
**The Department of Health and Human Services
and
The Department of Justice
Health Care Fraud and Abuse Control Program
Annual Report for Fiscal Year 2010**

January 2011

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GENERAL NOTE

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

EXECUTIVE SUMMARY

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a national Health Care Fraud and Abuse Control Program (HCFAC or the Program) under the joint direction of the Attorney General and the Secretary of the Department of Health and Human Services (HHS)¹, acting through the Inspector General, designed to coordinate Federal, state and local law enforcement activities with respect to health care fraud and abuse. In its fourteenth year of operation, the Program's continued success again confirms the soundness of a collaborative approach to identify and prosecute the most egregious instances of health care fraud, to prevent future fraud or abuse, and to protect program beneficiaries.

Monetary Results

During Fiscal Year (FY) 2010, the Federal government won or negotiated approximately \$2.5 billion in health care fraud judgments and settlements², and it attained additional administrative impositions in health care fraud cases and proceedings. The Medicare Trust Fund received transfers of approximately \$2.86 billion during this period as a result of these efforts, as well as those of preceding years, including over \$683.2 million in Federal Medicaid money similarly transferred separately to the Treasury as a result of these efforts. The HCFAC account has returned over \$18.0 billion to the Medicare Trust Fund since the inception of the Program in 1997.

Enforcement Actions

In FY 2010, the Department of Justice (DOJ) opened 1,116 new criminal health care fraud investigations involving 2,095 potential defendants. Federal prosecutors had 1,787 health care fraud criminal investigations pending, involving 2,977 potential defendants, and filed criminal charges in 488 cases involving 931 defendants. A total of 726 defendants were convicted for health care fraud-related crimes during the year. Also in FY 2010, DOJ opened 942 new civil health care fraud investigations and had 1,290 civil health care fraud matters pending at the end of the fiscal year.

In FY 2010, HHS' Office of Inspector General (HHS/OIG) excluded 3,340 individuals and entities. Among these were exclusions based on criminal convictions for crimes related to Medicare and Medicaid (894), or to other health care programs (263); for patient abuse or neglect (247); or as a result of licensure revocations (1,582). In addition, HHS/OIG imposed civil monetary penalties against, among others, providers and suppliers who knowingly submit false claims to the Federal government. HHS/OIG also issued numerous audits and evaluations

¹Hereafter, referred to as the Secretary.

²The amount reported as won or negotiated only reflects Federal recoveries and therefore does not reflect state Medicaid monies recovered as part of any global, Federal-State settlements.

with recommendations that, when implemented, would correct program vulnerabilities and save program funds.

INTRODUCTION

ANNUAL REPORT OF THE ATTORNEY GENERAL AND THE SECRETARY DETAILING EXPENDITURES AND REVENUES UNDER THE HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM FOR FISCAL YEAR 2010

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

STATUTORY BACKGROUND

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

As was the case before HIPAA, amounts paid to Medicare in restitution or for compensatory damages must be deposited in the Medicare Trust Fund. The Act requires that an amount equaling recoveries from health care investigations – including criminal fines, forfeitures, civil settlements and judgments, and administrative penalties – also be deposited in the Trust Fund.³ All funds deposited in the Trust Fund as a result of the Act are available for the operations of the Trust Fund.

The Act appropriates monies from the Medicare Trust Fund to an expenditure account, called the Health Care Fraud and Abuse Control Account (the Account), in amounts that the Secretary and Attorney General jointly certify as necessary to finance anti-fraud activities. The maximum amounts available for certification are specified in the Act. Certain of these sums are to be used only for activities of the HHS Office of Inspector General (HHS/OIG), with respect to the Medicare and Medicaid programs. In FY 2006, the Tax Relief and Health Care Act (TRHCA) (P.L. 109-432, §303) amended the Act so that funds allotted from the Account are “available until expended.” TRHCA also allowed for yearly increases to the Account based on the change in the consumer price index for all urban consumers (all items; United States city average) (CPI-U) over the previous fiscal year for fiscal years for 2007 through 2010.⁴ In FY 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act (P.L. 111-148, ACA)

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

⁴ The CPI-U adjustment in TRHCA did not apply to the Medicare Integrity Program (MIP).

extended permanently the yearly increases to the Account based upon the change in the consumer price index for all urban consumers or CPI-U.

In FY 2010, the Secretary and the Attorney General certified \$266.4 million in mandatory funding for appropriation to the Account. Additionally, Congress appropriated \$311.0 million in discretionary funding. A detailed breakdown of the allocation of these funds is set forth later in this report. HCFAC appropriations generally supplement the direct appropriations of HHS and DOJ that are devoted to health care fraud enforcement and funded approximately three-fourths of HHS/OIG's appropriated budget in FY 2010. (Separately, the Federal Bureau of Investigation (FBI) received \$126.3 million from HIPAA which is discussed in the Appendix.)

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

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

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

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

Additionally, language in HHS/OIG's FY 2010 appropriation (Public Law 111-117) accompanying additional discretionary HCFAC funding requires that this report "shall include measures of the operational efficiency and impact on fraud, waste, and abuse in the Medicare, Medicaid, and CHIP programs for the funds provided by this appropriation."

This annual report fulfills the above statutory requirements.

MONETARY RESULTS

As required by the Act, HHS and DOJ must detail in this Annual Report the amounts deposited to the Medicare Trust Fund, and the source of such deposits. In FY 2010, \$4.021 billion was deposited with the Department of the Treasury and the Centers for Medicare and Medicaid Services (CMS), transferred to other Federal agencies administering health care programs, or paid to private persons during the fiscal year. The following chart provides a breakdown of the transfers/deposits:

Total Transfers/Deposits by Recipient FY 2010	
Department of the Treasury	
Deposits to the Medicare Trust Fund, as required by HIPAA	
Gifts and Bequests	\$49,477
Amount Equal to Criminal Fines	\$1,205,600,509
Civil Monetary Penalties	\$21,739,469
Asset Forfeiture *	0
Penalties and Multiple Damages	\$611,786,212
Subtotal	\$1,839,175,667
Centers for Medicare and Medicaid Services	
HHS/OIG Audit Disallowances - Recovered	\$687,124,220
Restitution/Compensatory Damages	\$336,253,422
Subtotal	\$1,023,377,642
Grand Total of Amounts Transferred to the Medicare Trust Fund	\$2,862,553,309
Restitution/Compensatory Damages to Federal Agencies	
TRICARE	\$57,129,312
Veteran's Administration	\$33,215,359
HHS/OIG Cost of Audits, Investigations and Compliance Monitoring	\$11,717,923
Office of Personnel Management	\$46,492,777
Other Agencies	\$19,789,193
Federal Share of Medicaid	\$683,209,512
Subtotal	\$851,554,076
Relators' Payments**	\$307,620,401
TOTAL ***	\$4,021,727,786

*This includes only forfeitures under 18 U.S.C. § 1347, a Federal health care fraud offense that became effective on August 21, 1996. Not included are forfeitures obtained in numerous health care fraud cases prosecuted under Federal mail and wire fraud and other offenses.

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

***State funds are also collected on behalf of state Medicaid programs; only the federal share of Medicaid funds transferred to CMS are represented here.

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

- (1) Gifts and bequests made unconditionally to the Trust Fund, for the benefit of the Account or any activity financed through the Account;
- (2) Criminal fines recovered in cases involving a Federal health care offense, including collections under section 24(a) of Title 18, United States Code (relating to health care fraud);
- (3) Civil monetary penalties in cases involving a Federal health care offense;
- (4) Amounts resulting from the forfeiture of property by reason of a Federal health care offense, including collections under section 982(a)(7) of Title 18, United States Code; and
- (5) Penalties and damages obtained and otherwise creditable to miscellaneous receipts of the general fund of the Treasury obtained under sections 3729 through 3733 of Title 31, United States Code (known as the False Claims Act, or FCA), in cases involving claims related to the provision of health care items and services (other than funds awarded to a relator, for restitution or otherwise authorized by law).

PROGRAM ACCOMPLISHMENTS

EXPENDITURES

In the fourteenth year of operation, the Secretary and the Attorney General certified \$266.4 million in mandatory funding as necessary for the Program. Additionally, Congress appropriated \$311.0 million in discretionary funding. The following chart gives the allocation by recipient:

FY 2010 ALLOCATION OF HCFAC APPROPRIATION			
Organization	Mandatory Allocation⁵	Discretionary Allocation	Total Allocation
Department of Health and Human Services			
Office of Inspector General ⁶	\$178,704,551	\$29,790,000	\$208,494,551
Office of the General Counsel	\$8,713,598	\$0	\$8,713,598
Administration on Aging	\$3,779,000	\$0	\$3,779,000
Food and Drug Administration	\$1,650,000	\$0	\$1,650,000
Assistant Secretary for Planning & Evaluation	\$1,050,000	\$0	\$1,050,000
Assistant Secretary for Public Affairs	\$690,894	\$0	\$690,894
Centers for Medicare & Medicaid Services	\$16,509,000	\$251,420,000	\$267,929,000
Subtotal	\$211,097,043	281,210,000	\$492,307,043
Department of Justice			
United States Attorneys	\$31,400,000	\$11,510,367	\$42,910,367
Civil Division	\$18,972,139	\$6,934,219	\$25,906,358
Criminal Division	\$1,580,000	\$5,334,108	\$6,914,108
Civil Rights Division	\$2,376,000	\$2,064,352	\$4,440,352
Nursing Home and Elder Justice Initiative	\$1,000,000	\$0	\$1,000,000
Federal Bureau of Investigation	\$0	\$3,946,954	\$3,946,954
Subtotal	\$55,328,139	\$29,790,000	\$85,118,139
TOTAL⁷	\$266,425,182	\$311,000,000	\$577,425,182

⁵ In FY 2007, mandatory funds became available until expended.

⁶In addition, HHS/OIG obligated \$5.9 million in funds received as “reimbursement for the costs of conducting investigations and audits and for monitoring compliance plans” as authorized by section 1128C(b) of the Social Security Act, 42 U.S.C. § 1320a-7c(b).

⁷Amounts only represent those that are provided by statute, and do not include other mandatory sources or discretionary appropriated sources provided through Departments’ annual appropriations.

