

**The Department of Health and Human Services
And
The Department of Justice
Health Care Fraud and Abuse Control Program
Annual Report For FY 2003**

DECEMBER 2004

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GENERAL NOTE

All years are fiscal years unless
otherwise noted in the text.

EXECUTIVE SUMMARY

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a national Health Care Fraud and Abuse Control Program (HCFAC or 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. In its seventh year of operation, the Program's continued success again confirmed the soundness of a collaborative approach 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 2003, the Federal government won or negotiated more than \$1.8 billion in judgments and settlements in health care fraud matters. As a result of enforcement actions, judgments, settlements, and administrative proceedings, the Federal government collected more than \$1.4 billion and distributed more than \$1.03 billion during FY 2003. Over \$500 million that was collected during the FY 2003 reporting period was distributed in early 2004 and the distribution of these funds will be described in greater detail in the Annual Report for 2004⁽²⁾. Of the amount distributed to victim agencies in FY 2003, approximately \$723 million was returned to the Medicare Trust Fund and \$151.6 million was returned to the Centers for Medicare and Medicaid Services ("CMS") as the Federal share of Medicaid restitution. The HCFAC account has returned over \$5.69 billion to the Medicare Trust Fund since the inception of the program in 1997.

Enforcement Actions

Federal prosecutors filed 362 criminal indictments in health care fraud cases in 2003. A total of 437 defendants were convicted for health care fraud-related crimes during the year. There were also 1,277 civil matters pending, and 231 civil cases filed in 2003. HHS excluded 3,275 individuals and entities from participating in the Medicare and Medicaid programs, or other federally sponsored health care programs, most as a result of convictions for crimes relating to Medicare or Medicaid, for patient abuse or neglect, or as a result of licensure revocations.

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 2003**

**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, 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⁽³⁾.

The Act appropriates monies from the Medicare Trust Fund to an expenditure account, called the Health Care Fraud and Abuse Control Account (the Account), in amounts that the Secretary and Attorney General jointly certify 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 used only for activities of HHS/OIG, with respect to Medicare and Medicaid programs. In 2003, the Secretary and the Attorney General certified \$240.558 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 the Department of Justice (DOJ) that are devoted to health care fraud enforcement, though they provide the sole source of funding for Medicare and Medicaid enforcement by HHS/OIG. (Separately, the Federal Bureau of Investigation (FBI) received \$114 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 both:

1. the amounts appropriated to the Trust Fund for the previous fiscal year under various categories and the source of such amounts; and
2. 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 fulfills 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 2003, over \$1.03 billion was deposited with the Department of the Treasury and CMS, transferred to other federal agencies administering health care programs, or paid to private persons during the fiscal year. In addition, over \$500 million collected in 2003 was distributed in the first quarter of fiscal year 2004 and will be described in greater detail in the Annual Report for 2004⁽⁴⁾. The following chart provides a breakdown of the 2003 transfers/deposits:

Total Transfers/Deposits by Recipient FY 2003	
Department of the Treasury	
HIPAA Deposits to the Medicare Trust Fund	
Gifts and Bequests	0
Amount Equal to Criminal Fines*	2,474,513
Civil Monetary Penalties	7,149,975
Amount Equal to Asset Forfeiture **	0
Amount Equal to Penalties and Multiple Damages	232,882,476
Centers for Medicare and Medicaid Services	
OIG Audit Disallowances - Recovered	42,472,162
Restitution/Compensatory Damages	437,911,954
Sub Total	\$722,891,080
Restitution/Compensatory Damages to Federal Agencies	
Centers for Medicare and Medicaid Services	14,684,625
Office of Personnel Management	16,544,238
TRICARE	4,198,984
Other Agencies	5,662,788
Sub Total	\$41,090,635
Relators' Payments ***	\$269,563,831
TOTAL ****	\$1,033,545,546

*Due to a debt collection reporting system transition during FY 2003, reporting of criminal fines to the Department of Treasury for FY 2003 was limited to the 1st and 2nd quarters. Criminal fines recovered in the 3rd and 4th quarters of FY 2003 will be included in FY 2004 criminal fine collections.

**This includes only forfeitures under 18 U.S.C. § 1347, a 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.

***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. § 3730(b).

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

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 section 24(a) of title 18, United States Code (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, United States Code; and
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 Claims Act, FCA), 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 also requires an independent biannual review of these deposits by the General Accounting Office (GAO).

PROGRAM ACCOMPLISHMENTS

EXPENDITURES

In the seventh year of operation, the Secretary and the Attorney General certified \$240.558 million as necessary for the Program. The following chart gives the allocation by recipient:

FY 2003 ALLOCATION OF HCFAC APPROPRIATION (Dollars in thousands)
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Organization	Allocation
Department of Health and Human Services	
Office of Inspector General ⁽⁵⁾	160,000
Office of the General Counsel	4,527
Administration on Aging	3,250
Centers for Medicare and Medicaid Services	23,366
Assistant Secretary for Budget, Technology and Finance	0
Sub Total	\$191,143
Department of Justice	
United States Attorneys	30,400
Civil Division	14,459
Criminal Division	1,580
Civil Rights Division	1,976
Nursing Home Initiative	1,000
Sub Total	\$49,415
TOTAL	\$240,558

ACCOMPLISHMENTS

Overall Recoveries

In 2003, the Federal government won or negotiated more than \$1.8 billion in judgments and settlements in health care fraud matters. As a result of enforcement actions, judgments, settlements, and administrative proceedings, the Federal government was able to distribute during 2003 \$1.03 billion of the funds collected. Approximately \$723 million of this amount was returned to the Medicare Trust Fund, and \$151.6 million was recovered as the Federal share of Medicaid restitution. Some of the judgments, settlements, and administrative impositions in 2003 will result in distributions in future years, just as some of the distributions in 2003 are attributable to actions from prior years. As noted previously, over \$500 million collected in fiscal year 2003 was distributed early in fiscal year 2004.

This fiscal year, HHS and DOJ have brought to successful conclusion the investigation and prosecution of numerous health care fraud schemes. These achievements confirm once again the importance of coordination between HHS and DOJ to maximize recoveries for taxpayer-funded health care programs victimized by fraud and/or abuse, and to promote prompt detection, punishment and deterrence of those who exploit health care programs for personal or corporate gain. In addition to the enforcement actions described in this report, numerous audits, evaluations and other coordinated efforts have yielded substantial recoveries of overpaid funds, protected vulnerable beneficiaries, and prompted changes in Federal health care programs that reduce susceptibility to fraud. During FY 2003, the many significant accomplishments of the HCFAC Program included the following:

Pharmaceutical Companies

- AstraZeneca Pharmaceuticals and Zeneca, Inc. (AstraZeneca)**, a major pharmaceutical manufacturer, pled guilty and agreed to pay \$355 million to resolve criminal and civil fraud allegations arising from its marketing of Zoladex, a drug used to treat prostate cancer. As a result of an investigation conducted by the United States Attorney for the District of Delaware, working with the HHS/OIG, the Food and Drug Administration (FDA), the Defense Criminal Investigative Service and the FBI, AstraZeneca pled guilty to violating the Prescription Drug Marketing Act by causing false claims to be filed for Zoladex that was furnished to urologists as free samples. In addition, the company agreed to pay more than \$265 million to settle allegations that it caused false claims to be filed with Medicare, Medicaid, TRICARE and the Railroad Retirement Board, and another \$24.9 million for failing to pay proper rebates owed to states under the Medicaid Drug Rebate Program. AstraZeneca also entered into a rigorous 5-year Corporate Integrity Agreement (CIA) with the HHS/OIG, under which the company agreed to affirmatively report certain drug prices to Medicare and Medicaid, and to take other steps to promote proper billing practices.
- Bayer Corporation** paid more than \$257 million in global settlement of the FCA and criminal allegations that it attempted to evade paying required rebates to state Medicaid programs for sales of two drugs, Cipro (an antibiotic) and Adalat (an anti-hypertensive). In what is known as a "lick and stick scheme," Bayer allegedly sold re-labeled drugs to a large HMO at significant discount, then concealed the discounts and so avoided having to pay millions of dollars in rebates to Medicaid. Bayer also pled guilty to charges filed by the United States Attorney for the District of Massachusetts that it violated the Federal Food, Drug and Cosmetic Act by failing to notify FDA that it was producing private label Cipro. The company also agreed to extend an ongoing CIA with the HHS/OIG, and strengthen its terms to ensure that Bayer will accurately report its best price information to the government.
- GlaxoSmithKline (GSK)**, In a similar case, GSK settled its civil liability under the FCA for repackaging Paxil (an anti-depressant) and Flonase (a nasal spray) for sale at deep discounts to the same large HMO. Again, the company concealed these discounts, and so underpaid rebates due to the Medicaid program. GSK agreed to pay more than \$87 million, and to comply with the terms of a CIA designed to ensure that GSK will accurately reports its "best price" information to the government in the future.

The monies recovered in the AstraZeneca, Bayer and GlaxoSmithKline settlements were shared among the Federal Government, 49 states, the District of Columbia, and the Public Health Service.

- **Pfizer Corporation and Subsidiaries, Warner-Lambert and Parke-Davis (Pfizer)**, agreed to pay \$49 million to resolve alleged false claims arising from sale of the cholesterol-lowering drug, Lipitor. The company allegedly failed to report accurately to CMS its "best price" as required under the Medicaid Drug Rebate Program. By overstating its price, the company allegedly retained more than \$20 million in rebates owed to the Medicaid program. Pfizer also entered into a five-year CIA under which Pfizer must certify its process for determining best price, and adopt internal safeguards to prevent improper reporting in the future.

