

During FY 2007, the many significant HCFAC Program accomplishments included the following:

Pharmaceutical Fraud

- The Purdue Frederick Company, Inc., along with its President, Chief Legal Officer, and former Chief Medical Officer pled guilty to charges of misbranding Purdue's addictive and highly abusable drug, OxyContin. The government alleged that Purdue fraudulently misbranded OxyContin as being less addictive and less subject to abuse and diversion than other pain medications. As part of the global resolution, Purdue and the executives paid a total of \$634.5 million to resolve their criminal and civil liabilities. In particular, Purdue forfeited \$276.1 million to the United States, paid the United States and State government agencies \$160 million to resolve liability for false claims made to Medicaid and other government healthcare programs, set aside \$130 million to resolve private civil claims (with unclaimed amounts to revert to the United States), paid \$5.3 million to the Virginia Attorney General's Medicaid Fraud Control Unit to fund future health care fraud investigations, paid \$20 million to fund the Virginia Prescription Monitoring Program, and paid the maximum statutory criminal fine of \$500,000. In addition, the three Purdue executives paid over \$34.5 million to the Virginia Medicaid Fraud Control Unit.

- Bristol-Myers Squibb Company (BMS) and its generic division, Apothecan, paid the United States \$328 million to resolve a broad array of allegations involving illegal drug pricing and marketing activities. BMS and Apothecan agreed to pay an additional \$187 million to State governments based on the same allegations. The civil settlement resolves allegations that (1) BMS and Apothecan set and maintained inflated prices knowing that federal health care programs used these prices for reimbursement, and then marketed the "spread" – the difference between the reported price used by Medicare to set reimbursement rates and the price charged to customers – to induce sales by increasing providers' profits; (2) BMS paid kickbacks to doctors in the form of bogus consulting fees to induce them to purchase BMS's drugs; (3) BMS paid kickbacks to wholesalers and retail pharmacies to induce purchases of generic products; (4) BMS promoted its atypical antipsychotic drug, Abilify, for juvenile use and to treat dementia related psychosis – uses that were not approved by the Food and Drug Administration (FDA); and (5) BMS violated the Medicaid Drug Rebate Act, 42 U.S.C. § 1396r-8, by reporting false "best prices" to the government for its drug Serzone, which resulted in BMS underpaying quarterly rebates owed to the Medicaid program.

- Aventis Pharmaceuticals, Inc., paid \$180 million to resolve allegations that the company engaged in a scheme (1) to set and maintain fraudulent and inflated prices for its drug, Anzemet, knowing that federal health care programs established reimbursement rates based on those prices, and (2) to use the difference between the inflated prices reported and the actual prices charged to its customers to market, promote, and sell this drug. Aventis additionally paid \$10 million to several State governments based on the same allegations.

- InterMune, Inc., agreed to pay \$30.2 million to resolve allegations that it marketed its drug, Actimmune, for uses not approved by the FDA resulting in federal health program losses. The government alleged that InterMune marketed Actimmune for idiopathic pulmonary fibrosis (IPF), a fatal disease that causes scarring of lung tissue. Although the company had failed to demonstrate Actimmune’s efficacy for IPF, it nevertheless misled physicians and the public to believe that the drug trial had been successful. InterMune paid an additional \$6.7 million to state Medicaid programs.
- Jazz Pharmaceuticals, Inc., (Jazz) paid \$20 million to resolve criminal and civil allegations relating to the illegal marketing practices of its wholly-owned subsidiary, Orphan Medical, Inc., (Orphan). As part of this resolution, Orphan pled guilty to felony misbranding, in violation of the Food, Drug, and Cosmetic Act (21 U.S.C. §§ 331(a) and 333(a)(2)) in connection with its illegal promotion of the prescription medication Xyrem, also known as gamma-hydroxybutyrate or “GHB,” for unapproved uses. GHB is a powerful and fast-acting central nervous system depressant that has been subject to abuse as a recreational drug and is classified by HHS as a “date rape” drug.
- Cell Therapeutics, Inc., (CTI) of Seattle, Wash., paid \$10.5 million to resolve allegations that it off-label marketed its anti-cancer drug, Trisenox, to treat various forms of cancer for which the drug had not been approved by the FDA. The settlement further resolved allegations that CTI paid kickbacks in the form of sham consulting agreements to induce physicians to prescribe Trisenox.
- Medicis Pharmaceutical Corp. agreed to pay the government \$9.8 million to resolve allegations that the company promoted the use of a topical skin preparation, Loprox, for use in children under the age of 10, without approval of the FDA. The government alleged that from approximately November 2001 through April 2004, Medicis sales personnel targeted pediatricians and urged them to use Loprox as a treatment for diaper rash. The use of Loprox, which is approved by the FDA as a fungicide for patients over 10 years of age, is not a “medically accepted indication” for the treatment of diaper dermatitis and other skin disorders in children under age 10.

Fraud by Pharmacies

- The owner of Florida Pharmacy and F&M Medical was convicted by a federal jury in Miami for conspiring to defraud the government, submitting false claims to Medicare, and receiving kickbacks. The owner was sentenced to 151 months in Federal prison, ordered to pay \$3.5 million in restitution, and ordered to serve 3 years probation after imprisonment. The owner conspired with the owners of Med-Pro Billing and Unimed Pharmacy to obtain kickbacks in exchange for referrals to Unimed Pharmacy. The owner received half of what Medicare paid the pharmacy for medically unnecessary “compounded” aerosols. “Compounding” refers to the process used by pharmacists, rather than a pharmaceutical manufacturer, to make medication. Subsequently, from 2004 to 2007, the owner began dispensing medically unnecessary DMEs and compounded aerosols from the owner’s own pharmacy, collecting in excess of \$3 million from Medicare.

Evidence at trial established that the owner continued to improperly bill Medicare, even after arraignment in this case.

DME Fraud

- The SCOOTER Store, Inc., paid the United States \$4 million and gave up many millions more in pending claims for reimbursement to Medicare, to settle allegations that the company violated the FCA. The settlement resolved allegations that The SCOOTER Store engaged in a multi-media advertising campaign to entice beneficiaries to obtain power scooters paid for by Medicare, Medicaid, and other insurers. Instead of the “zippy” power scooters that were advertised, The SCOOTER Store sold the beneficiaries the more expensive power wheelchairs that they did not want, need, and/or could not use. By representing to physicians that their patients wanted and needed power wheelchairs, The SCOOTER Store obtained thousands of “Certificates of Medical Necessity” from physicians who, the government alleged, did not know about the company’s fraudulent practices. The SCOOTER Store then billed government and private health care insurers for power wheelchairs, which were far more costly than power scooters, and collected millions of Medicare and Medicaid dollars.
- In Texas, after a 2 week trial, a supplier of DME was found guilty of five counts of health care fraud due to the submission of false claims to the Medicare program. The jury heard evidence that the supplier hired recruiters to target elderly and disabled Medicare beneficiaries for unnecessary DME such as power wheelchairs. Through former employees and the recruiters, the supplier bought and sold false certificates of medical necessity for the items and sought reimbursement in excess of \$1.6 million from the Medicare program. The court sentenced the supplier to 120 months incarceration and restitution of over \$1.6 million.
- In Texas, a defendant was sentenced to 80 months incarceration and was found liable for an amount in excess of \$2 million for the defendant’s involvement in a motorized wheelchair scheme. As part of the scheme, over 500 Medicare beneficiaries were transported from Louisiana to a Texas clinic. For each beneficiary transported to the clinic, the defendant received between \$200 and \$1,000 from various DME suppliers. At the clinic, one of three doctors performed a psychiatric evaluation on beneficiaries and then signed certificates of medical necessity and prescriptions for wheelchairs.
- In Florida, three subjects were sentenced for their roles in a scheme to submit false claims to Medicare for medically unnecessary DME. The DME company owner was sentenced to 63 months in jail, and the owner’s spouse was sentenced to 6 months of home confinement. As part of the scheme, the company owner paid Medicare beneficiaries for the use of their Medicare numbers in order to submit the false claims. In addition, a physician was paid for fraudulent prescriptions for the medically unnecessary DME. For the physician’s involvement in the scheme, the physician was sentenced to 36 months in jail. The three subjects were ordered to pay \$1.3 million in joint and several restitution.

- In New York, an individual was sentenced to 15 months incarceration (time served) and ordered to pay \$334,000 in restitution for involvement in a scheme to bill for medically unnecessary services. The individual, who owned a DME company, was involved in a scheme to pay individuals to participate in staged accidents so patients could be given DME and be referred for treatments that were not provided and/or not necessary. In turn, insurance companies were billed for fraudulent claims.
- The owner of a Miami health care company was sentenced to 37 months incarceration, followed by 3 years of supervised release, and was ordered to pay restitution in excess of \$290,000, after pleading guilty to submitting more than \$2 million worth of fraudulent bills to the Medicare program. The owner of MV Research, Inc., a DME company, pleaded guilty to one count of engaging in a scheme to defraud Medicare. The owner admitted that from January 2007 through March 2007, approximately \$2.2 million worth of claims were submitted to the Medicare program for equipment that was never actually provided to Medicare beneficiaries. The owner's scheme involved obtaining Medicare numbers for approximately 250 Medicare beneficiaries, obtaining Medicare provider numbers for approximately 10 doctors, and submitting approximately 4,000 claims to Medicare.
- The owner and operator of a Florida DME company was sentenced to 121 months in prison and ordered to pay approximately \$1.7 million in restitution for submitting more than \$3 million worth of fraudulent claims to the Medicare program. At trial, the government called witnesses who testified that the owner paid kickbacks to Medicare beneficiaries throughout Miami-Dade County to gain access to their Medicare information. The owner then billed Medicare for unnecessary services on behalf of these patients, including oxygen concentrators and nebulizers. The patients testified that they participated in the scheme because they needed the money. According to trial testimony, the owner paid \$100 per month if the patients agreed to accept unneeded aerosol medications, such as Albuterol, and related respiratory equipment.

Hospital Fraud

- Raritan Bay Medical Center agreed to pay the government \$7.5 million and enter into a Corporate Integrity Agreement (CIA) with HHS/OIG to settle allegations that it defrauded the Medicare program. In addition to its standard payment system, Medicare pays supplemental reimbursement to hospitals and other health care providers in cases where the cost of care is unusually high. These cases are known as "outliers." Between January 1998 and August 2003, Raritan Bay purposefully inflated charges for inpatient and outpatient care to make these cases appear more costly than they actually were, and thereby obtained outlier payments from Medicare that it was not entitled to receive. The settlement was the result of qui tam complaints filed by three whistle blowers.
- Eleven Commonwealth of Pennsylvania hospitals agreed to pay approximately \$4 million to the Medicare Program to resolve allegations of erroneous infusion therapy and/or blood transfusion claims. These settlements were part of a larger investigation of 26

Pennsylvania hospitals which has returned approximately \$11 million to the Medicare program to date.