ACCOMPLISHMENTS

Overall Recoveries

During this fiscal year, the Federal government won or negotiated approximately \$2.5 billion in judgments and settlements, and it attained additional administrative impositions in health care fraud cases and proceedings. The Medicare Trust Fund received transfers of approximately \$2.86 billion during this period as a result of these efforts, as well as those of preceding years; and another \$683 million in Federal Medicaid money was transferred to the Treasury separately as a result of these efforts.⁸

In addition to these enforcement actions, numerous audits, evaluations and other coordinated efforts yielded recoveries of overpaid funds, and prompted changes in Federal health care programs that reduce vulnerability to fraud.⁹

The return-on-investment (ROI) for the HCFAC program, since 1997, is \$4.9 returned to every \$1.0 expended. The 3-year average (2008-2010) ROI is \$6.8 to \$1.0, which is \$1.9 higher than the historical average. Due to the fact that the annual ROI can vary from year to year depending on the number of cases that are settled or adjudicated during that year, DOJ and HHS use a three-year rolling average ROI for results contained in the report. Additional information on how the ROI is calculated can be found in the Appendix.

Departmental Collaboration

Health Care Fraud Prevention & Enforcement Action Team (HEAT)

The Attorney General and the HHS Secretary maintain regular consultation at both senior and staff levels to facilitate, coordinate and accomplish the goals of the HCFAC Program. On May 20, 2009, Attorney General Holder and Secretary Sebelius announced the Health Care Fraud Prevention & Enforcement Action Team (HEAT), a new effort with increased tools and resources, and a sustained focus by senior level leadership to enhance collaboration between the Departments of Health and Human Services and Justice. With the creation of the new HEAT effort, DOJ and HHS pledged a cabinet-level commitment to prevent and prosecute health care fraud. HEAT, which is jointly led by the Deputy Attorney General and HHS Deputy Secretary, is comprised of top level law enforcement agents, prosecutors, attorneys, auditors, evaluators, and other staff from DOJ and HHS and their operating divisions, and is dedicated to joint efforts across government to both prevent fraud and enforce current anti-fraud laws around the country. The Medicare Fraud Strike Force teams are a key component of HEAT.

⁸ Note that some of the judgments, settlements, and administrative actions that occurred in FY 2010 will result in transfers in future years, just as some of the transfers in FY 2010 are attributable to actions from prior years.

⁹ HHS collected approximately \$687 million in HHS/OIG recommended recoveries which are included in the total \$4.0 billion transferred to the Trust Fund in FY 2010.

The mission of HEAT is:

- **To marshal significant resources across government to prevent waste, fraud and abuse in the Medicare and Medicaid programs** and crack down on the fraud perpetrators who are abusing the system and costing us all billions of dollars.
- **To reduce skyrocketing health care costs and improve the quality of care by** ridding the system of perpetrators who are preying on Medicare and Medicaid beneficiaries.
- **To highlight best practices by providers and public sector employees** who are dedicated to ending waste, fraud and abuse in Medicare.
- **To build upon existing partnerships between DOJ and HHS, such as our Medicare Fraud Strike Forces** to reduce fraud and recover taxpayer dollars.

Since its creation in May 2009, HEAT has focused on key areas for coordination and improvement. HEAT members are working to identify new enforcement initiatives and areas for increased oversight and prevention to increase efficiency in pharmaceutical and device investigations. DOJ and HHS have expanded data sharing and improved information sharing procedures in order to get critical data and information into the hands of law enforcement to track patterns of fraud and abuse, and increase efficiency in investigating and prosecuting complex health care fraud cases. The departments established a cross-government health care fraud data intelligence sharing workgroup to share fraud trends, new initiatives, ideas and success stories to improve awareness across the government of issues relating to health care fraud.

Both departments also have increased training to prevent honest mistakes and help stop potential fraud before it happens. This includes CMS compliance training for providers, ongoing meetings at U.S. Attorneys' Offices with the public and private sector, and increased efforts by HHS to educate specific groups – including elderly and immigrant communities – to help protect them. DOJ launched a new Medicare Fraud Strike Force training program designed to teach the Strike Force concept and case model to prosecutors, law enforcement agents and administrative support teams. CMS and HHS/OIG are providing ongoing training to DOJ and HHS staff on the use of new technology to catch and quickly turn off funding to those who are defrauding the system.

To achieve the mission and objectives of HEAT, the Attorney General and HHS Secretary began several HEAT initiatives during the fiscal year:

- Expanded the Medicare Fraud Strike Force to Brooklyn, New York, Baton Rouge, Louisiana and Tampa, Florida bringing the total number of cities with Strike Force teams up to seven.
- Sent a letter to all state attorneys general urging them to work with HHS and Federal, state and local law enforcement officials to mount a substantial outreach campaign to educate seniors and other Medicare beneficiaries about how to prevent scams and fraud.
- Following a successful National Summit on Health Care Fraud (January 2010), initiated a series of regional fraud prevention summits around the country, beginning in Miami (July 2010) and Los Angeles (August 2010) and to include several other cities next fiscal year

to improve the exchange of information with partners in the public and private sector and educate beneficiaries, providers, and the public to better identify and prevent health care fraud.

- Expanded the use of regional and local health care fraud task force meetings to further coordinate anti-fraud efforts.
- Launched a new educational media campaign to educate Medicare beneficiaries about how to protect themselves against fraud.

In addition to the activities of HEAT, CMS and law enforcement agency representatives, such as members of the Civil and Criminal Divisions, the USAOs and Executive Office for United States Attorneys (EOUSA), the FBI, and HHS/OIG, meet on a periodic basis through numerous local or regional health care fraud working groups and task forces.

EOUSA and CMS also sponsor a monthly national conference call during which Assistant United States Attorneys (AUSA) from all districts have the opportunity to interact directly with CMS representatives, receive timely reports on CMS operations, and obtain answers to questions related to specific issues regarding current investigations. The Departments also convene interagency staff-level working groups as needed to develop mutual proposals for improving our health care fraud fighting capabilities.

Each Department routinely enlists senior staff from the other agency to participate in cross-training programs. DOJ's Criminal Division and HHS/OIG initiated a special program in 2007, which provides an opportunity for HHS/OIG counsel to serve six month details to gain experience managing criminal health care fraud investigations and trial experience in Federal court with Criminal Division colleagues. That program continues. In addition, attorneys from HHS/OIG have been detailed to the Fraud Section of the Criminal Division as Special Trial Attorneys and to U.S. Attorneys' Offices as Special Assistant U.S. Attorneys to provide USAOs with additional prosecutorial resources.

During FY 2010, the many significant HCFAC Program accomplishments included the following:

HEAT Medicare Fraud Strike Force

The first Medicare Fraud Strike Force (Strike Force) was launched in March 2007 as part of the South Florida Initiative, a joint investigative and prosecutorial effort against Medicare fraud and abuse among Durable Medical Equipment (DME) suppliers and Human Immunodeficiency Virus (HIV) infusion therapy providers in South Florida. The Strike Force teams use advanced data analysis techniques to identify high-billing levels in health care fraud hot spots so that interagency teams can target emerging or migrating schemes along with chronic fraud by criminals masquerading as health care providers or suppliers. Based on the success of these efforts and increased appropriated funding for the HCFAC program from Congress and the Administration, DOJ and HHS expanded the Strike Force to include teams of investigators and prosecutors in a total of seven cities – Miami, Florida; Los Angeles, California; Detroit, Michigan; Houston, Texas; Brooklyn, New York; Baton Rouge, Louisiana; and Tampa, Florida. The Departments will continue to expand the Strike Force to cities where Medicare claims data reveal aberrant billing patterns and intelligence data analysis suggest that fraud may be occurring.

Each Medicare Strike Force combines data analysis capabilities of CMS and the investigative resources of the FBI and HHS/OIG with the prosecutorial resources of the DOJ Criminal Division, Fraud Section and the USAOs. Strike Force accomplishments from cases prosecuted in all seven cities during FY 2010 include¹⁰:

- 140 indictments involving charges filed against 284 defendants who collectively billed the Medicare program more than \$590 million;
- 217 guilty pleas negotiated and 19 jury trials litigated, winning guilty verdicts against 23 defendants;
- Imprisonment for 146 defendants sentenced during the fiscal year, averaging more than 40 months of incarceration; and

In the three and a half years since its inception, Strike Force prosecutors filed 465 cases charging 829 defendants who collectively billed the Medicare program more than \$1.9 billion; 481 defendants pleaded guilty and 48 others were convicted in jury trials; and 358 defendants were sentenced to imprisonment for an average term of nearly 44 months.¹¹

Examples of successful cases initiated or concluded in districts where Strike Force prosecution teams were operational during FY 2010 – as well as other successful cases, organized by provider or fraud type follow.

Phase 1: Miami (Southern District of Florida)

- In July 2010, the U.S. district court in Miami sentenced the founder of a fraudulent Miami-area HIV/AIDS infusion clinic to 120 months in prison and the clinic's owner and operator to 70 months in prison on their trial convictions stemming from a \$5.8 million Medicare fraud scheme. The defendants defrauded Medicare by submitting claims for injection and infusion treatments that were medically unnecessary and, in most instances, not provided. They conspired to pay kickbacks to induce Medicare beneficiaries to provide their Medicare numbers and their signatures, which the clinic used to submit fraudulent claims to Medicare for injection and infusion services. Two other co-defendants pleaded guilty to the conspiracy charge and were sentenced to prison terms of 84 months and 33 months, respectively. The court also ordered the four defendants to pay, jointly and severally with each other, \$2.7 million in restitution.

¹⁰ The accomplishments figures presented in the bullets include all reported Strike Force cases handled by DOJ Criminal Division attorneys and Assistant United States Attorneys in the respective U.S. Attorneys' Offices during FY 2010. During previous fiscal years, the U.S. Attorneys' Offices in the Southern District of Florida and Central District of California implemented the Strike Force model for criminal health care fraud prosecutions. However, Strike Force prosecution statistics from previous years did not include all Strike Force cases because more complete reporting procedures were not in place at that time.

¹¹ These statistics are for the period of May 7, 2007 through September 30, 2010.