Prescription Drug Fraud

- A South Florida defendant was sentenced after conviction at trial to 10½ years' incarceration for her role as the mastermind behind a conspiracy that fraudulently billed Medicare for over \$20 million worth of prescription drugs. The conspiracy centered around four Miami pharmacies that illegally manufactured prescription aerosol drugs. The pharmacies sold the illegally manufactured drugs although in some cases, only labels or half-portions were actually delivered to DME companies that billed Medicare directly under Medicare rules that allow for payment for drugs taken by way of medical equipment. The fraudulently manufactured drugs were intended for bogus patients who had been paid for use of their Medicare numbers; approximately 1400 patients in the Miami area were involved in the scam. To enable the fraud, physicians were paid to sign blank prescriptions, and, in almost every case, the physicians never examined the patients or even looked at fraudulent charts that were concocted to fool Medicare inspectors. Five other individuals were also convicted at trial and sentenced to terms of incarceration for their participation in the conspiracy; eighteen other defendants entered pleas of guilty and were sentenced in connection with the scheme.
- A South Florida urologist pleaded guilty to 59 counts of health care fraud and unlawful distribution of prescription drugs. Between July 2000 and November 2001, he prescribed Lupron, a drug used for the palliative treatment of advanced prostatic cancer, to a number of patients, and undertook to administer it to the patients in the form of injections. However, the defendant did not administer the prescribed and requisite dosages of Lupron to at least 32 patients who came to him for treatment. The physician billed the patients and their health insurance carriers for the cancer treatments, regardless of whether the drug was actually administered. In addition, he unlawfully distributed Lupron wholesale through a series of sales totaling more than \$1.5 million. In pleading guilty, he was sentenced to 51 months of incarceration and 3 years of supervised release in addition to also surrendering his medical license.

Internet Pharmacy Fraud

- In October 2003, a Texas pharmacist was convicted of a drug king-pin count and for money laundering for his role in conspiring to illegally dispense hydrocodone in an Internet pharmacy operation he ran. The pharmacist, who owned Friendly Pharmacy located in Texas and MainStreet Pharmacy located in Oklahoma, employed three doctors and paid them \$40-100 per signed prescription. Customers of the internet websites would fill out a simple questionnaire, request their drug of choice (in most cases, hydrocodone - a Schedule III controlled substance) and then pay both a "doctor consultation fee" and the fee for the prescription drugs. The doctors reported they never declined a prescription, and never examined the patients. One doctor admitted at trial that he never reviewed the questionnaires filled out by the customers and another doctor fell asleep while signing the prescriptions. Neither of the online pharmacies had any way of verifying the age of the recipient. Unlike when the patient sees the doctor, a minor can easily log onto a website and fill out an inaccurate age. Tragically, a La Mesa, California high school honors student and athlete died at home from an overdose of Vicodin ordered from one of the pharmacies.

The pharmacist faces a mandatory 20 year to life sentence. All of the other participants were either found guilty by a jury or pled guilty. The government also obtained a \$5.6 million asset forfeiture judgment against the pharmacist.

- A South Florida husband and wife were sentenced to terms of 37 months and 24 months imprisonment, respectively, after being convicted by a jury of unlawfully distributing prescription drugs through the Internet. The defendants sold powerful prescription pain killers through web sites operated from their home without requiring a physician's review or a prescription and placed no restrictions on the quantities or frequency with which customers could purchase drugs. In an effort to evade detection by law enforcement, the defendants cut out the manufacturer's lot numbers placed on each of the drug containers they sold, thereby making the drugs untraceable; concealed their identities through using false names; used 32 variations of false return addresses on packages; and advertised that they were an overseas company. In little over a year, the defendants earned in excess of \$1.2 million in gross revenues, all of which went to an off-shore bank account in the Cayman Islands.

Hospitals

- **HCA Inc.** (formerly known as Columbia/HCA and HCA-The Healthcare Company), entered a settlement agreement with the Federal government, marking the end of the most comprehensive multi-agency health care fraud investigation of a provider ever undertaken by federal enforcement authorities. Under the agreement, HCA

paid \$631 million plus interest to resolve civil liability for alleged false claims arising from a variety of practices, including false cost reports to Medicare, Medicaid and TRICARE, and kickbacks. When added to earlier criminal pleas and a 2001 FCA settlement, and a separate settlement with the CMS, the government recovered a total of \$ 1.7 billion from HCA. The settlement agreement also incorporates the terms of a Corporate Integrity Agreement with the HHS/OIG, under which HCA will maintain comprehensive compliance measures into the year 2009.

- **Lovelace Health Systems, Inc.** (Lovelace) agreed to pay the government \$24.5 million and implement certain integrity requirements to resolve its liability under the FCA. The Cigna-owned hospital and health maintenance organization allegedly falsified its Medicare cost reports for the ten years ending in 1998. Among the allegations, Lovelace improperly shifted costs of its health maintenance organization (HMO) patients to Medicare and otherwise inflated Medicare reimbursement. The investigation stemmed from a *qui tam* filed by an employee of a financial consultant that prepared cost reports for Lovelace.
- **St. Luke's Subacute Hospital and Nursing Center, Inc.** and its president and CEO were convicted of six counts of Medicare fraud. The officer directed his employees to manipulate the company's books to inflate the amount of reimbursable nursing time spent on Medicare patients. In 1997, 1998 and 1999, he submitted reimbursement claims to Medicare for nursing costs that overstated St. Luke's Hospital's entitlement by nearly \$3 million. He then directed an employee to create false nursing schedules in an attempt to hide inflated nursing costs from Medicare auditors, a fraud that was uncovered when law enforcement compared the false nursing schedules to true nursing schedules that were seized during a 1996 search warrant.
- **Rapid City Regional Hospital** paid \$6 million to settle civil allegations arising from unlawful patient referrals from oncologists with whom the hospital had financial relationships. The parties allegedly violated the Ethics in Patient Referrals Act, better known as the "Stark" law, which is designed to ensure that patients receive the benefit of unbiased medical judgment from their physicians. The statute prohibits doctors from referring patients to clinical laboratories, diagnostic centers, and other facilities in which they hold financial interests, and prohibits hospitals from paying for referrals from physicians with whom they have financial relationships. The FCA case involved allegations that the hospital had supplied Oncology Associates with office space, staff services, and other benefits to induce the oncologists to refer their cancer patients to the hospital. The physician practice, Oncology Associates, also paid the United States an additional \$525,000 for overbilling Medicare for their patients' office visits.
- **Public Health Trust of Miami-Dade County, d.b.a. Jackson Memorial Hospital** paid the United States \$16.8 million to settle civil allegations that it had submitted duplicate claims for the same services as both outpatient clinic and inpatient services.
- **McLeod Regional Medical Center of Pee Dee, Inc.** paid the United States \$15.9 million to settle civil allegations that it submitted false claims to the Medicare, Medicaid and TRICARE programs for hospital and home health services ordered by physicians with whom McLeod, and its for-profit subsidiary, McLeod Physician Services, had unlawful compensation arrangements. The FCA suit alleged that McLeod's financial relationships with the physicians violated the Stark law and the Anti-Kickback Statute because the hospital had agreed to pay the physicians more than fair market value for their practices, then paid them salaries exceeding fair market value, to induce and maintain referral relationships with the physicians. The Government also alleged that McLeod included false claims for Medicare reimbursement of unallowable costs on the hospital's cost reports as a means to offset losses incurred in acquiring the practices.
- Five hospital subsidiaries of **Tenet Healthcare Corporation** agreed to pay over \$4.15 million to settle civil allegations that they "upcoded" Medicare patients' pneumonia and septicemia diagnoses. Hospitals receive Medicare reimbursement by assigning codes that reflect a patient's diagnosis at the time of discharge. Upcoding is the practice of assigning a code that reflects a falsely high level of patient acuity and medical service in order to generate higher reimbursement than the provider otherwise would receive. The five Florida hospitals involved were Coral Gables Hospital, Coral Gables; Florida Medical Center, Fort Lauderdale; Hialeah Hospital, Hialeah; Hollywood Medical Center, Hollywood; and Parkway Regional Medical Center, Miami.
- **Columbia University** paid \$5.1 million to settle civil charges that, for more than a decade, the university improperly billed the Medicaid program for deliveries and other obstetrical procedures conducted at New York-Presbyterian Hospital's Allen Pavilion. The Government alleged that the Obstetrics and Gynecology Department at the hospital routinely had physicians whose services would be reimbursed by Medicaid claim they themselves had treated patients when, in fact, the patients were seen by health care providers ineligible for reimbursement, such as midwives.

Durable Medical Equipment

- 20 defendants pleaded guilty in Arizona to engaging in a fraud scheme in which they falsely billed Medicare for more than \$25 million in DME. The defendants created approximately 30 sham DME entities in the western United States. For 3½ years, they used unlawfully obtained Medicare information to falsely bill Medicare for DME either not provided or not ordered by a physician, including expensive motorized wheelchairs, hospital beds with special mattresses, and products used for delivering nutrients directly into the gastrointestinal tract.

- A South Florida DME supplier was sentenced to 84 months in prison and ordered to pay nearly \$14.5 million in restitution for two schemes to defraud the Medicare and Medicaid programs. The court also entered a more than \$14.8 million forfeiture order. The defendant and others fraudulently billed Medicare and Medicaid for items such as motorized wheelchairs and alternating pressure mattresses. To date, 12 corporations and 14 individual defendants have pleaded guilty in connection with the schemes, and one person was convicted after a jury trial. The supplier also entered into a civil settlement agreement with the United States on behalf of himself and 15 business entities, resulting in a consent judgment being entered against him and the entities for more than \$29 million.
- The Texas owner and operator of two DME companies was convicted at trial, sentenced to 120 months incarceration, and ordered to pay \$384,984 in restitution for defrauding the Medicare and Medicaid programs. The defendant billed Medicare and Medicaid for items that were never supplied to patients, including alternating pressure mattresses, hydraulic patient lifts, and lymphedema pumps. In other instances in which items were supplied, she submitted billings with false patient diagnoses for patients who had not been evaluated by a physician and did not qualify for the product. The defendant's husband pled guilty in connection with the same scheme and was sentenced to 12 months and one day of incarceration.
- A physician convicted for obstruction of justice and mail fraud was sentenced to nearly 3 years imprisonment, and ordered to pay a \$7,500 fine and be deported upon his release. A fugitive since 1988, the physician performed cursory physical exams for a DME company which used these exams to justify prescriptions for transcutaneous electrical nerve stimulation (TENS) units to Medicare beneficiaries. However, the physician never actually performed the thorough examination required, nor did he advise the beneficiaries on the use and risks of the TENS units. The physician also signed blank certificates of medical necessity so that the TENS units could be billed to Medicare. His codefendants were previously sentenced for their roles in the scheme.

