

Feature

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Fraud in the American Health Care System Takes on Many Forms

An Insider's View of How Violations are Uncovered and What Happens as a Result

The number of schemes to defraud health care insurance are as varied as the services and care providers in the health care field. The opportunities to defraud the system are numerous. As a public service, the Inspector General of HHS publishes a semi-annual report. This report is available online at www.oig.hhs.gov and provides information about recent findings in audits by the Office of Audit Services (OAS), reports of inspections, short-term studies and evaluations conducted by the HHS, Inspector General's Office of Evaluation and Inspection (OEI). Also disclosed are the outcomes of recent concluded investigations, prosecutions, and settlements by the Office of Investigations, the U.S. attorney, and the OCIG.

In addition, the Inspector General publishes the OIG annual work plan, which sets forth the focus of the year in working to identify potential fraud or its intent to review certain areas. For example, the plan lists the focus on elements of Medicare hospitals, Medicare home health, Medicare nursing homes, Medicare physician and other health professionals, Medicare managed care, laboratory services, medical equipment and supplies, Medicare drug reimbursement, end stage renal disease, Medicaid/State Children's Health Insurance Program, Medicare contractor operations. This document is available to providers, health care insurers, and other interested parties.

A Semi-annual Report is provided to congress and highlights the reports, audits and criminal and civil actions concluded in the previous six months. These are easily found at the OIFG website at www.oig.hhs.gov.

A major concern has been fraud schemes by pharmaceutical manufacturers and distributors. In the past two years, investigations and prosecutions have led to the recovery of more than \$2 billion.

Anatomy of a Case

Cases involving fraud against Medicaid or Medicare are complex and time consuming. Until recently, records were kept in disparate electronic file format. The reconstruction of documents takes time and energy. Interviews, subpoenas, and grand jury appearances are techniques used by investigators to attempt to understand if any criminal act has taken place. There are cases that are brought to the attention of authorities allowing for the introduction of consensual monitoring to obtain further evidence.

In some circumstances, search warrants are obtained from state or federal courts to obtain documentary evidence, including files, notations, schedule books, or computer files. Many practices or institutions are maintaining files in digital format. More often, laptop computers, servers, or desktop computers are seized or imaged using court authority to obtain important evidence.

How Violations Are Uncovered

Hotline

At HHS-IG headquarters, a hotline was created to allow for reporting of potential fraud, waste, or abuse of departmental funds. The hotline is staffed with personnel to accept complaints and to forward the information to the appropriate IG regional office.

Additionally, each carrier has established a toll-free number for beneficiaries to call with questions about billing and to report potential overbilling or potential fraud. The Centers for Medicare and Medicaid Service (CMS) has also set up a hotline to allow for beneficiaries or other concerned individuals to lodge complaints about quality of care, overbilling, services not rendered, or other Medicare-related issues. These calls are logged and researched and sent forward to contractors or to local OIG/investigations offices for review and consideration.

Employee/Former Employee Complaints

Another source of referrals is from disgruntled, dissatisfied, or uncomfortable employees, or an employee that feels obligated to report potential fraud, waste, or abuse. These individuals generally contact the fiscal intermediary or hotline to discuss their concerns or lodge their complaint. These complaints are immediately referred directly to the local office of the HHS Inspector General's Office of Investigations. Generally, the employee will be contacted to better understand the complaint.

Beneficiary/Family Complaints

Often, patient beneficiaries or their family members review the explanation of medical benefits (EOMB). They find entries that do not seem appropriate and question the charges. If they do not receive satisfactory answers, they can call the hotline and report what they feel may be fraud. This information is reviewed, and the provider billing patterns are reviewed to look for anomalies. In many circumstances, a provider is contacted and provided guidance and education to correct the problem. The Medicare contractor can administratively recover any improper payments.

Medicare Modernization Act

The Medicare Modernization Act (MMA) was recently passed by Congress after much debate. The Prescription Drug Benefit (PDB) was originally touted as an important benefit for senior citizens. However, after scrutiny, the benefit is being looked at with suspicion. Dozens of companies competed for an opportunity to be granted status to provide PDB cards to eligible seniors. In the opening stages, there were countless complaints about unscrupulous vendors attempting to lure senior citizens to buy drug cards for companies that did not exist.

The Medicare Modernization Act will infuse additional funds with additional coverage that is scheduled to occur in 2006. In a CMS estimate, published in February 2005, the Prescription Drug Benefit (Medicare-Part D) is believed to add a cost of \$37.4 billion in the inaugural year. In CBO and CMS documents, it has been estimated that the additional services and coverage will cost taxpayers upwards of \$394-505 billion over the next ten years.

