The Department of Health and Human Services And The Department of Justice Health Care Fraud and Abuse Control Program Annual Report For FY 2000

January 2001

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GENERAL NOTE: All years are fiscal unless otherwise noted in the text.

EXECUTIVE SUMMARY

The detection and elimination of health care fraud and abuse is a top priority of federal law enforcement. Our efforts to combat fraud were consolidated and strengthened considerably by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA established a national Health Care Fraud and Abuse Control Program (the Program), under the joint direction of the Attorney General and the Secretary of the Department of Health and Human Services (HHS)(1), acting through the Department's Inspector General (HHS/OIG), designed to coordinate federal, state and local law enforcement activities with respect to health care fraud and abuse. The fourth year of operation under the Program saw a continuation of the collaborative efforts of Federal and state enforcement and oversight agencies to identify and prosecute the most egregious instances of health care fraud, to prevent future fraud or abuse, and to protect program beneficiaries.

Monetary Results

In 2000, the federal government won or negotiated more than \$1.2 billion in judgments, settlements, and administrative impositions in health care fraud cases and proceedings. As a result of these activities, as well as prior year judgments, settlements, and administrative impositions, the federal government in 2000 collected \$717 million. More than \$577 million of the funds collected and disbursed in 2000 were returned to the Medicare Trust Fund. An additional \$27 million was recovered as the federal share of Medicaid restitution.

Enforcement Actions

Federal prosecutors filed 457 criminal indictments in health care fraud cases in 2000 -- a 23 percent increase over the previous year. A total of 467 defendants were convicted for health care fraud-related crimes in 2000. There were also 1,995 civil matters pending, and 233 civil cases filed in 2000. In 2000, HHS excluded 3,350 individuals and entities from participating in the Medicare and Medicaid programs, or other federally sponsored health care programs.

INTRODUCTION

ANNUAL REPORT OF
THE ATTORNEY GENERAL AND THE SECRETARY
DETAILING EXPENDITURES AND REVENUES
UNDER THE HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM
FOR FISCAL YEAR 2000

As Required by Section 1817(k)(5) of the Social Security Act

STATUTORY BACKGROUND

The Social Security Act Section 1128C(a), as established by the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191, HIPAA or the Act), created the Health Care Fraud and Abuse Control Program (the Program), a far-reaching program to combat fraud and abuse in health care, including both public and private health plans.

The Act requires that an amount equaling recoveries from health care investigations -- including criminal fines, forfeitures, civil settlements and judgments, and administrative penalties, but excluding restitution, compensation to the victim agency, and relators' shares -- be deposited in the Medicare Trust Fund. All funds deposited in the Trust Fund as a result of the Act are available for the operations of the Trust Fund.

As stated above, the Act appropriates monies from the Medicare Trust Fund to a newly created expenditure account, called the Health Care Fraud and Abuse Control Account (the Account), in amounts that the Secretary and Attorney General jointly certify certain sums as necessary to finance anti-fraud activities. The maximum amounts available for certification are specified in the Act. Certain of these sums are to be available only for activities of the HHS/OIG, with respect to Medicare and Medicaid programs. In 2000, the Secretary and the Attorney General certified \$158 million for appropriation to the Account. A detailed breakdown of the allocation of these funds is set forth later in this report. These resources generally supplement the direct appropriations of HHS and DOJ that are devoted to health care fraud enforcement, though they provide the sole source of funding for Medicare and Medicaid enforcement by the HHS/OIG. (Separately, the Federal Bureau of Investigation (FBI) received \$76 million from HIPAA which is discussed in the Appendix.)

Under the joint direction of the Attorney General and the Secretary, the Program's goals are:

- (1) to coordinate federal, state and local law enforcement efforts relating to health care fraud and abuse;
- (2) to conduct investigations, audits, and evaluations relating to the delivery of and payment for health care in the United States;
- (3) to facilitate enforcement of all applicable remedies for such fraud;
- (4) to provide guidance to the health care industry regarding fraudulent practices; and
- (5) to establish a national data bank to receive and report final adverse actions against health care providers.

The Act requires the Attorney General and the Secretary to submit a joint annual report to the Congress which identifies:

- (A) the amounts appropriated to the HI Trust Fund for the previous fiscal year under various categories and the source of such amounts; and
- (B) the amounts appropriated from the Trust Fund for such year for use by the Attorney General and the Secretary and the justification for the expenditure of such amounts.

This annual report is submitted in fulfillment of the above statutory requirements.

MONETARY RESULTS

As required by the Act, HHS and DOJ must detail in this Annual Report the amounts deposited and appropriated to the Medicare Trust Fund, and the source of such deposits. In 2000, as a result of the combined anti-fraud actions of the federal and state governments and others, the federal government collected \$717 million in connection with health care fraud cases and matters (3). These funds were deposited with the Department of the Treasury and Health Care Financing Administration (HCFA), transferred to other federal agencies administering health care programs, or paid to private persons. The following chart provides a breakdown of the transfers/deposits:

Total Transfer/Deposits by Recipient 2000	
Department of the Treasury	\$ 5,501
HIPAA Deposits to the Medicare Trust Fund	57,209,390
Gifts and Bequests	5,220,177
Amount Equal to Criminal Fines	0
Civil Monetary Penalties	147,268,092
Amount Equal to Asset Forfeiture *	
Amount Equal to Penalties and Multiple	37,400,000
Damages	357,701,728
Health Care Financing Administration	
OIG Audit Disallowances - Recovered	
Restitution/Compensatory Damages	
Restitution/Compensatory Damages to	
Federal Agencies	7,569,623
Office of Personnel Management	2,514,122
Department of Defense	9,350,395
Other Agencies	2,889,951
Department of Health and Human Services -	
Other than HCFA	
Relators' Payments **	90,027,273
TOTAL ***	\$717,156,252

^{*}This includes only forfeitures under 18 United States Code (U.S.C.) 1347, a new federal health care fraud offense that became effective on August 21, 1996. Not included are forfeitures obtained in numerous health care fraud cases prosecuted under federal mail and wire fraud and other offenses.

The above transfers include certain collections, or amounts equal to certain collections, required by HIPAA to be deposited directly into the Medicare Trust Fund. These amounts include:

- (1) Gifts and bequests made unconditionally to the Trust Fund, for the benefit of the Account or any activity financed through the Account;
- (2) Criminal fines recovered in cases involving a federal health care offense, including collections under 1347 of title 18, U.S.C. (relating to health care fraud);
- (3) Civil monetary penalties in cases involving a federal health care offense;
- (4) Amounts resulting from the forfeiture of property by reason of a federal health care offense, including collections under section 982(a)(6) of title 18, U.S.C.;
- (5) Penalties and damages obtained and otherwise creditable to miscellaneous receipts of the general fund of the Treasury obtained under sections 3729 through 3733 Title 31, United States Code (known as the False

^{**}These are funds awarded to private persons who file suits on behalf of the federal government under the *qui* tam provisions of the False Claims Act, 31 U.S.C. sec 3730(b).

^{***}Funds are also collected on behalf of state Medicaid programs and private insurance companies; these funds are not represented here.

Claims Act), in cases involving claims related to the provision of health care items and services (other than funds awarded to a relator, for restitution or otherwise authorized by law).

HIPAA requires an independent review of these deposits by the General Accounting Office (GAO). On July 31, 2000, GAO submitted its report to the Congress covering Fiscal Years 1998 and 1999, concluding generally that reported transactions were properly related to HIPAA activities, and that there were no material weaknesses identified in HHS and DOJ processes for accumulating HCFAC financial information.

PROGRAM ACCOMPLISHMENTS

Expenditures

In the fourth year of operation, the Secretary and the Attorney General certified \$158 million as necessary for the Program. The following chart gives the allocation by recipient:

2000 ALLOCATION OF HCFAC APPROPRIATION		
(Dollars in thousands)		
Organization	Allocation	
Department of Health and Human Services Office of Inspector General (4) Office of the General Counsel Administration on Aging Health Resources Services Administration Departmental Appeals Board Total	\$119,250 1,949 1,450 396 55 123,100	
Department of Justice United States Attorneys Civil Division Criminal Division Justice Management Division Total	23,150 10,751 827 343 35,071	
Total	158,171	

These resources supplement the direct appropriations of HHS and DOJ that are devoted, in part, to health care fraud enforcement, though they provide the sole source of funding for Medicare and Medicaid antifraud efforts by the HHS/OIG. Separately, the FBI received an additional \$76 million in funding which is discussed in the Appendix to this Report.

Accomplishments

Collections

During this year, the federal government won or negotiated more than \$1.2 billion in judgments, settlements, and administrative impositions in health care fraud cases and proceedings. As a result of these activities, as well as prior year judgments, settlements, and administrative impositions, the federal government in 2000 collected \$717 million in cases resulting from health care fraud and abuse, of which more than \$577 million was returned to the Medicare Trust Fund, and \$27 million was recovered as the federal share of Medicaid restitution. It should be emphasized that some of the judgments, settlements, and administrative impositions in 2000 will result in collections in future years, just as some of the collections in 2000 are attributable to actions from prior years.