Physicians

- A Coral Gables, Florida, eye surgeon was convicted of 90 counts of Medicare fraud and ordered to pay \$812,216 in restitution and \$50,000 in fines for billing the Medicare program for services he did not provide. The surgeon fabricated medical charts and billing records, and submitted claims to Medicare, for various diagnostic tests he never conducted and laser eye surgeries that he never rendered. In many instances, elderly Medicare patients were led to believe that they had serious eye diseases that could result in blindness if not treated when in fact they did not have such illnesses. At one of the clinics, the defendant regularly claimed to have performed ophthalmic services when the equipment necessary to perform the procedures was not even present at the medical clinic on the claimed dates of service.
- Six Southern California physicians pleaded guilty to health care fraud for engaging in a scheme to defraud United States insurance companies. The defendants, who were Mexican nationals who practiced in Mexico, filed claims with United States insurance companies for medical treatment, services, and supplies supposedly provided to United States citizens in Mexico; in reality, the treatment, services, and supplies were not provided as claimed. The defendants were arrested as part of an FBI undercover operation dubbed "Operation Golden Tooth" in which the undercover agent - posing as a participant in the scam - persuaded the doctors to travel to the United States, where they were arrested upon arrival.

Home Health

- **Caremark, Rx, Inc.** (formerly MedPartners, Inc.) paid the United States \$7.5 million to settle civil allegations that false home health care claims had been submitted by a former MedPartners' subsidiary, AmCare, Inc., a Florida home health agency.

Home Health

- **Dialysis Holdings, Inc.** paid \$4,102,098 to settle an FCA action alleging that the company knowingly submitted requests to Medicare for medically unnecessary laboratory tests and blood draws. Dialysis Holdings, Inc. and its predecessor corporations provided dialysis services to thousands of terminally ill Massachusetts patients afflicted with end stage renal disease (ESRD), whose laboratory costs are covered by Medicare. Dialysis conspired with a clinical laboratory to perform unnecessary blood draws on ESRD patients, create thousands of referrals for laboratory tests that were not needed, split automated chemistry panels of tests so as to avoid a Medicare rule designed to control lab test costs, and deceive physicians and laboratory employees into unknowing participation in the scheme.
- **Dianon Systems, Inc.** paid \$4.8 million to resolve allegations of Medicare and TRICARE billing fraud under the FCA. Dianon, which conducts tests to detect various types of cancer, had billed for medically unnecessary DNA tests and second-opinion consultations and reports it failed to provide.
- **Mediq, Inc.** and its subsidiaries (collectively, Mediq), agreed to pay \$1 million to resolve their civil liability under the FCA. The case stemmed from allegations that Mediq billed Medicare for transtelephonic electrocardiograms (ECGs) when no such tests were performed. Instead, Mediq performed standard ECGs, a service that is reimbursed at a significantly lower rate.

Ambulance Services

- A New York ambulance company operator was sentenced to 78 months in prison, was ordered to pay restitution of more than \$57 million, and was subject to an \$8 million forfeiture order for health care fraud arising from his fraudulent operation of several ambulance and ambulance services. In March 1990, the HHS/OIG excluded the individual from participation in the Medicare and Medicaid programs for a period of 25 years. In order to evade this program exclusion, he established secret ownership of five ambulance and ambulance companies in Brooklyn, New York, and continued to bill Medicare and Medicaid for patient transportation. He also offered and paid bribes and kickbacks to employees of various hospitals to induce them to order ambulance and ambulance services from his companies.

Physical Therapists

- Two former operators of Texas medical clinics pleaded guilty to conspiracy to commit health care fraud, and paying kickbacks for the referral of Medicare and Medicaid patients in connection with several schemes that resulted in more than \$11 million of false billings to Medicare and Medicaid. The defendants and others operated six physical therapy clinics in the Houston area, and billed Medicare and Medicaid for claims for physical therapy services never performed, claims using a false diagnosis, and claims for services not ordered by a licensed physician or not performed under the supervision of a licensed physician. As part of the scheme, the defendants hired patient recruiters, known as "marketers," who were paid a kickback for each patient referred to the clinics for physical therapy; clinic employees were also paid kickbacks for referrals. Four co-defendants also pleaded guilty to health care fraud in connection with this matter; three other defendants, including two doctors, have proceeded to trial.

Medicare Contractors

- **Blue Cross of California (Blue Cross)**, a former Medicare fiscal intermediary, and its parent company, **Wellpoint Health Networks, Inc.**, agreed to pay \$9.3 million to resolve their potential civil and administrative liability for false claims. For ten years ending in 2000, Blue Cross allegedly falsified data regarding its performance of health care provider audits while under contract with CMS. The intermediary primarily falsified audit start and completion dates entered into an audit tracking database. The government alleged that these erroneous entries were intended to mislead CMS regarding its performance of required audit work so as to obtain a favorable annual evaluation, and to ensure renewal of its Medicare contract.
- In Missouri, a director and manager for a former Medicare contractor were sentenced for conspiring to falsify and conceal information about errors made by the contractor. The director was sentenced to 27 months in prison and fined \$6,000; the manager was sentenced to 3 months in prison. These former executives ordered the falsification of records, beneficiary files, claims and other official documents, which, when reviewed by CMS, gave the contractor the appearance of performing at a higher level of efficiency and quality than was actually the case. This appearance of exemplary performance enabled the contractor to secure and maintain its contract with the government by being ranked for many years as one of the top 10 in the country. In June 2002, the contractor agreed to pay the government \$76 million for its alleged misconduct.

Quality of Care

One area in which collaboration among the federal authorities responsible for health oversight has proved most effective has been in enforcement and oversight of issues relating to quality of care, as demonstrated by the following:

Prosecution:

- **Endo Vascular Technologies, Inc. (EVT)**, a wholly-owned subsidiary of the medical device manufacturer Guidant Corporation, pled guilty to 10 felonies and agreed to pay \$92.4 million as part of a global resolution of charges that it covered up malfunction of its device used to treat aortic aneurysms. These incidents of malfunction included 12 deaths and more than 50 emergency surgeries. Under Federal law, a company must submit a Medical Device Report to FDA every time its device may have caused serious injury or death. EVT filed 172 such reports, but in its guilty plea, admitted to failing to file reports in 2,600 additional incidents. Moreover, the government contended that the company was aware of the incidents, since a company representative was required to be present in the operating room each time the device was inserted.

This global resolution is among the first felony convictions for failing to file Medical Device Reports with the FDA, and represents the largest dollar amount ever paid by a defendant for such failure. The investigation was conducted by the FDA and the FBI. In addition to the settlement agreement, Guidant and EVT agreed to enter into a comprehensive compliance agreement with the HHS/OIG.

- **Redding Medical Center, Inc. (RMC)**, a hospital owned by Tenet Health Systems Hospitals, Inc., agreed to pay \$54 million in settlement of liability for performing and billing Medicare, Medicaid and TRICARE for unnecessary cardiac services for the time period 1997 through 2002. This represents the government's largest recovery ever in a case alleging lack of medical necessity for surgeries. RMC agreed to implement certain corporate compliance steps; nonetheless, possible exclusion from Federal health care programs was not waived in the settlement.
- **The University of Chicago and Northwestern Memorial Hospitals**, agreed to settle charges in connection with their organ transplant programs. The hospitals agreed to pay \$115,000 and \$23,587 respectively, to resolve charges that the hospitals falsely diagnosed certain patients as more ill than they actually were. Based on these

exaggerated diagnoses, the patients were allegedly moved ahead of others who were waiting for organs in that transplant region. The government also charged that the hospital billed Medicare or Medicaid for medically unnecessary services related to the overstated diagnoses.

Exclusions:

One important mechanism for safeguarding the care provided to program beneficiaries is through exclusions of providers and suppliers who have engaged in patient abuse or neglect or fraud. During 2003, the HHS/OIG excluded more than 3,000 such individuals from participation in Medicare, Medicaid and other Federal health care programs, among them:

- A Missouri pharmacist was sentenced to 30 years in prison and ordered to pay more than \$10 million in restitution and fines for diluting chemotherapy drugs he prepared for cancer patients. In 2003, both the pharmacist and his pharmacy were excluded from Medicare, Medicaid and other Federal health care programs the pharmacist for 50 years and his pharmacy for 25 as a result of this conviction. Such lengthy exclusions were justified by the pharmacist's reckless disregard for the life-threatening consequences of his conduct.
- A Kansas physician was excluded for 25 years based on his conviction for longstanding fraud against Medicare and TRICARE. His scheme involved luring patients into unnecessary surgeries based on false representations. The physician was also convicted of perjury. The court sentenced him to 6 years in jail, and the state suspended and then summarily revoked his medical license.

Nursing Home Studies:

Quality of nursing home care remains an area of intense interest for HHS/OIG. In recent years, the HHS/OIG conducted numerous studies assessing facets of the quality of life and care in nursing homes. In 2003, these studies included the following:

- **Quality Assurance Committees (QA Committees):** QA Committees are internal organizations that provide a key point of accountability for ensuring quality of care. Nearly all nursing homes were found to meet CMS requirements for committee membership and frequency of meetings. QA Committees had access to information they needed to assess care, but were nonetheless hampered by staff shortages, turnover, and members who are inexperienced in committee work.
- **Psychosocial Services Oversight:** Another inspection examined whether residents receive required psychosocial services, including a comprehensive initial assessment and periodic evaluations. Though most facilities employed a qualified social worker as required, more than one third of residents had incomplete care plans. Where plans existed, 46 percent of residents did not receive all the psychosocial services outlined in those plans. The HHS/OIG recommended enhanced oversight of this aspect of the residential assessment and care plan.
- **National Ombudsman Reporting System:** Data was examined in the National Ombudsman Reporting System. It was found that the data corroborated deficiencies in resident care. Complaints to Ombudsmen are on the rise, with the highest frequency of nursing home complaints involving resident care. Accidents and requests for assistance were the most common. Others in the top dozen were: complaints of personal hygiene, medication administration and symptoms unattended, and categories that include complaints of unexplained bruises, medications not given, or failure to address a resident's changed condition.

