## CRS Report for Congress

# Health Care Fraud: A Brief Summary of Law and Federal Anti-Fraud Activities

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#### Summary

Health care fraud and abuse commonly involve inappropriate billing for medical services and can encompass a variety of activities, such as overcharging, double billing, and charging for services not rendered. Estimates of health care fraud and abuse by the General Accounting Office (GAO) and others range from 5-10% of total health expenditures under both public programs and private insurance plans.

In recent years, the Congress, the Administration, and others have become increasingly concerned about the nature and extent of health care fraud particularly in the Medicare and Medicaid programs. The Department of Health and Human Services (HHS) and GAO have conducted a series of studies, audits, and related reviews which have both documented the pervasive nature of fraudulent and abusive actions in federal health care programs as well as outlining steps needed to combat these activities. Both the Office of the Inspector General (OIG) in HHS and the Department of Justice are devoting increasing resources to identifying and sanctioning program violators and have undertaken initiatives to combat fraud.

Congressional interest in combating fraud is not new. Since 1972, there have been a number of revisions to federal statutes which have been designed to strengthen the ability to identify and prosecute fraudulent providers. Most recently, the Congress significantly strengthened the federal role as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Balanced Budget Act of 1997 (BBA 1997). Federal penalties for fraudulent activities in health care include civil and criminal penalties as well as permissive and mandatory exclusions from federal health care programs. Medicare and Medicaid program-related anti-fraud provisions are generally found in Title XI of the Social Security Act. These provisions are reinforced by generic fraud provisions found elsewhere in federal statutes, including federal health care fraud criminal statutes in Title 18 of the United States Code.

The civil monetary penalties under the Medicare and Medicaid programs have recently been made applicable to similar violations in most other health care programs funded by the federal government. Federal criminal prosecutions for health care fraud and abuse include program-related felony and misdemeanor offenses, as well as the new federal health care crimes recently added to Title 18 of the United States Code which apply to violations in both public and private health care benefit programs. Mandatory and permissive exclusions of individuals and entities from participation in the Medicare and Medicaid programs may be imposed by the Secretary of HHS for a number of offenses and activities detrimental to these programs. In addition, under the recently added "three strikes and you're out" provision, a provider is excluded from federal health care programs for a second fraud-related offense, and permanently excluded from federal health care programs for a third offense.

It is anticipated that Congress will continue to monitor the success of the Administration's anti-fraud activities including increased responsibilities authorized by HIPAA as well as implementation of the tightened sanctions provisions.

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## Health Care Fraud: A Brief Summary of Law and Federal Anti-Fraud Activities

#### **Background**

#### What is Fraud?

Fraud and abuse commonly involve improper billing practices by health care providers and consumers, although consumer based fraud is not as common according to prosecution data. Examples include double billing, charging for services not rendered, billing for services not medically necessary, upcoding (billing for a more complex service than was actually performed) and unbundling (billing separately for services or equipment included in a global rate). These activities increase the amounts patients, employers and insurers pay for health care. Other activities are also considered fraudulent such as physicians or other health practitioners giving or receiving kickbacks for patient referrals or for prescribing certain items or services. 

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Health care *fraud* has been described as an intentional attempt to wrongfully collect money relating to medical services, while *abuse* has been described as actions which are inconsistent with acceptable business and medical practices. Charges of abuse customarily lead to civil suits, while accusations of fraud can result in either civil or criminal action. Some have suggested that the health system's moves to managed care arrangements will reduce the incentives and opportunities to commit fraud that exist under a fee-for-service system. However, other observers have suggested that while the types of fraudulent activities may change, substantial opportunities for fraud will still exist.

#### **Extent of Fraud**

Health care fraud is an expanding problem in the nation's health care system. In the past, fraud generally involved discrete acts on the part of single health care providers or consumers attempting to defraud the insurance industry. Over time, the schemes have become increasingly complex, frequently involving networks of people, sophisticated computer techniques and multiple geographic locations. The schemes generally involve multiple payers, including both private insurers and public programs such as Medicare and Medicaid.

<sup>&</sup>lt;sup>1</sup>A related issue involves "physician self-referrals" where patients are referred to medical facilities in which the physician has financial interests, thereby allowing the physician to profit from the referral. See U.S. Library of Congress. Congressional Research Service. *Health Care: Physician Self-Referrals*, "Stark I and II". CRS Report 97-5, by Jennifer O'Sullivan. (Hereafter cited as Congressional Research Service, *Health Care: Physician Self-Referrals*, "Stark I and II")

It is difficult to determine the amount of money lost to fraud each year. A frequently cited estimate was made by the General Accounting Office (GAO); it estimated that as much as 10% of health care spending in the nation was the result of fraudulent activities.<sup>2</sup> A more conservative estimate of 5% was offered by the Federal Bureau of Investigation (FBI).<sup>3</sup> The National Health Care Anti-Fraud Association (NHCAA), an association of private health insurers and federal/state law enforcement officials suggested a range of 3-10%.<sup>4</sup>