- In May 2010, the court sentenced an operator of two DME supply companies to a 144 month prison term following his trial conviction on charges of conspiracy to commit health care fraud and health care fraud. The court also ordered him to pay over \$6.2 million in restitution. The defendant controlled and operated a DME supply company in Miami-Dade County and caused the submission of more than \$4.8 million in false claims to Medicare over a six-month period by seeking reimbursement for the cost of DME items and services that were not prescribed by doctors or provided as claimed. The defendant then took control of and operated a second DME company in Miami-Dade County and along with a co-conspirator, caused the submission of more than \$14.5 million in false and fraudulent claims to Medicare seeking reimbursement for the cost of DME items and services that were not prescribed by doctors or provided as claimed. At sentencing, the judge noted the severe harm caused to the taxpayers as a result of defendant's conduct in stealing more than \$6 million of funds dedicated to the care of the elderly and disabled, especially in light of the current health care funding issues that exist in this country.
- In April 2010, the court sentenced a defendant who operated and controlled 13 DME companies and three medical clinics located in Miami-Dade and Hillsborough Counties, Florida, to a 151 month prison term and ordered him to pay restitution of more than \$11 million to Medicare. Using various companies, the defendant and his co-conspirators submitted nearly \$57 million of false claims to Medicare for medical equipment, prescription medications, and outpatient medical services. The defendant concealed his control of these DME companies and medical clinics by recruiting "nominee" or "straw owners" who were typically paid a percentage of the fraud proceeds to sign the necessary corporate records and Medicare applications. To execute the scheme, the defendant purchased the identities of various Medicare beneficiaries in Miami-Dade County, including their driver's licenses, Medicare cards, and other identification documents, and would then use the patients' Medicare numbers to submit fraudulent claims for a wide variety of high-priced medical equipment.
- In October 2009, the court sentenced a defendant who falsely claimed to be a physician's assistant and who worked for two separate Miami-area HIV-infusion clinics to 108 months of imprisonment following his conviction on charges of health care fraud, conspiracy to commit health care fraud, and obstruction of justice. The defendant examined patients, prepared treatment plans, and prepared false medical paperwork for the clinics which purportedly provided infusion treatments to HIV-positive Medicare beneficiaries. Over a two-year period, the clinics submitted more than \$12 million in false claims to Medicare for expensive HIV-infusion therapies when, in fact, they were providing the patients with nothing more than injections or infusions of Vitamins B-6 and B-12. After one of the HIV-infusion clinics received a grand jury subpoena, the defendant also created false medical records and placed phony test results inside patient files which were ultimately returned to the grand jury. The court also ordered the defendant to pay more than \$1.2 million in restitution to Medicare.
- In March 2010, the owner of a billing company in Florida that submitted fraudulent claims to Medicare on behalf of several DME companies was sentenced to 46 months

incarceration and ordered to pay \$15.9 million in joint and several restitution after pleading guilty to conspiracy to commit health care fraud. Investigators learned that the DME companies provided the owner with a list of physicians and Medicare beneficiaries, and the owner randomly paired the physicians and beneficiaries together and billed Medicare for medical supplies that were never needed or used. In return for the billing, the DME companies paid the owner a percentage of the amount reimbursed by Medicare.

Phase 2: Los Angeles (Central District of California)

- In June 2010, the U.S. district court in Los Angeles sentenced a co-owner of a DME supply company to a 57 month prison term following her guilty plea to a charge of conspiracy to commit health care fraud. The court also sentenced another co-conspirator to 30 months in prison, and sentences remain pending for the other co-owner and three other defendants who also pleaded guilty in this case. According to the indictment, the defendants conspired to falsely represent that the DME company had supplied Medicare beneficiaries with over \$1.8 million in enteral nutrition and feeding supply kits, as well as another \$500,000 in motorized wheelchairs and hospital beds, knowing that these supplies and services were not medically necessary and had not been delivered to Medicare beneficiaries. The final defendant in this case is scheduled to go to trial in February of 2011.
- In May 2010, the court sentenced a DME supply company owner and operator to a 55 month prison term following his guilty plea to submitting \$1 million in false claims to Medicare. The DME owner admitted that, between January 2006 and September 2009, he conspired with the owner of another DME company and others to purchase fraudulent prescriptions and medical documents. He then used those documents to submit false claims to Medicare for expensive, high-end, power wheelchairs and other equipment that he claimed to have supplied to Medicare beneficiaries who lived hundreds of miles from his company's store front location. He also admitted that he knew the beneficiaries did not need power wheelchairs and other DME that he had billed to Medicare.
- In March 2010, the court sentenced a former DME owner and operator to 108 months in prison and ordered him to pay over \$526,000 in restitution, the sum of payments received from Medicare, and a \$25,000 fine on his jury conviction for health care fraud. He billed Medicare approximately \$1.1 million for power wheelchairs costing up to \$7,000 each, on behalf of more than 170 beneficiaries, none of whom actually needed the wheelchairs. At trial, elderly and disabled Medicare beneficiaries testified that individuals known as "marketers" approached them on the street, at home or in church to get the beneficiaries to give the marketers their Medicare numbers and other personal information in exchange for free power wheelchairs. One beneficiary, who was blind, testified that he could not see to operate the wheelchair and never used it. Another beneficiary testified that an individual purporting to be from Medicare, but who was actually associated with the DME owner and his co-conspirators, threatened to terminate the Medicare benefits of the beneficiary and her husband unless they accepted two power wheelchairs that they did not need. Several Los Angeles-area physicians also testified at trial that their names on the prescriptions were forged, that they had never written prescriptions for power wheelchairs,

and that the prescriptions bearing their names were phony. After his conviction, the defendant fled the jurisdiction and is a fugitive.

Phase 3: Detroit (Eastern District of Michigan)

- In August 2010, the U.S. district court in Detroit sentenced a physician, following his conviction after a three-week jury trial, to serve 168 months in prison for his role in a five-year conspiracy to defraud the Medicare program and ordered him to pay restitution of \$9.5 million. The physician entered into an agreement with an owner of several fraudulent medical companies that purported to provide physical and occupational therapy services to Medicare beneficiaries and signed prescriptions and other documents to support the owner's billing for such services that were never provided. The owner, who was convicted for his role in this scheme and sentenced to 81 months in prison, paid cash kickbacks and other inducements to Medicare beneficiaries, including prescriptions signed by the physician for controlled substances and other drugs, in exchange for the beneficiaries' Medicare numbers and signatures on documents falsely indicating that they had received therapy services when they actually had not. In addition to receiving kickback payments from the owner, the physician also billed Medicare for fictitious "home visits" that he claimed to have made to beneficiaries whom the owner recruited into the scheme. Eight other co-conspirators, including several physical therapists and an office assistant have been convicted and sentenced to prison terms ranging from eight to 62 months in this case.
- In August 2010, the court sentenced a Miami resident who was an operator of a Detroit-area medical clinic to 56 months in prison for his role in a \$2.2 million scheme to bill Medicare for unnecessary medical and testing services. The defendant pleaded guilty in April and admitted managing a medical clinic in Livonia, Michigan, that paid patient recruiters between \$100 and \$150 per patient referral. He also instructed the patient recruiters to pay the patients \$50 from that amount for participating in the scheme. The Medicare beneficiaries who received the kickback payments also agreed to feign certain symptoms and subject themselves to medically unnecessary diagnostic tests and examinations which led to the patients' medical records to contain information about false symptoms. The co-conspirators used the falsified records to deceive Medicare about the legitimacy and medical necessity of the tests it performed. The court sentenced a co-conspirator who was a patient recruiter to a 24 month prison term in this case, and ordered the defendants to pay \$2 million in restitution to Medicare.
- In March 2010, the court sentenced an owner/operator of two fraudulent medical clinics to 96 months in prison for her role in a series of fraud schemes and ordered her, along with other co-conspirators, to pay over \$10.7 million in restitution to Medicare. The clinic owner, a Miami resident, devised the schemes with another co-conspirator to open and operate two clinics in Detroit that purported to specialize in infusion and injection therapy services when in fact the clinics' sole purpose was to defraud Medicare. She admitted that Medicare beneficiaries were not referred to the clinics by their primary care physicians, or for any other legitimate medical purpose, but rather were recruited through the payment of kickbacks in the form of cash and prescriptions for narcotic drugs. In exchange for those

kickbacks, the Medicare beneficiaries would visit the clinic and sign documents indicating that they had received the services billed to Medicare. A physician co-conspirator, who was convicted in a jury trial and sentenced to a 72 month prison term for his role in the scheme, routinely prescribed medications for patients that they did not need or were never provided. Five other co-conspirators, including a patient recruiter, have received prison sentences ranging from seven to 72 months, and three other defendants were sentenced to time served or one-day plus supervised release terms of at least two years, and two co-owners await sentencing in February 2011.

- In January and February 2010, two managers at separate infusion therapy clinics were sentenced to prison terms and ordered to pay a combined \$1.8 million in restitution for conspiracy to commit health care fraud. The manager and part owner of one clinic in Michigan was sentenced to 63 months in prison and ordered to pay \$1.7 million in restitution after pleading guilty to conspiracy to commit health care fraud. The manager/owner, along with other owners of the infusion therapy clinic, recruited and paid patients \$50 per visit to purport to have received legitimate services. The clinic then billed Medicare for beneficiary medications (primarily Cosyntropin and Interferon) and services that were medically unnecessary and/or not provided. The manager of a second clinic was sentenced to 1 year and 1 day of incarceration and ordered to pay \$81,762 in restitution for health care fraud. This individual obtained a doctor's provider enrollment information, without the doctor's knowledge, to apply for and obtain a Medicare provider number. He then used this information to submit false claims to the Medicare program for infusion therapy services that were never provided.

Phase 4: Houston (Southern District of Texas)

- In July 2010, the U.S. district court in Houston sentenced a patient recruiter for a fraudulent DME company to a 21 month prison term following her April trial conviction along with the DME owner. The court also ordered the patient recruiter to pay restitution in the amount of \$807,781 to Medicare. The defendant was a patient recruiter and the DME owner and other co-conspirators paid her kickbacks in exchange for providing the company with beneficiaries in whose names they could submit claims to Medicare for medically unnecessary DME, including power wheelchairs, wheelchair accessories and motorized scooters. The defendants billed Medicare using a special code that designated the equipment as replacements for wheelchairs lost during hurricanes that hit the Houston area in 2008. The code allowed the company to submit claims to Medicare without a doctor's order. Beneficiaries, all of whom could walk, testified at trial that the defendant came to their homes and offered them free power wheelchairs in exchange for their Medicare information, and that they did not need the wheelchairs which were often billed to Medicare at more than \$6,000 per chair. The DME owner is awaiting sentencing and a third co-conspirator is a fugitive.
- In June 2010, a Federal jury convicted a physician and two DME delivery drivers in a \$2.2 million dollar Medicare fraud scheme following a two-week trial. Trial evidence established that a Houston-area DME company fraudulently billed Medicare for power wheelchairs and orthotic devices from 2003 until late 2009. Seven other co-conspirators

have pleaded guilty for their participation in the scheme, including the company's owner and its operator. (All ten defendants are awaiting sentencing, which is scheduled for December 3, 2010.) According to evidence presented at trial, the DME owner worked with a Medicare biller (whose case has been transferred to another district) and others to submit false claims to Medicare using fraudulent documents which identified the convicted doctor as the prescribing physician for the DME. Upon learning about the prescriptions, the doctor asked and the DME owner agreed to pay \$10,000 in exchange for allowing the fraud scheme to continue. Trial evidence also showed that both delivery drivers were fully aware of the fraudulent business practices of the DME owner. One driver admitted that he hoped to open his own DME business. The other driver delivered DME such as power wheelchairs and orthotics to beneficiaries who testified that they did not want or need the equipment.