The prosecutions and settlements discussed above and throughout this report reflect the culmination of investigations that have been ongoing for several years. A more detailed description of 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 the accomplishments described herein reflect the combined efforts of HHS, DOJ and other partners in the anti-fraud efforts.

FUNDING FOR DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Certain of the funds appropriated under HIPAA are, by law, set aside for Medicare and Medicaid activities of HHS/OIG. During the seventh year of the Program, the Act provided that between \$150 and \$160 million be devoted to these purposes. The Secretary and the Attorney General jointly allotted \$160 million to HHS/OIG in 2003, an increase of \$15 million over 2002.

HHS/OIG conducted or participated in 819 prosecutions or settlements in 2003, of which 567, or 69 percent, were health care cases. A total of 3,275 individuals and entities were also excluded, many as a result of criminal convictions for crimes related to Medicare or Medicaid (707); or to other health care programs (130); for patient abuse or neglect (257); or as a result of licensure revocations (1,747).

In addition to the role played by the HHS/OIG's in the judgments and settlements described in the Accomplishments section, HHS acted on HHS/OIG recommendations and collected \$42.5 million in disallowances of improperly paid health care funds in 2003. HHS/OIG continues to work with CMS 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 2003, such funds not expended amounted to more than \$20.8 billion -- nearly \$16.9 billion in Medicare savings, and \$3.9 billion in savings to the Medicaid program.

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. Activities designed to promote or safeguard beneficiary care included the following.

Program Exclusions: The HHS/OIG excluded 3,275 individuals and entities from participation in Medicare, Medicaid and other Federal health care programs. Such exclusions are a vital way to prevent fraud and to protect program beneficiaries. Some of these exclusions are described in the Program Accomplishments section above. Others included the following:

- A Missouri pathologist was indefinitely excluded after his Wisconsin license was revoked for prescribing drugs over the Internet without having performed physical examinations of the patients. This physician held 29 known professional health care licenses from other jurisdictions. Several of those licenses have also been sanctioned by the appropriate state authorities.
- An Alaska physician was excluded for 20 years after being convicted on 234 counts ranging from forgery and theft of public funds from the Alaska State Medicaid Program to the unlawful manufacture, distribution, prescription, and dispensing of a controlled substance. The Superior Court for the State of Alaska sentenced him to 7 years in prison and ordered him to pay approximately \$240,000 in restitution. His license to practice medicine as a physician and surgeon was revoked in Alaska and Wisconsin.
- A Colorado certified nurse aide (CNA) was excluded for 35 years based on his conviction for sexual abuse. The court sentenced the CNA to a term of 16 years to life in prison, and the state revoked his nurse aide certificate.

Studies, Audits and Evaluations:

- **Prospective Payment System:** Medicare Part A serves an estimated 40 million beneficiaries. In addition to acute care hospitals, which are reimbursed under a Prospective Payment System (PPS), Part A covers inpatient care in psychiatric, rehabilitation, critical access and long-term care hospitals. All such specialty hospitals are exempt from PPS. Medicare paid approximately \$8.7 billion to PPS-exempt hospitals in 2000. HHS/OIG conducted a study to assess whether PPS-exempt hospital services were receiving the same oversight as acute care hospital services. The study found that routine statistical analyses and reviews for medical necessity and reasonableness were not being conducted of PPS-exempt inpatient services. Though fiscal intermediaries are free to review medical necessity of services provided in PPS-exempt settings, there is no funding dedicated to this undertaking. The study expressed concerns that without dedicated funding and explicit goals, oversight will likely remain uncertain. Moreover, to the extent that fiscal intermediaries do review PPS-exempt hospital services, the reviews will occur at the expense of oversight of other Part A providers, such as nursing homes and home health agencies. The OIG recommended that CMS ensure oversight of PPS-exempt hospital services, and CMS concurred.
- **Study of Mental Health Drug Expenditures:** HHS/OIG evaluated whether Medicaid pays more in net costs for mental health drugs than do other Federal purchasers -- the 340B Program, Federal Supply Schedule, Federal Ceiling Price and military payers -- and if so, how much more. Examining reimbursements for 25 drugs in the ten states that are the largest payers for Medicaid prescription drugs, HHS/OIG found that price differences resulted in Medicaid's paying between 11 and 29 percent more than other Federal purchasers. This means Medicaid paid on average between \$47 million and \$126 million more for the same drugs. The HHS/OIG recommended that CMS work with states to pursue more efficient means of purchasing pharmaceuticals and initiate a review of the Medicaid rebate program, and also suggested that CMS share this report with the states.
- **Study of Payment Variations Between Outpatient Departments and Ambulatory Surgical Centers (ASC):** The HHS/OIG measured the variation in Medicare reimbursement for services performed in ASCs, and the same services performed in hospital outpatient departments (OPDs). In most cases (66 percent), OPD rates for the same service were higher than those paid to ASCs. Because of these differences in reimbursement, Medicare paid an estimated \$1.1 billion more in program payments in 2001. In addition, the HHS/OIG concluded that Medicare's list of procedures that may be performed in ASCs contained many that are commonly or safely performed in physicians' offices. Under CMS regulations, these procedure codes should be dropped from the list of ASC-covered procedures. Failing to do so resulted in an estimated \$8 to \$14 million in additional program payments in 2001. The HHS/OIG recommended that rates between settings should be more uniform, a recommendation with which CMS concurred. The OIG also suggested that: 1) rates reflect only the costs necessary for the efficient delivery of health services, 2) timely survey data be used to reevaluate ASC payment

rates, and 3) procedure codes be removed from the list of ASC covered procedures using established criteria.

- **Outlier Payments:** Under Medicare, payments over and above the usual Diagnosis Related Group (DRG) are available for services associated with extraordinarily costly inpatient hospital stays. These "outlier" payments encourage hospitals to treat seriously ill patients, even though the cost will greatly exceed normal payment rates. Medicare outlier payments totaled about \$5 billion in calendar year 2001. The HHS/OIG audited several hospitals within a hospital chain that aggressively increased its charges and, in so doing, significantly increased this chain's outlier payments from approximately \$350 million in 2000, to more than \$750 million two years later. Under Medicare's regulatory system, some hospitals increased charges (not necessarily related to increased costs) and may have caused inequities in the amount of outlier payments made to other hospitals and harmed uninsured patients. In December 2002, the HHS/OIG issued an "Early Alert" to CMS, alerting it of the preliminary findings and recommending that CMS take steps to prevent such a situation in the future. CMS's June 2003 final rule addressed each of OIG's recommendations. In issuing that rule, CMS estimated that over the past 5 years, this practice caused the Medicare program to pay \$9 billion beyond legislatively mandated target amounts set by CMS.
- **Disproportionate Share Hospital Payments:** States' use of financing mechanisms designed to maximize Federal Medicaid reimbursement may sidestep Federal/State matching requirements and cast doubt on whether matching payments are being used to provide health care services for our vulnerable Medicaid populations. Medicaid authorizes states to make supplementary payments, called disproportionate share hospital (DSH) payments, to hospitals for the uncompensated costs of serving disproportionate numbers of low-income patients with special needs. Such payments may not exceed the individual hospitals' incurred uncompensated costs. The HHS/OIG continued its series of reviews in states across the country to assess both the propriety of DSH claims and to look more broadly at how states' use of DSH payments and intergovernmental transfers affect the Medicaid program as a whole.

During 2003, reviews in 7 states generated a number of HHS/OIG findings and recommendations. Several states lacked controls sufficient to ensure DSH payments did not exceed the actual cost of providing services. In one case, DSH claims were calculated by a contractor, without sufficient state oversight and verification, resulting in over \$50 million in duplicate claims. Another state made DSH payments that exceeded hospital limits by more than \$500 million because it lacked controls to ensure payments did not exceed the cost of providing services. In addition, the state did not properly account for the Medicaid shortfall, failed to verify the accuracy of the hospitals' self-reported charges, and used a proxy method to calculate charges for hospitals that did not furnish supporting data. Another state incurred excess DSH payments of more than \$252 million, in part, by not limiting total operating expenses to amounts allowable under Medicare.

Fraud and Abuse Prevention

HIPAA's increased resources have enabled HHS/OIG to broaden its efforts both to detect fraud and abuse, and to prevent it. Prevention initiatives, such as those listed below, inform and assist the health care industry and its patients. Equally important, prevention activities reduce program losses and enforcement costs.

- **Industry Guidance:** The core of the HIPAA guidance initiatives is an advisory opinion process through which parties may obtain binding legal guidance as to whether their existing or proposed health care business transactions run afoul of the Federal anti-kickback statute, the civil monetary penalties laws, or the exclusion provisions. During 2003, HHS/OIG issued 15 opinions. A total of 101 advisory opinions have been issued since 1997. The advisory opinion process serves to enhance HHS/OIG's understanding of new and emerging health care business arrangements, and informs the development of new safe harbor regulations, fraud alerts, and special advisory bulletins.

CIAs: Many health care providers that enter agreements with the government to settle potential liabilities for violations of the FCA also agree to adhere to a separate CIA. 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. At the close of 2003, HHS/OIG was monitoring more than 375 CIAs.

Recommendations for Systemic Improvements: Frequently, investigations, audits and evaluations reveal vulnerabilities or incentives for questionable or fraudulent financial practices in agency programs or administrative processes. As required by the Inspector General Act, HHS/OIG makes recommendations to address these vulnerabilities, and thereby promotes economy and efficiency in HHS programs and operations. Relying on the independent factual information generated by HHS/OIG, agency managers recommend legislative proposals or other corrective actions that, when enacted or implemented, close loopholes and reduce improper payments or 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 2003 and beyond. Examples of these reviews include the following:

- **School Based Health Services.** The HHS/OIG conducted a series of reviews focusing on Medicaid payments for school based health services. These multi-state audits assess whether Medicaid payments for school-based health services and associated administrative claims were proper. In 2002, reports were issued relating to 9 states; more are underway. There were a variety of audit findings and accompanying recommendations for corrective action. Among these findings were instances in which: Medicaid was billed for costs of special

education in the fee-for-service rates paid exclusively for health services; services were contracted out at lower-than Medicaid rates and the savings were not passed along to Medicaid; costs were claimed without necessary documentation; payments were made to unqualified providers; duplicate claims were not returned to Medicaid; billings were made to Medicaid for services that were provided free to other students; there was failure to make required matching payments; claims were submitted for absent students; improper reimbursement was granted for unallowable transportation services; and services were provided to ineligible children. Of course, no single state experienced all of these difficulties. HHS/OIG made recommendations to recover funds where appropriate, and to enhance oversight to avoid erroneous or improper payments.