A financial audit report issued by the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) in July 1997, estimated that improper Medicare payments made in FY1996 totaled \$23 billion or 14% of total Medicare benefit payments (excluding payments to health maintenance organizations (HMOs)) made in that year. These improper payments ranged from inadvertent mistakes to outright fraud and abuse. The OIG could *not* quantify what portion of the error rate was attributable to fraud. Almost all of the errors uncovered during the audit fell into four major categories: (1) documentation, including both insufficient and no documentation (47% of errors); (2) lack of medical necessity (37% of errors); (3) incorrect coding (9% of errors); and (4) noncovered or unallowable services (5% of errors). The following provider types accounted for the majority of improper payments: inpatient hospital care, physicians, home health agencies, hospital outpatient care; skilled nursing facilities, and clinical laboratories.<sup>5</sup>

Regardless of the exact dollar figure attributable to health care fraud, it results in increased expenditures under federal and state health care programs and higher insurance premiums. It can also pose a risk to patients if medically necessary services are not provided or unneeded services are provided. While both public and private programs are affected by fraudulent activities, this report focuses primarily on federal programs, administered by HHS.<sup>6</sup>

<sup>&</sup>lt;sup>2</sup>U.S. General Accounting Office. *Remedies Needed to Reduce Losses from Fraud and Abuse*. Janet Shikles, testimony before the Health Subcommittee, House Committee on Ways and Means, Mar. 8, 1993. Washington, 1993.

<sup>&</sup>lt;sup>3</sup>U.S. Federal Bureau of Investigation. Louis Freeh, testimony before Senate Special Committee on Aging, Mar. 21, 1995. Washington, 1995.

<sup>&</sup>lt;sup>4</sup>National Health Care Anti-Fraud Association. Testimony of William J. Mahon before the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on Government Reform and Oversight, June 15, 1995.

<sup>&</sup>lt;sup>5</sup>U.S. Dept. of Health and Human Services. Office of the Inspector General. Report on the Financial Statement Audit of the Health Care Financing Administration for Fiscal Year 1996. A-17-95-00096, July 1997. Washington, 1997.

<sup>&</sup>lt;sup>6</sup>Fraud and abuse as they affect Department of Defense and Veterans Administration programs, and the Federal Employees Health Benefits Program are not discussed.

#### Historical Overview of Federal Anti-fraud Statutes

While the original Medicare and Medicaid statutes, as enacted in 1965, did not contain program-specific fraud provisions, Congress did provide that the penalties for fraud which were contained in the Old Age, Survivors and Disability Program<sup>7</sup> were also applicable to the new Medicare and Medicaid programs. Then, in 1972, Congress added specific fraud provisions to both programs. Such provisions included misdemeanor penalties for false statements as well as penalties for kickbacks or bribes under either program. In 1976, Congress created the Office of Inspector General in the Department of Health, Education, and Welfare (now HHS), giving the Inspector General the authority "to conduct and supervise audits and investigations, relating to programs and operations of the Department to increase their economy and efficiency and to reduce the likelihood of fraud and abuse."

In 1977, Congress passed the Medicare-Medicaid Anti-Fraud and Abuse Amendments, P.L. 95-142, strengthening the existing fraud and abuse penalties by upgrading them from misdemeanor offenses to felonies. <sup>10</sup> In addition, the Secretary was given authority to suspend providers convicted of program fraud from participation in Medicare or Medicaid. Disclosure of ownership and financial information requirements were added for providers and suppliers who received Medicare or Medicaid funds.

Thereafter, Congress has amended these basic fraud and abuse provisions numerous times, strengthening penalties, adding offenses, both civil and criminal, as new fraudulent schemes have been uncovered. For example, in the Omnibus Budget Reconciliation Act of 1981, P.L. 97-35, Congress authorized the Secretary to assess a civil monetary penalty of up to \$2,000 for fraudulent claims under Medicaid and Medicare and to impose an assessment of twice the amount of the fraudulent claim, in lieu of damages. The Omnibus Budget Reconciliation Act of 1986<sup>11</sup> contained a number of additions and modifications to the fraud and abuse penalty provisions including clarifying the exclusion provisions and adding provisions concerning fraud hearings.

Extensive amendments were made to the fraud and abuse provisions by the Medicare and Medicaid Patient and Program Protection Act of 1987, P.L. 100-93. Included in the amendments were provisions to protect Medicare and Medicaid beneficiaries from unfit health practitioners, along with provisions re-codifying the anti-fraud provisions in the Social Security Act, and providing for additional exclusion

<sup>&</sup>lt;sup>7</sup>42 U.S.C. § 408 (1972).

<sup>&</sup>lt;sup>8</sup>Public Law 92-603. These program-related fraud provisions were added to Title XI of the Social Security Act.

<sup>&</sup>lt;sup>9</sup>S. Rept. 1324, 94<sup>th</sup> Cong., 2d Sess. 3-14 (1976); 42 U.S.C. § 3521 (1977).

<sup>&</sup>lt;sup>10</sup>Generally, misdemeanor offenses carry an imprisonment term of less than 1 year while felony offenses prescribe an imprisonment term greater than 1 year. Both offenses may also provide for fines.

<sup>&</sup>lt;sup>11</sup>Public Law 99-509.

provisions under the Medicare and Medicaid programs where an individual or entity has been convicted of a criminal offense related to neglect or abuse of patients. This 1987 statute also required states to have a system of reporting information with respect to formal proceedings concluded against a health care practitioner or entity by a state licensing authority. Congress also amended the fraud and abuse provisions in 1988, 12 1989, 13 1990, 14 and 1994, 15 further refining the criminal penalties, civil monetary penalties and exclusion provisions applicable to the Medicare and Medicaid programs.