- In August 2010, the court sentenced a retired nurse to a 33 month prison term following her trial conviction in January of charges of conspiracy to commit health care fraud and health care fraud for participating in a kickback arrangement with a DME company owner who agreed to pay her 10 percent of what Medicare paid his company for each patient the nurse referred to the company. In October 2010, the court gave a 22 month sentence to the DME company owner following his guilty plea and cooperation with the government investigation. The two co-conspirators submitted over \$740,000 in phony claims to Medicare for enteral nutrition supplies and for bundles of orthotics, referred to as "artho kits." Medicare regulations require that a beneficiary have a feeding tube in order to bill for enteral nutrition supplies. The forms the nurse provided indicated that the beneficiaries she referred to the DME supplier had a feeding tube when in fact trial evidence revealed that none of the patients actually had a feeding tube. The nurse also provided the DME owner with high-dollar Medicare codes for specialized enteral food supplements when in fact the co-conspirators gave patients over-the-counter supplements, one of which stated on the bottle that it was 'not for tube feeding.' Similarly, the nurse provided the DME owner with a product list of inexpensive over-the-counter products to be included in the artho kit and the Medicare codes to be used to instead bill for expensive high-end orthotics.

Phase 5: Brooklyn (Eastern District of New York)¹²

- On December 15, 2009, the Departments of Justice and Health and Human Services announced the expansion of Strike Force operations to Brooklyn, Baton Rouge and Tampa.
- On December 15, 2009 the U.S. district court in the Eastern District of New York unsealed an indictment charging an owner and operator of a Brooklyn medical provider and its director of customer service with conspiring to defraud Medicare for diabetic supplies and equipment that was not medically necessary from July 2006 through

¹²For new Strike Force locations which have recently been announced during FY 2010, the report includes indictments that have been filed during the fiscal year. Due to the timing, plea negotiations, trials and sentencing proceedings are currently pending. Successful cases will be included in the FY 2011 HCFAC report.

November 2009.

- On July 16, 2010, Strike Force prosecutors in Brooklyn unsealed charges against 22 defendants for their alleged participation in schemes to submit fraudulent claims totaling approximately \$78 million for physical and occupational therapy and DME. The cases included the following:
 - A criminal complaint and affidavit filed in support of an application for arrest warrants charging eight defendants, including two physicians, in a \$72 million scheme to defraud the Medicare program by submitting fraudulent claims for physical therapy and other medical services that were medically unnecessary or were not provided to beneficiaries at all. The government's investigation included the use of a court-ordered camera and microphone hidden in a room at the clinic, identified in the complaint as the "Kickback Room," in which the conspirators allegedly paid cash kickbacks to corrupt Medicare beneficiaries. The camera recorded the conspirators' payment of approximately one thousand bribes totaling more than \$500,000 during a period of approximately six weeks from April to June 2010. The Kickback Room was marked "PRIVATE" and featured a poster picturing a woman with a finger to her lips and the words "Don't Gossip" in Russian. The purpose of the kickbacks was to induce the beneficiaries to receive unnecessary medical services or to stay silent when services not provided to the patients were billed to Medicare. Federal agents searched the clinic at the time of the arrests.
 - A criminal complaint and affidavit in support of an application for arrest warrants charging three defendants for their involvement in a \$3.5 million scheme to defraud the Medicare and Medicaid programs by submitting fraudulent claims for DME involving oxygen equipment and supplies. Allegedly, the owner of an oxygen equipment services company and two patient recruiters targeted local churches to find Medicare and Medicaid beneficiaries whose personal information the defendants could use to facilitate their fraudulent billings.
 - A superseding indictment charging a corporate officer, consultant, patient recruiter, and two beneficiaries and a criminal complaint charging six "serial" or "over-utilized" Medicare beneficiaries for their roles in a \$2.8 million scheme to defraud the Medicare program by submitting fraudulent claims for physical and occupational therapy. Each of the defendant beneficiaries attended the medical clinic involved in the scheme for the purpose of receiving kickback payments, and either received medically unnecessary services or did not receive the medical services that were billed to the Medicare program. Each of the beneficiaries was "over-utilized" or "serial" in the sense that they purported to seek medical treatment from numerous providers who submitted multiple claims to Medicare for those purported treatments. During the period of January 2004 through February 2010, each of the defendant beneficiaries caused the submission of more than 2,200 claims for medical services under

their names, and the most “over-utilized” beneficiary caused the submission of more than 3,744 claims under her name.

Phase 6: Baton Rouge (Middle District of Louisiana)

- On July 16, 2010, 31 defendants were charged in Baton Rouge for various schemes allegedly involving fraudulent claims for DME totaling approximately \$32 million. The defendants include the owners and operators of nine different purported medical services companies and four doctors, 14 patient recruiters and other individuals who allegedly worked at the medical services companies. These cases include the following:
 - A criminal indictment charging two corporate officers and operators of three DME companies, two doctors, and ten patient recruiters for allegedly conspiring to submit more than \$21 million in false and fraudulent claims to Medicare. In addition, one corporate officer also was charged with four counts of aggravated identity theft. As charged, from June 2004 through October 2009, the operators of the DME companies allegedly paid kickbacks to patient recruiters in exchange for names and billing information of Medicare beneficiaries, as well as fraudulent prescriptions, for the purpose of billing Medicare for medically unnecessary DME. The indictment also charges that the doctors, one who is licensed in Louisiana, and the second who is licensed in Mississippi, provided prescriptions to patient recruiters for medically unnecessary DME, which included various orthotic devices, power wheelchairs and accessories.
 - A criminal indictment charging a DME owner and operator, a doctor, and two patient recruiters with conspiring to defraud Medicare of more than \$4.7 million over the period of December 2003 through March 2009. The DME owner allegedly paid kickbacks to the doctor for writing prescriptions for medically unnecessary DME and to the patient recruiters in return for referrals of Medicare beneficiaries whose names could be used to submit fraudulent claims to Medicare.

Fraud by Pharmaceutical and Device Manufacturers and Related Individuals

- In August 2010, Allergan, Inc. (“Allergan”) agreed to plead guilty to misdemeanor misbranding and pay \$600 million (including a \$375 million criminal fine and forfeiture and a \$225 million civil settlement) to resolve criminal and civil liability arising from the company’s promotion of Botox® for indications that had not been approved as safe and effective by the FDA, including headache, pain, spasticity and juvenile cerebral palsy. In addition to off-label marketing, the civil settlement resolves allegations that Allergan misled doctors about the safety and efficacy of Botox® for off-label indications, instructed doctors to miscode uncovered Botox® claims to ensure payment by government healthcare programs, and paid kickbacks to doctors. Allergan also entered into a 5-year Corporate Integrity Agreement (CIA) with HHS/OIG.

- In September 2010, Novartis Pharmaceuticals Corporation agreed to pay \$422.5 million to resolve criminal and civil liability arising from the illegal marketing of certain pharmaceutical products. The company agreed to plead guilty to a misdemeanor and pay a \$185 million combined criminal fine and forfeiture for off-label marketing of the anti-epileptic drug Trileptal. In addition the company agreed to pay \$237.5 million to resolve civil allegations that it unlawfully marketed Trileptal and five other drugs, Diovan, Zelnorm, Sandostatin, Exforge, and Tekturna. Specifically, the civil settlement resolves allegations of off-label promotion with regard to Trileptal and provision of kickbacks to health care professionals in connection with Trileptal and the five other drugs.
- In April 2010, AstraZeneca LP and AstraZeneca Pharmaceuticals LP (AstraZeneca) paid \$520 million to resolve FCA allegations that they marketed the atypical antipsychotic drug, Seroquel, for uses not approved by the Food and Drug Administration (FDA) and paid kickbacks to doctors. Of the \$520 million, \$301.9 million was the Federal share and \$218.1 million went to states that decide to participate in the agreement. In addition, AstraZeneca entered into a strict CIA with HHS/OIG.
- In March 2010, a subsidiary of KV Pharmaceutical pleaded guilty to felony charges pursuant to a plea agreement and paid a combined \$27.5 million in criminal penalties and restitution. The subsidiary, Ethex Corporation, failed to submit required “field alert reports” after it learned that it had manufactured and distributed oversized pills, including pills of a pain-relief drug, anti-arrhythmia drug, and a drug to treat attention deficit disorder in children.
- In October 2009, Mylan Pharmaceuticals Inc. (“MPI”), UDL Laboratories, Inc. (UDL), AstraZeneca Pharmaceuticals LP, and Ortho McNeil Pharmaceutical Inc. paid a total of \$124 million to resolve FCA allegations that they underpaid their rebate obligations with respect to certain of their drugs. By agreeing to participate in the Medicaid Rebate Program and signing these Rebate Agreements, these companies agreed to pay quarterly rebates to Medicaid that were based upon the amount of money that Medicaid paid for each company’s drugs. The precise amount of a rebate is determined in part by whether a drug is considered an “innovator” drug or a “non-innovator” drug. The rebate that must be paid for innovator drugs is higher than the rebate for non-innovator drugs. The government alleged that these companies misclassified their drugs as “non-innovator” to reduce their rebate obligations to Medicaid.
- In September 2010, Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc. agreed to pay more than \$313 million to resolve allegations of civil and criminal liability relating to obstruction of justice, the distribution of an unapproved new drug, Levothroid, and the illegal promotion of Celexa for use in treating children and adolescents. With respect to its civil liability, Forest paid \$89 million to federal programs and \$60 million to state Medicaid programs to resolve allegations that it caused the submission of false claims to federal health insurance programs by (1) illegally promoting the drugs Celexa and Lexapro for unapproved pediatric uses in treating depression, (2) paying kickbacks to physicians through a variety of programs designed to induce providers to prescribe Celexa

and Lexapro in violation of the Anti-Kickback Statute, and (3) distributing Levothroid in violation of the Food, Drug, and Cosmetic Act (FDCA). To resolve its criminal liability, Forest agreed to plead guilty to felony and misdemeanor counts and pay a \$164 million combined criminal fine and forfeiture.