Home Health Fraud

- In Ohio, the former owner of a home health company was sentenced to 13 years incarceration and ordered to pay \$564,000 in restitution for health care fraud, money laundering, and for drug and weapons charges. Investigation revealed that the owner solicited members of an immigrant community to accept unnecessary medical services and billed Medicaid for those services. To facilitate the fraud, doctors signed plans of care to indicate that patients were in need of skilled nursing and home health aid services. In reality, patients had not been seen by the doctors. In addition, reimbursements from claims submitted to Medicaid were diverted to support the owner's drug habit and to fund personal business ventures.
- In Ohio, a former owner of a home health agency was sentenced to 97 months in prison and ordered to pay \$2.7 million in restitution pursuant to a conviction for a scheme to defraud the Government. The investigation revealed that from October 2001 through May 2003 Medicaid was billed for skilled nursing services that were not rendered as claimed. The owner billed for 14 hours of services per week when only one hour per week or less of services was actually provided. During the trial, it was also revealed that the owner instructed employees to falsify nursing notes.
- In Iowa, the owner of several health care related companies, including Medicare-certified home health agencies, a pharmacy, and a medical supplies and equipment company, was sentenced to 46 months imprisonment upon convictions for Medicare fraud, and embezzling from an employee pension fund. The United States District Court ordered restitution in excess of \$2 million regarding the Medicare fraud and more than \$3 million regarding the employee pension fund. The defendant is also subject to forfeiture of real property and personal property in the amount of \$2.7 million. The defendant accomplished the Medicare fraud in a variety of ways including: concealing relationships with various business entities; "selling" goods and services from one company to another at inflated costs; and improperly passing on costs to Medicare that were not related to Medicare.

HMO Fraud

- In Illinois, the court entered a judgment for \$334 million against Amerigroup, Illinois Inc., after finding that the company had fraudulently skewed enrollment in its Medicaid HMO program by refusing to register pregnant women and by discouraging registration by individuals with pre-existing conditions. Amerigroup had entered into contracts with the Illinois Department of Public Health requiring the company to provide health care services to Medicaid eligible individuals in Illinois. In violation of these contracts, Amerigroup engaged in a "cherry-picking" scheme to ensure that those who enrolled in its HMO program represented a disproportionately healthy population of Medicaid-eligible individuals. As a result, Amerigroup reduced its medical losses and increased its profits.

Amerigroup has appealed the judgment. Damages for Illinois and the United States totaled \$48 million, but were automatically tripled under FCA and the Illinois Whistleblower Reward and Protection Act to \$144 million. Civil penalties in this case totaled \$190 million.

Kickbacks

- Medco Health Solutions (Medco) agreed to pay the government \$155 million plus interest and entered into a CIA with HHS/OIG to settle allegations that the New Jersey-based company submitted false claims to the government, solicited and accepted kickbacks from pharmaceutical manufacturers to favor their drugs, and paid kickbacks to health plans to obtain business. The settlement also covered allegations that Medco, among other conduct, cancelled valid prescriptions it could not timely fill in order to avoid paying penalties under its contract, shorted pills from prescriptions it filled, and, when filling prescriptions, used drugs other than those prescribed by the physicians to earn undisclosed rebates from drug manufacturers. This settlement arose from a qui tam complaint by relators, whose share of the settlement is approximately \$24 million.
- In Tennessee, the owner of a physical therapy company pled guilty to violating the anti-kickback statute and was sentenced to 4 months in prison and ordered to pay \$173,000 in restitution. The owner paid kickbacks to doctors based on the percentage of profits earned on patients referred to the company for physical therapy services. During the investigation, it was also revealed that the owner employed unlicensed physical therapists, billed for more therapy than was provided, and prepared fraudulent medical records for a Medicare audit.
- Rural/Metro Corporation, agreed to pay the United States over \$2.5 million and enter into a CIA with HHS/OIG to resolve allegations that the company submitted false claims to the government. The government alleged that the ambulance company provided illegal inducements to hospitals in Texas in exchange for referrals. The Arizona-based company provided or offered inducements to Texas hospitals in the form of contracts known as “swapping arrangements.” Such contracts gave the medical facilities discounts on transports in exchange for the referral of all or some of the ambulance transports of Medicare patients being discharged from the hospitals.
- Larkin Community Hospital in Miami and its current and former owners agreed to pay \$15.4 million and enter into a CIA with HHS/OIG to settle federal and Florida civil health care fraud claims against them. The government alleged that in 1997 Larkin paid kickbacks to physicians in return for patient admissions. Also, from 1998 to 1999, Larkin’s owners conspired with others to admit patients to Larkin for medically unnecessary treatment. Some of these patients came from assisted living facilities owned and operated by those involved in the scheme.
- Zimmer, Inc., Depuy Orthopaedics, Inc., Biomet Inc., and Smith & Nephew, Inc., manufacturers of hip and knee surgical implant products, agreed to pay \$311 million to settle claims that from at least 2002 through 2006 these companies used consulting

agreements with orthopedic surgeons to induce the purchase of their devices. In particular, the government's investigation found that the firms paid surgeons hundreds of thousands of dollars a year for consulting contracts and lavished them with trips and other expensive perquisites in exchange for using the companies' products exclusively. In addition to the civil settlements, the four companies executed deferred prosecution agreements requiring new corporate compliance procedures and the appointment of federal monitors to review their compliance with these procedures.

Prohibition on Self Referrals

- SCCI Health Services Corporation (SCCI) and its subsidiary, SCCI Hospital Ventures Inc., paid the United States \$7.5 million to settle allegations that the companies violated the statutory limitations on physician self-referrals and the False Claims Act. SCCI, which was purchased by Triumph Hospital in 2005, operates long term acute care facilities across the United States. The government alleged that from November 1996 through at least 1999, SCCI entered into prohibited financial relationships with three physicians and paid these physicians illegal payments in violation of the physician self-referral statute. The government further alleged that from November 1996 through at least 1999, SCCI either submitted or caused false claims to be submitted to the Medicare program, as a result of these prohibited financial relationships, in violation of the FCA.
- Northside Hospital and two physician owned entities, Blood and Marrow Transplant Group of Georgia (BMTGA) and Atlanta Blood Services (ABS), agreed to pay \$6.37 million to resolve allegations that they knowingly violated the physician self-referral statute by entering into improper referral relationships with each other to increase their Medicare reimbursement. Among other things, the government alleged that Northside hospital had purchased platelet products from ABS at an inflated price and had paid the physician owners of the transplant group medical directorship fees that exceeded fair market value.
- A corporation operating a sports medicine and rehabilitation facility, along with the owners of the real estate in which the facility was located, and 4 physicians, paid over \$1 million to settle allegations that they violated the physician self-referral statute by submitting claims to Medicare, based on referrals that were tainted by an improper financial relationship. The government's investigation and subsequent settlement was based on the filing of a whistle blower suit and focused on allegations that the rent paid to the property owner exceeded fair market value and reflected the value of the referrals that the facility received from the landlord.

Fraud by Physicians

- In Tennessee, a multi-agency health care fraud investigation of a 42-physician cardiology practice, resulted in a civil settlement of over \$1.7 million in recoveries to Medicare and the TennCare Medicaid program, as well as, a criminal pretrial diversion agreement requiring reimbursements of over \$1.2 million to more than 11,000 patients and multiple insurance programs. This investigation, initiated by the filing of a qui tam complaint,

focused on the knowing retention by the cardiology practice over the previous 10 years, of overpayments from Medicare, TennCare, private insurers and the practices' patients. During the latter overt part of the investigation prior to the settlement, the cardiology practice identified and issued refunds of an additional \$700,000 in overpayments owed to government programs, private patients, and their insurers.

- A former Florida dermatologist was sentenced to 22 years in prison, ordered to pay \$3.7 million in restitution, forfeit an additional \$3.7 million, and pay a \$25,000 fine for performing 3,086 medically unnecessary surgeries on 865 Medicare beneficiaries. The dermatologist was found guilty of health care fraud and false statements following a 4-week trial that showed that the doctor routinely falsely diagnosed patients with skin cancer in order to bill Medicare for expensive and unnecessary invasive surgeries. From 1998 through 2004, a detailed analysis showed that nearly all the biopsies performed were diagnosed as cancer and resulted in invasive surgeries. In fact, some of the specimens diagnosed as skin cancer were actually slides which contained chewing gum, Styrofoam, or skin tissue of the dermatologist's employees. During the trial, it was also revealed that the doctor had established a quota whereby five surgeries each day were performed for which Medicare paid between \$1,500 and \$2,000 per surgery.
- In Florida, a physician was sentenced to 24 months incarceration and ordered to pay \$727,000 in restitution for involvement in a health care fraud scheme. For cash payments, the physician signed blank prescriptions and certificates of medical necessity for patients the physician never saw. In turn, co-conspirators submitted claims to Medicare for DME and other items or services that were either not medically necessary or were not provided to beneficiaries.
- In Washington, D.C., a doctor was sentenced to 5 months incarceration and ordered to pay \$155,000 in restitution for health care fraud. From October 2001 through March 2003, the doctor submitted claims to Medicare for Reteplase injections that were not given. Reteplase is a drug generally given in a hospital emergency room within the first three hours of a patient experiencing myocardial infarction (or a "heart attack"). The doctor submitted claims for one patient who purportedly had been injected 119 times.
- In Oklahoma, a physician was sentenced to 33 months in prison and ordered to pay \$544,000 in restitution for health care fraud. From January 2000 to May 2005, the physician billed for dosages of Remicade and Procrit which far exceeded the amount of those drugs in the physician's inventory.
- In Florida, a doctor was sentenced to 78 months in prison and ordered to pay \$504,000 in restitution and forfeit an additional \$705,000 after a jury found the doctor guilty on all counts of an 89 count indictment which included 44 charges of health care fraud. The physician, who practiced dermatology, provided lesser services, or no services at all, but billed Medicare for highly complex surgical closure procedures.
- In Washington, D.C., an ophthalmologist was sentenced to 18 months in prison, 6 months home detention, and ordered to pay over \$1 million in restitution and a \$50,000 fine for

health care fraud and filing a false tax return. The ophthalmologist billed Medicare, other federal health care programs, and private insurers for services either not provided or not medically necessary. In addition, the ophthalmologist paid personal expenses and salaries to the ophthalmologist's children and housekeeper with funds from the medical practice and falsely recorded these payments on corporate records as legitimate business expenses. The ophthalmologist also took charitable deductions on personal income tax returns for contributions made to a non-profit organization that were used, in part, to pay for a family vacation.

