP, Washington, said that the past 10 years has seen the FCA emerge not only as the government’s “most reliable extractor of financial spoils; it has also become a weapon for inducing behavioral change in ways arguably far beyond its original intent. The FCA and its ramifications now dominate our practices.”

Brennan added that “once we have mastered, to various degrees, the relatively simple intricacies of Stark [physician self-referral law] and the anti-kickback law, most of us spend our time contemplating the expanding scope of the FCA’s realm, as we identify and digest the latest theories of the Act’s applicability (‘implied certification,’ extreme theories of ‘causation,’ and the like).”

Top Fraud Predictions for 2000 v. 2008

Health Care Fraud Report has featured a list of top health care fraud issues in its annual Outlook articles since 2000. Below is a list of the top issues predicted for 2000 versus the top issues predicted for 2008:

2000:

- Patient dumping regulations
- Nursing home oversight
- Quality of care issues
- Underutilization in managed care plans
- Pharmaceutical benefit managers
- Confidentiality protection regulations
- MFCUs investigating Medicare fraud

2008:

- State false claims acts
- Physician-hospitals arrangements
- Deficit Reduction Act of 2005 compliance
- Kickbacks to doctors
- Pharmaceutical off-label cases
- Part D fraud, waste, abuse guidance
- Medical device fraud
- Medicaid fraud enforcement
- Drug pricing

“When we are not defending them, we turn our efforts to educating our sometimes disbelieving clients on how to avoid this ever-broadening trap of treble damages, such as corporate integrity agreements and painful publicity.”

Supreme Court Decisions

Several decisions over the past 10 years by the U.S. Supreme Court addressed issues that either directly or indirectly affected the health care fraud area.

In 1997, the high court, in *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939 (1997), held that the 1986 FCA amendments do not apply retroactively to whistleblower lawsuits submitted before the amendments’ enactment, but failed to address whether the FCA permits employees of government contractors to file “parasitic” FCA actions.

Notably, the Supreme Court did not address whether the FCA imposes liability for alleged infractions of other

statutes or regulations regardless of whether such infractions result in false claims against the federal treasury.

The health care industry found the court’s ruling in 1998 in *United States v. Bajakajian*, 524 U.S. 321 (1998) important because it affects the question of whether large civil money penalties, such as those imposed under the FCA, may be so excessive in relation to the damages to the government that they become unconstitutional. The Supreme Court ruled 5-4 that a forfeiture that is punitive in nature must not be “grossly disproportional” to the underlying crime if it is to pass scrutiny under the Eighth Amendment’s excessive fines clause. The high court articulated for the first time, the test for determining when a punitive forfeiture is excessive—“judgments about the appropriate punishment for an offense belong in the first instance to the legislature” and “any judicial determination regarding the gravity of a particular criminal offense will be inherently imprecise.”

In a 1999 decision that allows the use of powerful federal remedies in insurance fraud claims, *Humana Inc. v. Forsyth*, 525 U.S. 299 (1999), the Supreme Court unanimously ruled that a class of Nevada plaintiffs who argued they overpaid millions in medical copayments could sue Humana Inc., a managed care organization, under the federal Racketeer Influenced and Corrupt Organizations Act (RICO). Under the decision, individuals can seek triple damages that are provided for under RICO, and attorneys’ fees.

In a 2000 decision, *Beck v. Prupis*, 529 U.S. 494 (2000), the high court held that the president of an insurance group, Robert Beck, who claimed he was fired because of his whistleblower activities against the company, could not bring a civil conspiracy claim under RICO. The court determined that the overt act that injured Beck was not independently wrongful under any substantive provision of the RICO statute. Attorneys for whistleblowers argued that the decision takes away federal protection for potential whistleblowers, forcing them to rely on various state laws that often do not provide protection.

In *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765 (2000), another 2000 decision that was of great importance to the health care industry because of the explosion of allegations of Medicare fraud, the Supreme Court held that private whistleblowers have legal standing to sue under the FCA on behalf of the United States if they believe fraudulent money claims were submitted to the federal government. However, relying on its long-standing presumption that “person” does not include the sovereign and the lack of congressional intent to hold states liable under the FCA, the unanimous court ruled that states are not subject to FCA liability in such actions.

The Supreme Court in the 2001 decision, *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001), held that state law fraud claims against a bone screw manufacturer and consulting company that allegedly supplied incorrect information to the Food and Drug Administration conflict with and are preempted by the Food, Drug, and Cosmetic Act. The decision was a victory for the Department of Justice, which argued that state law fraud-on-the-FDA claims clashed with the federal government’s exclusive authority to enforce the FDCA and the FDA’s decision to grant market clearance for bone screw devices.