- In July 2010, the government prevailed on post-trial motions by a defendant, who was convicted by a jury in September 2009 of wire fraud relating to statements made in an August 2002 press release announcing the results of a clinical trial of the biologic Actimmune. The defendant was President and CEO of Intermune, Inc., a biotechnology firm whose principal product was Actimmune, which was approved by the FDA for two rare childhood diseases. Intermune conducted a clinical trial to determine if Actimmune could be used as a treatment for idiopathic pulmonary fibrosis (IPF), a fatal lung disease. The trial failed, and upon learning of the results, FDA notified Intermune that it would not approve Actimmune as a safe and effective treatment for IPF based on that trial. Despite these facts, the defendant manipulated the trial data and published a press release announcing that the drug demonstrated a survival benefit in patients with IPF. After the press release was issued, sales of Actimmune increased dramatically, resulting in millions of dollars of revenue for the company. The defendant is scheduled to be sentenced in March 2011.
- In August 2010, Teva Pharmaceuticals paid \$100 million to resolve allegations that Teva knowingly reported inflated drug prices and thereby caused the submission of false claims to the Medicaid program. Many of the state Medicaid programs established their reimbursement rates for drugs based on the average wholesale prices reported by manufacturers such as Teva to three leading pricing compendia. By inflating the prices they reported to the compendia, Teva and other manufacturers could cause the government to set reimbursement rates far above the actual prices paid to them by their customers, such as retail pharmacies. The manufacturer would then “market the spread” between the actual prices it charged its customers and the amount the government would later reimburse the customer, in order to induce higher sales.
- In May 2010, Ortho-McNeil Pharmaceutical LLC and Ortho-McNeil-Janssen Pharmaceuticals Inc., both subsidiaries of Johnson & Johnson, paid more than \$81 million to resolve criminal and civil FCA liability arising from the illegal promotion of the epilepsy drug Topamax. The government alleged that Ortho-McNeil Pharmaceutical promoted the sale of Topamax for off-label psychiatric uses through a practice known as the “Doctor-for-a-Day” program. Using this program, Ortho-McNeil hired outside physicians to join sales representatives in their visits to the offices of health care providers and to speak at meetings and dinners about prescribing Topamax for unapproved uses and doses. As part of the global resolution, Ortho-McNeil Pharmaceutical LLC pled guilty to a misdemeanor and paid \$6.1 million criminal fine for the misbranding of Topamax in violation of the FDCA. In addition to the criminal fine, Ortho-McNeil-Janssen Pharmaceuticals paid \$75.4 million to resolve civil allegations under the FCA that they illegally promoted Topamax and caused false claims to be submitted to government health care programs for a variety of psychiatric uses that were not medically accepted indications and therefore not covered by those programs. Finally, Ortho-McNeil entered

into a 5-year CIA with HHS/OIG.

- In May 2010, Novartis Vaccines & Diagnostics, Inc. and Novartis Pharmaceuticals Corporation paid \$72.5 million to resolve civil FCA allegations arising from off-label marketing of the cystic fibrosis drug TOBI for diseases other than cystic fibrosis for patients who did not meet the parameters of the FDA-approved indication. The United States alleged that this conduct, carried out by Novartis and a predecessor company Chiron Corporation, caused false claims to be submitted to federal health care programs for certain off-label uses of the drug between January 1, 2001 and July 31, 2006.
- In March 2010, American pharmaceutical manufacturer Alpharma Inc. paid \$42.5 million to resolve FCA allegations in connection with the marketing of the morphine-based drug Kadian. The settlement resolves allegations that, between January 1, 2000 and December 29, 2008, Alpharma paid health care providers to induce them to promote or prescribe Kadian, and made misrepresentations about the safety and efficacy of the drug, which is used to treat chronic moderate to severe pain.
- In July 2010, Cardinal Health and Bindley Western Industries, Inc., wholesale pharmaceutical distributors and Department of Defense (DOD) Prime Vendors, agreed to pay \$5.5 million to resolve claims that they overcharged the government. Cardinal and Bindley had agreed to acquire pharmaceutical products from drug manufacturers and to distribute the products to DOD medical treatment facilities. Cardinal and Bindley had agreed not to charge the government more than the prices negotiated between the DOD and drug manufacturers. However, the United States contended that between June 1997 and December 31, 2000, Cardinal and Bindley charged the government more than the negotiated prices for certain pharmaceutical purchases, which resulted in an overpayment by the government.
- In December 2009, Boston Scientific Corporation paid \$22 million to resolve allegations that its subsidiary, Guidant Corporation, used post-market studies as vehicles to pay kickbacks to induce physicians to implant Guidant pacemakers and defibrillators. Post-market studies are studies that ostensibly assess the clinical performance of a medical device or drug after that device or drug has been approved by the FDA. The government alleged that Guidant knowingly and intentionally designed and used four post-market studies as a means of increasing device sales. Through the studies, according to the Federal government, Guidant paid physicians to select its devices to implant in their patients rather than devices manufactured by Guidant's competitors. Each of the four studies required participating physicians to implant multiple Guidant devices. As part of the settlement, Boston Scientific entered into a CIA with HHS/OIG.
- In December 2009, Spectranetics Corporation paid the United States \$4.9 million in civil damages plus a \$100,000 forfeiture to resolve FCA allegations that the company illegally imported unapproved medical devices and provided them to physicians for use in patients, conducted a clinical study in a manner that failed to comply with federal regulations and promoted certain products for procedures for which the company had not received FDA

approval or clearance. The company manufactures, distributes and sells certain medical lasers and peripheral devices for those lasers, such as lead wires that guide the lasers through vascular tissue and catheters that carry and contain the lasers inside the veins, including, specifically, the CVX-300 Medical Laser and the CliRpath Turbo Laser Catheter, the TURBO Elite Laser Ablation Catheter, and the TURBO-Booster Laser Guide Catheter. In addition to paying civil damages, Spectranetics entered a non-prosecution agreement with the United States and a CIA with HHS-OIG.

- In January 2010, Atricure, Inc., a medical device manufacturer, paid the United States \$3.7 million to resolve FCA claims in connection with the alleged promotion of its surgical ablation devices. Surgical ablation devices use focused energy to create controlled lesions or scar tissue on a patient's heart or other organs. The settlement resolves allegations that the Atricure marketed its medical devices to treat atrial fibrillation (the most common cardiac arrhythmia or abnormal heart rhythm), a use that is not approved by the FDA. Atricure also allegedly promoted expensive heart surgery using the company's devices when less invasive alternatives were appropriate, advised hospitals to up-code surgical procedures using the company's devices to inflate Medicare reimbursement, and paid kickbacks to health care providers to use its devices. The United States asserted that by engaging in this conduct, Atricure knowingly violated the FDCA and caused the submission of false and fraudulent claims in violation of the FCA.
- In February 2010, Eon Labs, Inc., a subsidiary of Sandoz, Inc., paid \$3.5 million to resolve FCA allegations relating to the company's drug Nitroglycerin Sustained Release (SR) capsules. In April 1999, the FDA determined that Nitroglycerin SR lacked substantial evidence of effectiveness and published a notice proposing to withdraw approval of the product. The government contended that, after the FDA notice, Nitroglycerin SR no longer was legally eligible for reimbursement by government health care programs such as Medicaid. The government further alleged that from April 1999, and continuing through September 2008, Eon submitted false quarterly reports to the government that misrepresented Nitroglycerin SR's regulatory status and failed to advise that Nitroglycerin SR no longer qualified for Medicaid coverage. As a result, the government contends, Eon knowingly caused false Medicaid claims to be submitted for Nitroglycerin SR.
- In October 2009, as part of a global criminal, civil, and administrative settlement, Biovail Corporation (Biovail) agreed to pay \$24.7 million to resolve its liability related to the marketing and promotion of the drug Cardizem, L.A., an extended-release version of a heart medication to control high blood pressure. From 2003 to 2004, Biovail Pharmaceuticals, Inc. (BPI), a U.S. subsidiary of Canada-based Biovail, allegedly paid physicians and other medical prescribers up to \$1,000 each to induce them to recommend and/or write prescriptions for Cardizem, L.A., thereby causing false and/or fraudulent claims for payment to be submitted to Medicaid. Under the civil resolution, Biovail agreed to pay \$2.5 million plus interest to settle its potential FCA liability. Under the criminal resolution, BPI pleaded guilty to conspiracy and kickback charges and was ordered to pay an assessment of \$2,800 and a criminal fine of \$22.2 million. In addition to the monetary settlement, Biovail agreed to enter a 5-year CIA with HHS/OIG.

Hospital Fraud

- In December 2009, Our Lady of Lourdes Health Care Services Inc., the parent company of two New Jersey hospitals, paid \$7.9 million to resolve FCA allegations that the hospitals defrauded Medicare. The settlement resolves allegations that the hospital wrongfully obtained excessive outlier payments. In addition to its standard payment system, Medicare provides supplemental reimbursement, called outlier payments, to hospitals and other health care providers in cases where the cost of care is unusually high. Congress enacted the supplemental outlier payments system to give hospitals the incentive to treat inpatients whose care requires unusually high costs.
- In July 2010, Mercy Health System of Southeastern Pennsylvania; Mercy Catholic Medical Center, Mercy Fitzgerald Hospital Division; Mercy Catholic Medical Center, Mercy Philadelphia Hospital Division; and Mercy Suburban Hospital paid the United States \$7.9 million to resolve FCA claims that the hospitals improperly billed Medicare for one day inpatient hospital admissions between October 1, 2001 and September 30, 2007 that should have been coded as observations or outpatient visits. Because inpatient admissions are compensated at a higher rate than observations or outpatient visits, admitting patients who did not meet Medicare/Medicaid criteria for admission resulted in a higher reimbursement for the hospitals.
- In December 2009, Kaiser Foundation Hospitals, Kaiser Foundation Health Plan, Inc., the Permanente Medical Group and Southern California Permanente Medical Group (collectively, “Kaiser”) paid a total of \$3.7 million to resolve allegations arising from voluntary disclosures that, during the period January 1, 1996, through October 1, 2002, Kaiser did not comply with Medicare guidance concerning billing by teaching physicians who supervise medical residents. Specifically, Kaiser disclosed that it billed Medicare for outpatient services performed by residents even though the teaching physicians were not physically present during the key and critical portions of the services rendered. The voluntary disclosures were made by Kaiser in 2005 to HHS/OIG pursuant to the HHS-OIG self-disclosure protocol. Of the total settlement amount, \$3.3 million represents the Federal share (Medicare and the Federal portion of Medi-Cal) and \$352,460 represents the state share of Medi-Cal.
- In February 2010, Brookhaven Memorial Hospital Medical Center of Patchogue, New York, paid \$2.92 million, plus interest, to resolve allegations that it misled the Medicare program about its costs of care and thereby obtained excessive Medicare outlier payments. Similarly, in November 2009, Lourdes Medical Center of Burlington County paid \$1.2 million and Helene Fuld Medical Center paid \$750,062 to resolve FCA allegations in connection with a scheme to seize excessive Medicare outlier payments. Outlier payments are supplemental funds that are intended to compensate hospitals for treating patients who are extraordinarily costly to treat relative to other patients with similar illnesses or injuries.
- In January 2010, Wheaton Community Hospital of Wheaton, Minnesota, a critical access hospital, settled allegations of admitting patients unnecessarily, resulting in fraudulent overpayments totaling more than \$1 million over a six-year period. A review of 170

admissions determined that about 30% of the admissions were unnecessary. Settlement was reached in the amount of \$1.31 million against the hospital and \$102,500 against an individual physician.