Fraud by Other Practitioners

- The Stryker Corporation (Stryker) and its former outpatient therapy division, Physiotherapy Associates, Inc., (Physiotherapy), paid the United States \$16.6 million to settle allegations that Physiotherapy defrauded Medicare and other federal health care programs. The settlement resolves allegations that Physiotherapy submitted claims for services to Medicare, state Medicaid programs, and TRICARE that were falsely billed as one-on-one services or that were rendered by providers other than licensed therapists. In addition, the settlement resolves the allegation that Physiotherapy improperly retained excess or duplicate payments it received from federal health care programs.
- In New York, a dentist was sentenced to 18 months in jail and ordered to forfeit \$5 million in assets as a result of being found guilty of defrauding the Medicaid program. The dentist had been excluded from participating in the Medicaid program in 1995. However, the dentist devised a scheme to maintain a dental practice, which was comprised of 95 percent Medicaid patients. The excluded dentist hired junior dentists with valid Medicaid provider numbers and paid them on a per diem basis to perform basic procedures so that treatment could continue to be provided to Medicaid patients. The excluded dentist provided the more complex procedures and billed Medicaid for all the services performed in the practice under the provider numbers of the junior dentists. In an attempt to cover up the scheme, the dentist created management companies so that the Medicaid funds received in the names of the junior dentists could be deposited.
- In Michigan, a dentist was sentenced to 15 months in prison and ordered to pay \$147,000 in restitution and a \$50,000 fine for health care fraud. The dentist's spouse was ordered to pay almost \$10,000 for making a false statement. The dentist submitted or caused to be submitted claims to insurers for services that were not rendered. The investigation revealed that claims were for services purportedly rendered when the dentist was actually on travel or for services purportedly rendered by the former owner of the practice who had been deceased since January 1996. In addition to the fraud scheme, it was revealed that the dentist, who had been diagnosed with Hepatitis, did not disclose the condition to patients or take certain precautionary measures when treating patients.
- In Kansas, a Wichita couple that operated a drug and alcohol counseling center was sentenced to 92 months in Federal prison and ordered to pay \$1.2 million in restitution. The couple engaged in a scheme to defraud Medicaid by submitting false claims for services that were not provided. The Medicaid beneficiaries who were supposed to have

received drug and alcohol counseling services included infants and children 12 years and younger. In one case, the beneficiary of counseling services named in the claim was only 36 days old. The defendants have appealed the court's decision.

- In New Jersey, the owner of two physical therapy clinics was sentenced to 54 months in prison and ordered to pay \$3.8 million in restitution after admitting to defrauding Medicare by submitting claims for physical therapy services, evaluations, and reevaluations allegedly provided to patients, which were false in one or more ways.
- In Texas, an owner/operator of a physical therapy clinic was sentenced to 51 months in prison for conspiracy to commit health care fraud. A co-defendant was previously sentenced to 33 months in prison. In addition, the two were ordered to pay \$1.3 million in joint and several restitution. The investigation revealed that from April 1999 through July 2000, claims submitted to Medicare and Medicaid were for physical therapy services that were not performed, or were not properly supervised.
- In Arizona, a podiatrist was ordered to pay \$400,000 in restitution for a previous guilty plea to theft of Government funds. The podiatrist billed Medicare for debridements when only routine foot care was provided. Routine foot care is a service not covered by Medicare.

Cost Report Fraud

- National Century Financial Enterprises, Inc., (NCFE), one of the nation's largest medical-finance outfits, provided billions of dollars in funding for its clients, including Homecare and Hospital Management, Inc., (HHM) in Kentucky. Companies such as NCFE provide medical accounts receivable financing. A health care provider is granted a credit line that is based on the net realized value for billings to third party payors, such as commercial insurance companies, HMO's, Blue Cross Blue Shield, Medicare and Medicaid. These receivables are pooled and sold as asset backed securities to institutional investors. Through its cost report submission, and with the assistance of NCFE, HHM improperly sought reimbursement from Medicare for NCFE financing costs that were actually associated with the agency's acquisition of other home health agencies. NCFE ceased doing business and filed for bankruptcy protection. Its successor settled claims in the amount of \$1.35 million.

Hospital Cost Report Fraud

- A Federal trial court found two plaintiffs, and their two single-employee corporations, RIB Medical Management Services, Inc., and Navatkuda, Inc., liable for more than \$15.6 million in treble damages and \$31,000 in civil penalties for having submitted false claims to the Medicare program. The court ruled that between 1997 and 1999, defendants billed Medicare for almost \$8 million in unallowable costs that included amounts for a fictitious lease, reimbursement for unused hospital space, and millions of dollars in costs that were actually attributable to the defendants' business enterprises unrelated to Bayview Hospital

and Mental Health Systems in Chula Vista, California. The defendants have appealed the judgment.

- Integris Baptist Medical Center, Inc. and Integris Health, Inc. (Integris) agreed to pay the United States \$12.2 million to resolve allegations they violated the FCA by submitting inflated claims to the Medicare program in their annual cost reports. This settlement resolved allegations that Integris: submitted false claims in its annual Medicare cost reports that included inflated costs related to Integris' organ transplant department; improperly sought payment from Medicare for post-transplant and non-transplant related costs that Integris knew were not reimbursable under the Medicare program; and sought Medicare reimbursement for liver and heart organ acquisition costs related to transplant services that were provided to patients who were not Medicare beneficiaries.
- Jackson Memorial Hospital paid the United States \$14.25 million to resolve allegations that it violated the FCA by submitting claims for unallowable costs in their annual cost reports. In particular, the government alleged that the hospital had submitted inflated Medicaid claims for inpatient services rendered and submitted inflated claims for Medicare disproportionate share payment adjustments for services provided to indigent patients.

Medicaid Fraud

- Maximus, Inc. agreed to pay \$42.7 million to settle allegations of fraud in connection with claims to the Medicaid program. The District of Columbia Child and Family Services Agency (CFSA) hired Maximus to assist it in submitting claims to Medicaid for targeted case management services provided by the District to children in its foster care program. The United States alleged that Maximus caused CFSA to submit claims for every child in the foster care program whether or not targeted case management services had been provided to the child. Maximus also entered into a deferred prosecution agreement with the United States Attorney's Office for the District of Columbia.
- In Illinois, a licensed speech-language pathologist was sentenced to 6 months home detention and ordered to pay \$60,000 in restitution for health care fraud. From January 2001 to September 2002, the speech-language pathologist billed the Medicaid program for services that were not provided. The investigation revealed that, to support this improper billing, the pathologist altered or caused to be altered records to make it appear as if undelivered services had in fact been delivered.
- In West Virginia, a billing company and its owner were sentenced in relation to a scheme to submit false claims to the Medicaid program. The billing company was sentenced to 5 years probation and ordered to pay \$353,000 in restitution. The investigation revealed that the Medicaid program was routinely billed twice for each ambulance transport service provided.

Secondary Payor Fraud

- Harris County Hospital District (Hospital District), in Harris County, Texas, paid the United States and the State of Texas \$15.45 million to settle allegations that the Hospital District submitted false claims and made false statements to the Medicare and Texas Medicaid programs. The government alleged that the Hospital District violated the Medicare and Medicaid secondary payer rules and improperly billed for services provided to imprisoned individuals. Under the secondary payer rules, a health care provider is generally required to bill a third party insurer, when available, rather than Medicare or Medicaid. Here, the government alleged that the Hospital District routinely sought payment from Medicare and Medicaid without regard to third party liability insurance. As a result, Medicare and Medicaid paid claims that should have been paid by third-party insurers.

Other Fraud

- Cook County Hospital (CCH) and the Hektoen Institute, a non-profit institute that provided administration services for Cook County Hospital's research projects, paid \$5.5 million to resolve allegations that they submitted false and fraudulent claims for a research grant funded by the National Institute on Drug Abuse (NIDA), a division of the National Institutes of Health. NIDA had awarded CCH a grant to study substance abuse treatment for drug addicted pregnant women and the effectiveness of that treatment as compared to the drug treatment that was already available (the control group). The settlement resolved allegations that CCH provided NIDA false numbers of project subjects in order to continue receiving government funding and that it misreported to NIDA that the study was randomized when it knew that its research assistants had compromised the randomization protocol.
- In Michigan, an attorney specializing in health care law was sentenced to 13 months incarceration and ordered to pay \$98,000 in restitution for mail fraud. The attorney was hired by a physician group to negotiate a contractual joint venture agreement with a physical therapy company. As part of the negotiations, the attorney was tasked with obtaining an official advisory opinion from HHS/OIG to ensure that the arrangement would not violate the anti-kickback statute. However, the attorney did not request and obtain an advisory opinion from HHS/OIG but instead prepared false documents on copied HHS/OIG letterhead which falsely stated the joint venture met with the approval of HHS/OIG.
- In California, the operator of a company which purported to provide health care coverage to more than 20,000 people across the country was sentenced to 25 years in Federal prison and ordered to pay more than \$20 million in restitution for a scheme which bilked small

businesses and their employees out of millions of dollars in health care premiums. Individual victims, who thought they were insured, were left facing more than \$20 million in unpaid claims when the company was shut down. The sentencing judge said the crime led victims to suffer a “gnawing fear about huge unpaid medical bills.” The company purported to operate pursuant to the Employee Retirement Income Security Act of 1974 (ERISA) which allows employers and certain organizations such as unions to offer health care coverage plans which are not subject to state insurance regulation. In 2004, the (then) United States General Accounting Office (GAO) issued a report that examined the actions of this company and other similar entities. The report, “Private Health Insurance: Unauthorized or Bogus Entities Have Exploited Employers and Individuals Seeking Affordable Coverage” (GAO 04-512T), was presented to the Senate Committee on Finance.

FUNDING FOR THE 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 the HHS/OIG. In FY 2007, The Secretary and the Attorney General jointly allotted \$165.9 million to the HHS/OIG.

The HHS/OIG participated in investigations or other inquiries that resulted in 709 prosecutions or settlements in FY 2007, of which 557 or 78 percent were health care cases. A number of these are highlighted in the Accomplishments section. During FY 2007, the HHS/OIG also excluded a total of 3,308 individuals and entities, barring them from participating in Medicare, Medicaid, and other federal and state health care programs. In addition, the Department of Health and Human Services collected approximately \$185.7 million in disallowances of improperly paid health care funds, based on HHS/OIG recommendations.

Program Savings

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, the HHS/OIG makes recommendations to agency managers to address these vulnerabilities. In turn, 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. During FY 2007, the HHS/OIG estimates that such corrective actions resulted in health care savings (i.e., funds put to better use as a result of implemented legislative or other program initiatives) of approximately \$39 billion -- \$29.8 billion in Medicare savings, and \$9.2 billion in savings to the Medicaid program. Additional information about savings achieved through such policy and procedural changes may be found in the HHS/OIG Semiannual Report, on-line at <http://oig.hhs.gov/publications/semiannual.asp>.

Exclusions

One important mechanism for safeguarding the care provided to program beneficiaries is through exclusion of providers and suppliers who have engaged in the abuse or neglect of patients or fraud. During FY 2007, the HHS/OIG excluded a total of 3,308 individuals and entities. Among these were exclusions based on criminal convictions for crimes related to Medicare or Medicaid (694), or to other health care programs (282); for patient abuse or neglect (268); or as a result of licensure revocations, suspensions or surrenders (1,681). This list of conduct is not meant to be exhaustive, but identifies the most prevalent causes underlying HHS/OIG's exclusions of individuals or entities in FY 2007. Among those excluded by HHS/OIG from participation in Medicare, Medicaid, and other federal health care programs were the following:

- A registered nurse (RN) in New Jersey was excluded for a minimum period of 95 years based on a conviction on multiple counts related to patient abuse or neglect. The RN was sentenced to multiple consecutive life sentences for the murder and the attempted murder of patients under the individual's care. In addition, the individual's nursing license was revoked in the states of New Jersey and Pennsylvania.
- A physician in Florida was excluded for a minimum period of 70 years based on a conviction related to a prescription drug fraud scheme. From April 1998 through March 2002, the physician prescribed controlled substances that were not medically necessary. As a result, one patient died of a drug overdose in 2001. The physician was sentenced to 50 years' incarceration, and surrendered the physician's license to practice medicine in the State of Florida.
- The owner of a Georgia-based pharmaceutical wholesale distributor, was excluded for a minimum period of 70 years based on a conviction related to a racketeering scheme involving prescription drugs that were unlawfully obtained and diverted from 1996 to 2003. The owner was sentenced to 20 years of incarceration and ordered to pay over \$27 million in restitution.
- An unlicensed physician in Colorado was excluded for a minimum period of 20 years based on a conviction for the illegal practice of medicine, perjury, theft, assault (recklessly causing bodily harm), and criminally negligent homicide. The physician did not have a license to practice as a doctor of naturopathic medicine, yet treated patients with illegal and unapproved substances and employed unapproved procedures for more than 30 months. The physician's actions caused the death of a patient, and the physician was sentenced to 8 years of incarceration.