- **Study of Donor Consent Rates.** An OIG inspection analyzed donor consent data for 190 of the nation's 255 transplant centers, comparing the number of patients who were medically eligible to be organ donors and the number of donors for whom consent was actually given. HHS/OIG found that the consent rate varied widely. Although the national average consent rate is 51 percent, the study found that of the 190 transplant centers reviewed, 18 had a consent rate below 30 percent. If these transplant centers had obtained consent at the average rate of the remaining 172 centers in the study, namely 54 percent, the 18 centers would have realized 130 more donors – resulting in an estimated additional 450 life saving organs.
- **DRG Payment Window.** Under the inpatient prospective payment system, hospitals are reimbursed a predetermined amount for inpatient services furnished to Medicare beneficiaries depending on the classification of their illnesses under a diagnosis-related group. Non-physician outpatient services (such as laboratory tests) rendered up to 3 days before the hospital admission must be included in the prospective payment. The intent of the payment "window" was to prevent separate reimbursement for preadmission services. OIG analyzed a statistical sample of Medicare payments for hospital inpatient stays and outpatient services that preceded that admission. OIG estimated that, for 10 diagnosis-related groups, Medicare reimbursed providers about \$37 million for preadmission services rendered 4 to 14 days before admission. Beneficiaries paid an additional \$35 million in coinsurance and deductibles for these services. OIG therefore recommended that CMS consider proposing legislation to expand the payment window to cover preadmission services rendered up to 14 days before admission. CMS agreed, but cautioned that such action could increase beneficiaries' health risks should providers schedule diagnostic tests outside the 14 day window. CMS will take such risks into account in proposing legislation to expand the payment window.
- **Health Plan Cost Report.** The HHS/OIG audited a cost-based HMO under contract with CMS to provide health services on a prepayment basis to enrolled Medicare members. Under such a cost-based arrangement, CMS makes an interim payment each month to the Plan based on a per capita rate for each Medicare member. The interim payments are reconciled with the HMO's annual cost report. For contract years 1999 and 2000, the Plan claimed \$6.8 million and \$6.9 million, respectively, for additional Medicare costs over the amounts received as interim payments. The HHS/OIG found that the HMO overstated Medicare claims in years 1999 and 2000 by a total of approximately \$8.2 million. In addition, the organization was not in compliance with the financial disclosure requirements for related-party administrative costs totaling about \$14 million for both years. The audit recommended that the organization file amended Medicare cost reports, decreasing the amount claimed by \$8.2 million, and take steps to properly report covered related-party transactions, and otherwise insure the integrity of its payment systems. The HMO generally concurred.

Focus on DME

Audits and Evaluations:

- **Semi-Electric Hospital Beds.** When a mattress and bedside rails are provided to a beneficiary at the same time as a semi-electric hospital bed, the suppliers are required to bill Medicare using an all-inclusive procedure code. Nationwide, Medicare reimbursement for this code during calendar year 2000 totaled \$189 million. Following up on an earlier review, the HHS/OIG assessed whether fee schedule amounts for the code are excessive. To do so, HHS/OIG compared the fee schedule amount for this global code against the schedule amounts for the codes of the components (e.g., bed, mattress, side rails), and concluded that using the component coding could result in estimated annual savings of more than \$34 million. Medicare beneficiaries, Medicaid programs, or supplemental insurers could also save nearly \$9 million in coinsurance. In addition to discontinuing the problematic code, HHS/OIG recommended that CMS issue a final rule on the application of its inherent reasonableness authority so that it can be used to adjust the fee schedule amounts for this code. CMS agreed in part with the recommendations.
- **Durable Medical Equipment Orders - Surrogate Unique Physician Identification Number (UPINs).** Medicare beneficiaries are eligible to receive necessary medical equipment when ordered by a physician and certain non-physician practitioners (here, collectively referred to as "physicians"). Each physician is assigned a unique physician identification number (UPIN) by Medicare. UPINs help ensure that Medicare beneficiaries utilize DME only when authorized by a qualified physician, and allow CMS to aggregate data by UPIN and identify aberrant ordering practices. DME suppliers must include the UPIN of the ordering physician on DME claims to Medicare. However, if the physician has not yet been assigned a UPIN, Medicare permits the supplier to temporarily use a global surrogate number. The HHS/OIG examined a sample of services for which a surrogate number was used for claims for the purchase of durable medical equipment, prosthetics, orthotics, and supplies. The HHS/OIG found that for 61 percent of services, the ordering physician had a permanent UPIN that should have been included on the claim; for one-third of these, the physician had the UPIN for at least 5 years. In addition,

supporting documentation was missing or incomplete for 45 percent of the sampled services. Medicare paid an estimated \$61 million for services billed with surrogate numbers that had missing or incomplete documentation in 1999. The HHS/OIG recommended that CMS perform targeted reviews of claims and continue to educate suppliers and ordering physicians about the use of accurate UPINs, and CMS concurred.

Other Judgments and Settlements.

In addition to the significant enforcement actions described in the Program Accomplishments section of this report, and those immediately above, HHS/OIG conducted or participated in numerous investigations that resulted in prosecution or settlement during 2003, involving all aspects of the health care industry. These include:

Kickbacks: The Balanced Budget Act of 1997 authorized the HHS/OIG to impose civil monetary penalties against those who pay or receive remuneration in violation of the anti-kickback statute. During 2003, the HHS/OIG stepped up enforcement efforts under this administrative authority. Among these actions were:

- **Cardiology Consultants, P.A.** and its member physicians agreed to pay \$611,000 in settlement of their administrative liability for possible kickbacks and physician self-referrals. The HHS/OIG alleged that the cardiology group paid hourly fees to physicians who were not members of their practice group. The contracting physicians monitored cardiac stress tests. The OIG alleged that the payments to the contracting physicians were in excess of fair market value and were not commercially reasonable. In addition to the settlement payment, the group agreed to lower its monitoring fees and entered into a 3-year CIA.
- **Inland Empire Lithotripsy, LLC** (formerly Inland Empire Lithotripsy, Inc.) self-disclosed conduct to the HHS/OIG and agreed to pay \$404,538 and enter into a 3-year CIA to resolve its liability under the Civil Monetary Penalties (CMP) provisions applicable to kickbacks. The HHS/OIG alleged that Inland, an entity owned by urologists, received payments from a hospital in excess of fair market value for rental of a lithotripter and provision of lithotripsy services in exchange for Inland's referral of Medicare patients to the hospital. The OIG has alleged that Inland terminated some of its physician members in retaliation for their failure to refer a sufficient number of patients to the hospital.
- Five separate settlements were reached with physicians who faced potential liability under the CMPs applicable to false claims and kickbacks. In each case, the HHS/OIG alleged that the physician received free samples of the prostate cancer drug Lupron from TAP Pharmaceutical Products, Inc., and billed at least some of those samples to Medicare and other payers. Settlement amounts with the five physicians ranged from \$40,000 to \$95,000. Each entered into a CIA with the HHS/OIG.

Office of the General Counsel

The Office of the General Counsel (OGC) was allocated \$4.53 million in HCFAC funding to support the Department's program integrity activities. These funds were used primarily for litigation activity, both administrative and judicial.

Accomplishments:

Litigation

- In nursing home enforcement, OGC opened 568 new administrative cases before the Departmental Appeals Board (DAB) in FY 2003, an increase of 83 percent over FY 2002. CMPs against nursing homes totaled over \$12 million, resulting from favorable DAB decisions and negotiated settlements. There were also twenty-five federal court cases opened as a result of nursing home enforcement actions.

False Claims and Qui Tam Actions

- OGC reviewed FCA qui tam claims to determine whether there was a failure to comply with Medicare or Medicaid statutes, regulations, program instructions, and general policies. For example, in 2003, OGC participated in FCA and related administrative matters involving HCA, Inc. that resulted in recovery of \$891 million which, when added to previous recoveries, culminated in a total of over \$1.7 billion obtained from the company over the past several years.

Medicare Secondary Payer

- OGC is involved in substantial product liability or tort claims brought against the tortfeasors as self-insured entities and/or their insurance companies. Challenges to Medicare's right to recover have arisen in the silicone breast implant litigation, In re Dow Corning Corp. and United States v. Baxter HealthCare (11th Cir.); the orthopedic bone screw case, Fanning v. United States (3rd Cir); defective product claim, Thompson v. Goetzmann (5th Cir); medical malpractice lawsuit, Brown v. Thompson (4th Cir.); beneficiary class action, Nygren v. United States and in several other cases.
- OGC continues successful Medicare Secondary Payer (MSP) partnership arrangements with various U.S. Attorney's Offices. In one region, OGC received a record number 1,486 new MSP cases in 2003 and is handling in excess of 2,000 pending MSP cases. As a result of establishing Medicare's right to recovery in some 1,160 cases, Medicare collected over \$6.92 million.

- OGC assisted CMS' implementation of a settlement agreement that resolved the long-pending McConaghy v. Thompson case in the First Circuit. This permitted CMS to determine whether Medicare has any MSP claims, and required CMS to be reimbursed for such claims before receivership assets can be disbursed to individuals.

Policy Guidance and Education.

- OGC continues to be significantly involved in CMS' efforts to upgrade the training of state and federal professionals who survey long term care facilities for compliance with Medicare requirements. This includes the presentation of training sessions on the legal aspects of surveying to surveyors and managers from across the United States and for DOJ and CMS partners.
- OGC utilizes established "practice groups" which identify national issues requiring policy clarifications and which identify the most effective and efficient means of litigating these matters. Practice groups are currently in place for long term care enforcement cases and bankruptcy matters.
- OGC continues to work with a U.S. Attorney's Office to assure laboratories whose Clinical Laboratory Improvement Amendments (CLIA) certificates are suspended/revoked do not continue testing in violation of CMS action.