In 1996, significant new health care fraud and abuse provisions were added to both the existing program-related laws in the Social Security Act and to the Federal Criminal Code by Title II of the Health Insurance Portability and Accountability Act, (HIPAA, P.L. 104-191). The Medicare and Medicaid program-related fraud provisions were made applicable to other federal health care programs, such as Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). Civil monetary penalties were increased from \$2,000 to \$10,000 for each item or service involved. New violations were added to the list of prohibited activities, such as for "upcoding," billing for unnecessary medical services and false certification of home health services. 16

Significant new criminal provisions specifically involving health care fraud were added to the Federal Criminal Code provisions found in Title 18 of the United States Code. These include new federal health care fraud criminal offenses (applicable to violations in both public and private health care benefit programs), such as for false statements, theft or embezzlement, obstructing justice and money laundering. Upon conviction, a court may order forfeiture of property derived from a federal health care offense.

The amendments in HIPAA also established a number of new programs to combat fraud, including a fraud and abuse control program to coordinate federal, state and local law enforcement efforts against fraud in federal and private health care programs; a Medicare integrity program providing for contracts with private entities to carry out activities such as audits and reviews of provider payments; a beneficiary incentive program to encourage individuals to report fraudulent activities against the Medicare program; and, a national health care fraud and abuse data collection program containing reports of final adverse actions against health care providers, suppliers, and practitioners. The Act also required the Secretary to issue written

<sup>&</sup>lt;sup>12</sup>Public Law 100-360; Public Law 100-485.

<sup>&</sup>lt;sup>13</sup>Public Law 101-234; Public Law 101-239.

<sup>&</sup>lt;sup>14</sup>Public Law 101-508.

<sup>&</sup>lt;sup>15</sup>Public Law 103-432.

<sup>&</sup>lt;sup>16</sup>Section 231 of Public Law 104-191 also amended the level of intent associated with fraud violations punishable by civil monetary penalties. Under the new standard, similar to the False Claims Act, a person is subject to civil monetary penalties if the person "knowlingly" presents a claim that the person "knows or should know" falls into one of the prohibited categories. Section 1128A(a) of the Social Security Act, 42 U.S.C. § 1320a-7a(a).

advisory opinions regarding whether a proposed transaction would violate antikickback restrictions.

Most recently, Congress has amended the Medicare and Medicaid fraud and abuse provisions in Title IV of the Balanced Budget Act of 1997 (BBA 1997, P.L. 105-33), focusing on keeping fraudulent providers out of Medicare and increasing the penalties for those caught committing fraud and abuse. The amendments include a "three strikes and you're out" provision permanently excluding from federal health care programs persons convicted of three health care-related crimes. The Secretary of HHS is given authority to refuse to contract with providers or suppliers convicted of felonies for an offense which the Secretary determines "is detrimental to the best interests of the program or program beneficiaries."17 A new civil monetary penalty is added for cases in which a person contracts with an excluded provider for the provision of health care services where the person knows or should know that the provider has been excluded from participation in a federal health care program. Providers and suppliers are also required to provide full and complete information as to persons with an ownership or control interest in the supplier, and are required to post a \$50,000 surety bond as a monetary guarantee of performance of statutory obligations. The Secretary is also directed to issue written advisory opinions concerning certain physician self-referral questions.

A detailed summary of current fraud and abuse penalty provisions is contained in the last section of this report.

#### Identification of Fraudulent Activities

#### **Federal**

Under current law, investigation and prosecution of fraud related to federal programs is the responsibility of the OIG within HHS, the FBI, and the Department of Justice. The OIG investigates federal cases of fraud regarding Medicare, Medicaid, and the Maternal and Child Health Block Grant programs; it is authorized by the Secretary to sanction fraudulent providers by imposing exclusions and civil monetary penalties. The FBI can investigate both federal and private payer cases of fraud but cannot impose sanctions. Both the OIG and the FBI refer investigative findings to the Department of Justice, at which time officials determine whether to pursue the case. In the event Justice decides to prosecute, the accused persons or providers may be brought up on criminal charges; damages may be sought through civil penalties; or exclusions from federal programs may be imposed.

#### State Medicaid Fraud Control Units

Federal funding is provided for 90% of the start-up costs and 75% of the operating costs of state Medicaid fraud control units. Forty-seven states have established these units which are usually part of the office of the state attorney

<sup>&</sup>lt;sup>17</sup>Section 4302 of Public Law 105-33

general. They are responsible for the investigation, prosecution, or referral for prosecution, of fraudulent activities associated with state Medicaid programs. During FY1996, the OIG administered an estimated \$74.8 million in grants to these entities.