Other Administrative Enforcement Actions – Civil Monetary Penalties

The Office of Inspector General has authority to impose civil monetary penalties (CMPs) against providers and suppliers who knowingly submit false claims to the Government, who participate in unlawful patient referral or kickback schemes, who fail to appropriately treat or refer patients who present at hospital emergency rooms, or who engage in other activities prescribed in statute. HHS/OIG has stepped up its affirmative enforcement actions under these authorities. Examples include:

- Medical Center of Arlington, Texas, (MCA) agreed to pay \$30,000 to resolve allegations that it violated the screening, stabilization, and transfer provisions of the patient dumping statute when a woman in her 39th week of pregnancy presented to MCA's labor and delivery department with contractions. After approximately 35 minutes of observation, an on-duty obstetrician ordered that the patient be discharged with instructions to go straight to another hospital that was nearly 21 miles away. The patient traveled with her husband by private automobile and upon arrival the patient was almost fully dilated.

- Advanced Neuromodulation Systems, Inc., (ANS) agreed to pay \$2.95 million and to enter into a 3-year corporate integrity agreement to resolve its liability for allegedly violating the Civil Monetary Penalties Law. The HHS/OIG alleged that, among other practices, ANS offered and paid remuneration to potential and existing referral sources in exchange for referrals to ANS for the purchasing, leasing, ordering, arranging for, or furnishing of medical devices that were manufactured by ANS and that were payable by a federal health care program.
- A research facility in California agreed to pay \$450,000 to settle allegations that it was in violation of regulations governing the Select Agent Program. The HHS/OIG alleged that the facility transferred vials of a select agent to two laboratories located in Florida and Virginia. During the transfers, the toxin was released from the shipped vials. An investigation of the packaging for the shipments revealed several violations of regulations governing the shipment of select agents. HHS/OIG also alleged that the facility failed to comply with security and access requirements by allowing an individual not authorized to have access to select agents to package the shipments.
- Midwest Medical Laboratory, Inc., (MML) agreed to pay more than \$711,000 and enter into a 5-year exclusion from participating in the federal healthcare programs for submitting claims to Medicare Part B for payment for services allegedly rendered to beneficiaries who are residents of skilled nursing facilities (SNFs) in a stay already covered by Medicare Part A.

Studies, Audits, and Evaluations

HHS/OIG conducts numerous studies, audits and evaluations that disclose questionable or improper conduct in Medicare and Medicaid, and recommends corrective actions that, when implemented, correct program vulnerabilities and save program funds. Among these were:

State Medicaid Financing Schemes. HHS/OIG has maintained its focus on questionable state financing schemes designed to maximize federal payments under Medicaid.

- **Provider Taxes.** Medicaid regulations permit a state to finance its share of the cost of its Medicaid program by imposing a broad-based and uniform tax on providers. HHS/OIG conducted an audit of Missouri's tax on its providers, and found that the state received \$23 million in federal matching funds as a result of using \$13 million in provider taxes not permitted by regulation. However, because of certain limitations contained in the regulations, HHS/OIG recommended the refund of only \$8 million.
- **Disproportionate Share Hospital (DSH) Payments.** States are required to make DSH payments to hospitals for the uncompensated costs of providing care for a disproportionate number of low-income patients or patients with special needs. An audit in New Hampshire found that the state did not comply with the DSH limits for 24 of the state's 28 DSH hospitals by not properly determining the hospitals' allowable costs in accordance with the Medicare principles of cost reimbursement, as CMS guidance requires.

HHS/OIG recommended that the state refund \$35.3 million to the Federal Government. Similarly, two audits in New Jersey found that two DSH hospitals received a total of \$22.2 million (\$11.1 million Federal share) in DSH overpayments by erroneously including nonreimbursable costs in its hospital-specific DSH limit calculations. HHS/OIG recommended that the two hospitals refund to the Federal Government \$10 million and \$1.1 million, respectively.

School-Based Health Services

- Medicaid covers the costs of providing children with school-based health services, such as physical therapy, speech pathology, and psychological counseling, as well as associated administrative costs. HHS/OIG audited the claims for school-based services submitted by three states. An audit in Maryland found that Maryland's use of an unsupported reimbursement rate of \$82 per service had not complied with reimbursement provisions specified in its CMS-approved state Medicaid plan. As a result, it received \$65.5 million (\$32.8 million Federal share) in overpayments between State fiscal years 2002 and 2004. HHS/OIG recommended the refund of the \$32.8 million Federal share. In Minnesota, HHS/OIG found that, when claiming the administrative costs of its school-based services, the state did not proportionally allocate the costs among all benefitting programs, included unallowable indirect costs in its calculations, and used inaccurate cost reports. The audit recommended that the Minnesota refund \$9.7 million to the Federal Government. Finally, in Nevada, HHS/OIG found that the state claimed \$5.8 million in unallowable administrative costs, and recommended their refund.

Medicaid Family Planning Services. The Federal Government reimburses the costs of Medicaid family planning services at an enhanced 90 percent matching rate. These services are intended to assist patients in preventing or delaying pregnancy or to otherwise control family size.

- **Medicaid Managed Care Programs.** In a report that consolidated the results of reviews of seven states' claims for the cost of family planning services provided through Medicaid managed care programs, HHS/OIG found that six states had inflated the factors or rates used to calculate the costs reimbursable at the enhanced federal matching rate. For the \$302.9 million in claims reviewed in the audit, six of the seven states claimed unallowable costs with a Federal share totaling \$21.7 million. HHS/OIG recommended that, among other steps, CMS issue specific guidance to states to quantify a reasonable portion of the managed care capitation payments that may be attributed to family planning services.
- **Medicaid Pharmacy Claims.** HHS/OIG found that two states improperly received enhanced Federal Medicaid funds for the cost of prescription drugs that do not qualify as family planning services. In New Jersey, HHS/OIG found that the state had incorrectly designated 227 drug codes as being related to family planning, and recommended that the state refund the resulting overpayment of \$2.2 million to the Federal Government. Similarly, New York incorrectly designated 246 drugs as being related to family planning, and recommended that the state refund the resulting overpayment of \$6.1 million to the Federal Government.

- Abortion-Related Services. Medicaid funds are available for abortion-related services only when the life of the mother would be endangered if the fetus were carried to term. The enhanced 90-percent matching rate for family planning services is not available for any abortion or abortion-related services. HHS/OIG found that New York improperly received federal reimbursement at the enhanced 90-percent matching rate for abortion-related laboratory services that either did not qualify as Medicaid family planning services, or were unallowable for reimbursement at all. HHS/OIG did not conduct a full medical review of all the claims, and so recommended only that the state work with CMS to determine the allowability of the \$3.2 million in payments for abortion-related services questioned in the audit.

Medicaid Community Mental Health Centers (CMHC)

- Under the Medicaid Rehabilitation Option (MRO) services program, clinical mental health services are provided to individuals, families, or groups living in the community who need aid intermittently for emotional disturbances or mental illness. HHS/OIG estimated that Indiana overpaid Community Mental Health Centers (CMHC) providers at least \$33.4 million (\$21.3 million Federal share) in reimbursement for MRO services provided during FY 2003. Of the 200 randomly selected MRO services provided by CMHCs in Indiana, 64 did not meet federal and state reimbursement requirements. HHS/OIG recommended that Indiana refund \$21.3 million to the Federal Government.

Medicaid Drug Pricing

- New Drug Pricing Data. HHS/OIG found that as of September 2006 many states had not yet decided whether to use Average Manufacturer Price (AMP) data and/or retail sales price (RSP) data to calculate the amount their state Medicaid programs reimburse for prescription drugs. States' use of this data has the potential to reduce Medicaid prescription drug expenditures, which reached \$41 billion in 2005. Although the Deficit Reduction Act of 2005 (P.L. 109-171, DRA) requires CMS to provide both AMP and RSP data to the states, the states are not required to use the data. To ensure that AMP and RSP data are accurate, reliable, and accessible, HHS/OIG recommended that CMS explicitly define AMP and its calculation; furnish states with interim guidance and/or information regarding AMP data; and explicitly detail the RSP's definition, calculation, and method of collection when distributing RSP data to states.
- Fluctuations in Average Manufacturer Prices. In a review of fluctuations in the average manufacturer prices (AMPs) of pharmaceuticals, HHS/OIG found that AMPs did not fluctuate substantially from the second quarter of 2005 to the second quarter of 2006 and that roughly equal numbers of AMPs decreased as increased, contrary to concerns raised by industry that the AMP was too volatile to serve as a payment basis. However, AMPs for single-source drugs (that is, brand name products for which there are no generic versions) were more prone to increases between quarters. The DRA requires CMS to make AMP data available to states as of July 1, 2006, for optional use in setting the reimbursement amounts paid to pharmacies that dispense prescription drugs to Medicaid

beneficiaries. States' use of AMPs is expected to help reduce Medicaid prescription drug expenditures.

- **Medicaid Federal Upper Payment Limits.** Beginning January 1, 2007, pursuant to DRA, Medicaid Federal upper limits (FUL) are to be based on 250 percent of the lowest AMP rather than 150 percent of the lowest price published in the national compendia. The Federal upper payment limits help ensure that the Federal Government acts as a prudent buyer by taking advantage of current market prices for multiple-source drugs. In a preliminary assessment, HHS/OIG found that provisions of the DRA are likely to cause substantial decreases in FUL amounts. HHS/OIG recommended that CMS take steps to identify when a new Federal upper limit amount may not be representative of a drug's acquisition cost to pharmacies and, in those situations, determine the proper course of action (working with Congress, if necessary). (However, a court-issued preliminary injunction has prevented CMS from implementing these new FULs. As such, FULs continue to be calculated using the prior formula, based on the lowest possible published price, i.e., AWP or the wholesale acquisition cost.)

Medicaid Eligibility

- In three states, HHS/OIG determined whether Medicaid beneficiaries met federal and state eligibility requirements and whether the states provided adequate documentation of eligibility determinations for payments made from January 1 through June 30, 2005. New York and California both made Medicaid payments on behalf of beneficiaries who did not meet federal and state eligibility requirements. Furthermore, the states did not always adequately document all eligibility determinations. Based on its sample results, HHS/OIG estimated that New York made more than 4.2 million payments totaling \$230.4 million (Federal share) on behalf of ineligible beneficiaries. In addition, HHS/OIG estimated that case file documentation did not adequately support eligibility determinations for an additional 15.3 million payments totaling \$2.8 billion (Federal share). Similarly, HHS/OIG estimated that California made 4.7 million payments totaling \$133 million (Federal share) on behalf of ineligible beneficiaries. It also estimated that case file documentation did not adequately support eligibility determinations for an additional 2.5 million payments totaling \$117 million (Federal share). HHS/OIG did not recommend recovery against either state because a disallowance may be taken only if the errors are detected through a State's Medicaid Eligibility Quality Control program, but did recommend that the states use the results of these reviews to ensure compliance with federal and state eligibility requirements.