Administration on Aging

In 2003, the Administration on Aging (AoA) was allocated \$3.25 million in HCFAC funds to support the Senior Medicare Patrol (SMP) Projects, and to maintain effective partnerships for detecting and reporting error, fraud and abuse. AoA provided technical assistance and support to the 57 SMP projects, and national community education efforts, with a particular focus on vulnerable populations, persons with low health literacy, culturally diverse backgrounds and persons living in rural areas. The SMP projects provided direct and widespread education to older Americans through an extensive network of senior volunteers, designed to increase recognition and reporting of potential errors and fraud in the Medicare and Medicaid programs.

Accomplishments:

- National Technical Assistance Resource Centers: AoA supported four national resource centers that provided SMP grantees and the aging network with materials, training, and other forms of technical assistance to enhance their efforts to educate hard-to-reach older Americans. The Centers focused on outreach strategies for educating minority, rural, low-literacy, and non-English-speaking individuals in health care fraud issues. AoA also solicited applications for one consolidated National Consumer Protection Technical Resource Center to become operational in FY 2004. This new center will result in streamlined communications with the grantees and enhance replication of successful practices nationwide.
- Regional Health Care Fraud and Abuse Control Program Conferences: AoA convened three regional conferences in Alexandria, Virginia; Dallas, Texas; and Seattle, Washington to provide guidance and technical assistance to SMP grantees; offer networking opportunities with other Federal partners, and exchange information on best practices and other innovative activities.
- Senior Medicare Patrol Projects: AoA developed a new program announcement that expanded the pool of eligible applicants to faith-based organizations and Federally recognized tribes. This action increased the program from 51 projects in 45 states to 57 projects in 50 states plus the District of Columbia and Puerto Rico. SMP projects recruit and train retired individuals to educate seniors in their communities about how they can help prevent and detect potential Medicare and Medicaid error, fraud, and abuse. In 2003, the projects trained approximately 8,500 senior volunteers who directly educated 505,000 Medicare beneficiaries in their communities through over 140,000 training sessions and one-on-one encounters. This training included how to read their Medicare Summary Notices, fraud awareness, and working with medical providers when potential errors are discovered among other topics. As a result of beneficiary educational efforts, the percent of beneficiaries familiar with efforts to reduce health care fraud, error and abuse has increased by 35 percent since 1997 and the number of beneficiaries who read their Medicare Summary Notices (MSN) increased by 21.4 percent. After SMP training, over 90 percent of beneficiaries indicated they would be willing to call their provider to discuss an error on their MSN.
- Consumer Awareness: AoA maintained a web site to provide information about Medicare and Medicaid error, fraud and abuse targeted to older Americans and community-based professionals who serve aging adults and their families. The site promotes consumer awareness and facilitates the sharing of information and best practices between Medicare and Medicaid beneficiaries and AoA's grantees and partners. In addition, HCFAC funding supported the design and distribution of personal health care journals and education brochures and videos in English, Spanish, and Mandarin Chinese. A particular emphasis was made to disseminate this information to AoA's nationwide network of aging service professionals, through a variety of television, radio, and print media events.
- Beneficiary Complaints and Resulting Recoupments: Over the 12 month period ending June 30, 2003, beneficiaries reported almost 14,000 complaints to the SMP projects. In addition, the OIG reports documentation of over \$743,000 in Medicare funds recouped during this period as a direct result of complaints referred to CMS contractors by SMP projects. Self-reported savings to other payers (primarily Medicaid) were approximately \$23

million during this period. While it is not possible to directly track all of the cases reported and dollars recovered through these community education activities, approximately \$103 million, primarily in Medicaid funds, has been recouped by the program from its inception in 1998 through June 30, 2003, as a result of documented complaints.

Centers for Medicare and Medicaid Services

In 2003, the Centers for Medicare and Medicaid Services (CMS) was allocated \$23.37 million to fund a variety of projects related to fraud, waste and abuse in the Medicare and Medicaid programs. Of this amount, \$10 million was specifically dedicated to combat fraud in the Medicaid program.

CMS has increased its efforts to use advanced technology to detect and prevent fraud and abuse and to ensure that CMS pays the right providers, the right amount, for the right service, on behalf of the right beneficiary. CMS fraud, waste, and abuse projects are described below.

Payment Accuracy Measurement (PAM) and State Children's Health Insurance Plan (SCHIP) Error Rate Pilot: HCFAC funding will allow for twenty-seven states to participate in the third year of the PAM project, which develops payment accuracy measurement methodologies and conducts pilot studies to measure and reduce state Medicaid payment errors.

During the third year of the PAM project, each of the 27 states will pilot test the CMS Model in their Medicaid and/or SCHIP programs. The CMS Model has been designed to produce state-specific payment error rate estimates, and through weighted aggregation, national level payment error rate estimates for Medicaid.

Accomplishments

- In response to the June 2003 all-state solicitation, CMS received applications from 27 states to participate in the third year of the PAM Project. All 27 states were awarded grants in September 2003. These states are: Alabama, Arizona, Arkansas, California, Colorado, Delaware, Florida, Idaho, Indiana, Iowa, Kentucky, Louisiana, Massachusetts, Minnesota, New Mexico, North Carolina, North Dakota, Oklahoma, South Carolina, South Dakota, Texas, Utah, Virginia, Washington, West Virginia, and Wyoming. Ten of these states previously participated in the project.
- Twelve of the states will pilot test the CMS Model in their Medicaid program; three States will pilot test the model in their SCHIP program; and fifteen States will pilot test the model in both their Medicaid and SCHIP programs. Approximately half of these 27 states will pilot test the model in both the fee for service and managed care components of their Medicaid and SCHIP programs.

Automating Medicaid State Plans: In 2003, HCFAC funds were allocated to Medstat, Inc., to research options for automating the Medicaid State Plan process, from plan amendment creation at the state level through the submittal and approval process at the regions and central office. This allows CMS to understand the current state-of-the-art choices for document management, information flow and analysis, and the timing and resources necessary to achieve these goals. A Medicaid State Plan database will allow broad and timely access to program information for CMS, the states and other partners.

Waiver Management System Database: In 2003, HCFAC funds were allocated to update and improve the current 1915(c) Waiver Management System Database (WMSD), including a web-based application for WMSD and to improve state long term care data collection and analysis in order to support financial oversight and accountability.

Annuities: In 2003, HCFAC funds were allocated to the CNA Corporation for a research project titled, "Collection and Analysis of Information and Analysis of State and Federal Policies Concerning the Use of Annuities to Shelter Assets in State Medicaid Programs." The project uses both qualitative and quantitative research methods to develop a comprehensive picture of states' experience with the use of annuities as an asset-sheltering device by Medicaid applicants and their spouses. This project also uses a methodology to estimate the cost of this practice to the Federal government and the states.

The research includes in-depth interviews and data collection in selected states and counties; review of litigation and administrative appeals pertaining to annuities; focus groups with seniors regarding awareness, attitudes, and likely use of various financing or asset sheltering mechanisms, including annuities to cover the costs of long term care; information-gathering from representatives of insurance industry groups, elder law attorneys, consumer advocates and others, regarding the annuities marketplace, sales practices, the secondary market for annuities, and related issues.

Financial Management Data Redesign Project (FMDRP): HCFAC funding was used to develop and enhance an integrated financial management tool that links existing CMSO data systems and tools. This tool was developed through a contract with Enterprise Technology Partners (ETP). The linked tools contain critical financial, statistical, administrative and other data.

This tool will allow CMSO to better focus its financial management reviews, targeting service areas of high financial exposure and supporting the key Administration goal of improved financial management for the Medicaid program. After CMS has reviewed and tested this tool, it will be rolled out to regional offices.

Medicaid Audits: In 2003, HCFAC funds were allocated to CMS to support a series of special Medicaid audits to be conducted by the HHS/OIG through an Interagency Agreement with CMS. A total of 16 audits were undertaken in states and issue areas specified by CMS. The targeted areas included: upper payment limits, school-based claims, adult rehabilitation services, home and community based services, and Medicaid administrative costs reported by state agencies other than the Medicaid single state agency.

Medicare/Medicaid Data Match Expansion Project: In 2003, HCFAC funds were allocated to the CMS to expand upon a joint Medicare and Medicaid data-matching project. The data-matching project was developed to examine the health care claims data from health care programs that share many common beneficiaries and providers and for aberrancies indicative of potential fraud or abuse that may not be evident when provider billings for either Medicare or Medicaid are viewed in isolation. The data match enables analysts and investigators to see the "whole picture" which, heretofore, had not been possible.

Continued operation of the California data-matching project has resulted in an estimated \$71 million worth of recoupments and savings. More than 90 potential investigations have been opened thus far by program safeguard contractors, and are in various stages of development. Given the overall success of the pilot project in California, CMS is developing the Medicare-Medicaid data match projects in Texas, Illinois, North Carolina, Florida, New Jersey and Pennsylvania, Ohio and Washington, as well as continuing operation and maintenance of the original project in California.

Medicare + Choice Steering and Discrimination Project: In 2003, HCFAC funding was allocated to the Division of Program Accountability and Payment (DPAP) to review the Medicare + Choice (M+C) plan benefit packages that may deny, limit, or condition the coverage or furnishing of benefits to individuals eligible to enroll in an M+C plan offered by an M+C organization on the basis of any factor that is related to health status. Statutory and regulatory provisions authorize CMS to develop and implement methods for detecting health screening and steering of Medicare beneficiaries. Over the past several years the M+C benefit packages have markedly changed and considerable concern has been raised by beneficiaries, Congress, and others about the potential for health screening through the types of benefits and cost-sharing structures offered to beneficiaries. CMS wants to ensure that groups are not being discriminated against or steered into or out of certain plans based on their health status.

FUNDING FOR DEPARTMENT OF JUSTICE

United States Attorneys

The ninety-three United States Attorneys and their assistants serve as the nation's principal prosecutors of federal crimes, including crimes committed by health care providers. Similarly, civil attorneys in the United States Attorneys' Offices (USAOs) are responsible for bringing affirmative civil cases to recover funds that federal health care programs have paid as a result of fraud, waste, and abuse, with support in those cases designated by the Civil Division for joint handling. USAOs also handle most criminal and civil appeals at the federal appellate level.