#### Sanctions

#### Office of Inspector General, HHS

During the 6-month period October 1, 1996-March 31, 1997, the OIG imposed 1,353 sanctions in the form of exclusions or money penalties against individuals and entities engaging in fraud or abuse of Medicare and Medicaid. Over half of the exclusions were based on conviction of program related crimes, conviction of controlled substance manufacture or distribution, conviction related to patient abuse or loss of license to practice. During this period, the government imposed exclusions on 1,344 individuals and entities. It recouped \$937 million through both the civil money penalty provisions and the False Claims Act civil settlements relating to the Medicare and Medicaid programs. <sup>18</sup>

State Medicaid fraud control units reported 389 convictions and \$16.5 million in fines, restitutions and overpayments collected for the period July 1, 1996-December 31, 1996.<sup>19</sup>

#### **Department of Justice**

The Department of Justice has significantly increased its health care fraud activities in recent years. In 1993, the Attorney General named health care fraud enforcement as one of the Department's top priorities. The FBI has seen a major increase in the investigative resources devoted to health care fraud and as a consequence the number of cases handled by federal prosecutors has also increased. The Department has also provided for increased coordination among investigative and regulatory agencies.

Health care fraud investigations handled by the FBI increased from 657 in FY1993 to 2,200 in FY1996. Criminal prosecutions increased from 83 cases and 116 defendants in FY1992 to 246 cases and 450 defendants in FY1996. Convictions (including guilty pleas and guilty verdicts) rose from 90 defendants in FY1992 to 307 in FY1996. Civil health care fraud efforts also increased with civil investigations handled by the Department increasing from 270 in FY1992 to 2,488 in FY1996. Recoveries by the Department's Civil Division totaled \$274 million for FY1995 and FY1996.

<sup>&</sup>lt;sup>18</sup>U.S. Dept. of Health and Human Services. Office of Inspector General. *Semi-Annual Report, Office of Inspector General. October 1, 1996 - March 31, 1997.* Washington, 1997. (Hereafter cited as HHS, Office of Inspector General, *Semi-Annual Report*)

<sup>&</sup>lt;sup>19</sup>HHS, Office of Inspector General, Semi-Annual Report.

#### **Recent Federal Initiatives**

In recent years considerable attention has been focused on allegations of health care fraud, particularly Medicare fraud. This attention has stemmed, in part, from a series of congressional hearings highlighting the pervasive nature of fraud, periodic reports in the media documenting egregious examples, and a series of reports from the OIG and the General Accounting Office (GAO) highlighting the need for improved mechanisms to combat fraud.

The sheer volume of Medicare claims (over 800 million annually) coupled with the program's administrative complexity makes it a target for fraudulent practices. In the past several years, federal agencies have intensified their efforts to identify, prosecute, and penalize providers and others involved in fraudulent activities. The agencies have targeted their efforts in those areas, such as home health care, where fraudulent practices appear to be the most widespread.

#### **Operation Restore Trust**

A major effort, launched by HHS in May 1995, is known as Operation Restore Trust (ORT). The initial 2-year pilot project focused on the five states (California, Florida, Illinois, New York, and Texas) which together accounted for 40% of Medicare and Medicaid beneficiaries. The project targeted three areas the OIG identified with systemic fraud — namely home health agencies, nursing homes, and durable medical equipment suppliers. ORT provided for coordination of enforcement activities by federal and state government representatives. The OIG assembled teams that included investigators from the OIG and state Medicaid fraud control units; auditors and evaluators from the OIG and the Health Care Financing Administration (HCFA); quality assurance specialists from state surveyors and durable medical equipment regional carriers; state long-term care ombudsmen through the Administration on Aging; and prosecutors from the Department of Justice and the State Attorneys General. These teams conducted financial audits, criminal investigations and referrals to federal and state prosecutors, civil and administrative sanctions and monetary recovery actions, and surveys and inspections of nursing facilities.

The OIG reported that as of March 31, 1997, 74 criminal convictions, 58 civil actions and 54 current indictments were obtained under the ORT operation. In addition, 219 providers were excluded from Medicare and Medicaid. The OIG also identified a total of more than \$167 million in fines, recoveries, settlements, and civil monetary penalties owed to the federal government.<sup>20</sup> Several other activities, including the establishment of a hotline, issuance of fraud alerts, and establishment of a voluntary disclosure program, were associated with ORT.

The 2-year demonstration project has ended. However, on May 20, 1997, HHS announced expansion of the ORT effort to several additional provider groups and services including partial hospitalization, psychiatric hospitals, and independent

<sup>&</sup>lt;sup>20</sup>HHS, Office of Inspector General. Semi-Annual Report.

physiological laboratories. Twelve new states were added to the effort. They are: Arizona, Colorado, Georgia, Louisiana, Massachusetts, Missouri, New Jersey, Ohio, Pennsylvania, Tennessee, Virginia, and Washington.

#### **Beneficiary Involvement**

In June 1995, HHS established a toll-free hotline (1-800-HHS-TIPS) for beneficiaries and others to report suspected cases of health care fraud involving Medicare and Medicaid. As of March 31, 1997, the hotline had received 13,794 complaints relating to HHS programs; resolving the complaints led to recoveries of \$5.2 million in overpayments.

In June 1997, HHS awarded \$2 million in grants to 12 advocacy groups to train seniors in fraud detection. Under the demonstration project, senior volunteers will be working in local areas to help seniors identify deceptive practices.