In another decision involving the False Claims Act, the Supreme Court in a 2003 ruling, *Cook County v. United States ex rel. Chandler*, 538 U.S. 119 (2003), held that local governments are “persons” subject to FCA qui tam actions. The definition of person has remained unchanged since the original FCA was passed and reflects the common understanding that corporations are persons, the court said. The Supreme Court also held that the increase of treble damages under the FCA served remedial purposes in addition to punitive objectives. Although the court found a punitive character of the treble damages provision as a reason to hold states are not persons subject to FCA qui tam actions in its *Vermont* decision, it found the damages also have compensatory traits.

Returning to a RICO issue, the Supreme Court in a unanimous 2003 decision, *PacificCare Health Systems Inc. v. Book (In re Humana Inc. Managed Care Litigation)*, 538 U.S. 401 (2003), ruled that ambiguities concerning remedies available under contracts between managed care companies and physicians rendered the questions concerning their enforceability “unusually abstract.” The decision gave arbitrators an opportunity to resolve claims physicians brought against members of the managed care industry under RICO. The court determined it would be premature to wade into the parties’ dispute over the reach of an arbitrator’s authority to resolve an alleged conflict between statutory remedies and contractual remedy limits.

In a 2005 decision, *United States v. Booker*, 543 U.S. 220 (2005), a divided Supreme Court ruled that the federal Sentencing Guidelines violate the Sixth Amendment right to a jury trial by providing for increases to the maximum term of the presumptive sentencing ranges based on facts found by the sentencing judge. Although health care attorneys saw little impact on health care compliance programs, they said the ruling will be important in specific cases. The high court put in place a sentencing system that makes the sentences in the guidelines merely advisory—judges are to consider the guidelines but are not bound to impose them. The court said it foresees the U.S. Sentencing Commission continuing to study sentencing and proposing amendments to the guidelines, but also expressly recognized that the advisory scheme is subject to Congress’s decision to step in and do something else. Since the *Booker* decision, a number of individuals convicted of health care fraud have challenged the sentences they received with mixed results.

Most recently, the Supreme Court’s 2006 decision in *Garcetti v. Ceballos*, 126 S.Ct. 1951 (2006), which held the First Amendment of the U.S. Constitution does not protect public employees from being disciplined for statements made as part of their official duties, could significantly affect government employees in the health care sector. Several attorneys told BNA the decision could have a chilling effect on the willingness of those who are the first to uncover evidence of fraud or patient safety problems, such as government oversight regulation employees, inspection agency employees, public health provider employees, and other public sector employees, to report concerns to their superiors. Although the court cited the availability of other avenues for speaking out publicly and the adequacy of existing statutory protections for whistleblowers, the consensus of several attorneys was that remedies provided by state

and federal laws were uneven, ineffective, and usually illusory.

Medicaid Fraud

Another upcoming anniversary will be celebrated on Oct. 25, when the National Association of Medicaid Fraud Control Units commemorates the 1977 signing of legislation that created the Medicaid Fraud Control Units, Barbara L. Zelner, counsel for NAMFCU, told BNA.

Signed by President Jimmy Carter, the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977 provided each state with the opportunity and resources to establish an MFCU to investigate and prosecute provider fraud and resident abuse, Zelner said. According to Zelner, NAMFCU is comprised of all 49 federally certified MFCUs (48 states and the District of Columbia).

In the past 10 years, NAMFCU added two new members—Nebraska and the District of Columbia. Zelner said North Dakota and Idaho are the only two states without MFCUs.

In 1978, the first MFCU was federally certified and 17 MFCUs received federal grant funds of \$9.1 million. In fiscal 2007, \$169 million was awarded to the 49 MFCUs, Zelner said.

NAMFCU’s role has been to provide a forum for MFCUs to exchange views and experiences and the association is designed to foster interstate cooperation on legal and law enforcement issues affecting the MFCUs, to improve the quality of Medicaid fraud and resident abuse investigations and prosecutions by conducting training programs, and to provide technical assistance to its members, Zelner said.

The organization has enabled MFCUs to deter some of the largest and most insidious health care provider frauds, recover program dollars, punish corrupt practitioners and prosecute those who abuse or neglect nursing home residents, Zelner said.

Global Settlements. The biggest change in the past 10 years has been the increase in global settlements and the number of joint state and federal prosecutions at the local level, Zelner said. There also has been an increase in resident abuse/neglect investigations and prosecutions.

NAMFCU serves as the coordinating agency that represents the interests of its members in multi-state/federal global investigations and cases. The state MFCUs are generally notified about an ongoing investigation or case when DOJ or a U.S. attorney’s office, qui tam relator’s counsel, defense attorney, or other source contacts NAMFCU and requests the assistance of the MFCUs, she said.