In 2003, the USAOs were allocated \$30.4 million dollars in HCFAC program funds to support civil and criminal health care fraud and abuse litigation as exemplified in the Program Accomplishment's section, *infra*. The USAOs dedicated substantial resources to combating health care fraud and abuse in FY 2003. HIPAA allocations have supplemented those resources by providing dedicated positions for attorneys, paralegals, auditors and investigators, as well as funds for litigation of resource-intensive health care fraud cases.

In addition to the staff positions funded by HCFAC, EOUSA's Office of Legal Education (OLE) uses HCFAC funds to train AUSAs and other Department attorneys, as well as paralegals, investigators, and auditors in the investigation and prosecution of health care fraud. In 2003, OLE conducted courses and presentations on health care fraud, including the Health Care Fraud and Affirmative Civil Enforcement seminar; the Health Care Fraud Coordinator's Conference (Civil and Criminal), the Health Care Fraud Symposium, the Health Care Fraud Special Topics Conference, and Justice Television Network broadcast trainings on the medical privacy provisions of HIPAA.

Civil Prosecutions

In 2003, the USAOs had 1,574 health care fraud criminal matters pending, involving 2,496 defendants. The USAOs filed criminal charges in 362 cases involving 531 defendants, and obtained 437 federal health care related convictions in 2003. USAOs receive referrals of health care fraud cases from a wide variety of sources, including the FBI, the HHS/OIG, Medicaid Fraud Control Units in State Attorney Generals' Offices, and other federal, state, and local law enforcement agencies. In FY 2003, USAOs received new case referrals involving 1,352 defendants, and obtained convictions of 437 defendants. Examples of just a few of the criminal cases USAOs brought this past year are set forth in the Program Accomplishments section of this report.

Criminal Prosecutions

The USAOs use affirmative civil enforcement litigation to recover monies wrongfully taken from the Medicare Trust Fund and other taxpayer-funded health care systems, and to ensure that the federal health care programs are fully

compensated for the losses and damages resulting from such thefts. The FCA is one of the most important tools the USAOs use for these purposes. The FCA subjects those who knowingly present false claims for payment to the government, including health care providers who submit claims to federal health care programs, to treble damages and civil penalties.

USAOs receive civil health care fraud referrals from a variety of sources, principally the federal investigative agencies that refer criminal cases, and by means of *qui tam* complaints. Under the FCA, a *qui tam* plaintiff (known as a "relator") must file his or her complaint under seal in a United States District Court, and serve a copy of the complaint upon the United States Attorney for that judicial district, as well as the Attorney General. USAOs routinely assign civil AUSAs to every *qui tam* case filed in their districts, as well as any matter referred by a law enforcement agency. At the end of FY 2003, the USAOs opened 870 new health care fraud matters (including *qui tam* actions), and had 1,277 matters pending. In order to maximize resources, Civil Division attorneys may become actively involved and participate with the USAOs in *qui tam* cases involving more than one district and with potential recoveries substantially over one million dollars. USAOs generally remain responsible in all other *qui tam* cases for investigating the relator's allegations and, where appropriate, litigating and/or settling the case. In 2003, USAOs filed or intervened in 231 civil health care fraud cases. The Program Accomplishments section includes just a few examples of the many civil matters that USAOs successfully resolved in 2003.

Civil Division

In 2003, the Civil Division was allocated \$14.5 million in HCFAC funds to support civil health care fraud litigation. (The Civil Division also administers the Nursing Home Initiative allocation of \$1 million.) Civil Division attorneys pursue civil remedies in health care fraud matters, working closely with the USAOs, the FBI, the HHS/OIG and the Department of Defense, CMS, 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, TRICARE, the Federal Employees Health Benefits Program (FEHBP), and other government health care programs.

Accomplishments

In 2003, the Division opened or filed a total of 230 health care fraud cases or matters. In addition to these new efforts, the Civil Division pursued 442 existing cases, often working with Assistant United States Attorneys. A significant number of these health care fraud cases have the potential for particularly high damages. Civil Division attorneys were actively involved in the recoveries described in the Program Accomplishments section, above.

The Civil Division is also staffing and providing a coordination function in the FCA investigations alleging pharmaceutical pricing fraud against government health care programs. These matters span multiple districts and present myriad legal and factual issues that require substantial coordinating efforts of the Civil Division. Since 2001, six cases involving allegations of pricing fraud by pharmaceutical manufacturers against Medicaid and Medicare have been settled by the government for a total recovery of \$1.66 billion.

In addition to their litigating responsibilities, Civil Division attorneys have played a role in coordinating and presenting the DOJ's views to HHS as its offices interpret and apply the Anti-Kickback statute and Stark laws prohibiting physician self-referral. For example, the Division has provided assistance to the HHS/OIG in issuing its advisory opinions regarding the Anti-Kickback statute and fraud alerts, and to CMS in connection with the issuance of CMS' final regulation on the physician self-referral prohibition. In addition, the Civil Division, working with other components of the Department of Justice, has provided views on the Pharmaceutical Industry Compliance Guidance.

In addition to these accomplishments, the Department's Nursing Home Initiative, coordinated by the Civil Division, promotes, among other things, increased prosecution and coordination at Federal, state and local levels to fight abuse, neglect, and financial exploitation of the nation's senior and infirm population. The Department is pursuing a growing number of cases under the FCA and other theories involving providers' egregious "failures of care." It also is in the forefront in developing the field of elder abuse and neglect forensics to improve detection, reporting, training, investigation, and prosecution in this emerging area.

Civil Division attorneys provide guidance and training to government attorneys to assure the Department's continued compliance with the Health and Human Services Standards for Privacy of Individually Identifiable Health Information, commonly known as the HIPAA privacy rule.

Also, the Civil Division continues to co-chair, with the Criminal Division, the Health Care Fraud Working Group to coordinate the health care fraud enforcement activities of all concerned federal and state agencies.

Criminal Division

In FY 2003, the Criminal Division was allocated \$1.58 million in HCFAC program funds to support criminal health care fraud litigation. The Fraud Section of the Criminal Division develops and implements white collar crime policy and provides support for 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, AUSAs and Criminal Division attorneys on criminal, civil and administrative tools to combat health care fraud, and worked on an interagency level through:

- coordinating large scale multi-district health care fraud investigations;
- 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 DOJ's responses to major regulatory initiatives, legislative proposals, and enforcement policy matters. Examples include issues such as provider education and regulation, medical records privacy, Internet sales of drugs and medical products and 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;
- working with CMS officials to promote more effective use of technologies and high-tech approaches for combating health care fraud and abuse. Examples include co-sponsoring with CMS two regional conferences and working with several USAOs to coordinate with CMS during its transition to Program Safeguard Contractors for conducting anti-fraud detection work in the Medicare program;
- 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, in conjunction with the Civil Division, the National Level Health Care Fraud Working Group to address fraud in health care and managed care; and
- participating in interagency working groups formed to address illicit Internet sales of drugs and medical products and nursing home fraud and resident abuse.

The Fraud Section has responsibility for handling and coordinating complex health care fraud litigation nationwide and is currently involved in national investigations of hospitals, medical equipment suppliers, and vocational rehabilitation and health care management services, as well as other health care providers. An example of a successful Fraud Section prosecution in 2003 follows:

- Two chiropractors who operated a medical clinic and an operator of a management consulting services company were convicted of conspiracy to commit health care fraud and of health care fraud in connection with a \$5 million fraudulent billing scheme. The defendants conspired to increase the chiropractic clinic's income by defrauding health care insurers by using marketing techniques to attract patients with "good" insurance. The chiropractic clinic then provided health care services based on insurance coverage rather than medical needs, and deceived Medicare and other insurers into believing that the treatment and services being billed were medically necessary and were provided under the direction and supervision of a medical doctor. The conspirators were thereby able to evade strict insurance coverage limits on chiropractic services. The management consulting services operator, who de facto controlled the chiropractic clinic through management contracts and lease agreements, also was convicted of engaging in a money-laundering conspiracy and of substantive money laundering.

In addition to its litigating responsibilities, the Fraud Section conducted numerous training sessions and workshops for Department attorneys and investigators, executive branch health care program integrity administrators, and state and local law enforcement personnel on the health oversight and law enforcement exceptions to the HIPAA medical records privacy regulations which became effective in April 2003. In partnership with the FBI, the Fraud Section prepared and disseminated HIPAA medical records privacy training materials to more than 16,000 state and local law enforcement agencies nationwide. The Section also developed a special electronic mail account to disseminate, upon request, additional supplemental HIPAA medical records privacy training and guidance materials prepared for state and local law enforcement agencies and has since responded to more than 1,200 state and local law enforcement agency requests for the supplemental training materials.

Civil Rights Division

In FY 2003, the Civil Rights Division was allocated \$1.98 million in HCFAC funds to support civil rights division litigation activities related to health care fraud. The Special Litigation Section of the Civil Rights Division pursues relief affecting public, residential health care facilities and has established an Institutional Health Care Abuse and Neglect Initiative to carry out the Department's initiative to eliminate abuse and grossly substandard care in Medicare and Medicaid funded nursing homes and other long-term care facilities.

The Section plays a role in the HCFAC Program and is the sole DOJ component responsible for the Civil Rights of Institutionalized Persons Act, 42 U.S.C. § 1997 (CRIPA). CRIPA authorizes investigation of conditions of confinement at state and local residential institutions (including facilities for persons with developmental disabilities or mental illness, and nursing homes) and initiation of civil action for injunctive relief to remedy a pattern or practice of violations of the constitution or federal statutory rights. The review of conditions in facilities for the mentally ill and for persons with

developmental disabilities, and nursing homes comprises a significant portion of the program. The Special Litigation Section works collaboratively with the USAOs around the country and with HHS.

Accomplishments

As part of the Department's Institutional Health Care Abuse and Neglect Initiative, and as an enhancement to the Department's ongoing CRIPA enforcement efforts, the Special Litigation Section staff preliminarily reviewed conditions and services at 38 nursing home facilities in 19 states during FY 2003. The task in preliminary inquiries is to determine whether there is sufficient information supporting allegations of unlawful conditions to warrant formal investigation under CRIPA. The Section reviewed information pertaining to areas such as: abuse and neglect, medical and mental health care, use of restraints and seclusion, fire and environmental safety, and placement in the most integrated setting appropriate to individual needs.