Judgments/Settlements

Working together, we have brought to successful conclusion the investigation and prosecution of numerous costly health care fraud schemes. Among them, are the following.

- The world's largest provider of kidney dialysis products and services agreed to pay the United States government \$486 million to resolve a sweeping investigation of health care fraud. The criminal fine and the civil settlement are the largest ever recovered by the United States in a healthcare fraud investigation. Two former Vice Presidents of the company have pled guilty and other executives were indicted and are awaiting trial. Under the criminal plea agreement, the company agreed to pay a record \$101 million in criminal fines for submitting false claims to Medicare for nutritional therapy provided to patients during their dialysis treatments, for hundreds of thousands of fraudulent blood testing claims, and for kickbacks. Under the civil settlements, the successor company will pay a record setting \$385 million to resolve civil claims relating to nutritional therapy, kickbacks, blood laboratory tests, improper reporting of credit balances, and billing for services that were provided to dialysis patients as part of clinical studies. The civil settlements compensate the United States for damages to five federal health insurance programs -- Medicare, U.S. Railroad Retirement Board Medicare, Tricare, the Veterans Administration and the Federal Employees Health Benefits Program (FEHBP) 12.1/2 and also pay for damages to state Medicaid programs. The company also agreed to a comprehensive eight year corporate integrity agreement. The investigation, audit and prosecution spanned 5 years, and its success was the result of collaboration among many government organizations, including the HHS-OIG, the FBI, the Defense Criminal Investigative Service (DCIS), the Pension and Welfare Benefits Administration of the Department of Labor, Office of Inspector General, Office of Personnel Management, and the U.S. Attorney's Offices and the Civil Division of the Department of Justice.
- The government entered a global settlement agreement with the nation's largest operator of nursing homes to resolve allegations that it fabricated records to make it appear that nurses were devoting much more time to Medicare patients than they actually were. Although the company received an estimated \$400 million in overpayments from Medicare, the settlement requires the company to pay \$170 million in civil settlement, a figure negotiated based on the chain's limited ability to pay. Because of their financial position, repayment of most of this amount will be accomplished through reduction of future Medicare payments. In addition, the company entered one of the most comprehensive corporate integrity agreements established to date, an agreement that will remain in effect until the company has fulfilled all of its payment obligations under the civil settlement (an estimated eight years). In addition, a subsidiary company, which owns 10 nursing homes, entered guilty pleas for wire fraud and false statements, and agreed to pay \$5 million in fines. The company must divest the 10 nursing homes to unrelated qualified operators approved by the government. While divestiture is being accomplished, other terms of the agreement will ensure that residents receive high quality care.
- A former Medicare fiscal intermediary agreed to pay \$74 million to resolve claims that it falsified interim payments on settled hospital cost reports in order to meet HCFA's Contractor Performance Evaluation standards. In so doing, the contractor caused improper Medicare payments or reduced offsets to a number of hospitals, overpayments that exceeded \$30 million. Since this settlement, HCFA has opted not to renew this fiscal intermediary contract. The company continues to operate under a corporate integrity agreement. Since 1993, over one dozen investigations of Medicare contractors under the False Claims Act have been resolved, with recoveries exceeding \$350 million.
- A prominent Texas doctor, his attorney brother, their mutual certified public accountant, a physician's assistant, a physical therapist, office managers and respective patients, and staff as well as clients were engaged in a sophisticated scheme to defraud local, state and federal government health programs, and private insurers, of over \$46 million from 1986 to 1998. The conspiracy involved a large cross-referral scheme of auto-accident, personal injury and workers compensation patients/clients between the brothers. Potential auto-accident victims were telephoned using information obtained from police accident reports, which is illegal in Texas. Callers would solicit the accident victims to become clients of the attorney and later patients of his brother. Once the victims were solicited, the medical services were inflated in order to generate higher insurance settlements. Medical and legal services relating to workers compensation claims were also fabricated or inflated. With the assistance of their CPA, the fraudulent proceeds were laundered by diverting them through a series of bank accounts and businesses within the United States, Mexico and the Cayman Islands.

An FBI computer analysis of the billing records indicated that the doctor consistently upcoded his services, falsified medical reports and engaged in multiple billing. He billed for over \$1 million in office visits when he was out of town. During 1994, he would have had to work approximately 90 hours a day to accomplish the number of office visits he claimed to perform. As a result of this scheme, the brothers were paid over \$34 million and laundered over \$31 million. After a five year inter-agency investigation --with the Justice Department, the Internal Revenue Service, the United States Department of Labor, the United States Postal Inspection Service, the United States Marshals Service, the DCIS, the Cayman

Island Government, the EI Paso Police Department, the Texas Workers Compensation Commission and private insurance company investigators participating it is nine subjects were indicted, and over \$2 million in property and cash were seized and forfeited. Of the nine indicted, four pleaded guilty, one was acquitted and on May 12, 2000, four were convicted. Both brothers were convicted and sentenced to steep fines, forfeitures and restitution, and prison.

These and other settlements reflect the culmination of investigations that have been ongoing for several years. Though settled in 2000 the fines and restitution generated by some of these cases will not be credited to the Medicare Trust Funds until 2001.

Collaboration

Effective health care fraud and abuse control requires close collaboration and regular exchanges of information among federal, state and local law enforcement entities. One example of such collaborative effort is the National Health Care Fraud and Abuse Task Force. Chaired by the Deputy Attorney General, the task force brought together top officials from federal, state and local law enforcement agencies responsible for fighting health care fraud and abuse, among them, the Department of Health and Human Services, Federal Bureau of Investigation; the National Association of Attorneys General, the National District Attorneys Association; and National Association of Medicaid Fraud Control Units. The task force was designed to foster communication and coordination at the highest levels where policy development and implementation can make a significant difference. At their initial meeting in 1999, the Task Force set various goals toward working together to protect the vulnerable nursing home population and in stepping up efforts to exclude dishonest providers from Medicare, Medicaid and other federal health programs.

During Fiscal Year 2000, significant progress was made toward accomplishing those goals. Though the following are by no means the only collaborative efforts undertaken to combat health care fraud and abuse, they are illustrative:

Nursing Home Training. A series of regional training conferences were held over the course of 1999 and 2000, that brought together over 800 representatives of federal, state, and local law enforcement, regulatory, survey, oversight and advocacy entities. During the conferences, State Working Groups (SWG) were formed (or expanded where they existed), including representatives of the many entities that play a role in nursing home quality of care. These SWGs provide an on-going opportunity to promote quality of care by establishing a forum for key players to meet, share information and skills, identify problem facilities, best practices, and ways to address quality of care given the unique situations in the various states. In June 2000, a national meeting of representatives of state working groups' was held to address the challenges and successes of training programs for prosecutors, investigators and other law enforcement officials, with an emphasis on the development of "best practices" and the use of interagency efforts to combat health care fraud.

Data Tech Conference. The National Health Care Fraud Task Force called for an examination of the use of information technology in detecting health care fraud and abuse. In June of 2000, HCFA and DOJ fulfilled this goal by co-sponsoring a national conference, which explored technologies and approaches to combat health care fraud and abuse in the 21st Century. The conference drew nearly 300 attendees from a wide universe of health care program and law enforcement officials dedicated to combating fraud and abuse in Medicare, Medicaid, and other government health programs. Attendees included staff from HCFA Central and Regional Offices, Medicare contractors, TRICARE, Medicaid State Agencies, other Federal health programs, State Medicaid Fraud Control Units, U.S. Attorney's Offices, the FBI, the DCIS, the HHS/OIG and other federal and state law enforcement agencies.

The conference focused on two basic themes. The first was an exploration of where technology is driving the science of fraud detection in the 21st Century. Tools incorporating advanced data mining, neural networking, fuzzy logic and artificial intelligence hold great promise for identifying program vulnerabilities earlier than ever. The second theme addressed approaches to combating fraud and abuse. Advancing technology makes it all the more vital that all stakeholders involved in combating health care fraud and abuse maintain close partnerships. Because bad actors do not discriminate among health programs they defraud, joint program integrity efforts are increasingly important.

• Stepped up exclusion efforts. Federal, state and local prosecutions are critical to protecting the integrity of our programs by prosecuting dishonest providers. State Licensing Boards play a vital role in protecting quality of care providing to our beneficiaries," said June Gibbs Brown, HHS Inspector General. "Exclusion from these programs is a second equally powerful tool in our fight against waste, fraud and abuse. We will be expanding our efforts to educate prosecutors and state licensing authorities about this critical tool, and the increase number of referrals. In part because of these efforts, exclusions in 2000 were at a record high it 2/2 a total of 3,350 individuals and entities were excluded from participation in Federal programs. This is a 12.56 percent increase from 2,976 exclusions in 1999.

Other significant collaborative efforts during 2000 included:

Drug Pricing. Efforts continue to ensure that the government pays providers only reasonable and appropriate amounts for prescription drugs. Toward this end, allegations of false claims were settled in principle with a major drug manufacturer for inflating reported drug prices. These reported prices are relied on by the federal and state governments to set reimbursement rates for Medicaid; accordingly, the overstated reports allegedly caused providers to submit inflated reimbursement claims to Medicaid. Allegations were also settled that the drug manufacturer knowingly underpaid Medicaid for rebates owed to it under the Medicaid Rebate Program. The company agreed to pay \$14 million, and agreed to a 5-year corporate integrity agreement under which it will change its drug pricing practices, and submit to monitoring. The agreement will be finalized when it has been ratified by participating states.