- In April 2010, the former chief financial officer of Tustin Hospital and Medical Center of Tustin, California, pleaded guilty to paying illegal kickbacks for patients who were recruited from the “Skid Row” area of Los Angeles. The defendant admitted operating a scheme to pay illegal kickbacks to “marketers” who recruited homeless persons from Los Angeles’ Skid Row and had them transported to Tustin Hospital. In this scheme, the defendant paid the operator of a center on Skid Row, which recruited homeless people to receive unnecessary health services, and others to refer homeless Medicare and Medi-Cal beneficiaries to Tustin Hospital for in-patient hospital stays. As part of the scheme, Tustin Hospital entered into sham “consulting” contracts intended to conceal the illegal kickbacks. Tustin billed Medicare and Medi-Cal for in-patient services provided to the recruited homeless beneficiaries, including those for whom in-patient hospitalization was not medically necessary. The defendant is the fifth person to be convicted in relation to an ongoing investigation into health care fraud related to Skid Row residents.
- In October 2009, SCCI Hospitals of America, Inc., which operates a chain of long-term acute-care hospitals (LTACH), agreed to pay \$830,166 to resolve its liability under the FCA. Between October 1, 2004, and September 2, 2005, SCCI allegedly (1) improperly admitted patients to its Michigan facility who did not meet LTACH criteria, (2) held and treated patients who no longer needed hospitalization in order to increase Medicare reimbursement, (3) requested referring physicians to modify original orders to circumvent medical-necessity requirements, (4) inappropriately discharged patients who were not well enough for discharge, and (5) upcoded diagnosis-related group (DRG) classifications.

Fraud by Physicians

- In March 2010, the United States executed a \$12 million dollar settlement of allegations that a physician and Melbourne Internal Medicine Associates (MIMA) violated the FCA by submitting false claims to Medicare and TRICARE. In the complaint filed by the United States on October 16, 2009, the government alleged that from the time of its inception through 2008, the MIMA Cancer Center, led by the physician, defrauded the federal health care programs by improperly inflating claims through various schemes specifically designed to cloak MIMA Cancer Center’s fraudulent practices. In particular, the MIMA Cancer Center allegedly billed for services not supervised, duplicative and unnecessary services, services not rendered, and upcoded services.
- In February 2010, a physician and his wife were sentenced in relation to a health care fraud scheme to defraud Medicare, Medicaid, and other health care benefit programs through his pain management business located in Ohio. The scheme involved millions of dollars of fraudulent claims for payment for medical services that were either not performed or that were not medically necessary. The medical doctor, who is an Egyptian national here on a work visa, was sentenced to 42 months imprisonment with 36 months of supervised release, and ordered to forfeit and pay \$6.9 million in restitution to his

victims. The defendant physician agreed to surrender his license to practice medicine in the state of Ohio. Upon recommendation of both the United States and the defense, the physician's wife was sentenced to 24 months of probation, which includes 12 months of home detention with electronic monitoring. The defendants will be deported to Egypt after completion of their respective sentences.

- In August 2010, a Louisiana psychiatrist pleaded guilty to fifteen counts of failing to prepare and maintain records, with intent to defraud and mislead, in connection with clinical trials to evaluate the efficacy and safety of Paxil in children and adolescents with Obsessive-Compulsive Disorder (OCD). Defendant, a clinical investigator for SmithKline Beecham d/b/a GlaxoSmithKline, included psychiatric diagnoses inconsistent with patients' psychiatric histories; prepared multiple psychiatric evaluations on study patients which contained different diagnoses and treatment plans; reported symptoms of OCD when she knew that the study subject did not demonstrate such symptoms; and reported that she had examined study subjects when she had not. The defendant was sentenced to 13 months in prison and ordered to pay restitution to GlaxoSmithKline in the amount of \$91,824 and \$1,500 in special assessments.
- In December 2009, the owner and managing pharmacist of The Rx Shop was sentenced to 18 months' incarceration and ordered to pay \$738,000 in restitution after pleading guilty to submitting false claims to Medicare and Medicaid. From 2005 through 2007, this individual submitted false claims for prescription medications that were never dispensed. The investigation was conducted jointly with the Florida Department of Law Enforcement and the Florida Medicaid Fraud Control Unit (MFCU).
- In March 2010, a Virginia hematologist and oncologist was convicted following a jury trial, sentenced to 63 months incarceration, and ordered to pay \$790,641 in restitution for health care fraud, false statements relating to health care matters, and alteration of records to obstruct an investigation. This individual defrauded Medicare and TRICARE by billing for more chemotherapy drugs than patients received and for submitting claims for office visits at a higher reimbursement level than what was rendered. He also directed his staff to alter and falsify patient record entries to support the false claims.
- In May 2010, a Pennsylvania physician was sentenced to 12 months and 1 day in prison for health care fraud. Previously, the physician agreed to pay \$3.3 million to resolve his liability under the FCA. The civil settlement resolved allegations that from January 2003 to August 2008, he submitted claims to Medicare, TRICARE, and the Federal Employees Health Benefits Program for services not rendered to his patients either because the physician was not in the office or the patients were in hospitals under the care of other physicians on the dates claimed. He also regularly billed for treatments that his patients never received
- In June 2010, a Pennsylvania pediatrician was sentenced to 96 months incarceration and ordered to pay \$7.1 million in restitution after pleading guilty to charges of health care fraud, mail fraud, and forfeiture. From 2003 through 2009, the pediatrician submitted

fraudulent claims to Medicaid, TRICARE, and private insurance companies for services not rendered. The investigation involved the South Carolina Attorney General's MFCU and Insurance Fraud Division, and the Cumberland County, Pennsylvania District Attorney's Office.

Fraud by Other Practitioners

- In January 2010, FORBA Holdings LLC, a dental management company that provides business management and administrative services to 69 clinics nationwide known as "Small Smiles Centers", agreed to pay the United States and participating states \$24 million, plus interest, to resolve FCA allegations that it caused bills to be submitted to state Medicaid programs for medically unnecessary dental services performed on children insured by Medicaid. In particular, the United States alleged that FORBA was liable for causing the submission of claims for reimbursement for a wide range of dental services that were either medically unnecessary or performed in a manner that failed to meet professionally-recognized standards of care. These services included performing pulpotomies (baby root canals), placing crowns, administering anesthesia (including nitrous oxide), performing extractions, and providing fillings and/or sealants. As part of the resolution, FORBA entered into a 5-year CIA with HHS/OIG.
- In January 2010, in Arkansas, a former Licensed Practical Nurse was sentenced to 78 months imprisonment and ordered to pay restitution of \$611,800 to the hospital, \$131,000 to the hospital's insurer for a dishonest employee loss claim, and approximately \$300,000 to federal health care programs for the false claims paid. The defendant was convicted of paying cash kickbacks to a hospital employee to order large amounts of the orthopedic products for which defendant's wife received commissions.
- In January 2010, a doctor of podiatric medicine was sentenced to a term of 18 months in prison on health care fraud charges. The defendant joins seven other doctors of podiatry who have been sentenced for their participation in a large-scale Medicare and health care fraud scheme at podiatry clinics located throughout New York City. At various times during the course of the scheme, the defendant employed other podiatrists at a number of affiliated foot-care clinics located in Manhattan, the Bronx, Queens, and Brooklyn (the "Citywide Clinics"). Through the Citywide Clinics, the defendant participated in orchestrating a scheme to cheat Medicare and private insurance companies by several means, including soliciting patients off the street with flyers offering "free treatment," when in fact the treatment was "free" only because Medicare's requirement that patients be responsible for the 20 percent co-payment was ignored. The scheme also involved falsifying the nature of their patients' medical conditions in order to obtain reimbursement from Medicare and private health care insurance companies for routine foot care services which otherwise would have been non-reimbursable; and directing the podiatrists at the Citywide Clinics to perform unnecessary medical procedures on their elderly patients.
- In December 2009, a Virginia man was sentenced in the District of Columbia to 13 months in prison followed by three years of supervised release for impersonating a doctor.

In addition, the defendant was ordered to pay \$16,800 in restitution. The defendant pretended that he was a doctor and prescribed medicine by using the identities of four different victim doctors. In truth, the defendant was never a licensed medical doctor and was not authorized to practice medicine. He also lacked the authority to prescribe controlled substances, as he did not hold the necessary Drug Enforcement Administration (DEA) registration number or state and local licenses. Over the course of the scheme, more than 200 patients saw the defendant and believed him to be a licensed medical doctor capable and authorized to treat mental health illnesses. During the time, the defendant wrote approximately 226 prescriptions for controlled substances for patients and forged the signature of a doctor for each of these prescriptions.

- In July 2010, two defendants were sentenced in Texas to 61 months and 30 months in prison respectively, for their roles in a \$400,000 healthcare fraud scheme and ordered to pay restitution in the amount of \$366,000. The defendants, doing business as Narvaez Family Provider Services, conspired to defraud the Texas Medicaid and Title XX Block Grants to States for Social Services programs administered by the Texas Department of Aging and Disability Services (DADS). The defendants admitted that after fraudulently obtaining a DADS provider license and a contract to provide services to program recipients, they engaged in a corrupt and systematic practice of falsifying client records, forging physician certifications and billing DADS for unauthorized services and services not rendered.
- In November 2009, a podiatrist was sentenced to 36 months' incarceration and ordered to pay \$5.4 million in restitution for health care fraud and making false statements. The podiatrist systematically billed Medicare for routine foot care not covered by Medicare and billed for services not rendered, such as costly nerve conduction tests and abscess drainages. In addition to his sentencing, this individual surrendered his license to practice podiatry in the state of New York.