Anti-Kickback Statute/Stark Violations

A concern in the Medicare and Medicaid programs are conflict of interest issues, referred to as Stark violations. These are violations where doctors or other practitioners provide or are provided kickbacks for business or referrals.

A Stark violation occurs when you refer a Medicare or Medicaid patient to a health care entity in which you or a family member has a financial interest. Financial interest includes ownership as well as direct or indirect compensation arrangements. A violation can exist only if no exception applies. The exceptions are extremely important.

The categories of designated health services for these referrals include clinical laboratory services; physical and occupational therapy and speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parental and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.

The regulations use common procedure terminology (CPT) and the healthcare common procedure coding system (HCPCS) to specify the DHS in the first four categories. The list of codes is updated annually to coincide with publication of the physician Medicare fee schedule. The complete list of codes is available in the *Federal Register*.¹

False Claims Act

A modern version of an old federal law is often used to recover payments made to entities or individual providers under false pretenses. The False Claims Act imposes civil liability on any person or entity that submits a false or fraudulent claim for payment to the U.S. Government. The False Claims Act prohibits:

- Making a false record or statement to get a false or fraudulent claim paid by the government
- Conspiring to have a false or fraudulent claim paid by the government
- Withholding property of the government with the intent to defraud the government or to willfully conceal it from the government
- Making or delivering a receipt for the government's property which is false or fraudulent
- Making a false statement to avoid or deceive an obligation to pay money or property to the government

It is also improper to cause someone else to submit a false claim. For example, if a subcontractor provides false information to a contractor, who in turn bills the government based on that false information, the subcontractor is liable for causing the submission of a false claim.

Under the False Claims Act, a person who violates the Act may be held to repay up to three times the amount of damages suffered by the government plus a mandatory civil penalty of at least \$5,500 and no more than \$11,000 per claim, for all claims made after September 29, 1999.²

Pharmaceutical Fraud Schemes

Over the past five years, the U.S. Department of Justice has taken an aggressive posture in prosecuting pharmaceutical manufacturers that have been found to use unethical and illegal marketing and other schemes to gain market share with prescription drugs. This posture has returned over \$2 billion dollars to the Medicare trust fund over the past two years.

The schemes include off label marketing of drugs for unapproved uses, kickbacks to providers to induce a referral or a reward for past referrals, false reporting under the Medicaid drug rebate law, and provision of off invoice discounts in violation of Medicaid drug rebate laws.

In Boston, the District of Massachusetts had great success in bringing civil and criminal action against TAP Pharmaceuticals and Bayer. The TAP investigation centered on the sales and marketing practices to urologists. In order to gain market share, TAP representatives offered inducements to change to their prostate cancer drug. These included unrestricted educational grants, trips, free samples, televisions, and computers.

In addition to action against the corporation, several high-ranking corporate executives and sales personnel were charged and convicted to criminal violations. Several urologists were convicted of fraud, and dozens more physicians were fined under the civil monetary penalty laws for their part in charging the Medicare program for Lupron doses that were provided for free.

That amount is for filing false and fraudulent claims with Medicare and Medicaid as a result of fraudulent drug pricing schemes and sales and marketing misconduct. Senator Chuck Grassley is the co-author of the 1986 amendments to the False Claims Act. Those amendments strengthened the Act's *qui tam*, or whistleblower, provisions and gave federal prosecutors one of their most effective tools against defrauding the government.

Sen. Grassley made the following comment on the settlement of the TAP case:

Medicare and Medicaid are public programs. Every tax dollar that goes to fraud robs taxpayers and doesn't help a sick patient. I'm glad the False Claims Act was there when prosecutors needed it. If not for that law, this case might never have surfaced. The False Claims Act helps whistleblowers drive bad actors from the shadows into the light of day.³

In Maine, nearly two dozen were arrested and convicted for their roles in bilking Medicaid for countless prescriptions of the dangerous drug Oxycontin. In several instances, individuals obtained Medicare cards, under fraudulent means, and through "doctor shopping" obtained stockpiles of Oxycontin, in some cases paying only \$0.50 for a copayment to receive 30 to 60 day supplies. These drugs were then abused or sold to support substance abuse habits.

Other issues that have been investigated include the misbranding and/or mislabeling of drugs, provision of samples that were later billed, off-label usage, and Prescription Drug Marketing Act violations.

These cases surrounded the marketing approaches of certain manufacturers in providing medical practitioners free drug samples, which were then billed to Medicare and Medicaid. Another issue that was uncovered was a scheme to avoid payment of Medicaid drug rebates to states.