Once the relevant information is obtained and a determination is made that it is appropriate for the states to participate, the NAMFCU president appoints a team to work with the federal government and to represent the states’ interests, Zelner told BNA. Selection of team members may be based upon a particular state or number of states involvement in the investigation and individual team members’ abilities and experience, she said.

The team is responsible for drafting the state settlement agreement, working with each of the participating states to ensure that their state settlement agreement is

Health Care Fraud Settlements Over \$100 Million (1990–2006)

Name of Company	Year	Total Recovery	Criminal Fine
National Health Labs	1992	\$111,000,000	\$1,000,000
National Medical Enterprises	1994	\$379,000,000	\$54,800,000
Caremark, Inc.	1995	\$161,000,000	\$29,000,000
Damon Clinical Laboratories	1996	\$119,000,000	\$35,000,000
Integrated Health Services, Inc., through its subsidiary First American Health Care of Georgia Laboratory Corporation of America	1996	\$255,000,000	
Laboratory Corporation of America	1996	\$187,000,000	\$5,000,000
Roche Biomedical Laboratories	1997	\$113,840,776	
SmithKline Beecham	1997	\$325,000,000	
Blue Cross Blue Shield Illinois	1998	\$144,000,000	4,000,000
Health Care Services Corporation	1998	\$144,000,000	\$4,000,000
Abbott Laboratories, Inc.	1999	\$100,000,000	
Beverly Enterprises, Inc.	2000	\$175,000,000	\$5,000,000
Fresenius Medical Care	2000	\$486,000,000	\$101,000,000
HCA (Columbia HCA)	2000	\$840,000,000	\$95,000,000
TAP Pharmaceutical	2001	\$875,000,000	\$290,000,000
Vencor, Inc.	2001	\$219,000,000	
Schering-Plough Corp.	2002	\$500,000,000	
Abbott Laboratories, Inc., and Ross Product Division	2003	\$615,000,000	\$200,000,000
Bayer Corporation	2003	\$257,200,000	\$5,590,800
HCA (Columbia HCA)	2003	\$631,000,000	
Zeneca, Inc. and AstraZeneca Pharmaceuticals LP	2003	\$354,900,000	\$63,872,156
Gambro Healthcare	2004	\$350,500,000	\$25,000,000
HealthSouth Corporation	2004	\$325,000,000	
Pfizer Corp., subsidiaries Warner Lambert, Inc. and Parke-Davis	2004	\$430,000,000	\$240,000,000
Schering-Plough Corp., through its subsidiary Schering Sales Corporation	2004	\$345,469,482	\$52,500,000
Caremark, Rx, Inc.	2005	\$137,500,000	
King Pharmaceutical	2005	\$124,000,000	
Serono, Inc.	2005	\$704,000,000	\$136,935,000
SmithKline Beecham Corporation, d/b/a GlaxoSmithKline	2005	\$150,000,000	
Schering-Plough Corporation, through its subsidiary Schering Sales Corporation	2006	\$435,000,000	\$180,000,000
SmithKline Beecham Corporation, d/b/a GlaxoSmithKline	2006	\$149,000,000	
St. Barnabas Hospitals	2006	\$265,000,000	
Tenet Healthcare Corporation	2006	\$900,000,000	

Source: This chart was adapted from a more detailed chart covering 1990-2006 in the **2006 Cumulative Supplement to Prosecuting and Defending Health Care Fraud Cases**, published by BNA Books. Visit <http://www.bnabooks.com> for order information.

completed, signed, and returned to the defense attorneys.

Congress passed the Ticket to Work and Work Incentives Improvement Act of 1999 that gave MFCUs limited authority to address fraud in the Medicare program that they encountered while investigating Medicaid fraud. Zelner told BNA that law did not lead to much change.

“I think the reason is that there are so many state/federal health care fraud task forces and so many MFCU prosecutors are cross-designated and work closely with assistant U.S. attorneys as well as those MFCU investigators working with OIG agents that there does not seem to be as much need for a MFCU to get

permission from OIG to investigate or prosecute a Medicare provider,” she said.

However, Zelner told BNA some MFCUs are using the optional authority to investigate allegations of resident abuse in non-Medicaid-funded facilities, board and care facilities.

Financial Incentives. DRA contained various provisions relating to fighting Medicaid fraud that Silverman said enhanced authority at the state level by providing financial incentives for states to enact their own false claims acts.

Thus, in addition to the enforcement measures under the federal FCA, individual states can be expected to

bring their own actions against those who allegedly have defrauded the public fisc, Silverman said.

Additionally, under DRA Section 6033, Congress mandated certain Medicaid entities that receive or pay \$5 million in Medicaid funds annually to establish written policies for educating all employees, contractors, and agents on the federal False Claims Act, Silverman said. To enhance tools to root out Medicaid fraud, he said, in Section 6035, Congress provided for a Medicaid Integrity Program, with funding for that fraud fighting initiative.