The HHS Office of Inspector General continued evaluations focused on HCFA methodologies for setting Medicare prescription drug prices. Although Medicare Part B does not cover most prescription drugs, it does reimburse for those used in conjunction with certain durable medical equipment and some that are furnished during dialysis. HHS/OIG studies concluded that the Medicare program could save dramatic sums of money if it reimbursed for the drug albuterol and certain end stage renal disease drugs at the same rate as Medicaid, and achieve even more savings if it could use rates available to the Veterans Administration (VA). For example, savings for albuterol would reach \$120 million if Medicaid rates were available to the Medicare program; and \$209 million at the VA acquisition rates. Medicare allowed amounts would be nearly halved for five ESRD drugs if amounts were based on the rates available to the VA.

HCFA's methodology for reimbursing for drugs is set by statute -- very generally, Medicare reimburses for the Average Wholesale Price (AWP) of drugs, less 5 percent. HCFA has sought legislative change under which Medicare reimbursement would more closely approximate actual acquisition costs; however, these proposals have not been passed by the Congress. Partly in response to recent enforcement efforts, in September, HCFA alerted its contractors through a Program Memorandum that new, more accurate estimates of AWP for 32 drugs were available, and could result in potential savings of \$400 million per year. Contractors may take advantage of the new pricing data beginning in 2001. Section 429(c) of P.L. 106-554, establishes a moratorium on decreases in payment rates for drugs and biologicals furnished on or after January 1, 2001, until review of a Comptroller General study on appropriate payment methodologies.

Healthcare Integrity and Protection Data Bank. HIPAA mandates that the OIG and Department of Justice establish a national health care fraud and abuse data collection program, for the reporting and disclosure of certain health care related final adverse actions taken against health care providers, suppliers and practitioners. The data collection program, named the Healthcare Integrity Protection Data Bank (HIPDB), has been developed as an electronic system that will collect, store and disseminate reports on civil, criminal and administrative actions submitted by Federal and State agencies and health plans. These Federal agencies and entities are also eligible to query the HIPDB. Although the OIG retains policy oversight authority over the HIPDB, the OIG has arranged with Health Resources and Services Administration (HRSA), through an Memorandum of Understanding, to run the day-to-day operations of the HIPDB. The HIPDB became operational on March 6, 2000. Since becoming operational, the HIPDB has averaged between 20,000 and 25,000 queries per week.

A more detailed description of these and other accomplishments of the major federal participants in the coordinated effort established under HIPAA follows. While information in this report is presented in the context of a single agency, most of these accomplishments reflect the combined efforts of HHS, DOJ and other partners in the anti-fraud efforts. The continuing accomplishments of the DOJ and HHS and our partners in the coordinated anti-fraud effort, as well as prevention efforts, demonstrate that the increased funds to battle health care fraud and abuse continue to be sound investments, as well as good public policy.

FUNDING FOR DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Certain of the funds appropriated under HIPAA are, by statute, set aside for Medicare and Medicaid activities of the HHS/OIG. During the fourth year of the Program, the Act provides that between \$110 and \$120 million be devoted to these purposes. The Secretary and the Attorney General jointly allotted \$118.3 million to the HHS/OIG in 2000, an increase of \$18.5 million over 1999. An additional \$916,000 was spent on operational costs associated with the HIPDB.

HHS/OIG conducted or participated in 771 prosecutions or settlements in 2000, of which 586 were health care cases. A total of 3,350 individuals and entities were also excluded, many as a result of criminal convictions for crimes related to Medicare or Medicaid (581); or to other health care programs (111); for patient abuse or neglect (342); based on licensure revocations (1,646).

In addition to the HHS/OIG's role in bringing about the judgments and settlements described in the Overview of Accomplishments, the Department of Health and Human Services acted on HHS/OIG recommendations and disallowed \$110.7 million in improperly paid health care funds in 2000. HHS/OIG continues to work with HCFA to develop and implement recommendations to correct systemic vulnerabilities detected during HHS/OIG evaluations and audits. These corrective actions often result in health care funds not expended (that is, funds put to better use as a result of implemented HHS/OIG initiatives). In 2000 such funds not expended on improper or unnecessary care amounted to more than \$14.1 billion -- about \$12 billion in Medicare savings, and nearly \$2.1 billion in savings to the Medicaid program.

HHS/OIG moved closer to its goal of extending its investigative and audit staffs to cover all geographical areas in the country, particularly those that were previously underserved. During 2000, HHS/OIG "full-time equivalent" positions devoted to HCFAC activities increased from 942 to 1,003 by the end of the year. HHS/OIG opened 14 new investigative offices, with the result that OIG now is physically present in 47 states.

Fraud and Abuse Prevention

The increased resources made available under HIPAA have enabled the HHS/OIG to expand activities designed not just to uncover existing fraud and abuse, but to *prevent* it. Vital prevention initiatives, such as those listed below, inform and assist the health care industry, and patients. Equally important, these prevention activities reduce the government's enforcement costs and program losses. **Compliance Guidance**. A key element of HHS/OIG's prevention efforts has been the development of compliance program guidance to encourage and assist the private health care industry to fight fraud and abuse. The guidance, developed in conjunction with the provider community, identifies steps that health providers may voluntarily take to improve adherence to Medicare and Medicaid rules. In 2000, the HHS/OIG developed and released final compliance program guidance for hospices, Medicare+Choice organizations offering coordinated care plans, nursing facilities, and individual and small group physician practices..

Corporate Integrity Agreements. Many health care providers that enter agreements with the government in settlement of potential liability for violations of the False Claims Act also agree to adhere to a separate "corporate integrity agreement." Under this agreement, the provider commits to establishing a program or taking other specified steps to ensure its future compliance with Medicare and Medicaid rules. The duration of most corporate integrity agreements is 5 years, during which time the provider must submit periodic reports to HHS/OIG. These agreements require a substantial effort by the provider to ensure that the organization is operating in accordance with Federal health care program requirements and the parameters established by the corporate integrity agreement. Breach of the agreement may result in a variety of sanctions, including exclusion of the provider. At the close of 2000, HHS/OIG was monitoring more than 475 corporate integrity agreements.

Industry Guidance. The centerpiece of the HIPAA guidance initiatives was an advisory opinion process through which parties would obtain binding legal guidance as to whether their existing or proposed health care business transactions ran afoul of the Federal anti-kickback statute, the civil monetary penalties laws, or the exclusion provisions. During 2000, the HHS/OIG issued 11 opinions. A total of 50 advisory opinions have been issued since 1997. The advisory opinion process serves to enhance the HHS/OIG's understanding of new and emerging health care business arrangements and informed the development of new safe harbor regulations, fraud alerts, and special advisory bulletins. During 2000, information gleaned from the advisory opinion process contributed to the final regulatory safe harbors for ambulatory surgical centers and practitioner recruitment, as well as the proposed safe harbor for ambulance restocking and the special fraud alert on rentals of space in physician offices.

In addition, the HHS/OIG has made frequent presentations to industry groups on areas of suspected fraud and abuse and measures they can take to avoid trouble.

The HHS/OIG made significant strides toward resolving pending safe harbor regulations. Formal clearance was begun for a proposed anti-kickback safe harbor for ambulance restocking arrangements between hospitals and ambulance providers who transport patients to hospital emergency rooms and a proposed safe harbor under the civil money penalty law for inducements to beneficiaries to protect certain payments by ESRD facilities of insurance premiums for their patients. Two final anti-kickback statute safe harbor rules were finalized for issuance in early 2000 -- one promulgating eight new safe harbors and a series of clarifications to existing safe harbors (originally proposed in 1993 and 1994), and another addressing the statutory exception for shared risk arrangements.

In addition, HHS/OIG has made frequent presentations to industry groups on areas of suspected fraud and abuse and measures they can take to avoid trouble.

"Clean" Audit Opinion: This past year, HCFA achieved an important milestone in financial accountability. In its report on HCFA's FY 1999 financial statements, HHS/OIG issued an unqualified, or "clean," audit opinion. This means that HCFA successfully resolved previously reported opinion issues and that the 1999 statements reliably presented financial information. During 1999, HCFA initiated a major effort to validate and document accounts receivable. The project, which was jointly conducted by HCFA, HHS/OIG, and two independent accounting firms, enabled HHS/OIG to report, for the first time, that the receivables balance was fairly presented as of the year's end. However, HHS/OIG found that HCFA and the Medicare contractors still did not have adequate internal controls to ensure that future receivables would be properly reflected in their financial reports. Absence of a fully integrated financial management system also continued to impair HCFA's ability to accumulate, reconcile, analyze, and report financial information in a timely manner. Weaknesses continued in EDP general controls at the HCFA central office and the Medicare contractors, as well as in application controls at the contractors' shared systems. The HCFA concurred with HHS/OIG's recommendations and is in the process of taking corrective action.