The fraud uncovered relating to pharmaceutical fraud led to the pharmaceutical industry proposing and adopting voluntary compliance guidelines on sales and marketing practices to medical professionals.

Counterfeit Drugs Infiltrate System

Over the past 15 years, there has been a proliferation of counterfeit pharmaceuticals that have entered the health care channels. *Business Week* published a story in 2001 that cited 8 percent of bulk drugs imported into the United States were counterfeit, unapproved, or substandard.⁴ The article cited that these counterfeits were originating from Nigeria, India, Pakistan, and other Asian countries. This has been of great concern to HHS' Food and Drug Administration—Office of Criminal Investigations.

The common violations include look-alike drugs that have little or no active ingredient, rejected lots due to purity or potency concerns, and expired lots — relabeled and repackaged to show a current expiration date. Another concern is for formulations that are manufactured without quality control and are sub-potent, super-potent, or without the active ingredient.

For example, Nutropin, a growth hormone for children, was found to contain insulin. In another matter, contraceptive patches were found to have no active ingredient whatsoever. Counterfeit drug investigations are on the rise, and the proliferation of online, foreign suppliers are of great concern because of the lack of quality control.⁵

Exclusion

An important action that can be taken by HHS is exclusion of a provider from billing federal insurance programs or serving in any institution or practice that receives federal funds. Based upon a health care conviction, a process can be initiated to exclude the offending individual from participating in the Medicare and Medicaid repayment program. However, this action does not bar a person from getting medical care under such programs.

The OIG, under Congressional mandate, established a program to exclude individuals and entities affected by these various legal authorities, contained in sections 1128 and 1156 of the Social Security Act. The OIG also maintains a database of all currently excluded parties called the list of excluded individuals/entities, which is located at www.oig.hhs.gov.

The basis for exclusion includes convictions for program-related fraud and patient abuse, licensing board actions, and default on health education assistance loans. The effect of an exclusion (not being able to participate) is that no payment will be made by any federal health care program for any items or services furnished, ordered, or prescribed by an excluded individual or entity. Federal health care programs include Medicare, Medicaid, and all other plans and programs that provide health benefits funded directly or indirectly by the United States (other than the federal employees health benefits plan).

No program payment will be made for anything that an excluded person furnishes, orders, or prescribes. This payment prohibition applies to the excluded person, anyone who employs or contracts with the excluded person, any hospital or other provider where the excluded person provides services, and anyone else. The exclusion applies regardless of who submits the claims and applies to all administrative and management services furnished by the excluded person.

Corporate Integrity Agreements

The OIG often negotiates compliance obligations with health care providers and other entities as part of the settlement of federal health care program investigations arising under a variety of civil false claims statutes. A provider or entity consents to these obligations as part of the civil settlement and in exchange for the OIG's agreement not to seek an exclusion of that health care provider or entity from participation in Medicare, Medicaid, and other federal health care programs.

False claims submitted in violation of the False Claims Act or Civil Monetary Penalties Law give rise to the OIG's permissive exclusion authority under 42 U.S.C.1320a-7(b)(7). Providers who settle these cases often deny that they were liable or that they committed the alleged conduct.

The typical term of a comprehensive corporate integrity agreement (CIA) is five years (three years for national project cases). These compliance measures seek to ensure the integrity of federal health care

program claims submitted by the provider. The more comprehensive integrity agreements include requirements to hire a compliance officer/appoint a compliance committee; develop written standards and policies; implement a comprehensive employee training program; review claims submitted to federal health care programs; establish a confidential disclosure program; restrict employment of ineligible persons; and submit regular reports to the OIG.

While many CIAs have common elements, each agreement addresses, in part, the specific facts of the conduct at issue and is tailored to comport with the existing capabilities of the provider. The integrity agreements often attempt to accommodate and recognize many of the elements of pre-existing voluntary compliance programs.⁶

Grant Fraud

HHS provides funding for medical research through department components, including the National Institutes of Health, Public Health Service. In addition, funding is provided for medical training for residency programs and through the Health Education Assistance Loans (HEAL).

HHS dispenses grants to medical teaching hospitals and other grants to provide services. With an annual budget of more than \$27 billion, NIH provided grants for HIV/AIDS research, heart and lung research, and cancer research.

The NIH is made up of dozens of Institutes including the National Cancer Institute, National Institute on Drug Abuse, National Institute of Biomedical Imaging and Bioengineering, National Eye Institute, National Institute of Mental Health, to name a few. Other grants are focused on medical training and medical research. For example, NIH awarded \$2.77 billion in contracts to universities, hospitals, state and local government agencies, non-profit and commercial organizations, in fiscal year 2001.⁷

Transportation Fraud

In many situations, patients need to receive ambulance services. However, there have been many unscrupulous ambulance services that have billed Medicare illegally. In a recent case, American Medical Response (AMR) was charged and entered into a settlement agreement for \$20 million dollars with the Department U.S. Attorney's Office in Boston.