Silverman also said that state law has evolved since 1996 as greater clarity has been provided by state courts on enhanced duties of members of the board of directors and senior management to guard against improprieties and prevent mismanagement and financial fraud.

Compliance

Ten years ago, the health care compliance industry was in its infancy. Compliance programs were few, and where they existed, they largely focused on billing issues.

That has changed, and compliance officers and the programs they run involve a broad range of issues and are integral parts of operations in their organizations, Health Care Compliance Association Chief Executive Officer Roy J. Snell said.

Snell noted that HCCA—also celebrating its 10-year anniversary—has 4,700 members, reflecting enormous growth in the compliance industry.

Attorney Kirk J. Nahra, Wiley Rein LLP, Washington, agreed, saying compliance programs have emerged from being an “afterthought” for many organizations to being “a high priority focus of attention at most reasonable health care businesses. There is a clear recognition of the risks of failing to have an effective compliance program.”

According to Peter M. Leibold, executive vice president and chief executive officer of the American Health Lawyers Association, “The late 1990s was the compliance era. It was a successful initiative and gave rise to more awareness and more creativity in FCA cases. Now, prosecutors and defense counsel are thinking more about false claims.”

AHLA president Anthea Daniels said that everyone is monitoring and amending compliance programs and asking questions about what has to be done in compliance, whereas 10 years ago providers were asking if they even needed compliance programs.

“I know now when I speak with clients about these issues, they understand the importance—when before they didn’t feel that it affected them,” Daniels said. “Their reaction 10 years ago was, ‘What is the chance of being audited?’”

OIG Impact on Compliance. Levinson said one of the OIG’s most significant contributions to the health care fraud enforcement era has been guidance to the industry to promote voluntary compliance.

“One of the most significant ways in which OIG has effected change is by reaching out to the health care industry to promote a culture of compliance,” Levinson said. “Over the past decade, OIG has implemented a comprehensive program to promote voluntary compliance by health care providers and suppliers. To date,

the OIG has issued voluntary compliance program guidance for 11 major health care sectors.”

In addition, Levinson noted that the corporate integrity agreements that the OIG negotiates as part of False Claims Act settlements generally require providers to establish comprehensive compliance systems and policies that “have been a catalyst for change in corporate culture and result in comprehensive internal control systems.”

Furthermore, Levinson said that during his tenure, the OIG has begun tailoring CIAs to address the specific conduct associated with the fraud committed in a case.

Among the most important changes for the health care compliance industry in the past 10 years, Snell said, is that compliance officers have greater independence within their organizations and many report to the highest levels of leadership in their organizations, such as chief executive officers and boards of directors.

In addition, he said, compliance matters no longer are just the concern of compliance officers.

“More boards are asking for regular reports and devoting more of their time to ensuring that the compliance program is effective,” Snell said. “Many compliance professionals now have the budget and the ability to contract for outside legal consulting services to assist them in their investigations. This is a significant change from 10 years ago, when there were many stories of compliance professionals who were asked to let some problems go.”

Compliance officers’ broadened role in organizations has meant greater reach into operational issues. For example, Snell said, compliance officers are more involved than in the past with contractual relations between physicians and other partners. Compliance officers also are involved in research and quality of care.

“Larger organizations have added compliance officers to cover subspecialty areas such as research,” he said. “Larger organizations that previously had one compliance officer for dozens of locations now have several compliance professionals.”

Also, unlike in compliance’s early years, organizations are less resistant today to compliance education, Snell said.

However, Snell said, “What has not seemed to change as much are the problems most resources are dedicated to fixing.” He added that compliance officers continue to cite many of the same day-to-day concerns now as they did 10 years ago.

Nahra noted that among areas that health care payers need to continue improvement is in stopping improper claims before they are paid, an undertaking in which CMS also is engaged.

“This is a difficult combination of adverse rules (such as prompt-pay laws that prevent effective investigations) and technology gaps, but the payment of improper claims is still a major economic drain on the health care system,” Nahra said.

‘Policy Fraud.’ The nature of compliance programs has changed, in part, in response to law enforcement trends. While the government and health care organizations have responded to outright fraud schemes that have developed in the past 10 years, attorneys also cite compliance challenges with what they call “policy fraud” or fraud based on technicalities.

“We have seen large-scale battles between health care providers and law enforcement on what I could call

policy fraud issues—areas where the fraud is not as clear cut or not as obviously wrong,” Nahra explained. “These situations may be illegal, and may cost the health care system millions or billions of dollars, but are not as obviously wrong in any absolute sense as submitting a claim for a service that was not provided.”

Attorney Thomas S. Crane, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo PC, Boston, agreed, saying that an enforcement trend in health care fraud cases has been the “scheme to defraud” theory in which the government cannot point to a specific regulation that was violated, but rather that an arrangement was a scheme to defraud Medicare.