Fraud by Pharmacies

- In December 2009, Meijer, Inc., a retail grocery and merchandise store with locations in four states, paid nearly \$2 million to the United States to resolve FCA allegations involving the Medicare, Medicaid, and TRICARE programs. Additional amounts were disbursed to states. Over at least a 6-year period, Meijer employed four pharmacists on the HHS/OIG exclusion list, and Meijer billed the government for prescription drugs dispensed by the pharmacists. The pharmacists had been initially placed on the exclusion list following convictions for illegal drug possession and related charges. After learning of the problem, Meijer submitted a self-disclosure to HHS/OIG in 2007. The settlement resulted from that disclosure.
- In March 2010, in Connecticut, a pharmacist and the former owner of RG Pharmacy, Inc. paid \$1.1 million to resolve allegations that he submitted claims to Medicare and Medicaid from 1999 to 2007 for false dispensing fees that pharmacies are allowed to charge for filling prescriptions. Through a fraudulent billing scheme, the pharmacist and

RG Pharmacy were able to receive multiple dispensing fees for each filled prescription instead of the one fee to which the pharmacy was entitled to. In addition to settling their civil liability, the pharmacist and RG Pharmacy also agreed to be excluded from participation in all federal health care programs for seven years.

- In October 2010, a New Jersey pharmacy, PBR Drugs, Inc., doing business as Towne Pharmacy, pleaded guilty to one count of health care fraud, and was sentenced to one year of probation and ordered to pay \$730,258 in restitution. PBR Drugs' managing pharmacist, also pled guilty to one count of conspiracy to commit health care fraud, and was sentenced to three years' probation and to the payment of restitution (as noted above). At the time of his plea, defendant admitted that he conspired to submit claims for reimbursement to various health insurers for medications that the pharmacy never dispensed.
- In April 2010, a Pennsylvania pharmacist was sentenced to 18 months in prison and ordered to pay \$576,000 in restitution after pleading guilty to charges of drug adulteration and misbranding, health care fraud, mail fraud, and aiding and abetting. The pharmacist, who owned and operated Bergman Pharmacy as a compounding pharmacy, replaced proprietary drugs with compounded versions without physician direction. He then billed Medicare and private insurers as if the proprietary drugs were dispensed. The investigation also revealed that the pharmacist's compounded drugs were contaminated with bacteria, and that he manufactured the compounded drugs without using medicinal quality water, wearing gloves, or wearing a mask. Additionally, in making a budesonide-based drug intended for asthma patients, he used chemicals such as ethyl alcohol and Everclear (a pure grain alcohol), which are severe irritants to the respiratory system.
- In August 2009, two individuals were found guilty in an unlawful prescription drug operation whereby they distributed powerful, addictive painkillers and anti-anxiety medications to thousands of customers nationwide. In May 2010, the first conspirator was sentenced to 75 months in prison and the second was sentenced to 60 months in prison for conspiracy to distribute schedule III and schedule IV controlled substances, distribution of a schedule III controlled substance, and aiding and abetting the unlawful distribution of controlled substances. According to evidence presented at trial, the two conspired with others to distribute prescription painkillers and anti-anxiety medications based on illegitimate prescriptions from one of the conspirator's online pharmacy. Individuals with no training or authority to write prescriptions conducted telephone interviews with customers, and then created drug orders bearing a doctor's photocopied signature. The defendants faxed the drug orders to Woody Pharmacy. The court found that this unlawful operation contributed to the deaths of three former customers. Previously, the owner of Woody Pharmacy was sentenced to 40 months in prison for charges related to this scheme.

Fraud by Clinics

- In October 2009, an employee of an infusion clinic was sentenced to 78 months' incarceration and ordered to pay \$14.0 million in restitution for her participation in a health care fraud conspiracy. The employee recruited and paid cash kickbacks to Medicare beneficiaries in exchange for allowing their Medicare numbers to be billed at numerous Miami-based infusion therapy clinics for medically unnecessary and nonrendered infusion therapy medication.
- In November 2009, the operator of three health care clinics was sentenced to 78 months' incarceration and ordered to pay restitution of \$1.5 million for health care fraud. This individual submitted claims to Medicare for office visits, physical therapy, and/or other procedures and diagnostic tests that were not needed and/or not rendered. The operator and others entered into illegal relationships with physicians and laboratories to establish medical practices using the providers' names and operated the practices as if they were run by the providers when, in fact, they were not. Once established, the operator controlled the practices and often paid physicians a relatively small flat fee to bill Medicare under their provider numbers. Kickbacks were given to "cappers" who recruited patients to come to the clinics in return for "freebies," such as DME and cash payments.

Fraud by Medical Equipment Suppliers

- In November 2009, Positive Home Oxygen, LLC (Positive), its owner, and the company's medical director were sentenced related to a DME fraud scheme. Positive was ordered to pay \$809,169 in restitution and was permanently excluded from the Medicare program. The owner was sentenced to 18 months' incarceration and ordered to pay \$200,000 in restitution, and the medical director was sentenced to 3 months' home detention and ordered to pay \$200,000 in restitution. Investigators determined that the owner and his company fraudulently billed Medicare for providing motorized wheelchairs to beneficiaries who did not qualify for the chairs. The medical director signed certificates of medical necessity for the chairs in exchange for referrals to his practice and cash.
- In March 2010, the owner of Enuda Healthsource, a DME company, was sentenced to 90 months' incarceration and ordered to pay \$4.6 million in joint and several restitution after pleading guilty to charges related to a scheme to defraud the Medicare program. From about December 2004 through July 2008, the owner, along with the owner of another DME company, submitted claims for more expensive DME than was delivered to beneficiaries and for DME that was medically unnecessary or not delivered at all. Employees from both DME companies falsely represented during presentations at Medicare beneficiaries' homes and churches that they could receive free medical equipment from the government. After the employees obtained beneficiaries' Medicare numbers, physicians' names, and their medical conditions, they completed fraudulent prescription forms for submission to Medicare. The owner of the second DME company was previously sentenced to 26 months incarceration and ordered to pay \$575,430 in restitution for health care fraud.

Quality of Care

- In FY 2010, nine employees at MultiEthnic Behavioral Health Services, Inc. (MEBH) were sentenced for charges related to health care fraud and the death of an at-risk child who was under MEBH's care. MEBH's co-founders, supervisor, and an employee were convicted of health care fraud, wire fraud, and conspiracy to obstruct a matter within the jurisdiction of a federal agency. One of the co-owners was also convicted of making false statements. Five other MEBH employees previously pleaded guilty to charges in connection with the fraud scheme. The nine defendants were sentenced to prison terms ranging from 15 months to 17 years and 6 months and were ordered to pay restitution ranging from \$316,000 to \$1.2 million. MEBH, a contractor for the Philadelphia Department of Health Services, came under Federal and local investigation in 2006 after the death of a 14-year-old special-needs child with cerebral palsy who was supposed to be receiving services from MEBH. Instead, the child was severely neglected to the point that she suffered severe bed sores and slowly starved, until she weighed only 42 pounds and died. After her death, one of the co-founders orchestrated a cover-up, including the destruction of old records and the fabrication of new false records.

Fraud by Nursing Homes

- In January 2010, five nursing homes operated by Cathedral Rock, a Texas corporation, pled guilty to felony health care fraud related to the failure to provide adequate care to the Medicare and Medicaid residents living in those homes. The majority owner of Cathedral Rock also entered into a criminal deferred prosecution agreement for a period of two years. Under the plea and deferred prosecution agreement, the five nursing homes and the owner jointly paid \$1 million in criminal fines and penalties. In addition, Cathedral Rock entities and the owner paid \$628,000 to resolve civil FCA allegations that they submitted false and fraudulent claims to Medicare and Missouri Medicaid. As part of the plea deal, the nursing homes admitted that, at times, their staffing was insufficient to provide adequate nursing care or to provide wound care; that residents often did not receive their medication as prescribed; that medical records were falsified and a "charting party" occurred to fill in medical records so that it appeared that all medication had been properly given, regardless of whether the medication was actually given or not; and that the nursing homes submitted fraudulent claims to Medicare and Missouri Medicaid for services that were not provided or were worthless.
- In May 2010, in South Dakota, Good Samaritan, a corporation which operates 230 nursing home facilities in virtually every state, agreed to pay \$480,137 to resolve allegations that the corporation employed a registered nurse who had been excluded by HHS. As part of the settlement, Good Samaritan was required to do a compliance review and certification during which the corporation uncovered six additional excluded employees working in facilities outside of South Dakota. Good Samaritan terminated those employees and voluntarily repaid an additional \$200,000. This case is particularly noteworthy, because what started as a relatively isolated, yet important deficiency, resulted in Good Samaritan improving its compliance program for all 230 facilities.

Kickbacks and Self-Referrals

- In December 2009, St. John Health System, paid \$13 million to resolve FCA allegations that it submitted claims to Medicare and Medicaid that were tainted by the hospital's financial relationships with referring physicians. Specifically, the United States determined that St. John made payments to 23 individual physicians or physician groups to induce referrals for medical services. The Stark law prohibits healthcare providers like St. John from billing a federal health care program for referrals from doctors with whom the providers have a financial relationship, unless that relationship falls within certain exceptions. Additionally, the Anti-Kickback Statute prohibits the payment of kickbacks for the referral of services that are paid for under a federal health care program. This settlement resulted from the company's self-disclosure to the HHS/OIG in April 2008.
- In May 2010, the Health Alliance of Greater Cincinnati and one of its former member hospitals, The Christ Hospital, located in Cincinnati, Ohio, paid \$108 million to settle claims that they violated the FCA by billing the Medicare and Medicaid programs for cardiac services that were referred to The Christ Hospital in exchange for improper financial incentives in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). Specifically, cardiologists were allocated time at The Christ Hospital's Heart Station, an outpatient cardiology unit where patients received non-invasive heart procedures such as electrocardiograms, echocardiograms and stress tests, based solely on the amount of coronary arterial bypass graft procedures and catheter laboratory revenues generated by each cardiologist, or cardiology group, for The Christ Hospital during the previous year. Cardiologists who were rewarded with time at the Heart Station had the opportunity to generate additional income by billing for the patients they treated at the Heart Station and for any follow-up procedures that these patients required.
- In November 2009, Omnicare, Inc., the nation's largest nursing home pharmacy, agreed to pay \$98 million, plus interest, to resolve FCA allegations that Omnicare submitted false claims to federal health care programs as a result of: providing consultant pharmacist services to nursing homes at below-cost and below-fair-market-value prices as a kickback to induce the nursing homes to use Omnicare's dispensing pharmacist services and purchase drugs from Omnicare; soliciting and receiving \$8 million in kickbacks from defendant IVAX Pharmaceuticals, Inc. (IVAX), in exchange for Omnicare's agreement to purchase \$50 million in drugs from IVAX; paying a multi-million dollar kickback, disguised as the purchase amount for a business, to defendants Mariner Health Care, Inc. (Mariner), and SavaSeniorCare Administrative Services, LLC (Sava), in exchange for agreements by Mariner and Sava to continue using Omnicare's pharmacy services for 15 years; and soliciting and receiving millions of dollars in kickbacks from defendant Johnson & Johnson in exchange for purchasing and recommending the drug Risperdal for use by patients in facilities served by Omnicare. In addition, IVAX agreed to pay \$14 million to resolve liability for its role in this scheme.
- In May 2010, Universal Health Services paid \$27.5 million to settle claims that it violated the FCA, the Anti-Kickback Statute and the Stark Law between 1999 and 2006, by paying

illegal compensation to doctors in McAllen, Texas, in order to induce them to refer patients to the company's hospitals. The settlement involved allegations that the defendants had entered into financial relationships with several doctors in McAllen in order to induce them to refer patients to the defendants' hospitals. The government alleged that these payments were disguised through a series of sham contracts, including medical directorships and lease agreements. Under the Stark Law, Medicare providers are prohibited from billing Medicare for referrals from doctors with whom the providers have a financial relationship, unless that relationship falls within certain exceptions. As part of the resolution, Universal Health Services also entered a five-year CIA with HHS/OIG.