Florida generally made Medicaid payments on behalf of beneficiaries who met federal and state eligibility requirements and provided adequate documentation of eligibility determinations. HHS/OIG recommended that Florida use the results of the review to help ensure continued compliance with federal and state Medicaid eligibility requirements.

Medicaid Services to Deceased Beneficiaries

- HHS/OIG found that providers in 8 of 10 audited states received an estimated total of \$27.3 million (\$15.1 million Federal share) in Medicaid overpayments, which the states never recovered, for services claimed to have been provided after beneficiaries' deaths. HHS/OIG recommended that CMS work with states to ensure that they use all available data sources to identify deceased beneficiaries, match those data against paid claims files and recover identified overpayments, and encourage states to establish post payment reviews to mitigate the effect of delays in receiving data regarding beneficiaries' dates of death.

Medicaid Provider Enrollment Safeguards: Medical Equipment Providers

- In a study of 15 states, HHS/OIG found that states employed a variety of provider enrollment standards to safeguard their Medicaid DME programs. Such standards included licensure of providers, posting a sign and hours of operation, and obtaining surety bonds. HHS/OIG found that only seven of the states required Medicaid providers to enroll as providers in the Medicare program, which subjects Medicaid providers in these states to Medicare standards. The remaining eight states did not require providers to enroll in the Medicare DME program. Despite the presence of standards, HHS/OIG found that most of the 15 states were not routinely verifying whether providers met all state DME provider enrollment standards, and 7 of the 15 states were not conducting routine site visits at initial enrollment. Finally, only 6 of the 15 states reported that they either routinely re-enrolled providers or had recent initiatives to re-enroll providers to ensure all met the provider enrollment standards.

Medicare DME

- On the basis of unannounced site visits in 2006 to 1,581 suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) in Miami-Dade, Broward, and Palm Beach Counties, HHS/OIG found that 31 percent (491) did not maintain facilities or that their facilities were not open for business or staffed, in violation of Medicare regulations. As of November 30, 2006, these DMEPOS suppliers billed Medicare for almost \$237 million and were allowed over \$97 million between January 1 and November 30, 2006. HHS/OIG referred these suppliers to CMS to consider potential revocation of their Medicare billing numbers. Through unannounced site visits, HHS/OIG also found that 14 percent of the suppliers (216) did not meet one of three other Medicare requirements reviewed, such as the need to post hours of operation. HHS/OIG recommended that CMS strengthen the supplier enrollment process for DMEPOS suppliers and ensure that suppliers meet Medicare standards and suggested several specific actions CMS could take to do so.

Prescription Drug Plan Sponsors' Compliance Plans

- In an examination of adherence on the part of 79 prescription drug plan sponsors to guidance relating to the establishment of compliance plans, HHS/OIG found that although all prescription drug plan sponsors had compliance plans, 72 of 79 compliance plans did not address one or more of CMS's 17 requirements. One required element of compliance plans is the development of a comprehensive plan to detect, prevent, and correct fraud, waste and abuse. This requirement was addressed in some way by all plans, yet only 15 of 79 compliance plans addressed all 11 of CMS's recommendations regarding the design of these anti-fraud plans.

Medicare Home Oxygen Equipment

- In a study of home oxygen equipment, HHS/OIG found that if Medicare rental payments for oxygen were limited to 13 months, the program and its beneficiaries would save approximately \$3.2 billion over 5 years. HHS/OIG found that based on the 2006 median fee schedule, Medicare will allow \$7,215 for 36 months for concentrators that cost only \$587, on average, to purchase. Over the 36 months, beneficiaries will incur \$1,443 in coinsurance. Suppliers commonly provide used concentrators, which can last for several years. If Medicare treated concentrators like capped rental items by limiting rental payments to 13 months, the program and its beneficiaries would realize considerable savings. HHS/OIG recommended that CMS work with Congress to further reduce the rental period for oxygen equipment.

Certification and Oversight of Medicare Hospices

- In a study of state oversight of Medicare hospices, HHS/OIG found that, as of July 2005, 86 percent of Medicare hospices were certified by state agencies within 6 years, as required at that time, and 14 percent averaged 3 years past due. In addition, HHS/OIG found that 46 percent of the hospices surveyed were cited for at least one health deficiency, and 15 percent received repeat citations for the same deficiency during previous surveys. CMS and state agencies rarely use methods other than certification surveys and complaint investigations to monitor or enforce hospice performance. HHS/OIG recommended that CMS provide guidance to state agencies and CMS regional offices regarding analysis of existing data and identification of at-risk hospices; include hospices in federal comparative surveys and annual state performance reviews; seek regulatory or statutory changes to establish specific requirements for the frequency of hospice certification; and seek legislation to establish additional enforcement remedies, in addition to termination, for poor hospice performance.

Hospital Wage Data

- In a summary report on 21 hospitals' cost reports, HHS/OIG found wage data totaling \$377.9 million that did not comply with Medicare requirements. Under the acute care hospital inpatient prospective payment system, CMS adjusts the Medicare prospective

payment system (PPS) base rate paid to participating hospitals by the wage index applicable to the area in which the hospital is located. CMS updates wage indexes annually based on data that hospitals include in their cost reports. However, the 21 hospitals reported unallowable, misstated, unsupported, and misclassified wages and other costs, as well as related hours. As a result, 17 of the 21 hospitals overstated their average hourly wage rates, and the remaining 4 hospitals understated their rates. Generally, hospitals that overstate wage data will receive higher Medicare reimbursement at the expense of hospitals that report accurate or understated wage data. HHS/OIG therefore recommended that CMS develop a corrective action plan to address hospital reporting errors and offered specific steps for CMS's consideration.

Medicare Outlier Payments

- Under the outpatient PPS, CMS may make additional payments, called outlier payments, if the cost of care is extraordinarily high in relation to the average cost of treating comparable conditions or illnesses. HHS/OIG determined that CMS's practice of not retroactively adjusting erroneous outpatient outlier payments creates vulnerabilities in the outpatient outlier program and is inconsistent with CMS's general policy on revisiting incorrectly calculated payments, as well as CMS's policy of retroactively adjusting inpatient PPS outlier payments. Based on prior reviews, HHS/OIG calculated that the CMHCs received net outlier overpayments totaling \$24.4 million, and recommended that CMS issue regulations to require adjustments of outpatient outlier payments at final cost report settlement, or after the settlement, retroactive to the beginning of the cost report period when an error caused by the fiscal intermediary or provider is identified after the cost report is settled.

Medicare's Program Safeguard Contractors: Activities To Detect and Deter Fraud and Abuse

- HHS/OIG found that program safeguard contractors (PSC) differed substantially in the number of new investigations and case referrals to law enforcement. Some had minimal activity in these primary workload categories. Neither the size of a PSC's budget nor its oversight responsibility (dollar amount of Medicare paid claims) was strongly correlated with the number of new investigations or the number of new case referrals produced in 2005. HHS/OIG also found that most PSCs had minimal results from proactive data analysis. HHS/OIG recommended that CMS review PSCs with especially low volumes of activity in investigations and case referrals for Medicare Parts A and B, and that CMS require PSCs to provide more detailed explanations of their investigations, case referrals to law enforcement, and proactive data analysis activities in their monthly reports.

Infusion Therapy for Beneficiaries with HIV/AIDS

- HHS/OIG found that CMS has had limited success controlling the aberrant billing practices of infusion therapy providers in South Florida. In the last half of 2006, three counties in South Florida accounted for half of the total amount – and 79 percent of the

amount for drugs – billed nationally for Medicare beneficiaries with HIV/AIDS. CMS and its contractors tried to control inappropriate payments to providers in these three South Florida counties using various tools, including payment suspensions, prepayment reviews, provider number revocations, claims processing edits, and onsite investigations of existing providers. HHS/OIG determined that these efforts have not been effective because aberrant HIV infusion providers have adjusted their billing patterns and circumvented controls, and recommended that, among other steps, CMS treat South Florida as a high-risk area and mandate announced and unannounced site visits for certain infusion therapy providers.

Oversight of CMS Error Rate Testing

- In a review of the FY 2006 Comprehensive Error Rate Testing (CERT) program, HHS/OIG found that CMS had ensured that its two CERT contractors had appropriate controls to ensure that medical and quality assurance reviews and initial and follow-up document requests followed established procedures and operated effectively. In addition, CMS described several actions it had taken toward initiatives to reduce the CERT error rate. CMS and the contractors have taken appropriate action on the recommendations in HHS/OIG's FY 2005 audit report.

Industry Outreach and Guidance

- Advisory Opinions. Central to 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 CMP laws, or the exclusion provisions. During FY 2007, the HHS/OIG, in consultation with DOJ, issued 18 advisory opinions. A total of 166 advisory opinions have been issued during the 11 years of the HCFAC program.
- Corporate and Other Integrity Agreements. 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, Integrity Agreement or other similar agreement. Under these agreements, 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 FY 2007, HHS/OIG was monitoring compliance with more than 380 such agreements.

Centers for Medicare & Medicaid Services

In FY 2007, the Centers for Medicare & Medicaid Services (CMS) was allocated approximately \$23 million to fund a variety of projects related to fraud, waste, and abuse in the Medicare and Medicaid programs. 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. Projects include:

Medicaid/State Children's Health Insurance Plan (SCHIP) Financial Management Project:

During late 2004 and throughout 2005, CMS hired 100 funding specialists, including accountants and financial analysts, who work to improve CMS's financial oversight of the Medicaid program. The primary goal for the Medicaid funding specialists during 2007 was to assist in the reduction of cumulative questionable reimbursement by 15 percent. Through the efforts of these specialists, CMS identified and resolved \$4.3 billion of approximately \$8 billion in cumulative questionable costs. Furthermore, an estimated \$652 million in questionable reimbursement was actually averted due to the funding specialists' preventive work with states to promote proper state Medicaid financing methods prior to implementation. The funding specialists activities have included reviews of proposed Medicaid state plan amendments that relate to reimbursement; development of financial management reviews; research regarding state Medicaid financing policy and practices; working with states to resolve the Medicaid and SCHIP portions of the Office of Management and Budget (OMB) Circular A-133 "Single State" audits⁹; and, identify the sources of the non-Federal share of Medicaid program payments to ensure proper financing of Medicaid program costs.

Payment Error Rate Measurement (PERM)

PERM is the program that CMS uses to implement the Improper Payments Information Act of 2002 (IPIA), which requires HHS to measure improper payments in Medicaid and SCHIP. In order to comply with the IPIA, CMS elected to use federal contractors to measure Medicaid and SCHIP error rates in a subset of states every year. In 2006, CMS measured the national fee-for-service Medicaid error rate, and the interim results of the measurement based on the first two quarters of 2006 were published in the 2007 Performance and Accountability Report (PAR). States participating in the 2006 cycle were also provided with their individual error rates. As of 2007, the PERM project was expanded into measuring error rates for fee-for-service and managed care in both the Medicaid and SCHIP programs. The PERM contractors will also calculate and report on beneficiary eligibility error rates for both programs even though the states conduct the actual reviews.