For example, he said, in the lab cases that involved the bundling of tests onto pre-existing panels or profiles, “the government took issue with labs’ requisition forms even though there is no regulation that governs their content.”

In addition, Crane cited average wholesale price cases as those that rested on no regulatory violations but instead on the government’s theory that manufacturers illegally marketed the spread because doctors could buy drugs for less than the price at which the government reimbursed.

“On the compliance side, this is a huge challenge,” Crane said. “It has become essential in my practice to not only advise my clients what the Medicare rules are, but to think through how a proposed arrangement could be attacked as a scheme to defraud.”

Crane said the other significant change in the compliance advice he gives to clients is seeing provider clients becoming more cautious.

“It is often that, while they don’t scorn my creative thinking on how to accomplish their goals, they don’t want to take much risk,” he said. “At least for the past five years, one effect of the enforcement juggernaut is that many of my clients reject sensible business deals because I can’t give them the level of assurance they need that the proposed arrangement won’t end up being unwound in an expensive, debilitating investigation.”

Sarbanes-Oxley. In recent years, compliance programs also have been challenged with accountability standards set forth in the Sarbanes-Oxley Act of 2003.

Silverman said the law has, for the first time, made high-level executives in organizations, including health care companies, responsible for compliance as part of corporate culture. The new standards also have opened new doors for fraud enforcement, he added, meaning compliance departments have heightened responsibilities.

“All of these influences have brought greater accountability and transparency to all companies, including health care providers, and prospects for more fraud prosecutions,” Silverman said.

“The days are now past when prosecutors investigating fraud allegations will stop at lower level company employees,” he said. “New accountability, and poten-

FRAUD STATISTICS—HEALTH & HUMAN SERVICES¹

October 1, 1996—September 30, 2006
Civil Division, U.S. Department of Justice

FY	NEW MATTERS ²		SETTLEMENTS AND JUDGMENTS ³			TOTAL QUI TAM AND NON QUI TAM
	NON QUI TAM	QUI TAM	NON QUI TAM ³	QUI TAM		
			TOTAL	TOTAL	RELATOR SHARE ⁴	
1996	20	204	63,059,873	52,876,698	9,624,568	115,936,571
1997	49	298	354,371,325	565,978,803	56,744,071	920,350,128
1998	36	287	40,107,920	257,320,610	47,807,528	297,428,530
1999	29	310	38,000,792	404,488,079	45,415,582	442,488,871
2000	37	223	208,899,015	708,090,743	113,594,529	916,989,758
2001	36	180	435,849,179	855,576,637	144,208,957	1,291,425,816
2002	24	197	74,117,427	938,122,925	149,533,552	1,012,240,352
2003	26	217	536,834,879	1,299,636,860	279,722,852	1,836,471,739
2004	28	276	34,816,447	476,076,860	97,514,920	510,893,307
2005	34	268	204,821,548	915,787,965	123,452,837	1,120,609,513
2006	16	110	1,087,314,755	1,208,428,854	149,215,240	2,295,743,609

NOTES:

1. The information reported in this table covers matters in which the Department of Health and Human Services is the primary agency.
2. “New Matters” refers to newly received referrals and investigations, and newly filed *qui tam* actions.
3. Non *qui tam* settlements and judgments do not include matters delegated to United States Attorneys’ offices. The Civil Division maintains no data on such matters.
4. Relator share awards are calculated on the portion of the settlement or judgment attributable to the relator’s claims which may not be the entire settlement or judgment amount. Relator share awards do not include amounts recovered in subsection (h) or other personal claims. See 31 U.S.C. § 3730(h).

Source: U.S. Department of Justice

tial legal exposures, now rests with a company's senior management. These reforms have generated heightened expectations for compliance programs within a company."

To that end, he continued, companies can be sanctioned for failing to adequately establish and monitor compliance programs, further raising risk of exposure to criminal and civil penalties in cases of fraud.

Private Attorney Practices

In the last 10 years, health care attorneys in private practice have seen an increase in the use of the False Claims Act, in cases involving kickback issues, and in compliance plan involvement, AHLA's Daniels said.

Leibold said health care fraud issues may change slightly, but interest does not wane. He said that AHLA has placed great emphasis on providing more services to those who work in those life science areas and that "health care fraud is one of those issues that carried over into life sciences."

The AHLA practice group on health care fraud is the largest of AHLA's practice groups, with more than 2,000 members, Daniels said. "Health care fraud is probably the hottest topic year after year at our conferences and it maintains its importance," she said. Daniels added that the combination of AHLA's list serves on fraud, compliance, and the FCA includes roughly 5,500 members.