In FY 2003, the Special Litigation Section opened CRIPA investigations of two nursing homes: A. Holly Patterson Geriatric Center in Uniondale, New York, and Nashville Metropolitan Bordeaux Hospital in Nashville, Tennessee. Staff participated in ongoing nursing home investigations, including the investigation of Laguna Honda Hospital and Rehabilitation Center in San Francisco, California, the largest public nursing home facility in the United States, and Bradley County Health Care and Rehabilitation Center in Cleveland, Tennessee.

The Division sent letters of findings to appropriate public officials for our investigations of Banks-Jackson-Commerce Medical Center and Nursing Home in Commerce, Georgia; Mercer County Geriatric Center in Trenton, New Jersey; Nim Henson Geriatric Center in Breathitt County, Kentucky; Reginald P. White Nursing Facility in Meridian, Mississippi; and Claudette Box Nursing Facility in Mt. Vernon, Alabama. These investigations involved on-site evaluation tours with expert consultants, review of documentary evidence, and interviews of staff. Section staff continued to monitor our agreement in Bergen Regional Medical Center in Paramus, New Jersey.

In addition, the staff initiated CRIPA investigations of facilities for persons with developmental disabilities including: Conway Human Development Center in Conway, Arkansas; Woodbridge Developmental Center in Woodbridge, New Jersey; and Boston Higashi School in Randolph, Massachusetts. Special Litigation Section staff conducted tours of the Conway and Woodbridge facilities, accompanied by expert consultants, reviewed documents, and interviewed facility staff.

The Section continued its investigations of the following residential facilities for the developmentally disabled: Agnews and Sonoma Developmental Centers in San Jose and Eldridge, California; Pinecrest and Hammond Developmental Centers in Pineville and Hammond, Louisiana; Landmark Learning Center in Opa-Locka, Florida; Holly Center in Salisbury, Maryland; Rainier Residential Rehabilitation Center and Frances Haddon Morgan Center in Buckley and Bremerton, Washington; and Woodward and Glenwood Resource Centers in Woodward and Glenwood, Iowa. In many of these investigations, negotiations toward settlement are continuing regarding the correction of remaining deficient conditions. In some of these matters, the Section is reviewing voluntary compliance to improve conditions.

In 2003, the Section found that conditions and practices at two state-operated facilities for persons with developmental disabilities violate the residents' federal constitutional and statutory rights. Those facilities are: Oakwood Communities in Somerset, Kentucky, and New Lisbon Developmental Center in New Lisbon, New Jersey.

The Section continued its investigations of the following mental health facilities: John Umstead Hospital, Dorothea Dix Hospital, Cherry Hospital, and Broughton Hospital in Butner, Raleigh, Goldsboro, and Morgantown, North Carolina; and Metropolitan State Hospital in Norwalk, California. The Section sent a letter of findings concerning the investigation of the Children and Adolescent programs at Metropolitan State Hospital during the fiscal year.

The Section staff also conducted compliance reviews in ongoing CRIPA cases involving a variety of facilities. In each of these cases, staff reviewed compliance with the terms of previously filed agreements and court orders.

A. Facilities for persons with developmental disabilities: Southbury Training School (United States v. Connecticut (D. Conn.)); Embreeville Center (United States v. Pennsylvania (E.D. Pa.)); Arlington Developmental Center (United States v. Tennessee (W.D. Tenn.)); Clover Bottom Developmental Center, Greene Valley Developmental Center, and Harold Jordan Center (United States v. Tennessee (M.D. Tenn.)); Southern Wisconsin Developmental Center and Central Wisconsin Developmental Center (United States v. Wisconsin (W.D. Wis.)); Centro de Servicios Múltiples de Camaseyes, Centro de Servicios Múltiples Rosario Bellber and community-based services (United States v. Commonwealth of Puerto Rico (D. P. R.)); and Ft. Wayne Developmental Center and Muscatatuck Developmental Center (United States v. Indiana (S.D. Ind.)).

B. Facilities for persons with mental illness: Hawaii State Hospital, the children and adolescent residential services at Queens Medical Center and Kahi Mohala Behavioral Treatment Center and community-based mental health services (United States v. Hawaii (D. Haw.)); Guam Adult Mental Health Unit (United States v. Territory of Guam (D. Guam)); Pilgrim Psychiatric Center (United States v. New York (E.D. N.Y.)); and Memphis Mental Health Institute (United States v. Tennessee (W.D. Tenn.)).

C. Other Facilities: New Mexico School for the Visually Handicapped (United States v. New Mexico (D. N. Mex.)). In addition to its law enforcement activities regarding health care fraud activities, the Special Litigation Section is responsible for representing the Department and the Civil Rights Division on an inter-agency committee on elder care

issues. The Section has also participated in public education and outreach by speaking and participating at conferences on quality of care in health care facilities.

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 2003, \$114,000,000."

Under HIPAA, the FBI was budgeted \$114 million in 2003 for health care fraud enforcement. This money was used to support 878 positions (507 Agent/371 Support), an increase of 68 positions over FY 2002 (42 Agent, 26 Support.). As the FBI has increased the number of agents assigned to health care fraud investigations, the number of pending investigations has increased more than 400 percent, from 591 cases in 1992 to 2,262 cases through 2003. FBI-led investigations resulted in 414 criminal health care fraud convictions and 523 indictments and informations being filed in FY 2003.

With health care expenditures rising at three times the rate of inflation, it is especially important to coordinate all investigative efforts to combat fraud within the health care system. The FBI is the primary investigative agency involved in the fight against health care fraud that has jurisdiction over both the federal and private insurance programs. With more than \$1 trillion being spent in the private sector on health care and its related services, the FBI's efforts are crucial to the success of the overall program. The FBI leverages its resources in both the private and public arenas through investigative partnerships with agencies such as the HHS/OIG, Food and Drug Administration, Defense Criminal Investigative Service, Office of Personnel Management, Internal Revenue Service and various state and local agencies. On the private side, the FBI is actively involved with national groups, such as the National Health Care Anti-Fraud Association (NHCAA), the Blue Cross and Blue Shield Association and the Coalition Against Insurance Fraud, as well as many other professional and grass-roots efforts to expose and investigate fraud within the system.

Health care fraud investigations are among the highest priority investigations within the FBI and rank behind only Public Corruption and Corporate Fraud in the FBI's White Collar Crime Program Plan. In addition to being a partner in the majority of investigations listed in the body of this report, the FBI last year launched the Outpatient Surgery Initiative to combat the growing problem of fraudulent surgeries performed at certain outpatient facilities in Southern California. This nationwide scheme has drawn participants from 48 of the 50 states who have traveled to California to have unneeded surgery in exchange for a cash kickback, and has resulted in billings to the insurance companies in excess of \$500 million. The FBI partnered with the NHCAA to collect intelligence on the problem, and launched a nationwide investigation. As part of the initiative, the FBI teamed with a media outlet to profile the matter on television in an effort to stem the tide of willing participants and expose the fraud to the public.

The majority of HIPAA funding received by the FBI is used to pay personnel costs associated with the 878 funded positions. Funds not used directly for personnel matters are used to provide operational support for major health care fraud investigations and national initiatives focusing on pharmaceutical fraud, outpatient surgery centers, and transportation providers. Further, the FBI continues to support individual investigative needs such as the purchase of specialized equipment and expert witness testimony on an as-needed basis.

GLOSSARY

The Account-The Health Care Fraud and Abuse Control Account

ACE-Affirmative Civil Enforcement

AoA-Administration on Aging

ASBTF-Assistant Secretary for Budget, Technology and Finance

ASC-Ambulatory Surgical Centers

AUSA-Assistant United States Attorneys

CIA-Corporate Integrity Agreement

CLIA-Clinical Laboratory Improvement Amendments

CMP-Civil Monetary Penalties

CMS-Centers for Medicare and Medicaid Services

CMSO-Center for Medicaid and State Operations

CNA-Certified Nurse Aide

CRIPA-Civil Rights of Institutionalized Persons Act

DAB-Departmental Appeals Board

DME-Durable Medical Equipment

DOJ-The Department of Justice

DRG-Diagnosis Related Group

DSH-Disproportionate Share Hospital

DPAP-Division of Program Accountability and Payment

ECG-Transtelephonic Electrocardiogram

ESRD-End Stage Renal Disease

FBI-Federal Bureau of Investigation

FCA-False Claims Act

FDA-Food and Drug Administration

FEHBP-Federal Employees Health Benefits Program

FMDRP-Financial Management Data Redesign Project

GSK-GlaxoSmith Kline

GAO-General Accounting Office

HCFAC-Health Care Fraud and Abuse Control Program

HHS-The Department of Health and Human Services

HI-Hospital Insurance Trust Fund

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

HMO-Health Maintenance Organization

M+C-Medicare + Choice

MSN-Medicare Summary Notices

MSP-Medicare Secondary Payer

NHCAA-National Health Care Anti-Fraud Association

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

OPD-Outpatient Departments

PAM-Payment Accuracy Measurement

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

SCHIP-State Children's Health Insurance Plan

SMP-Senior Medicare Patrol

TAG-Technical Advisory Group

TENS-Transcutaneous Electrical Nerve Stimulation

USAO-United States Attorney's Office

UPIN-Unique Physician Identity Number

WMSD-Waiver Management System Database

1. Hereafter, referred to as the Secretary.

2. In addition, over \$380 million from cases settled in FY 2003 was collected and disbursed in FY 2004 and will be reported in detail for that period.

3. Also known as the Hospital Insurance (HI) Trust Fund. All further references to the Medicare Trust Fund refer to the HI Trust Fund.

4. In 2003, DOJ collected, or continued to hold in suspense, additional funds from health care fraud cases and matters that were not distributed to the affected agencies and/or the Account in 2003 due to: (i) ongoing litigation regarding relator shares in qui 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 2004.

5. In addition, HHS/OIG obligated \$1.7 million 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).