#### **Hospital Initiatives**

Physicians at Teaching Hospitals (PATH). Medicare pays for the services of teaching physicians at teaching hospitals according to the type of service rendered. Physicians may bill under Part B only if they personally provide direct and identifiable services to Medicare patients or they are physically present when the services are furnished by residents and interns. Other services performed by teaching physicians, such as supervising interns and residents are considered part of their medical education function. Medicare pays under Part A for both the direct and indirect medical education costs associated with the training of residents and interns.

Under a nationwide PATH initiative, the OIG has undertaken a review of the compliance with Medicare rules governing reimbursement to physicians at teaching hospitals. While payment is being made under Part A for medical education activities, the OIG is concerned that physicians have also been billing for some services under Part B without having met the appropriate criteria. A number of hospitals indicated concern with the PATH initiative. They stated that teaching hospitals had not been given clear and consistent guidelines on complying with Medicare regulations; further, questions were raised as to whether the OIG was applying the policy retroactively in certain cases. The report of the House Appropriations Committee accompanying the HHS FY1998 appropriations bill reiterated these concerns.<sup>21</sup> The HHS indicated in July that it was discontinuing audits at those teaching hospitals which had not received clear instructions from carriers (i.e., Medicare claims processing entities) prior to December 1992.

**Diagnosis Related Group 72-Hour Window Project.** Medicare makes payments for inpatient hospital services under a prospective payment system (PPS). Under PPS, a fixed amount is paid on the basis of the patient's diagnosis. The PPS payment is intended to cover the costs of all services provided to the Medicare patient

<sup>&</sup>lt;sup>21</sup>U.S. Congress. House. Committee on Appropriations. Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriation Bill, 1998. Report 105-205, 105<sup>th</sup> Cong., 1<sup>st</sup> Sess., July 25, 1997. Washington, GPO, 1997.

(except for physician's services which are paid for separately). The law prohibits separate payments for outpatient diagnostic services and other services related to an inpatient admission that are provided within 72 hours of such admission. The OIG found that many hospitals were submitting Part B claims for these services. As a result, in 1995, it initiated a national project which identified 4,600 hospitals that had submitted improper claims. These hospitals are being notified of the erroneous claims and their potential exposure under the Federal Civil False Claims Act.. The hospitals will be given the opportunity to enter into a settlement with the federal government; such agreement must include compliance measures to prevent and detect erroneous billings. As of March 31, 1997, 804 hospitals had settled. The total anticipated recovery is \$90-\$110 million over the next 2 years.<sup>22</sup>

Home Health Agencies. One of the major areas targeted for closer scrutiny is that of home health agencies. In July 1997, the OIG reported on the results of an ORT audit of home health services in four states (California, Illinois, New York, and Texas). The review found that 40% of services did not meet Medicare reimbursement requirements either because the services were not reasonable and necessary; they were provided to patients who were not homebound; or, they were for services that did not have valid physician orders or other supporting documentation. A second OIG study found that 25% of home health providers in the five ORT states were problem providers who had abused or defrauded Medicare. Both reports found that Medicare's controls over home health care were inadequate. Medicare's fiscal intermediaries (the entities that process home health claims) review only about 3% of claims because of limits on financial resources. In contrast, intermediaries reviewed 50% of home health claims in 1988.

Several provisions in the recently enacted Balanced Budget Act of 1997 (BBA 1997) are expected to address some of the problems; these include development of a prospective payment system for home health services and the requirement that home health agencies post \$50,000 surety bonds before they are certified. HHS has also stepped up its efforts. On September 15, 1997, the Administration announced a moratorium on the entry of any new home health agency into Medicare. During the temporary moratorium period, the agency will implement program safeguards included in the BBA and work on other key changes. New measures will include a requirement that home health agencies supply information about related businesses that they own. The Department also expects to propose regulations that will require agencies to re-enroll in Medicare every 3 years. As part of the re-enrollment process, agencies will have to submit an independent audit of their records and practices. The Department also plans to double the number of home health care audits.

<sup>&</sup>lt;sup>22</sup>HHS, Office of Inspector General. Semi-Annual Report.

<sup>&</sup>lt;sup>23</sup>U.S. Dept. of Health and Human Services. Office of Inspector General. Results of the Operation Restore Trust Audit of Medicare Home Health Services in California, Illinois, New York and Texas. Report A-04-96-02121, July 1997. Washington, 1997.

<sup>&</sup>lt;sup>24</sup>U.S. Dept. of Health and Human Services. Office of Inspector General. Home Health: Problem Providers and Their Impact on Medicare. Report OEI-09096-00110, July 1997. Washington, 1997.

#### Clinical Laboratories

The OIG, in conjunction with other law enforcement agencies is concluding a 3-year initiative which has targeted abusive billing practices in the country's largest independent clinical laboratories. Another interagency project, the Laboratory Unbundling Project, is a joint effort by the OIG and the Department of Justice to target fraud in hospital-based outpatient laboratories. The project, which began in hospitals in Ohio, was created to identify facilities which unbundled laboratory tests when using automated equipment, either by billing for each analysis separately, or billing for the automated test as well as several of the analyses separately. In effect, the facility receives a higher payment than for tests bundled into a single panel. Under the lab unbundling project, facilities are allowed to participate in a self-disclosure process (which allows disclosure of improper billing and which may prevent the imposition of more severe penalties). The project has recently been expanded to other states.