Daniels, an attorney with Calfee Halter & Griswold LLP, Cleveland, told BNA, "From AHLA's standpoint, health care fraud enforcement has never waned over the years, but instead it has grown. ... It never seems to lose its interest, the number of fraud investigations with DOJ, OIG, and states is still growing."

Daniels said that in the area of abuse, "several years ago DOJ and HHS used quality of care issues in fighting health care abuse and I don't think it has lightened up. Since using the FCA, there has been more emphasis on quality of care."

In addition, she said, with the expansion of FCA, many attorneys are now involved in litigation or settlements with the government.

"One thing we didn't see 10 years ago was the white collar criminal aspect of health care fraud, although I still think there is more involvement by our members in the civil area under the FCA," Daniels said. "Most types of subpoenas are civil, which is a good thing. Our members are giving good counsel to their clients in helping them avoid criminal prosecutions."

Criminal Prosecution Grows. Just because most health care fraud cases involve civil allegations does not mean criminal prosecution is on the wane.

Mahon said that over the last 10 years, the courts increasingly are imposing significant prison time on convicted health care fraud perpetrators.

A 22-year term given to the California Rolling Labs ringleader, Michael Smushkevich, in the early 1990s was an anomaly at the time, Mahon said. However, since the early part of the 21st century, individual providers have been sentenced to terms from seven to 30 years—and several more sentenced to life in federal prison, he said.

Nahra said when he started working in the health care fraud area almost 20 years ago, health care fraud was a little known topic and few people in the health

care industry were paying attention and even fewer in the law enforcement community cared about the problem.

"My work—unlike most people who are health care fraud lawyers—has focused on the payer side, representing health insurers and other payers in attempting to recover the proceeds of health care fraud and otherwise deal with the problems of health care fraud," Nahra said. "So, one of the biggest changes I have seen is that I no longer have to deal with the question, 'What is health care fraud?' or 'Is there really health care fraud?'"

There clearly is much more awareness—in law enforcement, the insurance industry, the provider community, legislators, customers, and others—of the existence of health care fraud and the general magnitude of the problem, Nahra said. The health insurers—Nahra's clients—also do not have to be persuaded that they need to have an organized, effective effort to fight health care fraud.

Enforcement 'Juggernaut.' Crane said the 10-year history includes a virtually new health care compliance industry—complete with compliance officers, codes of ethics, policies, and training. Also new are self-disclosure protocols and corporate integrity agreements.

"On the enforcement front, many years ago in a BNA special article, *Congress Strengthens Anti-Fraud and Abuse Juggernaut*, I labeled what we were seeing in the mid-1990s as the enforcement 'juggernaut,'" Crane said. "It still keeps coming and coming. We have seen prosecutors and qui tam plaintiffs sweep cyclically through the clinical lab industry, hospitals, pharmaceutical manufacturers, and now their focus is turning to medical device manufacturers."

The relationship between attorneys and compliance officers has improved greatly over the years, Daniels said. At first there was some apprehension, but now attorneys understand the role of corporate compliance officers. In fact, AHLA published with the OIG a public interest document for inhouse counselors and compliance officers, she said.

Resource Limits. Brennan said he practiced law in an 18-attorney health care boutique in 1997. Despite the limits of the firm's resources, he described the attorneys as smart, aggressive, and, as with any small firm, quite flexible.

"We handled all kinds of fraud and abuse matters that year—from a federal criminal/civil kickback investigation of a large multiple site, national health care company to a simple false claims case involving a local neurologist and his 'creative' bookkeeper spouse," Brennan said. "We dealt with criminal investigations, civil lawsuits, and administrative exclusions. We did it all, and with good success."

If that boutique law firm existed today, he said, "the local neurologist would remain well-served by that knowledgeable, efficient group; the large national company, however, most likely would not. ... This has nothing to do with the skills and talents of the lawyers involved, but is more a commentary on the evolution of health care fraud defense work."

Today, Brennan said he practices in a 350-attorney, international law firm where the health care group alone is double the size of the old boutique, and where his group's numbers are augmented by the firm's False

Claims litigators, the white collar defense group, and reimbursement experts.

His decision to change practice venues, he said, reflected an individual choice regarding the nature and complexity of the health care fraud cases, which parallels some disturbing trends in the prosecution of health care fraud, and how the defense of those cases has evolved as a result.

Fraud Cases More Prevalent, Dangerous. Health care fraud cases have become far more prevalent and far more dangerous to his firm's clients. "Yesterday's overpayment mistake is today's false claim treble damage risk," Brennan said.

The theories of liability occupy a far broader sweep and are far more creative and complex, Brennan said. The government's prosecutorial weapons are more sophisticated and coordinated, well-publicized settlements have emboldened (and even helped fund) prosecutorial initiatives, and the attitude of government adversaries is generally tougher—sometimes, in some situations, even arrogant, he said.