Medicare Error Rate: For the 1996 financial statement audit period, HHS/OIG developed the methodology to measure noncompliance with laws and regulations in the Medicare fee-for-service program. The HHS/OIG developed the estimate of improper payments with the support of medical experts from the Medicare contractors and peer review organizations who, with the HHS/OIG, reviewed a comprehensive, statistically valid sample of Medicare fee-for-service claims expenditures and supporting medical records to determine the accuracy and legitimacy of the claims. This resulted in the first-ever, statistically valid, national rate of improper Medicare payments. At HCFA's request, HHS/OIG has continued these reviews annually. For the 1999 financial statement audit period, HHS/OIG reported that improper Medicare fee-for-service payments totaled an estimated \$13.5 billion. That estimate is about \$1 billion more than the previous year's estimate and is \$9.7 billion less than that for 1996. While the latest estimate is higher than the previous year, HHS/OIG cannot conclude that there is a statistical difference between the 1998 and 1999 error rates.

In response to the OIG work, HCFA has demonstrated vigilance in monitoring changes in the error rate and developing appropriate corrective action plans. The audit results also show that the majority of health care providers submit claims to Medicare for services that are medically necessary, billed correctly, and documented properly. For both 1998 and 1999, HHS/OIG estimated that over 90 percent of the fee-for-service payments met Medicare reimbursement requirements. While HHS/OIG's 4-year analysis indicates continuing progress in reducing improper payments, there are indicators that documentation errors and medically unnecessary services have been and continue to be pervasive problems. These two error categories accounted for over 70 percent of the total improper payments over the 4 years. The HCFA needs to sustain its efforts to maintain progress in reducing these improper payments.

Recommendations for Systemic Improvements: Frequently, investigations (and resulting civil settlements or criminal prosecutions), audits and evaluations reveal vulnerabilities or incentives for fraud in agency programs or administrative processes. As required by the Inspector General Act, the HHS/OIG makes recommendations to correct these vulnerabilities, and thereby promote economy and efficiency in HHS programs and operations. Relying on the independent factual information generated by HHS/OIG, agency managers fashion legislative proposals and other corrective actions that, when enacted or implemented, close loopholes and avoid ineffective expenditures or improper conduct. The net savings from these joint efforts toward program improvements can be substantial. Many of the studies described throughout this report offered evidence and ideas supporting proposals for significant cost savings during 2000 and beyond. Prominent examples of these reviews include Medicaid's upper payment limits, and Medicare payments for home health, as follows:

Medicaid Enhanced Payments to Public Providers: Based on work in three States, HHS/OIG testified before the Senate Committee on Finance regarding States' use of manipulative financing schemes that exploit a provision in Medicaid's "upper payment limit" regulations governing enhanced payments to certain providers. This issue was brought to HHS/OIG's attention by HCFA officials, who provided

information that assisted in selecting States for review. They are also providing technical assistance, as needed, during HHS/OIG's ongoing work in other States.

The HHS/OIG noted that some States are using intergovernmental transfers to artificially generate excessive Federal matching payments at the expense of other States and contrary to the intent of the program. These abusive practices increase the Federal share of Medicaid without a corresponding increase in the States' share or in the amount or quality of services provided to Medicaid patients. In response to these findings, HCFA quickly drafted a regulation to redefine the types of facilities properly included in upper payment limit classifications. These regulations are estimated to save approximately \$55 billion over the next 10 years. The HHS/OIG also offered recommendations should the Congress want to act to close this loophole.

Medicare Home Health Services: The HHS/OIG's review of home health services in four States with large Medicare expenditures "¿½ California, Illinois, New York, and Texas "¿½ revealed that 40 percent of payments for such services for a 15-month period ending March 1996 were improper or inappropriate. The audit report contained various recommendations which HCFA implemented. The HHS/OIG's followup review, conducted at HCFA's request, covered the same four States and used 1998 home health data. That review revealed that HCFA's corrective actions were working, since the improper payment rate had fallen to 19 percent. An improper or inappropriate payment for a home health service is one that lacked a valid physician order, was provided to a beneficiary who was not homebound, could not be documented, or allegedly took place at a terminated home health agency where service records could not be found.

HCFA agreed with HHS/OIG recommendations to further revise Medicare regulations to require the certifying physician to examine the patient before ordering home health services and see the patient at least once every 60 days, and to instruct the fiscal intermediaries to collect the identified overpayments.

Outpatient Rehabilitation Facilities: Over the past several years, Medicare payments for outpatient rehabilitation facility (ORF) services increased substantially i.i. from \$378 million in 1993 to \$572 million in 1997. HHS/OIG conducted an audit of outpatient physical therapy, occupational therapy, and speech pathology services to determine if they were provided and billed in accordance with Medicare requirements. The HHS/OIG's work was supported by HCFA and the medical review staffs at HCFA's contractors.

The HHS/OIG reviewed Medicare payments to ORFs for the fiscal year ended June 30, 1998 in six States that accounted for about 50 percent of total ORF payments nationwide during CY 1997. Based on a statistical sample, HHS/OIG estimated that Medicare paid \$173 million for unallowable or highly questionable ORF services. These payments were made to beneficiaries who exhibited no functional impairment, evidenced no active participation with the therapist, and/or had no expectation for significant improvement within a reasonable and predictable length of time.

The HHS/OIG recommended and HCFA agreed to consider implementing a review process for new providers to include an evaluation of whether the services provided to beneficiaries meet Medicare requirements, consider a periodic recertification requirement for ORFs, and instruct fiscal intermediaries to recover the identified overpayments and review other ORF claims for the sampled beneficiaries and recover additional overpayments. Further, HHS/OIG proposed that HCFA require the intermediaries to provide in-house educational services to new providers, conduct a prepayment medical review of claims submitted by new providers, and intensify medical review of claims submitted by ORFs.

Focus on Quality of Care

HHS/OIG investigations, audits and evaluations focus not just on improper billing for health care services, but also the quality of care provided to program beneficiaries. These efforts include:

Prosecution and Exclusion of Dangerous Provider. A New York ophthalmologist was sentenced to 4 years in custody, 3 years supervised release and a \$75,000 fine for conspiring to submit false claims to Medicare. In accordance with his plea agreement, the ophthalmologist also previously repaid the Government \$8.55 million, representing the second largest single provider recovery in the United States and the largest in the Eastern District of New York. He was also permanently excluded from participating in the Medicare program. Investigation by HHS/OIG into the ophthalmologist's activities revealed that he performed cataract surgeries on patients who did not have cataracts and performed glaucoma laser procedures on patients who did not have glaucoma. He also billed for other ophthalmological procedures that were either not performed or were not medically necessary. As a result of the investigation, the New York State Office of Professional Medical Conduct revoked his license to practice medicine.

Vaccinations for Nursing Home Residents. An objective of HHS's Healthy People 2010 public health goal is to increase vaccination rates for influenza and pneumococcal disease in nursing homes to 90 percent. Although Medicare covers both of these vaccines, data suggests that nursing homes fall short of this mark. After evaluating HCFA and the Centers for Disease Control and Prevention's (CDC) vaccination efforts in this area, the HHS/OIG recommended that HCFA consider requiring nursing homes to assess residents for vaccinations upon admission and add vaccination data to the Minimum Data Set which nursing homes are required to collect. In addition, HCFA and CDC can use the Minimum Data Set to identify and reach out to nursing homes with low vaccination rates through their network of regional and field offices which are familiar with local nursing homes and the populations they serve.

Infusion Therapy Services in Skilled Nursing Facilities: In a review of three infusion suppliers for the period 1995 through 1998, HHS/OIG determined that they provided Medicare-reimbursed skilled nursing facilities (SNF) with infusion therapy services that were medically unnecessary and excessively priced. In addition, the three infusion suppliers billed certain infusion services incorrectly, causing those costs to be misclassified on the SNFs' cost reports. This occurred because the reimbursement system was vulnerable to abusive billing schemes. Patients were placed at undue risk, Medicare overpaid the SNFs, and the overpayments may have been included in base-year costs used to establish the prospective payment system (PPS) rates.

The HHS/OIG recommended and HCFA agreed to consider the impact of improper payments for infusion therapy services before making any refinements or updates to the PPS rates, identify and recover overpayments made to SNFs for unnecessary and overpriced infusion services prior to the adoption of PPS, and direct its contractors to perform medical reviews of selected SNF patients to ensure that patients receive appropriate levels of infusion therapy. This work received congressional attention during discussions before enactment of the Balanced Budget Refinement Act of 1999.

Patient Anti-Dumping Enforcement. HHS continues to vigorously pursue potential violations under the Emergency Medical Treatment and Labor Act (EMTLA), also called the patient anti-dumping statute. In 2000, HHS/OIG obtained 48 settlement agreements and judgments with hospitals and physicians and collected civil monetary penalties of nearly \$1.2 million. This reflects the continued commitment of both HCFA and HHS/OIG to ensure patient access to appropriate emergency medical services.