In a related development, the OIG released a model laboratory compliance plan in February 1997. This plan describes the fundamentals of an effective program of provider compliance with rules in federal health care programs. The purpose is to help providers self-regulate, self-report and prevent health care fraud.

#### Implementation of Provisions in the HIPAA

As noted above, HIPAA included a number of provisions designed to strengthen federal anti-fraud and abuse efforts. HHS and the Department of Justice are in the process of implementing the new provisions. Some of these activities are noted below:

Health Care Fraud and Abuse Control Program. HIPAA provided for the establishment of a new Health Care Fraud and Abuse Control program to be jointly administered by the Secretary of HHS and the Attorney General. The program was viewed as an extension and expansion of existing interagency and intergovernmental anti-fraud efforts including ORT and other anti-fraud working groups. The Secretary and Attorney General developed implementing guidelines and announced establishment of the program in January 1997. It is intended to promote the coordination of federal, state and local law enforcement, conduct investigations, audits, and evaluations relating to the delivery and payment for health care services; facilitate the enforcement of civil, criminal and administrative statutes, provide industry guidance (including advisory opinions, safe harbors, and special fraud alerts) relating to fraudulent practices; and establish a national data bank to receive and report final adverse actions against health care providers.

HIPAA provided that the Fraud and Abuse Control Program would be funded by recoveries from health care cases. These recoveries would be transferred to the Medicare Part A trust fund and subsequently be appropriated to a new Health Care Fraud and Abuse Control Account. A specified amount (between \$60 and \$70 million

<sup>&</sup>lt;sup>25</sup>Office of the Inspector General. Publication of the OIG Model Compliance Plan for Clinical Laboratories. Notice. *Federal Register*, v. 62, no. 41. March 3, 1997.

in FY1997 and between \$80 and \$90 million in FY1998) is earmarked for the OIG for Medicare and Medicaid work. An additional amount (\$47 million in FY1997 and \$56 million in FY1998) is to be appropriated from the general fund of the U.S. Treasury to the Account for transfer to the FBI for health care enforcement activities. This stable funding source provides increased resources for both the OIG and the FBI. The OIG plans to increase its staff by 20% in 1997.

Medicare Integrity Program. HIPAA also provided for the establishment of a new Medicare Integrity Program under which the Secretary enters into agreements with private entities to carry out certain activities including medical review, audits, and secondary payer reviews. A specified amount (\$440 million in FY1997 and \$490-\$500 million in FY1998) is to be appropriated to the Health Care Fraud and Abuse Control Account from the Medicare Part A trust fund for this program. The Department is developing implementing regulations.

#### **Federal Penalties for Fraud**

Federal penalties for fraudulent activities in health care include civil and criminal penalties as well as permissive and mandatory exclusions from federal health care programs. Medicare and Medicaid program-related anti-fraud provisions are generally found in Title XI of the Social Security Act, 42 U.S.C. §§ 1320a-7 et seq. These provisions are supplemented by generic fraud provisions found elsewhere in federal statutes, including federal criminal statutes in Title 18 of the United States Code, and civil statutes such as the Federal Civil False Claims Act, 31 U.S.C. § 3729. Many states have similar laws used to combat health care fraud and abuse.

#### **Civil Monetary Penalties**

Civil monetary penalties under Medicare and Medicaid are found generally in section 1128A of the Social Security Act, 42 U.S.C. § 1320a-7a.<sup>27</sup> These provisions are also applicable to similar violations in other health care programs funded by the federal government, such as CHAMPUS. Civil penalties of up to \$10,000 for *each* item or service involved, as well as additional assessments, may be imposed for false claims submitted to Medicare, Medicaid, or state health care programs receiving funds under the Maternal and Child Health Services Block Grant or the Social Services Block Grant. Civil monetary penalties may also be imposed for other fraudulent activities such as inflating charges for services, providing services when not a properly licensed physician, "upcoding," billing for medically unnecessary services, falsely certifying that an individual meets the requirements for home health services, and

<sup>&</sup>lt;sup>26</sup>Under this statute providers may be liable for three times the amount of damages sustained by the government as the result of a false claim and for civil penalties of between \$5,000 and \$10,000 for each false claim submitted. In addition, a private citizen can bring a "qui tam" action under this statute, and receive a percentage of the recovery, plus attorney's fees.

<sup>&</sup>lt;sup>27</sup>Regulations implementing the civil monetary penalty authority are found at 42 C.F.R. Part 1003.

offering remuneration to individuals eligible for Medicare or Medicaid to influence such individuals to receive items or services from particular providers. In addition, civil penalties may be assessed against a health care provider who fails to comply with certain statutory obligations, such as providing health care services only when medically necessary, under Section 1156 of the Social Security Act, 42 U.S.C. § 1320c-5. Procedural provisions outlining the administrative process for the imposition of civil monetary penalties include notice and an opportunity for a hearing, representation by counsel and appeal rights following an adverse determination by the Secretary to federal circuit court.<sup>28</sup>

Other civil monetary penalty provisions may be found throughout the Medicare and Medicaid statutes. A number of these provisions apply to HMOs and other Medicare and Medicaid managed care organizations which fail to provide medically necessary items or services to beneficiaries; or which impose premiums in excess of permitted amounts; or which expel or refuse to re-enroll beneficiaries in violation of Medicare or Medicaid law; or for other enumerated violations. HMOs must also periodically survey their membership to determine their participants' degree of access to services and satisfaction with quality, and provide this information to HHS or face civil fines of up to \$25,000 per violation and suspension of enrollments or plan payments under 42 U.S.C. § 1395mm(i)(8).