⁹OMB Circular A 133-Audits of States, Local Governments, and Non-Profit Organizations, is issued pursuant to the Single Audit Act of 1984, P.L. 98-502, and the Single Audit Act Amendments of 1996, P.L. 104-156. It sets forth standards for obtaining consistency and uniformity amount Federal agencies for the audit of States, local governments, and non-profit organizations expending Federal awards.

The results of the 2007 measurement will be published in the 2008 PAR, as well as a final national annual Medicaid fee-for-service component error rate based on all four quarters of 2006.

Administration on Aging

In FY 2007, the Administration on Aging (AoA) was allocated \$3.128 million in HCFAC funds to develop and disseminate consumer education information targeted to older Americans, with a particular focus on persons with low health literacy, individuals from culturally diverse backgrounds, persons living in rural areas, and other vulnerable populations. AoA and its nationwide network of agencies support community education activities designed to assist older Americans and their families to recognize and report potential errors or fraudulent situations in the Medicare and Medicaid programs.

The \$3.128 million in HCFAC dollars specifically support infrastructure, technical assistance and the other SMP program support and capacity-building activities designed to enhance the effectiveness of state-wide Senior Medicare Patrol programs (SMP) which are funded from a separate Congressional appropriation. These SMP programs recruit retired professionals to educate and assist Medicare beneficiaries to detect and report health care fraud, error, and abuse in the Medicare and Medicaid programs. According to the most recent annual performance report from the Assistant Inspector General for Evaluation and Inspections dated May 2008, during 2007, over 10,300 active volunteers served the 57 SMP projects. These volunteers perform an essential function of this program, contributing over 308,000 hours in efforts to share the SMP message of fraud awareness and prevention within the senior community.

Outreach to senior consumers is a key element of the SMP program. During 2007, SMP projects conducted over 13,700 media events and held over 8,400 community education events to increase beneficiary awareness about issues related to Medicare and Medicaid integrity. In addition, almost 240,000 beneficiaries were educated through group sessions conducted by SMP programs, and, over 131,000 were educated through one-on-one counseling sessions.

As a result of educating beneficiaries, the projects received over 70,000 inquiries from or on behalf of beneficiaries and resolved 87 percent of the inquiries. In addition, SMP projects received over 17,600 complex issues, requiring further research, assistance, case development and/or referral. While the SMP program staff was able to address the majority of these issues for beneficiaries, over 4,000 of these issues, with an estimated dollar value of over \$1.5 million, were referred to law enforcement, CMS integrity contractors, state Medicaid Fraud Control Units, or other entities for further action. During 2007, over \$7.4 million in healthcare expenditures were avoided as a result of actions taken by the SMP program.

Since the program's inception, SMP projects have educated approximately 3.26 million beneficiaries and received close to 105,000 complex issues (complaints) from beneficiaries who have detected billing or other discrepancies based on that information. While it is not possible to directly track all of the cases reported and dollars recovered through SMP community education activities, or quantify the "sentinel effect" in fraud costs avoided due to increased consumer awareness, over \$105.6 million has been reported as savings attributable to the program since its inception.

Office of the General Counsel

In FY 2007, The Office of General Counsel (OGC) was allocated approximately \$5.13 million in HCFAC funding to supplement OGC's efforts to support program integrity activities. OGC provides legal support consistent with the statutory authority of the HCFAC program. While a considerable portion of these funds supported OGC's litigation activity, both administrative and judicial, OGC placed an increased focus upon program integrity review in 2007.

FCA and Qui Tam Actions: OGC provides litigation support to DOJ in actions relating to Medicare or Medicaid fraud under the FCA. In 2007, OGC participated in FCA matters that recovered over \$1.1 billion for the Medicare and Medicaid programs.

Suspensions and Revocations: OGC assists HHS in deciding whether to suspend payments to Medicare providers and suppliers, or to revoke billing privileges when problems are discovered. During 2007, OGC attorneys were involved in hundreds of suspension and revocation actions involving millions of Medicare dollars and many different segments of the healthcare industry, including DME suppliers, ambulance companies, physicians, therapists, home health agencies, and diagnostic testing facilities. Some OGC offices experienced dramatic increases in the volume of suspension and revocation work, because of satellite CMS offices (in Los Angeles and Miami) which aggressively focused on identifying overpayments and curbing fraud and abuse in problem-prone areas.

Civil Monetary Penalties (CMPs): CMS has the responsibility for administering numerous civil monetary penalty provisions enacted by Congress to enforce program compliance and payment integrity. For example, CMS is authorized to impose CMPs on nursing homes which fail to meet certification standards. During 2007, OGC provided legal advice to CMS regarding the development and imposition of CMPs and defended CMS in administrative appeals and judicial litigation resulting from these cases. OGC recovered or established the right to recover over \$8.5 million in CMPs in 2007.

Nursing Home Enforcement: OGC devotes considerable resources to assist CMS in its efforts to assure that nursing home residents receive the high quality of care that the law requires. OGC provides legal advice to CMS regarding the imposition of remedies and defends HHS in administrative hearings when enforcement decisions are challenged. OGC worked very closely with CMS during 2007 to refine its policies with respect to "special focus facilities." These nursing facilities, which are habitually out of compliance with federal certification requirements, have become the top priority for CMS enforcement efforts as the agency tries to maximize its limited resources to target the nation's poorest performing nursing homes.

Other Provider Enforcement: OGC provided a variety of legal services in support of CMS's efforts to ensure quality of care and enforce participation requirements at hospitals and other types of providers, including home health agencies, hospices and rehabilitation facilities. Terminations of providers are particularly sensitive matters, particularly in rural or semi-rural areas without readily accessible alternative providers, generally causing exceptional community anxiety and me-

dia scrutiny. Therefore, OGC works closely with CMS in developing appropriate responses in such matters.

Bankruptcy Litigation: OGC protects Medicare funds by asserting CMS's recoupment rights to collect overpayments, arguing to continue suspension or termination actions against debtors, seeking adequate assurances from the bankruptcy court that CMS's interests in the debtor's estate will be protected, arguing for the assumption of the Medicare provider agreement as an executory contract, and petitioning for administrative costs where appropriate. OGC's bankruptcy workload continues to be extensive and complex. In 2007, OGC vigorously asserted CMS's interests in numerous bankruptcy and receivership actions, negotiated agreements to recover overpayments, and aggressively advanced the use of Medicare's recoupment authority.

Medicaid Integrity: The DRA created within CMS a new Medicaid Integrity Program having responsibility for federal audits of Medicaid providers and increased support for state program integrity efforts. During 2007, OGC provided wide-ranging legal advice to CMS to help establish the Medicaid Integrity Group. OGC saw increased involvement in 2007 in Medicaid Integrity issues as CMS devoted more resources to financial reviews and oversight, including placing CMS accountants on site at state Medicaid agencies and as states continue to present innovative proposals to reconfigure their programs and to draw down federal financial participation (FFP) at or beyond the margins of the regular Medicaid program. OGC saw a significant increase in the provision of legal advice to CMS regarding proposed disallowances and the filing of Medicaid disallowance appeals before HHS' Departmental Appeals Board (DAB) During 2007, OGC was successful in obtaining decisions upholding millions of dollars in disallowances of FFP.

Review of Regulations and Manual Provisions Implementing the MMA: OGC provided extensive advice to CMS on developing a compliance program for Part D sponsors and Medicare Advantage (MA) plans, including identifying enforcement options against sponsors that are noncompliant or violate program rules, such as Marketing Guidelines. The compliance program will likely serve as an important deterrent of fraud in the Part D program. OGC spent a significant amount of time during 2007 helping CMS propose changes to its compliance regulations for the MA and Part D programs. As part of these proposed changes, CMS has a more efficient and streamlined approach to taking actions against plans that fail to meet regulatory requirements. In many cases, changes were proposed to make the requirements uniform across MA and Part D plans. Also, CMS specified timeframes for contract determinations, and rules by which parties can appeal a CMP. The proposed rule was published in the Federal Register on May 25, 2007.

HIPAA Enforcement: During 2007, OGC supported the CMS Office of e-Health Standards and Services in investigating security incidents as part of HIPAA Security Rule enforcement efforts. OGC also drafted the HIPAA Security Guidance, published December 28, 2006, addressing the disclosures of electronic protected health information following the loss, theft, or misuse of data stored on laptops or other portable devices, or accessed remotely. OGC supported HHS' establishment and operation of a Personally Identifiable Information Breach Response Team. Additionally, OGC supported CMS efforts to educate and assist covered entities within the health care industry to prepare to comply with the provisions of the HIPAA National Provider Identifier Rule, codified at 45 CFR. Part 162.

Health Resources and Services Administration

In FY 2007, the Health Resources and Services Administration received an allocation of over \$450,000 from the HHS/OIG to supplement the overall operations and maintenance of the Healthcare Integrity and Protection Data Bank (HIPDB) program.

The primary focus of the HIPDB is to prevent or reduce fraud and abuse in the medical system and to enhance quality health care by serving as a repository for collecting, maintaining, and reporting on final adverse actions taken against health care providers, suppliers and practitioners. This information helps prevent practitioners, providers, and suppliers with problem backgrounds from moving from state to state unnoticed by licensing, government and health plan officials, thus improving health care quality. It also assists law enforcement officials in their efforts against health care fraud and abuse.

As a result of continual efforts to maximize advancements in information technology, in May 2007, HIPDB introduced and executed the Proactive Disclosure Services (PDS) Prototype. With this service, all eligible entities that choose to register their practitioners with the National Practitioners Data Bank and/or the HIPDB will be notified of new reports that name any of their registered practitioners as subjects within 24 hours of the HIPDB's receipt of the report. This service will be offered in addition to, and not as a replacement of, the traditional HIPDB querying service. This service will, in effect, continuously query enrolled practitioners. The PDS service has the potential of improving the quality of health care and patient safety by ensuring that entities that credential, license, and/or employ health care practitioners are alerted to the existence of a reported adverse action or medical malpractice payment immediately. As of September 30, 2007, the HIPDB has successfully processed 7,147,056 queries from health plans, state and federal agencies.

Office of the National Coordinator for Health Information Technology

In FY 2007, the Office of the National Coordinator for Health Information Technology (ONC) was allocated \$490,000 in HCFAC funding.

In FY 2006, ONC contracted with RTI International for a project to reduce the incidence of improper payment and fraudulent activities in Electronic Health Record Systems. In June 2007, RTI submitted its final report to ONC, entitled "Recommended Requirements for Enhancing Data Quality in Electronic Health Record Systems". This report included recommendations for model requirements for electronic health records which included proactive approaches to prevent inappropriate access to electronic health information and to prevent fraud and medical identity theft.