Focus on Mental Health Services

Audits of the Partial Hospitalization Program. Under the partial hospitalization program (PHP), Medicare pays for intensive outpatient psychiatric services for acutely ill individuals who would otherwise require hospitalization. These services can be provided by either hospital outpatient departments or community mental health centers (CMHC). Earlier HHS/OIG audits identified sizable Medicare payments for unallowable or highly questionable services at CMHCs. In 2000, HHS/OIG assessed the propriety of provider claims for outpatient services at acute care hospitals and at additional CMHCs. HHS/OIG worked in collaboration with HCFA and medical review staffs at the Medicare contractors. The HHS/OIG selected claims from acute care hospitals in the 10 States with the highest charges for outpatient psychiatric services: California, Connecticut, Florida, Illinois, Louisiana, Massachusetts, Michigan, New York, Pennsylvania, and Texas. In reviewing 200 claims from the 10 States for CY 1997 totaling \$168,857, HHS/OIG concluded that \$94,716 of the charges did not meet Medicare criteria for reimbursement because they were not documented in accordance with Medicare requirements, not reasonable and necessary, and /or rendered by unlicensed personnel. Based on this sample, HHS/OIG estimated that for CY 1997, acute care hospitals submitted claims to Medicare totaling more than \$224 million (approximately 59 percent of the amount claimed) for unallowable or unsupported psychiatric services in the 10 States. The HHS/OIG recommended that HCFA consider implementing a first-claim medical review of a random sample of new outpatient psychiatric claims; require Medicare fiscal intermediaries to increase postpayment reviews of outpatient psychiatric service claims; require intermediaries to initiate recovery of payments for claims found in error; and further emphasize its documentation requirements for all types of outpatient psychiatric services through seminars, educational sessions, and newsletters.

Reviews at five individual hospitals found similar unallowable charges. Based on statistical samples, HHS/OIG estimated that outpatient psychiatric claims submitted over a 1-year period were overstated by about \$1.9 million for one hospital, \$1.1 million for each of two hospitals, over \$750,000 for another, and at least \$314,000 for the last hospital. Additional outpatient psychiatric costs claimed on the hospitals' Medicare cost reports were also determined to be unallowable. In all cases, HHS/OIG referred the review results to the fiscal intermediaries for appropriate financial adjustments. The HHS/OIG also recommended that the hospitals strengthen their procedures to ensure that charges for outpatient psychiatric services are covered and properly documented.

A separate review of partial hospitalization services provided by a CMHC over a 1-year period disclosed that 100 percent of the services included in the sampled claims should not have been paid by Medicare, resulting in estimated improper payments of more than \$4.4 million. At another CMHC, HHS/OIG

estimated that \$1.1 million in charges were not reasonable and necessary or not appropriate for the patients' conditions. In addition to recommending financial adjustments, HHS/OIG proposed that the centers ensure that any future services submitted to Medicare for reimbursement are covered and documented in accordance with Medicare requirements.

Civil Settlement of Improper PHP. This year also saw a significant civil settlement for potentially improper partial hospitalization claims. A Pennsylvania health system agreed to pay the Government \$12 million to resolve its successor liability under the False Claims Act for improper partial hospitalization program billing practices by the hospital it acquired. Initiated through a qui tam suit, this settlement resolved allegations of billing misconduct that occurred between 1993 and 1997. The allegations included billing for patients who were so impaired they were unable to benefit from PHP services; billing for services of a purely recreational, non-therapeutic nature; billing for more time than was actually provided; and billing for improperly supervised services. In addition to paying \$12 million, the health system also agreed to extend the scope of its preexisting 3-year corporate integrity agreement for pneumonia upcoding violations to encompass PHP services as well. The health system ceased operating the previous hospital's PHP programs which formed the basis for the case.

Focus on Managed Care, and Medicare + Choice:

Medicare Managed Care Payments: The Balanced Budget Act of 1997 modified the methodology used to determine managed care organization (MCO) payments, partly because of concerns that many MCOs were overcompensated. MCO industry representatives claimed that these payment changes were too severe. Therefore, at HCFA's request, HHS/OIG, through multiple studies, examined the impact of the changes and reported that (1) the basis on which monthly capitation payment amounts were calculated was flawed, (2) Medicare payments were used to fund unnecessary administrative costs and excess profits, (3) investment income was not accounted for by MCOs in the Medicare payment formula, and (4) improper payments were made to MCOs for erroneously classified beneficiaries. The cumulative impact of these issues is that MCOs receive more than an adequate amount of funds to deliver the Medicare package of covered services. Therefore, HHS/OIG recommended that HCFA use all of this work to modify the present monthly rates to a level fully supported by empirical data. The HCFA agreed with the overall finding that MCO payments are adequate to fund the Medicare package of covered services. First Settlement with Medicare Managed Care Company. As the result of an HHS/OIG audit, a publicly traded Medicare managed care company agreed to pay \$14.5 million to settle allegations that the company provided inaccurate enrollment data to Medicare. This is the first False Claims Act settlement that involved billing misconduct in the Medicare managed care program. Specifically, the audit revealed that the company received Medicare payments for Medicare beneficiaries who were members of the company's plans and were incorrectly listed by the plans as dually eligible for both Medicare and Medicaid. As part of the settlement agreement, the company has entered into a comprehensive 5-year corporate integrity agreement.

Other Judgments and Settlements. In addition to the significant enforcement actions described in the Program Accomplishments section of this report, the HHS/OIG conducted or participated in over 586 investigations that resulted in prosecution or settlement during 2000, involving all aspects of the health care industry. These include:

- Kickback Cases: A Texas corporation agreed to pay the Government \$10 million and entered into a comprehensive corporate integrity agreement to resolve liability for misconduct on the part of two of its Florida subsidiaries. The corporate subsidiaries are mail-order pharmacies providing respiratory medications and diabetic supplies to Medicare beneficiaries nationwide. The agreement settles allegations that these entities made, or caused to be made, improper payments to DME companies for the referral of Medicare beneficiaries and routinely waived coinsurance charges. An OIG investigation and audit showed that from 1990 to 1997, the subsidiaries made payments to numerous DME companies and individuals to induce the companies to refer patients to them for the purchase of supplies. The patients typically referred were patients to whom the DME companies previously provided medical equipment and oxygen. Both defendant corporations also routinely waived certain coinsurance amounts in connection with their sale of respiratory medication.
- Contractor Impropriety: A regional Medicare carrier agreed to pay the Government close to \$9 million for allegedly submitting false administrative cost reports, and entered into a corporate integrity agreement with the HHS/OIG. The company improperly charged HCFA for unallowable costs in connection with its Medicare carrier contract with the agency, and thereby received overpayments for costs incurred in operating the Medicare program. The HHS/OIG investigation and audit substantiated that the company knowingly over-counted costs incurred in printing Medicare checks and explanation of benefits forms, and charged HCFA for unallowable overhead costs (including risk insurance costs that were never incurred). During the HHS/OIG audit, the company knowingly failed to disclose these known overcharges.

Office of the General Counsel

In FY 2000, the Office of General Counsel (OGC) was allocated \$1.95 million in funding from the HCFAC. From 1999 to 2000, OGC continued to see an increase in its overall workload. The number of pending cases end of year increased from 2,512 matters to 3,106 matters, a 20 percent increase. New cases increased from 2,153 to 2,242, a 4 percent increase.

The major program areas in which the largest increase of cases has been seen include: (1) Civil Money Penalties (CMPs) and other sanctions imposed on nursing facilities; (2) revocations, terminations or denials of provider status (especially nursing facilities, home health agencies, as well as CMHCs (under the ORT CMHC Initiative); and, (3) suspensions of Medicare payments to providers and suppliers.

OGC also reviews matters involving the Clinical Laboratory Improvement Act (CLIA) of 1988 (P. L. 100-578) which requires, among other things, that HHS establish certification requirements for any laboratory that performs tests on human specimens, and certify through issuance of a certificate, that those laboratories meet the certificate requirements established by the Department. Laboratories holding CLIA certificates are subject to inspections to determine their compliance with the requirements for issuance of the certificate, and with standards assuring consistent performance by the laboratories of valid and reliable laboratory examinations and other procedures.

In addition, the Business Administration and Law (BAL) Division coordinated and reviewed contract agreements dealing with contractor integrity prevention, monitoring and reporting for HCFA's Office of Acquisition and Grants as well as providing legal advice to HCFA on contractor debarment and suspension decisions.

Initiatives for Preventing Health Care Fraud:

Community Mental Health Center (CMHC) Initiative - Efforts continue in a large number of administrative appeals as a result of HCFA's CMHC Initiative. HCFA launched the Initiative in 1997 in an attempt to more effectively insure that Medicare reimbursement for partial hospitalization (an intensive and multimodal program of services intended for individuals who would otherwise require inpatient psychiatric care) would only be made to CMHCs and prospective CMHCs which met applicable statutory and regulatory requirements. To date, many of our offices have been successful in defending these appeals filed by CMHCs and prospective CMHCs before the Civil Remedies Division of the Departmental Appeals Board. For example, OGC Region IV office has to date, successfully defended ten (10) appeals.