#### **Criminal Penalties**

Federal criminal prosecutions for health care fraud and abuse have been brought under as many as 30 different statutes.<sup>31</sup> Such prosecutions may be based upon the program-related provisions of section 1128B of the Social Security Act,<sup>32</sup> which apply to Medicare, Medicaid, or state health care programs receiving funds under the Maternal and Child Health Services Block Grant or the Social Services Block Grant. Program-related felony convictions, which usually apply to providers, may result in fines of up to \$25,000 or imprisonment for up to 5 years or both. For persons other than providers, program-related convictions are generally misdemeanors.

<sup>&</sup>lt;sup>28</sup>Section 1128A(c) of the Social Security Act, 42 U.S.C. § 1320a-7a(c).

<sup>&</sup>lt;sup>29</sup>Section 1876 of the Social Security Act, 42 U.S.C. § 1395mm. This section provides for penalties of up to \$25,000 per violation, with more severe penalties for violations involving misrepresentation of information to HHS. In addition, entities that overcharge beneficiaries can also be assessed an amount equal to twice the excess amount charged, with the excess amount deducted from the penalty and returned to the beneficiary. 42 U.S.C. § 1395mm(i)(6)(B). Similar provisions apply to Medicaid HMOs under Section 1903(m) of the Social Security Act, 42 U.S.C. § 1396b(m)(5)(A),(B).

<sup>&</sup>lt;sup>30</sup>The same procedural provisions as are applicable generally for civil monetary penalties under Section 1128A of the Social Security Act apply to HMOs under Section 1876 of that Act, 42 U.S.C. § 1395mm(i)(6)(B)(iii).

<sup>&</sup>lt;sup>31</sup>Bucy, Pamela H. Crimes by Health Care Providers, 1995. UNIV ILL L REV 589, 591 (1996).

<sup>&</sup>lt;sup>32</sup>42 U.S.C. § 1320a-7b.

Program-related criminal penalties include making false statements in matters relating to benefits or payments under federal health care programs, making claims for physicians services knowing that the individual who furnished the service was not licensed as a physician, and knowingly and willfully soliciting or receiving a kickback, bribe or rebate in return for referral of a patient for services paid for under a federal health care program.<sup>33</sup> There are explicit statutory exceptions to the general anti-kickback prohibitions,<sup>34</sup> and the HHS Inspector General has the authority to issue "safe harbor" regulations delineating business practices which could cause suspicion of fraud but which are in fact legitimate, provided they meet certain guidelines. If the guidelines are adhered to, the outlined practices are protected from federal civil penalties or criminal prosecution.<sup>35</sup>

Section 217 of HIPAA added a new crime to the list of prohibited activities under section 1128B of the Social Security Act, making it unlawful for a person to knowingly and willfully dispose of assets in order to become eligible for benefits under the Medicaid program, if disposing of the assets resulted in the imposition of a period of ineligibility. More recently, Congress has amended this section to make it a crime for a person, for a fee, to counsel or assist an individual to dispose of assets in order for the individual to become eligible for Medicaid, if disposing of the assets results in the imposition of a period of ineligibility under that program. This offense is a misdemeanor and carries with it a fine of not more than \$10,000 or imprisonment for not more than 1 year, or both.

Federal criminal prosecutions may also be brought under the more general health care fraud provisions recently added to Title 18 of the United States Code,<sup>38</sup> or under the generic fraud provisions in Title 18 such as mail fraud (18 U.S.C. § 1341), false claims to government agencies (18 U.S.C. § 287 and § 1001) and conspiracy to defraud the federal government (18 U.S.C. § 371). The new federal health care offenses generally apply to violations involving both public and private health care benefit programs. Upon conviction of a federal health care offense a court may order forfeiture of property derived from such an offense.

<sup>&</sup>lt;sup>33</sup>Section 1128B of the Social Security Act, 42 U.S.C. § 1320a-7b(b).

<sup>&</sup>lt;sup>34</sup>Section 1128B(b)(3) of the Social Security Act, 42 U.S.C. § 1320a-7b(b)(3).

<sup>&</sup>lt;sup>35</sup>There are also physician self-referral prohibitions, generally banning physician referrals to facilities in which they themselves have an ownership interest or from which they receive compensation. These are found in Section 1877 of the Social Security Act, 42 U.S.C. § 1395nn. See Congressional Research Service, *Health Care: Physician Self-Referrals*, "Stark I And II".

<sup>&</sup>lt;sup>36</sup>42 U.S.C. § 1320a-7b(a)(6). This provision became effective January 1, 1997.

<sup>. &</sup>lt;sup>37</sup>Section 4737 of H.R. 2015, as passed by Congress on July 31, 1997. This amendment was effective upon enactment.

<sup>&</sup>lt;sup>38</sup>See, e.g., 18 U.S.C. § 1347 (health care fraud), 18 U.S.C. § 669 (theft or embezzlement in connection with health care fraud), 18 U.S.C. § 1035 (false statements relating to health care matters) and 18 U.S.C. § 1518 (obstruction of criminal investigations of health care offenses).