ONC's current anti-fraud project, while funded in 2007, will be conducted in 2008. ONC has contracted with Booz Allen Hamilton for a medical identity theft project to engage experts and the public in a public town hall meeting to develop a knowledge base for medical identity theft and to develop a report and a roadmap for actions to help prevent, detect, and remedy medical identity theft. Part of ONC's mission is to ensure that patients' health information is secure and protected

in electronic health information exchanges and in electronic health records. Preventing medical identity theft is a key component to building consumer trust in electronic health information exchange. This project builds upon ONC's previous projects and brings together both governmental and private stakeholders.

FUNDING FOR THE DEPARTMENT OF JUSTICE

United States Attorneys

In FY 2007, the United States Attorneys' Offices (USAOs) were allocated approximately \$31.35 million in HCFAC funding to support civil and criminal health care fraud and abuse litigation as exemplified in the Program Accomplishments section. The USAOs dedicated substantial resources to combating health care fraud and abuse in 2007, and HCFAC allocations have supplemented those resources by providing funding for attorneys, paralegals, auditors and investigators, as well as funds for litigation of resource-intensive health care fraud cases.

The 93 United States Attorneys and their assistants, or AUSAs, are the nation's principal prosecutors of Federal crimes, including health care fraud, and each district has a designated Criminal Health Care Fraud Coordinator and a Civil Health Care Fraud Coordinator. Civil cases are also obtained by USAOs by means of qui tam complaints. Under the FCA, a qui tam plaintiff (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 USAO for that judicial district, as well as the Attorney General.

In addition to the positions funded by HCFAC, the Executive Office for United States Attorneys' Office of Legal Education uses HCFAC funds to train AUSAs and other DOJ attorneys, as well as paralegals, investigators, and auditors in the investigation and prosecution of health care fraud. In 2007, courses and presentations on health care fraud included the Civil and Criminal Health Care Fraud Trial Practice Seminar and the Affirmative Civil Enforcement for Auditors, Investigators and Paralegals Seminar. USAOs also handle most criminal and civil appeals at the Federal appellate level.

Criminal Prosecutions

In FY 2007, the USAOs received 878 new criminal matters involving 1,548 defendants, and had 1,612 health care fraud criminal matters pending,¹⁰ involving 2,603 defendants. The USAOs filed criminal charges in 434 cases involving 786 defendants, and obtained 560 federal health care fraud related convictions.

Civil Matters and Cases

USAOs play a major role in health care fraud enforcement by bringing affirmative civil cases to recover funds that federal health care programs have paid as a result of fraud, waste, and abuse. 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. Civil AUSAs, similar to their criminal counterparts, litigate a wide variety of health care fraud matters including false billings by doctors and other providers of medical services, overcharges by

¹⁰When a USAO accepts a criminal referral for consideration, the office opens it as a matter pending in the district. A referral remains a pending matter until an indictment or information is filed or it is declined for prosecution.

hospitals, Medicaid fraud, kickbacks to induce referrals of Medicare or Medicaid patients, fraud by pharmaceutical companies, and failure of care allegations against nursing home owners.

In FY 2007, USAOs opened 776 new civil health care fraud matters. At the end of FY 2007, the USAOs had 1,284 civil health care fraud matters and 743 cases pending. Civil health care fraud referrals are often made to USAOs through the law enforcement network described herein, and these cases are usually handled primarily by the USAOs, though they are sometimes handled jointly with the Civil Division. The other principal source of referrals of civil cases for USAOs is through the filing of qui tam (or whistleblower) complaints. These cases are often handled jointly with trial attorneys within the Civil Division, but may be handled solely by the USAO.

Civil Division

In FY 2007, the Civil Division was allocated approximately \$15.88 million in HCFAC funding to support civil health care fraud litigation (this amount includes \$1.1 million allotted for the Elder Justice and Nursing Home Initiative). Civil Division attorneys pursue civil and criminal 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 (FEHB), and other government health care programs.

Civil Division attorneys litigate a wide range of health care fraud matters, including cases involving allegations of overcharging by hospitals, and other Medicare Part A institutional providers; similar claims against suppliers of durable medical equipment and other supplies under Part B of Medicare; similar allegations involving state Medicaid programs; claims that doctors and others have been paid kickbacks or other remuneration to induce referrals of Medicare or Medicaid patients, in violation of the Anti-Kickback Act and Physician Self-Referral laws; claims of false price reporting and illegal marketing of pharmaceuticals and medical devices by companies and related entities; and allegations that nursing homes have failed to provide necessary care to the elderly. Among these are multi-district cases involving large health providers and suppliers that typically require coordination among affected Federal agencies, USAOs, state Medicaid Fraud Control Units and other state agencies, and various investigative organizations.

The Civil Division continues to staff and provide a critical coordination function in the FCA investigations alleging pharmaceutical price reporting fraud against government health care programs. These matters involve hundreds of manufacturers and related entities, span multiple districts and present myriad legal and factual issues. Civil Division attorneys have spearheaded substantial efforts to share information and evidence, as appropriate, with the USAOs and other components of DOJ, as well as HHS components including FDA. In addition, close communication with state Medicaid Fraud Control Units and state attorneys general is ongoing to ensure that federal and state investigations and litigation are coordinated.

In addition to these accomplishments, the Elder Justice and Nursing Home Initiative, coordinated by the Civil Division, among other things, supports enhanced 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 does this, in part, by enforcing the civil FCA against skilled nursing facilities and other long term care providers that knowingly bill Medicare or Medicaid for services that were not provided or were so deficient as to render them worthless. DOJ, through the initiative, also makes grants to promote prevention, detection, intervention, investigation and prosecution of elder abuse and neglect, and to improve the scarce forensic knowledge in the field.

Criminal Division

In FY 2007, the Criminal Division was allocated \$2.18 million in HCFAC funding to support criminal health care fraud litigation, prevention and interagency coordination. The Criminal Division's Fraud Section supports the federal white collar crime enforcement community through litigation, coordinating investigations and initiatives, implementing white collar crime policy, and conducting policy and legislative work. The Fraud Section initiates and coordinates complex health care fraud litigation and supports the USAOs with legal and investigative guidance, training, and, in certain instances, provides trial attorneys to prosecute health care fraud cases.

During FY 2007, the Fraud Section opened or filed 78 health care fraud cases involving charges against 144 defendants; obtained 65 guilty pleas; and litigated three jury trials, winning guilty verdicts on all counts charged. While most of the section's litigation involved Medicare Fraud Strike Force cases handled with the United States Attorney's Office for the Southern District of Florida described previously in this report, section attorneys also prosecuted the following cases involving physicians and a clinic owner:

- A physician who pleaded guilty to conspiring to defraud Medicare of \$5.1 million for the physician's role in causing the submission of claims for unnecessary drugs to be taken by injection by alleged HIV patients when it was known that the drugs were unnecessary and could harm the patients if actually taken.
- A physician who pleaded guilty to conspiring to defraud Medicare, Medicaid, and other health care benefit programs of more than \$1.8 million by causing medically unnecessary cardiology tests to be administered to patients. As a condition of the plea agreement, the physician agreed to give up the physician's medical license and to be permanently excluded from participation in federal health care programs.
- A medical clinic owner who pleaded guilty, along with 20 other codefendants, to conspiring to submit \$2.5 million in private insurance payments under personal injury protection provisions for alleged victims in a staged automobile accident scheme.

In addition to its health care fraud litigation, the Fraud Section also provided legal guidance to FBI and HHS agents, health program agency staff, AUSAs and Criminal Division attorneys on

criminal, civil and administrative tools to combat health care fraud, and worked on an interagency level through the following activities:

- . 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 patient medical records, including HIPAA medical privacy requirements, compliance with the Substance Abuse Patient Medical Records Privacy Act and regulations, and coordinating referrals from the HHS Office for Civil Rights on possible criminal violations of the HIPAA privacy statute;
- . providing training and training materials for AUSAs, investigative agents, support staff, program agency officials, and state and local law enforcement on health care fraud enforcement and medical records privacy issues;
- . monitoring and coordinating DOJ responses to legislative proposals, major regulatory initiatives, and enforcement policy matters related to prevention, deterrence and punishment of health care fraud and abuse;
- . reviewing and commenting on health care provider requests to the HHS/OIG for advisory opinions, and consulting with the HHS/OIG on draft advisory opinions per HIPAA requirements;
- . working with USAOs and CMS to improve Medicare contractors' fraud detection, referrals to law enforcement for investigation, and case development work;
- . preparing and distributing to all USAOs and FBI field offices periodic summaries of recent and significant health care fraud cases; and
- . organizing, overseeing and participating in interagency working groups to address cases and initiatives, often in conjunction with the Civil Division and EOUSA.

As part of the Criminal Division's effort, the Organized Crime and Racketeering Section supports investigations and prosecutions of health care fraud and other criminal abuses directed at private sector employee health benefit plans through which more than 130 million Americans receive health care insurance. Employment based group health plans are the primary source of health insurance for Americans who are not yet eligible for Medicare. Such employee health plans have been the target of fraud and abuse by corrupt insurers, employers, labor union officials and benefit service providers. The Organized Crime and Racketeering Section supports the USAOs with legal and investigative guidance, assistance with drafting indictments, motions, jury instructions and appellate briefs. The Organized Crime Section routinely provides guidance and training to the Department of Labor's Employee Benefits Security Administration and Office of Inspector General in connection with investigations of criminal fraud and abuse involving employee health benefit plans. The Section reviews and comments on legislative proposals affecting employee benefit plans and coordinates criminal legislative initiatives affecting employee health benefit plans.

Civil Rights Division

In FY 2007, the Civil Rights Division was allocated approximately \$2.38 million in HCFAC funding to support Civil Rights Division litigation activities related to health care fraud and abuse. The Civil Rights Division pursues relief affecting public, residential health care facilities. The Division has also established an initiative to eliminate abuse and grossly substandard care in public, Medicare and Medicaid funded nursing homes and other long-term care facilities.

The Division plays a critical role in the HCFAC Program. The Special Litigation Section of the Civil Rights Division is the sole DOJ component responsible for the Civil Rights of Institutionalized Persons Act, 42 U.S.C. § 1997 (CRIPA). CRIPA authorizes the 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 persons who have mental illness, facilities for persons with developmental disabilities, and nursing homes comprises a significant portion of the program. The Special Litigation Section works collaboratively with the USAOs and HHS.

Fiscal Year 2007 Accomplishments

As part of DOJ's Institutional Health Care Abuse and Neglect Initiative, and as an enhancement to ongoing CRIPA enforcement efforts, the Special Litigation Section staff conducted preliminary reviews of conditions and services at 23 health care facilities in eleven states during FY 2007. 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 reviews information pertaining to areas such as abuse and neglect, medical and mental health care, use of restraints, fire and environmental safety, and placement in the most integrated setting appropriate to individual needs. Separately, in FY 2007, the Section opened or continued formal investigations, entered remedial agreements, or monitored existing remedial agreements regarding 57 health care facilities in 22 states, the District of Columbia, and the Commonwealth of Puerto Rico.