Emergency Medical Treatment and Active Labor Act (EMTALA) Update:

 OGC assisted HHS/OIG in drafting a Special Advisory Bulletin to clarify the applicability of the EMTALA provisions to managed care organizations. In addition, the office assisted HCFA in drafting a regulation to clarify the scope of EMTALA so that hospitals will know when their obligations under EMTALA begin and end, and whether the obligations under EMTALA apply to hospital inpatients. In 2000, both the provider enrollment regulation and the EMTALA regulation were finalized although not yet promulgated.

Policy Guidance and Education:

- The Region V office worked to improve the effectiveness of the Nursing Home Initiative (NHI) enforcement effort by: (1) recommending legislation and submitting comments on draft legislation (ultimately included in the Department's legislative package) to bar federal court jurisdiction over attempts by Medicaid-only facilities to enjoin HHS enforcement actions; (2) assisting with the proposed changes in the State Operations Manual; (3) commenting on and suggesting revisions (in concert with the HCF Division and Region IX) to HCFA's model enforcement notice letters; (4) proposing changes to the regulations governing appeals; (5) making presentations to HCFA surveyors and enforcement staff, state surveyors (Minnesota) and state survey agency attorneys (Illinois) on survey and enforcement issues; and (6) Region V prepared a 160-page digest of all administrative decisions in nursing home enforcement cases, which is now used by HCFA and OGC offices nationwide.
- The Region VI office has conducted outreach with various interested stakeholders in the Medicare program. These efforts included presentations to state survey agency attorneys, CLIA surveyors, fiscal intermediaries, the Texas Trial Lawyers' Association and various other bar associations. Topics presented included the long term care appeals process, the CLIA survey process, the Medicare Secondary Payer program, Medicare and bankruptcy and suspension of payments. They are also actively involved in the State of Texas' Nursing Home Initiative Workgroup. This Workgroup, which is composed of numerous organizations, including the Texas Department of

- Human Services, the Texas Attorney General's office, the FBI and the OIG, meets several times a year to coordinate long term care enforcement activities in Texas.
- Bankruptcy/NHI Conference OGC sponsored a training conference to bring together DOJ and HCFA to discuss issues in long term care and bankruptcy. The participants reviewed and revised regulations that would improve our effectiveness; reviewed the Department's jurisdiction and enforcement strategies, and established procedures to improve consistent application of policies and practices as well as instituted procedures to identify and resolve cross-cutting issues more expeditiously.

Administration on Aging

In fiscal year 2000, the Administration on Aging (AoA) was allocated \$1.45 million in HCFAC funds to train and educate both paid and volunteer aging network staff to recognize and report potential practices and patterns of fraud, waste, and abuse in the Medicare and Medicaid programs. These activities were focused on training nursing home ombudsmen, health insurance counselors, state and area agency on aging staff, senior center directors, social workers, eldercare information specialists, and other professionals in 18 states how to identify and report potentially fraudulent practices.

This funding also helped to support the technical assistance and nationwide infrastructure for educating beneficiaries to be the "eyes and ears" of the Medicare system. The AoA and its network agencies engaged in coordinated outreach and educational activities designed to assist older persons and their families to recognize and report fraudulent and abusive situations and to prevent or minimize victimization of such behavior.

Accomplishments

- The 18 grantees trained more than 10,000 staff and volunteers to be Medicare resources and educators in their communities.
- With the collaboration and assistance of HCFA, the HHS/OIG, health care providers, and other
 professionals from around the country, the projects developed community-based training manuals,
 educational brochures, and public information documents designed to recruit volunteers, involve
 providers in the campaign, and inform beneficiaries regarding what they should do if they have questions
 regarding their Explanation of Medicare Benefits Statement or Medicare Summary Notice.
- The AoA's grantees convened more than 1,600 community education events which trained and informed nearly half a million individuals through public forums how to identify and report health care waste, fraud, and abuse. An additional 20 million individuals were reached through the projects' more than 500 media events.
- The AoA conducted an outreach campaign designed to reach members of the African American, Hispanic, and Chinese communities. As part of this initiative, the AoA developed videos and informational brochures in English, Spanish, and Mandarin Chinese. The materials were distributed to more than 12,000 senior volunteers nationwide who provide training and education to Medicare and Medicaid beneficiaries.
- The AoA's projects were able to directly document more than \$20 million recovered, to be recouped primarily through Medicaid funds. There is also likely a sentinel effect to these efforts, whereby fraud and errors are reduced in light of beneficiaries scrutinizing their bills.

HCFAC funding also provided vital technical assistance to support AoA's 48 Senior Medicare Patrol Projects which have been highly successful in recruiting and training retired professionals to report waste, fraud, and abuse. During 2000, these projects trained an additional 5,000 community volunteers, who educated more than 200,000 Medicare and Medicaid beneficiaries how to scrutinize their Medicare bills and summary notices.

Health Care Financing Administration and Assistant Secretary for Management and Budget

At the end of 2000, \$451,000 of HCFAC funds was allocated to HCFA (\$395,500) and the Assistant Secretary for Management and Budget (ASMB) (\$55,500) to fund contractual consultant services on establishing a formal risk management function within each organization. The contract was awarded to Booz�Allen and Hamilton in September, 2000. The funding provides consulting services over a six month period, ending March 1, 2001.

HCFA intends to centrally coordinate the development and implementation of best practices in risk identification, assessment, and response management throughout the operations of Medicare and Medicaid. It is anticipated that this will enable improved benchmarking and effectiveness in managing the organizational vulnerabilities to health care fraud and abuse. Based on the resulting White Papers and recommendations, HCFA will adopt and implement a new risk management framework.

ASMB is using the consultant's services to explore whether an organization-wide risk management approach would help the ASMB fulfill his roles and responsibilities in mitigating financial systems and other risks to the Medicare and Medicaid programs that can adversely affect the Department's efforts to prevent fraud and abuse. These risks, which are inherent in such large scale programs, currently are managed through a variety of ASMB functions, including analysis of information technology and systems decisions, financial management analysis and reviews, and oversight of budgetary issues and program performance information. Based on the resulting White Papers and recommendations, ASMB will decide whether to adopt a new risk management framework that better integrates these functions, and if so, how this approach will be implemented.

FUNDING FOR DEPARTMENT OF JUSTICE

United States Attorneys

Health care fraud involves a variety of schemes that defraud public and private insurers and providers nationwide. In addition to Medicare and Medicaid, a number of federally funded health benefit programs have been the targets of these schemes. The fraudulent activity may include double billing schemes, kickbacks, billing for unnecessary or unperformed tests, or may be related to the quality of care provided to patients. In addition to monetary losses, in some instances these improper activities endanger patient safety. United States Attorneys' offices (USAOs) are responsible for civilly and criminally prosecuting health care professionals, providers, and other specialized business entities who engage in health care fraud and abuse.

USAOs continue to strengthen cooperative efforts with federal, state and local law enforcement agencies involved in the prevention, evaluation, detection, and investigation of health care fraud and abuse. In addition to the FBI, HHS/OIG and HCFA, USAOs offices work with State Medicaid Fraud Control Units, Offices of Inspectors General for a number of federal agencies, the Drug Enforcement Administration, and the DCIS and TRICARE Support Office. Each USAO has appointed both a civil and criminal health care fraud coordinator to assist in coordination and facilitate communication between federal, state and local law enforcement groups. In addition, many cases are investigated in a parallel fashion, so that potential criminal and civil remedies are addressed more efficiently, by the attorneys and the agencies investigating the wrongdoing. The criminal and civil judgments and settlements with the worlds largest provider of kidney dialysis products and services and the nations largest operator of nursing homes discussed in the program accomplishments above were among the many significant accomplishments of the USAOs and are examples of such parallel investigations and prosecutions.

Prior to the enactment of HIPAA, USAOs dedicated substantial resources to combating health care fraud and abuse. HIPAA allocations have supplemented these efforts.

Training

The Executive Office for the United States Attorneys' Office of Legal Education (OLE) is tasked with the responsibility for providing health care fraud training for USAO and DOJ attorneys, investigators, and auditors. During 2000, OLE conducted a number of courses and presentations on health care fraud, including:

- · Civil Health Care Fraud for Attorneys
- · Criminal Health Care Fraud for Attorneys
- Health Care Fraud Seminar for Attorneys it 1/2 Criminal and Civil
- · Affirmative Civil Enforcement for attorneys (includes a health care fraud component)
- · Affirmative Civil Enforcement for auditors and investigators (includes a health care fraud component)

While the primary participants in OLE sponsored courses were DOJ employees, agency counsel and investigative personnel were also invited to participate as presenters and students. In addition to OLE sponsored training a number of USAO attorneys, auditors and investigators participated in multi-agency health care fraud training courses over the last year.

Accomplishments - Criminal Prosecutions

The primary objective of criminal prosecution efforts is to ensure the integrity of our nation's health care programs and to punish and deter those who, through their improper activities, adversely affect the health care system and the taxpayers.

Each time a criminal case is referred to a USAO from the FBI, HHS/OIG, or other law enforcement agency, it is opened as a matter pending in the district. A referral remains a matter until an indictment or information is filed or the case is declined for prosecution. In 2000, the USAOs had 1,939 criminal matters pending involving 3,049 defendants, a 2.7 percent decrease in the number of criminal matters over 1999. During 2000, 457 cases were filed involving 668 defendants. This represents a 23 percent increase over cases filed in 1999. A total of 467 defendants were convicted for health care fraud-related crimes in 2000. Health care fraud convictions include both guilty pleas and guilty verdicts.