#### **Exclusion Provisions**

Section 1128 of the Social Security Act,<sup>39</sup> authorizes the Secretary to impose mandatory and permissive exclusions of individuals and entities from participation in the Medicare program, Medicaid program and programs receiving funds under the Maternal and Child Health Services Block Grant or the Social Services Block Grant.<sup>40</sup> Mandatory exclusions are authorized for convictions of specified criminal offenses related to the delivery of health care services under Medicare and state health care programs, as well as for convictions relating to patient abuse in connection with the delivery of health care services, and for convictions of felony offenses relating to health care fraud or controlled substances. Mandatory exclusions are for a minimum period of 5 years.

Permissive exclusions are authorized for a number of offenses relating to fraud, kickbacks, obstruction of an investigation, and controlled substances, and for activities relating to license revocations or suspensions, claims for excessive charges or unnecessary services, and the like. There is a minimum period of exclusion for permissive exclusions, ranging from 1 to 3 years, depending on the basis for the permissive exclusion. In addition, the Secretary has the authority to bar certain felons from participation in federal health care programs. The Secretary may exclude individuals with ownership or control interest in a sanctioned entity and, under certain circumstances, may also exclude entities controlled by a family member of a sanctioned individual.

An individual who is excluded from program participation is entitled to reasonable notice and opportunity for a hearing by the Secretary, and to judicial review of the Secretary's final decision in federal district court. If the HHS Inspector General excludes an individual or entity from Medicare program participation, state Medicaid agencies must also exclude that individual or entity from participation in Medicaid for the same period of time, although a state may request that exclusion from state health programs be waived. In addition, under the recently added "three strikes and you're out" provision, a provider is excluded from federal health care programs for 10 years for a second fraud-related offense, and permanently excluded from federal health care programs for a third offense.

<sup>&</sup>lt;sup>39</sup>42 U.S.C. § 1320a-7.

<sup>&</sup>lt;sup>40</sup>Regulations implementing the authority for Medicare exclusions are at 42 C.F.R. Pt. 1001, with the Medicaid exclusion regulations at 42 C.F.R. Pt. 1002.

<sup>&</sup>lt;sup>41</sup>Section 1128(c) of the Social Security Act, 42 U.S.C. § 1320a-7(c). The Secretary has the authority to shorten or lengthen the period of exclusion under the statute depending upon mitigating factors.

<sup>&</sup>lt;sup>42</sup>Section 1128(f) of the Social Security Act, 42 U.S.C. § 1320a-7(f).

<sup>&</sup>lt;sup>43</sup>42 U.S.C. § 1320a-7(d).

<sup>&</sup>lt;sup>44</sup>Section 4301 of H.R. 2015, as passed by Congress on July 31, 1997.

#### **Advisory Opinions and Other Statutory Requirements**

The Secretary is required to solicit proposals in the *Federal Register* for modifications to existing safe harbors and new safe harbors under the Medicaid Patient and Program Protection Act provisions. These provisions specify certain business practices which are normally prohibited, but which are nevertheless protected, as safe harbors, from criminal prosecution or civil sanction under the anti-kickback provisions. The Secretary may modify existing safe harbors or establish new safe harbors, as appropriate. The Secretary is also directed to issue written advisory opinions regarding whether a proposed transaction would violate anti-kickback restrictions and whether certain physician self-referrals are prohibited under federal law. The opinions are binding between the Secretary and the requesting party. Individuals may also request the Inspector General to issue special fraud alerts informing the public of practices which the Inspector General considers to be suspect or of particular concern under Medicare or State health care programs. Special fraud alerts are published in the *Federal Register*.

The HIPAA contained a provision requiring the Secretary of HHS to establish a national health care fraud and abuse data collection program containing reports of final adverse actions against health care providers, suppliers, and practitioners. <sup>48</sup> Certain information is to be included in the report submitted by federal and state governmental agencies and health plans, including a description of the acts or omissions and injuries upon which the final adverse action was based. Information in the data base may be disclosed to federal and state agencies and health plans under certain circumstances. At the same time, the Secretary is to include procedures to protect the privacy of individuals receiving health care services. The Secretary also has authority to impose a civil monetary penalty of \$25,000 on health plans that fail to report adverse actions under this health care data collection program. <sup>49</sup>

<sup>&</sup>lt;sup>45</sup>Section 1128D(a) of the Social Security Act, 42 U.S.C. § 1320a-7d(a).

<sup>&</sup>lt;sup>46</sup>Section 1128D(b) of the Social Security Act, 42 U.S.C. § 1320a-7d(b). On February 19, 1997, the OIG issued regulations which specify the specific procedures to be employed by the OIG, in conjunction with the Department of Justice, in issuing these opinions. To date, one opinion has been issued.

<sup>&</sup>lt;sup>47</sup>Section 1128D(c) of the Social Security Act, 42 U.S.C. § 1320a-7d(c).

<sup>&</sup>lt;sup>48</sup>Section 221 of Public Law 104-191, Section 1128E of the Social Security Act, 42 U.S.C. § 1320a-7e.

<sup>&</sup>lt;sup>49</sup> Section 4331 of Public Law 105-33.