In other instances, ambulance companies have "up coded" in order to bill more money for services. There have been cases where ambulance services have transported patients, using basic life support (BLS) or advanced life support (ALS) rigs, that are ambulatory (can walk) and charge the full fee for medical transport. This is generally allowed with a wheel chair car. Companies have been able to bill upwards of \$7 million dollars for less than a dozen patients being transported for dialysis over a year period.

In another scheme, a Maine ambulance company used ALS and BLS trucks to transport elderly to a shelter after a serious ice storm. The company billed Medicare for a full \$450 medical ride, rather than a \$50 charge for medical transport in a wheel chair car. The owner of the company was found guilty and found to have altered trip tickets to show a medically necessary transport ride rather than a wheel car ride.

Provider Fraud

While the great majority of medical providers are responsible, caring practitioners, there are some that take advantage and violate the faith and trust of their profession. Many cases have been investigated that have caused doctors, dentists, podiatrists, nurse practitioners, physical therapists to be convicted and excluded from future medical practice.

For example, an ear, nose, and throat physician steered most patients to nasal surgery, later found to be unnecessary. An ophthalmologist continued to treat patients and bill Medicare long after his license had been suspended. A pharmacy director was employed for nearly 20 years while not holding a license from the state. It was found that during that period the pharmacy director would provide false documents relating to the licensure and had been dispensing without a license. The employing hospital never checked the authenticity of the licensing documents with the state.

Successes over the Years

From 1999 to 2002, more than 3,600 civil actions were successful. In this same period, there were more than 19,000 exclusions. HHS has been involved in more than 1,300 *qui tam* investigations over the past five years. In the most recent HHS-OIG Semi-annual report, HHS reported the successful conclusion of 258 criminal convictions, 105 federal civil actions and 1,695 exclusions from the federal healthcare program.

Qui Tams

There is a mechanism for a whistleblower to file suit if he or she has information that fraud, waste, or abuse has occurred. In order to allow for knowledgeable parties to provide information to authorities, the *qui tam* is often filed with federal or state authorities. The whistleblower statute gives protection to the filers of *qui tams*. Generally, whistleblowers seek representation from lawyers.

The False Claims Act allows an individual, often referred to as a whistleblower, who knows about a person or entity who is submitting false claims to bring a suit, on behalf of the government, and to share in the damages recovered as a result of the suit. The whistleblower that brings the case is called a *qui tam* relator. In the past 13 years, hundreds of *qui tam* suits have been filed. These suits have resulted in almost four billion dollars in recoveries for the United States Treasury. The whistleblowers that filed these suits have received more than one hundred million dollars for their efforts.⁸

Qui tams are a growing source of investigative referrals. Anyone can file a *qui tam* through a court, but generally a relator or whistleblower seeks the assistance of a lawyer to represent his or her interests. Black's Law Dictionary defines a *qui tam* action as "an action brought by an informer, under a statute which establishes a penalty for the commission or omission of a certain act," and provides that if any money is recovered in a civil action, part of the penalty may go to any person who will bring such action and the remainder to the state or some other institution.

Qui tam is a provision of the federal Civil False Claims Act that allows private citizens to file a lawsuit in the name of the U.S. government charging fraud by government contractors and others who receive or use government funds, and share in any money recovered. This unique law was enacted by Congress in order to effectively identify and prosecute government procurement and program fraud and recover revenue lost as a result of the fraud.

In 1986, the U.S. Congress amended the *qui tam* provisions of the U.S. False Claims Act in a way to make it more probable that a private citizen could file and win a *qui tam* suit. This move to amend the complaint was driven by the proliferation of news stories of companies defrauding the federal government, especially in the area of national defense. Some of the improvements included the trebling of damages, expanding the role of the *qui tam* relator, guaranteeing the relator a set percentage of the money that the government recovers, and the whistleblower protection clause.

By trebling (tripling) the damages of the amount of fraud discovered, the *qui tam* relator was in a better position to convince others, especially attorneys, that it was worth the costs involved to bring a suit. One million dollars of fraud discovered could mean three million dollars back to the U.S. Treasury and a higher percentage of money to the relator. The trebling of damages also encourages companies who have defrauded the government to settle the case rather than to risk the trebling of damages found by a jury.