In FY 2007, the Section commenced investigations of 7 state-operated facilities for persons with mental illness, four state facilities for persons with intellectual and developmental disabilities, and one state veterans nursing home. The facilities are:

Georgia Regional Hospital in Atlanta, Georgia; Georgia Regional Hospital in Savannah, Georgia; Northwest Georgia Regional Hospital in Rome, Georgia; Central State Hospital in Milledgeville, Georgia; Southwest State Hospital in Thomasville, Georgia; West Central Georgia Regional Hospital in Columbus, Georgia; East Central Georgia Regional Hospital in Augusta, Georgia; Clyde L. Choate Developmental Center in Anna, Illinois; Beatrice State Developmental Center in Beatrice, Nebraska; Northwest Habilitation Center in St. Louis, Missouri; Howe Developmental

Center in Tinley Park, Illinois; and Tennessee State Veterans Homes in Murfreesboro and Humboldt, Tennessee.

The Section found that conditions and practices at two state facilities for persons with intellectual and developmental disabilities and one state facility for persons with mental illness violate the residents' Federal constitutional and statutory rights. Those facilities are: Lubbock State School in Lubbock, Texas; Bellefontaine Developmental Center in St. Louis, Missouri; and Connecticut Valley Hospital in Middletown, Connecticut.

The Section entered settlement agreements to resolve its investigations of one District of Columbia facility for persons with mental illness, one state-operated facility for persons with intellectual and developmental disabilities, and one state-operated nursing home. Those facilities are: St. Elizabeths Hospital in Washington, DC; Frances Haddon Morgan Center in Bremerton, Washington; and Fort Bayard Medical Center and Nursing Home in Ft. Bayard, New Mexico.

The Section continued its investigations of 7 residential facilities for persons with developmental disabilities: Agnews Developmental Center, in San Jose, California; Sonoma Developmental Center, in Eldridge, California; Lanterman Developmental Center, in Pomona, California; Rainier Residential Rehabilitation Center, in Buckley, Washington; Frances Haddon Morgan Center, in Bremerton, Washington; Conway Developmental Center, in Conway, Arkansas; Lubbock State School, in Lubbock, Texas; and, Bellefontaine Developmental Center, in St. Louis, Missouri. The division also continued its investigation of Oregon State Hospital in Portland, Oregon, a facility for persons with mental illness. In addition, the Section continued its investigations of three publicly-operated nursing homes: Charlotte Hall Veterans Home, in Charlotte Hall, Maryland; the Laguna Honda Hospital and Rehabilitation Center, in San Francisco; California, and C.M. Tucker Nursing Care Center in Columbia, South Carolina. In some of these matters, the Section is reviewing voluntary compliance to improve conditions.

The Section monitored the implementation of remedial agreements for 13 facilities for persons with developmental disabilities: Fort Wayne State Developmental Center, in Fort Wayne, Indiana; Pinecrest Developmental Center, in Pinecrest, Louisiana; Hammond Developmental Center, in Hammond, Louisiana; Clover Bottom Developmental Center, in Nashville, Tennessee; Greene Valley Developmental Center, in Greeneville, Tennessee; Harold Jordan Center, in Nashville, Tennessee; Arlington Developmental Center, in Arlington, Tennessee; New Lisbon Developmental Center, in New Lisbon, New Jersey; Southbury Training School, in Southbury, Connecticut; Woodward Resource Center, in Woodward, Iowa; Glenwood Resource Center, in Glenwood, Iowa; Woodbridge Developmental Center in Woodbridge, New Jersey; and Oakwood Community Center in Somerset, Kentucky. It also monitored the implementation of remedial agreements regarding community placements from facilities for persons with developmental disabilities in Indiana, Puerto Rico, and Washington, D.C.

The Section monitored the implementation of remedial agreements for five nursing homes: Banks-Jackson-Commerce Medical Center and Nursing Home, in Commerce, Georgia; Nim Henson Geriatric Center, in Jackson, Kentucky; Reginald P. White Nursing Facility, in Meridian, Mississippi; Mercer County Geriatric Center, in Trenton, New Jersey; and A. Holly Patterson

Extended Care Facility in Uniondale, New York. The Section also monitored the implementation of remedial agreements regarding nine state-operated residential facilities for persons with mental illness: Vermont State Hospital, in Waterbury, Vermont; Dorothea Dix Hospital, in Raleigh, North Carolina; Broughton Hospital in Morganton, North Carolina; Cherry Hospital, in Goldsboro, North Carolina; John Umstead Hospital in Butler, North Carolina; Metropolitan State Hospital, in Norwalk, California; Napa State Hospital, in Napa, California; Atascadero State Hospital, in Atascadero, California; and Patton State Hospital, in Patton, California. The Section also monitored the implementation of remedial agreements in community-based mental health facilities in Hawaii.

Finally, the Section monitored the implementation of a remedial agreement regarding one residential facility for children with visual disabilities: New Mexico School for the Visually Handicapped, in Alamogordo, New Mexico.

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 2007, \$118,218,000.”

In FY 2007, the FBI was separately allocated \$118.2 million in HCFAC funds for health care fraud enforcement. The FBI was allocated \$4.2 million in funding for cost of living adjustments through the Tax Relief and Health Care Act of 2006 in addition to the prior existing statutory amount. This yearly appropriation was used to support 759 positions (454 Agent, 305 Support) in FY 2007, a decrease of 16 positions from the positions supported in FY 2006 (1 Agent, 15 Support). The number of pending investigations has shown steady increase from 591 pending cases in 1992 to 2,493 cases through 2007. FBI-led investigations resulted in 625 criminal health care fraud convictions¹¹ and 835 indictments and informations being filed in 2007.

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 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. More than \$1 trillion is spent in the private sector on health care and its related services and the FBI's efforts are crucial to the overall success of the program. The FBI leverages its resources in both the private and public arenas through investigative partnerships with agencies such as the HHS/OIG, the FDA, the Drug Enforcement Administration (DEA), the Defense Criminal Investigative Service, the Office of Personnel Management, the 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 National Insurance Crime Bureau, as well as many other professional and fundamental efforts to expose and investigate fraud within the system.

Health care fraud investigations are considered a priority within the White Collar Crime Program Plan. In addition to being a partner in the majority of investigations listed in the body of this report, FBI field offices throughout the U.S. have pro-actively addressed significant health care fraud through coordinated initiatives, task forces, and undercover operations to identify and pursue investigations against the most egregious offenders which may include organized criminal activity and criminal enterprises. Organized criminal activity has been identified in the operation of medical clinics, independent diagnostic testing facilities, durable medical equipment companies and other health care facilities. The FBI is committed to addressing this criminal activity through

¹¹This number includes state and local convictions.

disruption, dismantlement and prosecution of criminal organizations.

The FBI initiated the Internet Pharmacy Fraud Initiative which focuses on Internet web sites and individuals selling illegal prescription drugs and controlled substances. The overall goal of the Internet Pharmacy Fraud Initiative is to identify fraudulent Internet pharmacies and target physicians who are willing to write prescriptions for financial gain outside of the doctor/patient relationship and with no legitimate medical purpose. Also in the scope of this initiative are investigations involving the sale of counterfeit and diverted pharmaceuticals on the Internet.

During 2007 the FBI continued its support of the Medicare Fraud Strike Force (MFSF) which was initiated to combat the prodigious Medicare fraud problem endemic to South Florida. Its mission was to adapt the traditional investigative and prosecutorial methodology to more appropriately address the contemporary way in which Medicare fraud is committed. The Strike Force was a concerted effort from DOJ, the United States Attorney's Office in the Southern District of Florida, the FBI, HHS/OIG, the Florida Medicaid Fraud Control Unit, and the Hialeah Police Department. In 2008 the FBI will continue to support the Strike Force and will work closely with the DOJ as this strike force concept is expanded to other areas of the country.

The FBI has also initiated a new and aggressive training program. The FBI realizes that the most important resource for the successful investigation of health care fraud violations is that of human capital. Therefore, in 2007 and continuing the FBI has begun an aggressive training curriculum to include expanding the ability of those who investigate health care fraud matters to attend additional training sponsored by private entities such as the NHCAA. In addition the FBI is revamping its virtual academy training sites to include specific blocks related directly to health care fraud investigations.

The majority of funding received by the FBI is used to pay personnel costs associated with the 759 funded positions. Funds not used directly for personnel matters are used to provide operational support for major health care fraud investigations and national initiatives currently focusing on Internet Pharmacy fraud, Training and the DOJ Strike Force. 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 Of Terms

The Account - The Health Care Fraud and Abuse Control Account

Atlanta Blood Services - ABS

AoA - Department of Health and Human Services, Administration on Aging

ANS - Advanced Neuromodulation System

AMP - Average Manufacturer Prices

AUSA - Assistant United States Attorney

AWP - Wholesale Acquisition Cost

BMS - Bristol Meyers Squibb

BMTGA - Blood and Marrow Transplant Group of Georgia

CCH - Cook County Hospital

CERT - Comprehensive Error Rate Testing

CIA - Corporate Integrity Agreement

CMHC - Community Mental Health Centers

CMP - Civil Monetary Penalty

CMPL - Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a

CMS - Department of Health and Human Services, Centers for Medicare & Medicaid Services

CRIPA - Civil Rights of Institutionalized Persons Act

CTI - Cell Therapeutics, Inc.

DAB-Department of Health and Human Services, Departmental Appeals Board

DEA - Drug Enforcement Administration

DME - Durable Medical Equipment

DMEPOS - durable medical equipment, prosthetics, orthotics, and supplies

DRA - Deficit Reduction Act of 2005

DOJ - The Department of Justice

DSH - Disproportionate Share Hospital

EOUSA - Executive Office for the United States Attorneys

FBI - Federal Bureau of Investigation

FCA - False Claims Act

FDA - Food and Drug Administration

FEHBP - Federal Employees Health Benefits Program

FFP - Federal Financial Participation

FTE-Full-time equivalent

GAO - Government Accountability Office

GHB - Gamma-Hydroxybutyrate

HCFAC - --Health Care Fraud and Abuse Control Program or the Program

HHM - The Department of Health and Human Services

HHS/OIG - The Department of Health and Human Services - Office of the Inspector General

HI - Hospital Insurance Trust Fund

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

HIPDB - Healthcare Integrity and Protection Data Bank

HIV - Human Immunodeficiency Virus

HMO - Health Maintenance Organization

IPF - Idiopathic Pulmonary Fibrosis

IPIA - Improper Payments Information Act of 2002, P.L. 107-300

HRSA - The Department of Health and Humans Services - Health Resources and Services Administration

MA - Medicare Advantage plan

MFSF - Medicare Fraud Strike Force

MMA - Medicare Prescription Drug, Improvement and Modernization Act of 2003

MML - Midwest Medical Laboratory

MRO - Medicaid Rehabilitation Option

NCFE - National Century Financial Enterprises

NHCAA - National Health Care Anti-Fraud Association

NIDA - National Institute on Drug Abuse

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

ONC - Office of the National Coordinator for Health Information Technology, The Department of Health and Human Services

PAR - Performance and Accountability Report

PCS - Program Safeguard Contractors

PERM - Program Error Rate Measurement

PDS - Proactive Disclosure Service

PPS - Prospective Payment Systems

The Program - The Health Care Fraud and Abuse Control Program

RN - Registered Nurse

RSP - Retail Sales Price

SCCI-SCCI Health Services Corporation

SCHIP - State Children's Health Insurance Plan

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

SMP - Senior Medicare Patrol

SNF - Skilled Nursing Facilities

USAO - United States Attorney's Office