As a result, defense attorneys must engage far more often in pitched battles from the first minutes of a fraud investigation (although most cases still settle), Brennan said. Even getting to settlement, though, has become far "more vexatious and expensive" for his clients, requiring more legal expertise and "negotiation sophistication," more investigatory manpower, and, more frequently, the involvement of multiple legal specialties and outside consultants in the process, he added.

Brennan found that clients facing this new, "no holds barred" world of health care fraud prosecutions often come to his office in one of two very distinct situations. First, he said, there are those (usually publicly traded corporate) clients who are able to tough it out at least for a time, bear the enormous costs of investigation and negotiation, and thus achieve a "fairer" settlement.

More often than not, the large, faceless national company will "throw money at the problem" and pay millions of dollars—sometimes hundreds of millions of dollars—in settlement (often seeing its stock bounce positively when it does so). No one gets hurt personally, and the company survives, Brennan said.

The second group are those less fortunate clients, such as the local neurologist, who simply cannot afford to mount that type of defense. Brennan said those are the clients whose fate often are at the mercy of the "discretion" employed by the aggressive prosecutor.

Despite far less significant financial transgressions, the solo physician, unable to fight a fair fight, runs the very real risk of having his world turned upside down, Brennan said. He (or she) and the family often will face unaffordable double or treble damage settlement resolutions, frequently coupled with the professional death knell of program exclusion, he said.

"And so the world of health care fraud defense continues to turn, as it becomes more challenging to those who practice in this complex area, and as it poses greater dangers to those clients whom we serve," Brennan said. "The 'rules' we have come to live by are all

Significant Health Care Fraud Events 1997-2007

1997: Federal funding mechanism in HIPAA takes effect for DOJ/OIG; OIG issues first Advisory Opinion; CMS sets up its Medicare Integrity Program

1998: DOJ distributes guidelines to state and federal prosecutors instructing them how to share health care fraud investigation information with private insurers; OIG unveils new voluntary disclosure program

1999: OIG issues a "Special Advisory Bulletin" declaring that gainsharing arrangements between hospitals and physicians are illegal and telling hospitals to "expeditiously terminate" such programs; HCFA/DOJ develop guidelines for referring nursing home cases

2000: Fresenius Medical Care North America agrees to \$486 million in criminal and civil penalties to resolve allegations of health care fraud by three subsidiaries of its kidney dialysis business, National Medical Care Inc.

2001: HHS IG June Gibbs Brown resigns; the Health Care Financing Administration changes its name to the Centers for Medicare & Medicaid Services; landmark \$875 million settlement reached with TAP Pharmaceutical Products Inc.; Janet Rehnquist confirmed as HHS IG

2002: OIG issues compliance program guidance for pharmaceutical manufacturers; HHS Secretary Tommy Thompson unveils CMS nationwide nursing home quality initiative; Stark Phase I rules take effect

2003: Rehnquist resigns as HHS IG, Dara Corrigan named acting principal deputy IG; the Medicare Prescription Drug, Modernization and Improvement Act is passed, creating a Part D drug benefit and re-naming the Medicare+Choice program to Medicare Advantage; Columbia/HCA enters \$1.7 billion settlement, involved allegations of Medicare cost report fraud and payment of kickbacks to physicians

2004: Dara Corrigan leaves the post of acting principal deputy IG for private law practice; Daniel R. Levinson is nominated for IG position; Stark Phase II interim final rule published

2005: Deficit Reduction Act of 2005 signed into law, creating new fraud fighting obligations for the HHS OIG and a Medicaid Integrity Program, and encourages states to enact state-based false claims laws at least as effective as the federal False Claims Act. Levinson confirmed as new IG

2006: Schering-Plough Corp. and its subsidiary Schering Sales Corp. agree to pay \$435 million to resolve criminal charges and civil liabilities related to illegal sales and marketing of the drugs Temodar and Intron A, and to Medicaid best price violations involving Claritin RediTabs; CMS issues Part D fraud, waste, and abuse guidance

2007: U.S. Supreme Court expected to decide False Claims Act case, involving eligibility as an "original source" (*Rockwell International Corp. v. United States*, U.S., No. 05-1272, oral argument 12/5/06).

very hard to explain to those who do not toil in this particular vineyard.”

Old Days: Making Case Law. Snyder said her first health care false claims case in the early 90s involved Medicare.

“We were defending an insurance company on the issue of processing Medicare Secondary Payer claims,” Snyder said. “Each issue I addressed was novel. There was very little case law. Indeed, we made case law on the issue of public disclosures.”

During the early years, most of the company targeted cases were civil in nature, and the assistant U.S. attorneys needed some education about the regulatory issues in the particular health care case, Snyder said. For many, it was their introduction to Medicare and Medicaid issues.