In Ohio, a DME company owner was sentenced for conspiracy to commit mail fraud and money laundering to 70 months imprisonment, payment of \$15.1 million in restitution, and 3 years supervised release. The owner pled guilty to charges of defrauding Medicare through a multimillion dollar fraud scheme in which he billed the program for urinary incontinence supplies not provided. In actuality, he provided diapers, bed pads and other supplies not covered by Medicare. Additionally, a jury convicted the DME company's former vice-president of corporate affiliates for her participation in this scheme. She also utilized improper billing codes for non-covered diapers and skin care supplies. To hide the scheme from Medicare, she altered certificates of medical necessity, billing codes, amounts billed and supplies provided. She was sentenced to 10 years imprisonment, 3 years probation and payment of restitution, including payment of \$135,047 to a private insurance company affected by the scheme.

In New York, four individuals were convicted on charges of participating in a scheme involving false billing for health care services for senior citizens to defraud the Medicare program. After a 6-week jury trial, the four defendants were found guilty of conspiracy and receiving kickbacks in exchange for referring lab tests billed to Medicare. The four were also convicted of numerous substantive charges of health care fraud, submitting false statements in connection with the delivery and payment of Medicare benefits, and fraudulently seeking Medicare payments based on false claims for physicians' services. The four defendants ran a program that claimed to provide valuable home-care medical services to senior citizens enrolled in the Medicare program. Senior citizens in urban areas of New York and New Jersey were contacted by telemarketers working for the defendants' company who set up appointments for the senior citizens to be visited in their homes. Unlicenced graduates of foreign medical schools then visited the Medicare beneficiaries, performed a few simple, non-invasive tests, and obtained a rudimentary physical history, along with the senior citizens' Medicare beneficiary numbers. According to the trial evidence, after these visits, practicing physicians and the defendants used Medicare-issued provider numbers to submit more than \$12 million in fraudulent claims to Medicare for thousands of cardiac and vascular procedures and lab tests on urine specimens.

In Indiana, a chiropractor, was sentenced to 21 months' imprisonment, followed by 3 years' supervised release, and ordered to pay \$1,000,000 restitution for filing false claims with the Medicaid Program. The defendant owned and operated two chiropractic clinics. He employed marketeers to canvass the areas around his clinics to seek out Medicaid-eligible children ages 16 and younger who would then be brought to his clinics for various treatments. The defendant instructed his staff to perform Temperature Gradient Studies on every child who came to the clinics, even though these studies were not typically necessary, and were neither viewed nor used by the attending chiropractor prior to or during treatment of the young patients.

In Delaware, a doctor specializing in pain management services was convicted of health care fraud, mail fraud and money laundering and sentenced to six and one half years in jail for scheming to defraud insurance companies of over \$2 million. The doctor was convicted of submitting bills for pain management services that she did not perform. Instead, the doctor copied test results from one patient to another and submitted falsified tests to insurance companies in support of her claims for payment. In many cases the test results from one patient were "cut and pasted," so that one patient's name was taped over the name of another. In other cases, the name of one patient was removed with white out, and used to the support claims for services claimed to be provided to other patients. In over 100 cases, test results between two patients matched identically, which according to expert testimony, is a physical impossibility. The money laundering conviction involved the doctor's efforts to conceal the proceeds of the health care fraud by engaging in convoluted financial transactions to send the money overseas.

A former State Senator was sentenced to serve five years in prison, and to pay \$98,175 in restitution and \$50,000 in fines, for conspiring to defraud Medicare. The conspiracy involved more than five additional actors, with the State Senator as the organizer/leader. The state senator was the unofficial owner of two home health nursing companies through which the conspirators billed false claims.

Accomplishments - Civil Cases

Civil health care fraud efforts constitute a major focus of Affirmative Civil Enforcement (ACE) activities. The ACE Program helps ensure that federal laws are obeyed and that violators provide compensation to the government for losses and damages they cause. Civil health care fraud matters ordinarily involve the United States utilizing the False Claims Act, as well as common law fraud remedies, payment by mistake, unjust enrichment and conversion to recover damages from those who have submitted false or improper claims to the United States.

Each time a civil referral is made to a USAO it is opened as a matter pending in the district. Civil health care fraud matters are referred directly from federal or state investigative agencies, or result from filings by private persons known as "relators," who file suits on behalf of the Federal Government under the 1986 qui tam amendments to the False Claims Act. Relators may be entitled to share in the recoveries resulting from these lawsuits. At the end of 2000, the USAOs had 1,995 civil health care fraud matters pending. A matter becomes a case when the United States files a civil complaint, or intervenes in a qui tam action, in United States District Court. The vast majority of civil health care fraud cases and matters are settled without a complaint ever being filed. In 2000, 233 civil health care fraud cases were filed.

In Maryland, a life insurance company agreed to pay the United States approximately \$9 million to resolve civil claims, brought to the government's attention principally under the qui tam provisions of the False Claims Act. The complaint alleged that the company submitted false cost reports to the HCFA. The settlement resolved allegations that: (1) for the 1990-1997 fiscal years, the company double-counted paper costs that were incurred in printing Explanation of Medicare Benefit forms and Medicare checks; (2) knowingly charged HCFA for unallowable overhead costs; (3) knowingly charged for costs it did not incur, or which were overstated; and (4) failed to disclose the overcharges to the Office of Audit Services of the HHS-OIG during a 1995 audit. As part of the settlement, the company also agreed to enter into a comprehensive Corporate Integrity Agreement with the HHS/OIG.

In Louisiana, a health center agreed to pay the United States approximately \$1.5 million for submitting false claims under the Medicare and Medicaid programs. Pursuant to the settlement agreement, the health center admitted that it submitted false claims for anesthetic services provided by a doctor which were never performed. and also admitted that it submitted false claims for anesthesia services by the same doctor when it knew he did not meet the licensure requirements to be a physician in the state. The health center agreed to implement a Corporate Integrity Program to prevent fraud, abuse, and false billings to Medicare, Medicaid and all other federal health care programs.

Civil Division

Civil Division attorneys vigorously pursue civil remedies in health care fraud matters, working closely with the USAOs, the FBI, the Inspectors General of the Department of Health and Human Services and the Department of Defense, the HCFA, and other federal and state law enforcement agencies. Cases involve providers of health care services, supplies and equipment, as well as carriers and fiscal intermediaries, that defraud Medicare, Medicaid, the TRICARE program of the Department of Defense, the FEHBP, and other government health care programs.

Accomplishments

In 2000, a total of 128 health care fraud cases or matters were filed or opened. In addition to these new efforts, the Civil Division pursued over 400 existing cases. A significant number of the Division's health care fraud cases have the potential for particularly high damages. Civil Division attorneys were actively involved in the successful recoveries described in the overview. The following discussion demonstrates the breadth and significance of other cases in which the Division was involved during 2000.

Lab Tests: In culmination of an investigation begun in early 1997, a dialysis services company based in Sweden, and two of its Florida subsidiaries, agreed to pay the Government more than \$53 million to settle allegations of submitting false claims to Medicare, Medicaid and TRICARE for end stage renal disease (ESRD) laboratory services. The laboratories allegedly billed Medicare for medically unnecessary lab tests; double billed for lab tests included in ESRD composite rate payments; and violated the 50 percent rule, which specifies that if 50 percent or more of the laboratory tests performed as a profile of tests are included in the composite rate, then the entire profile is considered to be included in the composite rate. As part of the settlement agreement, the company entered into a 5-year comprehensive corporate integrity agreement targeting ESRD lab billing risk areas and covering any and all ESRD labs owned or operated by the company.

Upcoding: One of the largest operators of hospitals in rural areas and small cities agreed to pay the Government \$31.8 million for allegedly submitting false claims to Medicare, Medicaid and TRICARE, and to adhere to a corporate integrity agreement. The nationwide settlement resolved allegations of upcoding diagnostic codes through which the company received increased reimbursement amounts at 36 of its hospitals. The investigation revealed that the company initiated an aggressive coding procedure referred to as the optimization program. The program encouraged the chain's hospitals to meet very high, and often unrealistic,

coding volume goals, which led to excessive rates of reimbursement by Medicare, Medicaid and TRICARE. The investigation further determined that the inappropriate coding occurred based on improper guidance and instruction provided by officials from the company's headquarters in Tennessee.

More than 70 entities that provided, or assisted in the provision of, radiation oncology services to cancer patients, as well as their billing companies, agreed to pay almost \$10 million to settle allegations of false claims to federally-funded health care programs. The settlement also resolved claims that the defendants fraudulently transferred assets to avoid repaying the United States. During 2000, the United States recovered \$2.6 million from the clients of an Oklahoma-based physician billing service to settle claims of overpayments based on false claims submitted by the company. These settlements follow on the heels of a September 1999 settlement with the same company and its physician founder for \$15 million for fraudulent billing to Medicare, Medicaid, TRICARE, and the FEHBP. Including settlements in prior years, recoveries from this one Oklahoma-based company's clients themselves top \$13 million; the United States continues to pursue other clients of the company.