The role of the *qui tam* relator was expanded by the 1986 amendment because, before, the relator did not have the right to play a role once the government intervened in the case. Although the government has the primary role if it intervenes in the case, the relator "shall have the right to continue as a party to the action." This clause gives you and your attorney the right to watch the Justice Department's handling of the case before settlement and allows you to go to the judge if you believe that the case is not being handled well or not in your best interests.

Before the 1986 amendment, the court could arbitrarily set the percentage of award for the *qui tam* relator. The 1986 amendment guaranteed a minimum of 15 percent of the recovery and a maximum of 30 percent. That was another help for the relator in finding an attorney willing to commit the time and money into a case.

The whistleblower protection clause is one of the strongest protection clauses in federal law. It not only protects the relator but anyone who investigates, initiates, testifies in furtherance of, or assists in a case. In Section 3730(h), whistleblowers that have proven harassment are entitled to "all necessary relief necessary to make the employee whole" including "reinstatement with the same seniority status... two times the

amount of back pay, interest on any back pay, and compensation for any special damages." This clause not only helps the relator keep his or her job if he or she is still employed while the case is proceeding but also makes a company think twice about harassing any employees who cooperate with exposing the fraud. Unfortunately, this clause does not help subcontractors and independent contractors who want to cooperate with the investigation.

The effect of the 1986 amendment has dramatically changed the way that attorneys view whistleblowers. Before the False Claims Act was amended, attorneys had very little financial incentive to help whistleblowers, and most legal help for whistleblowers consisted of attorneys helping whistleblowers protect their rights *pro bono* (for free) or through long, painful, and personal wrongful discharge suits. The amended *qui tam* provisions changed that by showing attorneys that they could share in the recovery as a reward for fronting costs and taking risks on potentially complicated litigation.

The good news is that whistleblowers' complaints are now seen as valuable to both the government and the attorneys. The bad news is that, as in any profession, there are attorneys that are willing to take unfair advantage of the whistleblower, and the whistleblower must be careful to make informed decisions about obtaining legal help.

The *qui tam* provision has had the effect of privatizing government legal remedies by allowing private citizens to act as "private attorneys general" in the effort to prosecute government procurement and program fraud. Although most of the early successes in *qui tam* actions have been against defense contractors, more and more actions are being filed that involve other governmental agencies such as HHS, EPA, DOE, DOEd, NASA, USDA, and DOT. Successful recoveries for a *qui tam* case, to date, have been as high as \$125 to \$150 million.⁹

Access to Information

Information is freely available by accessing the Internet. There are a number of different reports available for download by visiting www.oig.hhs.gov. There is substantial information relating to investigative and administrative action taken in the semi-annual report to Congress, as well as federal regulation notices, hearings testimony, reports, and publications.

Conclusion

The issues that arise with health care fraud are tremendous. The losses of taxpayer dollars are difficult to quantify. As the aging population in America grows, the call for services will increase, and the expenditures will rise rapidly. The pharmaceutical drug benefit will add additional opportunities to defraud and deplete Medicare resources.

CMS is in the process of awarding contracts for the development of fraud units to detect and refer cases for administrative or criminal action. The Medicare Drug Integrity Contractors, termed MEDIC's, will have primary responsibility for Program Integrity.

Since the announced roll-out of the Prescription Drug Program, there have been unscrupulous vendors attempting to enroll seniors into bogus prescription card programs. Law enforcement has remained busy responding to complaints of beneficiaries. The drug benefit is believed to unleash a number of fraud schemes that will defraud Medicare of millions of dollars.

Medicare and Medicaid fraud schemes are numerous. There are a number of unscrupulous consultants and billing companies that offer to increase or enhance the Medicare revenues. These entities conduct training and educational seminars intended to advise practices how to maximize reimbursements.

The "pay and chase" cycle has been perpetuated, when unscrupulous fraud schemers set up a lab or clinic, obtain a provider number and patient billing numbers and set to charge for a short period, receive payment and pull up stakes on the clinic, very often moving to another locale for another round of health care fraud.

As soon as attention is paid to one scheme, those keen on defrauding the government change their schemes until it is detected. This "cat and mouse" game requires constant review and utilization surveillance. The Program Safeguard Contractor, in conjunction with the HHS-Office of Investigations and the FBI respond to the countless complaints to assess those most egregious and commence investigations, generally in conjunction with the local Office of the United States Attorney.

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The article was drawn from many sources and constitutes an overview of the state of health care fraud in the United States. It is not meant to be all-inclusive. Sources have been incorporated into the paper that include information from the public domain, generally from the U.S. Department of Health and Human Services, and other available and cited sources.

Footnotes:

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****As a sidebar, please list the following.****

For additional information about health care fraud in the United States, please refer to the column titled "Fraud and Abuse."