For manufacturers, in particular, the last 10 years have been the hardest, Snyder said. The OIG’s initial pronouncement years ago about the extent to which exclusion would not be enforced against an indirect provider may have made that industry less focused on the wave of FCA cases hitting the rest of the health care industry.

However, with a change in the OIG’s posture, the 1990 Medicaid Drug Rebate and related price reporting obligations directly with CMS, the FCA tidal wave has hit the manufacturers particularly hard, Snyder said. The next 10 years should be even more challenging to all sectors of the health care industry, she predicted.

The infrastructure for extensive federal (and even some state) FCA enforcement is in place, but the infrastructure for compliance also is in place—especially in those companies that have lived under a CIA or currently live under a CIA, Snyder said. Health care companies are spending significant time and resources to minimize the risks of noncompliance and to conduct appropriate self-policing.

The issue becomes whether the government will take different policy positions going forward, Snyder said.

“Will there be tangible rewards for voluntary disclosures?” she asked. “Will the government not intervene in some of the more esoteric false claims allegations coming from the whistleblowers and their bar? Will the government decline a case where the government sees that there is compliance but where there may have been errors or a failure of the whistleblower to utilize the company’s compliance program before proceeding with the litigation? Only time will tell.”

Medical Necessity, Intensity of Cases Grows. Commenting on enforcement over the past 10 years, Francis J. Serbaroli, with Cadwalader, Wickersham & Taft LLP, New York, commented that 10 years ago, the OIG and DOJ were pursuing what would become a \$1.7 billion case against Columbia/HCA, and multiple fraud cases against large clinical laboratory companies.

“What lies ahead? Apparently, much more, given the federal government’s estimate that fraud and abuse accounts for up to 10 percent of all health care expenditures in the United States,” Serbaroli said. “Congress is pressuring states and offering them significant federal dollars and other incentives to enact whistleblower laws and expand their fraud-fighting capabilities.”

Meanwhile, Congress, DOJ, and OIG are assessing the potential for fraud in the new Medicare Part D entitlement, Serbaroli said. The federal government continues its highly lucrative anti-fraud campaign against

pharmaceutical and medical equipment companies, he said.

Hospitals continue to be a dependable source of Medicare fraud recoveries, Serbaroli said. Nursing homes, which account for a sizable portion of Medicare and Medicaid expenditures, also are feeling the pressure of increased scrutiny. More cases are being brought against a variety of providers alleging that charges and payments for substandard care amount to fraud, he said.

Previously, many health insurers devoted few resources to fighting fraudulent claims. Now, however, they have become more aggressive in their claims review and in their fraud prevention efforts, Serbaroli said.

In addition to investigating the medical necessity of services and determining whether the services were provided, insurers have begun looking “behind the curtain” to determine whether providers’ operations are structured properly from a legal perspective (i.e., compliant with licensing requirements, corporate practice and fee-splitting prohibitions, anti-referral and anti-kickback statutes, etc.), he said.

Serbaroli said his law firm has been handling more investigations of all kinds of industry players by both the federal and state governments—far more than 10 years ago. The varieties of matters under investigation, and the dollars at stake, and the pressures from prosecutors are much greater than those faced by the defense industry many years ago, he added.

“Moreover, whistleblower [law]suits under the False Claims Act are proliferating, thereby forcing DOJ to keep them under seal for a longer period of time pending a review and decision on whether or not to intervene,” Serbaroli said. “Over the next decade, we foresee significant growth in this area.”

From Relative Obscurity to Front Lines. McElroy said that the past decade has seen awareness of health care fraud and abuse issues move from relative obscurity to the front line for many health care providers and their attorneys.

In the latter part of 1996, DOJ and state Medicaid Fraud Units were establishing new protocols for working in tandem in the government’s first industry-wide enforcement initiative against clinical laboratory providers, casually referred to as “Labscam,” McElroy said.

The first industry-wide corporate integrity agreement for the Labscam settlements was being rolled out, and the plaintiff’s bar was awakening to the potential profitability of filing private-sector class actions on the coattails of the clinical lab settlements, she said.

“The enforcement initiative against pharmaceutical marketing was barely conceived and I would be surprised if one in 10 health care lawyers could have told a BNA reporter what ‘AWP’ meant,” McElroy said. “In hindsight, I attribute much of the development of health care enforcement on the prosecutorial side to the result of the Health Insurance Portability and Accountability Act of 1996.”

HIPAA’s most significant impact is the large number of sharp prosecutorial arrows that were added to the government’s quiver, McElroy said, including the right to prosecute private health care fraud, injunctive asset seizures and forfeiture, additional civil monetary and exclusionary penalties and—perhaps most

importantly—the earmarking of funding for health care enforcement agents, prosecutors, and grants to investigate and prosecute fraud in the previous decade.