In addition to these case-specific accomplishments, the Department's Nursing Home Initiative, coordinated by the Civil Division, promotes increased prosecution and coordination at federal, state and local levels to fight the abuse, neglect, and financial exploitation of the nation's senior and infirm population. The financial crisis in the nursing home industry has to date resulted in bankruptcy filings by five of the seven largest nursing home chains and several smaller chains. These bankruptcy cases are the largest ever involving health care providers, and raise the specter of failure of care as well financial issues, thus requiring significant on-going coordination between the Civil Division's Corporate Finance and Civil Fraud sections, the Criminal Division, HCFA, and HHS/OIG.

Also, the Civil Division continues to chair the Managed Care Fraud Working Group, which meets quarterly and coordinates the managed care enforcement activities of all concerned federal and state agencies.

Vital resources were made available from the Account to provide the Civil Division with Automated Litigation Support (ALS), auditors, and consultants. These resources supplemented other Civil Division funds. During 2000, ALS was provided to 8 cases while auditor/consultant support was provided to 26 cases, included in those cases receiving support was the Department's tobacco litigation. Four of the supported cases have settled, yielding \$584 million. Recoveries in the remaining cases are projected to reach hundreds of millions of dollars.

Criminal Division

The Fraud Section of the Criminal Division develops and implements white collar crime policy and provides support to the federal white collar enforcement community. The Fraud Section supports the USAOs with legal and investigative guidance and, in certain instances, provides trial attorneys to prosecute criminal fraud cases. For several years, a major focus of Fraud Section personnel and resources has been to investigate and prosecute fraud involving federal health care programs.

The Fraud Section has provided guidance to FBI agents, Assistant United States Attorneys and Criminal Division attorneys on criminal, civil and administrative tools to combat health care fraud, and worked on an interagency level through:

- providing frequent advice and written materials on confidentiality and disclosure issues arising in the course of investigations and legal proceedings regarding medical records.
- monitoring and coordinating Departmental responses to major regulatory initiatives addressing medical records privacy and the Medicare + Choice program, as well as legislative proposals addressing Internet sales of drugs and medical products and possible expansion of the Medicare program to provide prescription drug benefits.
- reviewing and commenting on numerous requests for advisory opinions submitted by health care
 providers to the HHS/OIG and consulting with the HHS/OIG on draft advisory opinions per the
 requirements of HIPAA.
- cosponsoring a national conference on technologies and high-tech approaches for combating health
 care fraud and abuse. The conference provided a forum for representatives from the Department of
 Justice, Health and Human Services, and Defense, as well as state and local health program and law
 enforcement agencies to exchange information on electronic tools, analytical techniques, and
 collaborative approaches for detecting and preventing health care fraud and abuse. A conference
 proceedings report is being prepared with recommendations for future follow-up actions, including
 forming regional technology users groups and conducting regional training conferences.

- preparing and distributing to all USAOs and FBI field offices periodic updates on major issues, interagency initiatives, and significant activities of DOJ's health care fraud component organizations as well as periodic summaries of recent cases.
- organizing and overseeing the National level Health Care Fraud Working Group.
- participating on interagency working groups and task forces formed to address fraud in health care and managed care as well as newly emerging problem areas involving illicit online sales of drugs and medical products and nursing home fraud and resident abuse.

Justice Management Division

The Justice Management Division, Debt Collection Management Staff continues to perform for the program various administrative and coordination duties. The duties of this office include: budget formulation, oversight and coordinating with the Office of Management and Budget and HCFA; development and data collection for internal program evaluation; coordinating with HHS/OIG and the Department of the Treasury on the tracking of collections; coordinating with the GAO on required audits; and preparation and coordination of the annual report. In addition, the Staff assisted other components of DOJ with the organization and running of training conferences around the country in support of the Department's Nursing Home and Elder Abuse Initiative and the Data Technology Initiative.

APPENDIX

Federal Bureau of Investigation Mandatory Funding

"There are hereby appropriated from the general fund of the United States Treasury and hereby appropriated to the Account for transfer to the federal Bureau of Investigation to carry out the purpose described in subparagraph (C), to be available without further appropriation - (I) for fiscal year 2000, \$76,000,000."

Successful health care fraud enforcement cannot be achieved by any one agency alone. Investigations must be a cooperative effort if they are to be successful in combating the increasing problem of health care fraud. The FBI is involved in this cooperative effort. The FBI works many health care fraud cases on a joint basis with other federal agencies, including the HHS/OIG. These two federal agencies collaborate through attendance at health care fraud working groups, attend each other's training conferences, and have a liaison program between the two organizations. In addition, the Health Care Fraud task forces represent the coordinated efforts of the FBI, state and local law enforcement, investigative agencies such as Inspectors General, and private industry. The FBI and HHS/OIG continue to share a common commitment to ending fragmented health care fraud enforcement efforts and encouraging the coordination of investigative resources.

In addition to providing new statutory tools to combat health care fraud, HIPAA specified mandatory funding to the FBI for health care fraud enforcement. In 2000, \$76 million was provided by HIPAA for 651 positions (380 agents). The FBI used this funding, in large part, to fund an additional 35 agents and 77 support positions for health care fraud and to create several new dedicated Health Care Fraud Squads. This increase in personnel resources along with the direct FBI funding increased the number of FBI agents addressing health care fraud in the fourth quarter of 2000 to approximately 520 agents as compared to 112 in 1992.

As the FBI has increased the number of Agents assigned to health care fraud investigations, the caseload has increased dramatically from 591 cases in 1992, to 2,980 cases through 2000. The FBI caseload is divided between those health plans receiving government funds and those that are privately funded. Criminal health care fraud convictions resulting from FBI investigations have risen from 116 in 1992, to 550 in 2000.

Health care fraud investigations are among those investigations having the highest priority within the FBI. The investigations are generally complex and require specific knowledge, skills and abilities to successfully investigate. Often sophisticated, innovative and creative ideas are needed to combat and eventually prosecute the perpetrators of these crimes. As the complexity and long-term nature of health care fraud investigations increase, the FBI anticipates that the number of FBI investigations and convictions will begin to level off.

A considerable portion of the increased funding was utilized to support major health care fraud investigations. In addition, operational support has been provided for FBI national initiatives focusing on pharmaceutical diversion, chiropractic fraud, and medical clinics. Further, the Health Care Fraud Unit, FBI Headquarters, supported individual field offices with equipment and supplies to assist in numerous individual investigations.

The funding made available through HIPAA also made possible two Basic Health Care Fraud training conferences which provided the expertise necessary for FBI Agents assigned to health care fraud investigations. Around 300 Agents received specialized training on the fraud schemes plaguing a particular provider service that has been historically vulnerable to fraud. The HIPAA funding also allowed FBI headquarters staff to conduct specialized training sessions in a number of FBI field offices and to make numerous presentations to various industry groups.

GLOSSARY

The Account - The Health Care Fraud and Abuse Control Account

ACE - Affirmative Civil Enforcement

ALS - Automated Litigation Support

AoA - Administration on Aging

AUSA - Assistant United States Attorney

CDC - Centers for Disease Control and Prevention

CMHC - Community Mental Health Centers

CMP - Civil Monetary Penalty

DCIS - Defense Criminal Investigative Service

DOJ - The Department of Justice

EMTALA - Emergency Medical Treatment and Active Labor Act

ESRD - End-stage Renal Disease

FEHBP - Federal Employees Health Benefits Program

FBI - Federal Bureau of Investigation

GAO - General Accounting Office

HCFA - Health Care Financing Administration

HHS - The Department of Health and Human Services

HIPAA, or the Act - The Health Insurance Portability and Accountability Act of 1996, P.L. 104-191

HIPDB - Healthcare Integrity and Protection Data Bank

HRSA - Health Resources and Services Administration

MCO - Managed Care Organization

OGC - The Department of Health and Human Services, Office of the General Counsel

OIG - The Department of Health and Human Services, Office of Inspector General

OLE - Office of Legal Education, located within the Executive Office for the United States Attorneys

ORF - Outpatient Rehabilitation Facilities PHP - Partial Hospitalization Program

PPS - Prospective Payment System

The Program - The Health Care Fraud and Abuse Control Program

Secretary - The Secretary of the Department of Health and Human Services

SNF - Skilled Nursing Facility

USAO - United States Attorney's Office

- 1. Hereafter, referred to as the Secretary.
- 2. Also known as the Hospital Insurance (HI) Trust Fund. All further references to the Medicare Trust Fund refer to the HI Trust Fund.
- 3. In 2000, DOJ collected, or continued to hold in suspense, additional funds from health care fraud cases and matters that was not disbursed to the affected agencies and/or the Account in 2000 due to: (i) on-going litigation regarding relator shares in gui tam cases that will affect the amount retained by the federal government; and (ii) receipt of funds late in the year that were then processed in FY 2001.
- 4. In addition, the HHS/OIG obligated \$1,607,000 in funds received as "reimbursement for the costs of conducting investigations and audits and for monitoring compliance plans" as authorized by section 1128C(b) of the Social Security Act, 42 U.S.C. 1320a-7c(b).