- In May 2010, the Health Alliance of Greater Cincinnati, two of its member hospitals (The Fort Hamilton Hospital and The University Hospital), and University Internal Medicine Associates Inc. paid \$2.6 million to settle claims that they violated the Anti-Kickback Statute and the False Claims Act by engaging in a kickback-for-referral scheme. In particular, the government asserted that University Internal Medicine Associates, a physician group based at The University Hospital in Cincinnati, offered to provide the interventional cardiology coverage that The Fort Hamilton Hospital needed for the clinical trial, but only if the hospital agreed to refer cardiology patients and procedures to the physician group on a preferential basis. The government contended that the preferential referral arrangements sometimes resulted in patients being transferred to The University Hospital, or being seen by cardiologists with University Internal Medicine Associates, rather than the hospital or cardiologist of their choosing.
- In May 2010, Intercare Health Systems, Inc. (formerly doing business as City of Angels Medical Center), paid \$10 million to resolve FCA allegations that it paid recruiters to deliver homeless Medicare or Medi-Cal beneficiaries by ambulance from the "Skid Row" area in Los Angeles to the hospital for medically unnecessary treatment. The hospital billed Medicare and Medi-Cal for the services, whether necessary or not, provided to the homeless beneficiaries. The United States contended that these services were induced by illegal remuneration in violation of the Anti-Kickback statute. In addition to the civil fine the former co-owner of the hospital was sentenced to 37 months and ordered to pay \$4.1 million in restitution for his role in the kickback scheme. Two other individuals involved with the scheme also pled guilty for their involvement in the kickback scheme and are scheduled to be sentenced.
- In March 2010, Rush University Medical Center in Chicago, Illinois, paid \$1.5 million to resolve allegations that it submitted false claims to Medicare and Medicaid during the period 2000 through 2007 by entering into certain leasing arrangements for office space with two individual physicians and three physician practice groups that violated the Stark Law, which prohibits a hospital from profiting from patient referrals made by a physician with whom the hospital has an improper financial arrangement.
- In December 2009, Kerlan Jobe Orthopaedic Clinic (KJOC), a sports medicine clinic in Los Angeles, agreed to pay the United States \$3 million to resolve allegations that KJOC had financial relationships with HealthSouth Corporation (HealthSouth) that violated the Anti-Kickback Statute and/or Stark Law, and that these illegal relationships caused the

submission of false claims to Medicare. The alleged illegal financial relationships included stock options granted by HealthSouth to KJOC; donations by HealthSouth to the Kerlan Jobe Foundation; and a disproportionately high ownership interest awarded to KJOC by HealthSouth in a jointly owned ambulatory surgery center.

- In May 2010, Parma Community Hospital (Parma), Norton Healthcare (Norton), and St. Jude Medical, Inc. (St. Jude), agreed to pay the government \$40,000, \$133,300, and \$3.7 million, respectively, to resolve allegations of illegal kickbacks resulting in false claims submitted to Medicare. St. Jude, a heart device manufacturer, was alleged to have offered and paid kickbacks to Norton and Parma, which agreed to buy certain percentages of St. Jude manufactured implantable cardioverter-defibrillators and pacemakers. The kickbacks took the form of account credits towards the hospitals' future purchases of other St. Jude devices.
- In October 2009, South Texas Health System (STHS) agreed to pay \$27.5 million and enter into a 5-year CIA to resolve its liability for violations of the Stark Law, Anti-Kickback Statute, and the FCA. STHS allegedly engaged in improper financial relationships, including medical directorships and leases, with seven doctors during various periods from January 1, 1999, to December 31, 2006. STHS submitted claims to Medicare and Medicaid for services rendered to patients referred by these doctors to its hospitals.

Home Health Fraud

- In December 2009, Nursing Personnel Home Care (Nursing Personnel), Extended Home Care (Extended) and Excellent Home Care (Excellent) paid the United States and the state of New York a total of \$24 million to resolve FCA allegations that they submitted false claims to the New York Medicaid and Medicare programs. The New York Medicaid program provides coverage for home health aides only if those aides have valid certificates showing that they received proper training. The government contended that Nursing Personnel knowingly supplied aides with phony training certificates to Extended and Excellent, which then billed New York Medicaid for the aides' services; that Extended and Excellent knowingly billed for aides with phony certificates who were untrained; and that Extended and Excellent knowingly submitted claims to the Medicare program for home health aide services purportedly rendered by aides supplied by Nursing Personnel that were not actually provided. The United States is receiving approximately \$9.7 million out of the total settlement amount.
- In December 2009, Visiting Physicians Association paid the United States and the state of Michigan \$9.5 million to settle FCA allegations that the association submitted false claims for home health services to Medicare, TRICARE and the Michigan Medicaid program. In particular, the government alleged that Visiting Physicians Association submitted claims for unnecessary home visits and care plan oversight services, for unnecessary tests and procedures, and for more complex evaluation and management services than the services that Visiting Physicians Association actually provided.

- In October 2009, Omni paid the United States \$1.97 million to resolve FCA allegations that it billed Medicare for home health services without obtaining certain required physician signatures. Under the Medicare program, a physician must sign plan of care forms for the initial home care, and must re-certify the plan at least every 60 days. In August 2008, Omni submitted a disclosure to HHS/OIG, in which Omni stated that the required physician signatures were not timely obtained for certain services provided at its Evansville, Indiana facility. The settlement resulted from the company's disclosure.

Other Medicare/Medicaid Fraud

- In April 2010, a defendant in Maine was sentenced to 60 months imprisonment after pleading guilty to health care fraud and distribution of methadone and other controlled substances. The defendant was a methadone clinic patient who made false statements in order to receive "take-home" methadone from her clinic and prescription drugs from her physician, all paid for with Medicaid funds. She then sold, gave away, traded or otherwise distributed some of the methadone and prescription drugs. In April 2005, the defendant's brother died within hours after ingesting methadone and benzodiazepines that she gave to him.
- In November 2009, Ambulance Service, Inc. (ASI), and Northern Maine Medical Center (NMMC) agreed to pay a total settlement amount of \$1.0 million to resolve their liability under the FCA. ASI also entered into a 5-year CIA with OIG. The settlement resolves ASI's and NMMC's liability for allegedly submitting improper advanced life support transport claims to Medicare and Medicaid between January 1, 2003, and December 31, 2005. Investigators found that an ASI employee was improperly billing and coding for ASI's services in 2003 and 2004. In 2005, NMMC took over the billing and coding functions for ASI, and in doing so, hired the same ASI biller who had been improperly billing and coding. The government concluded that ASI and NMMC failed to adequately supervise the employee or ensure that she was properly trained. As a result of the investigation, NMMC terminated the employee.
- In June 2010, Metropolitan Ambulance & First Aid Corp. (now known as SEZ Metro Corp.), Metro North Ambulance Corp. (now known as SEZ North Corp.) and Big Apple Ambulance Service, Inc. (formerly known as United Ambulance) paid the United States \$2.8 million to resolve FCA allegations that the companies used, or caused the use of, falsified records to appeal a Medicare program refund demand. In particular, the government contended that the companies used hundreds of forged letters to support the medical necessity of the ambulance services.
- In October 2009, Surgical Concepts LLC (Surgical Concepts) agreed to pay \$242,528 to settle its liabilities under the FCA. From January 1, 2006, through December 31, 2007, Surgical Concepts submitted claims to Medicare, TRICARE, and the Federal Employees Health Benefits Program for physician time and effort reviewing neurological test data before surgery and providing real-time intraoperative neuromonitoring services. However, the test results were not reviewed by a physician before surgery, and no

physician provided real-time monitoring services during surgery. Instead, a physician conducted a “post hoc” review of the data in the days or weeks after the surgeries.

- In June 2010, the owner of a sham medical transportation company, Lane Medical Transportation (Lane Medical), was sentenced to 24 months’ incarceration and ordered to pay \$1.2 million in restitution after pleading guilty to conspiracy to commit health care fraud. Lane Medical did not own or use any ambulances, but submitted false claims for non-existent ambulance trips and basic life support. Investigators interviewed beneficiaries who Lane Medical claimed to have transported, but the beneficiaries had never heard of the company.

Identity Theft

- In October 2009, an Iowa physician was sentenced to 85 months’ incarceration and ordered to pay \$71,375 in restitution for mail fraud, aggravated identity theft, and money laundering. The physician obtained names and dates of birth of Medicaid beneficiaries (primarily children) through family members and friends and used this information to bill the maximum number of chiropractic manipulation services allowed by Medicaid for each beneficiary per year. In one example in 2006, the defendant billed the annual maximum chiropractic services (24) on nearly consecutive days for premature twin newborns who were patients in a neonatal intensive care unit at the time of the purported services.

Other Fraud

- In May 2010, a former account manager for Medical Provider Services (MPS) in Louisiana, a company that provides billing services for physicians and other medical providers, pleaded guilty to three counts of health care fraud and was sentenced to 37 months in prison for embezzling hundreds of thousands of dollars from medical providers’ accounts and ordered to pay \$621,737 in restitution. The defendant altered MPS records to reflect that certain treatments and medications were ordered by the physicians when in fact such treatments and medications were neither ordered nor performed. After altering the records, the defendant then fraudulently billed the patients’ insurance companies to obtain payments, which defendant then deposited into her personal checking account after forging their endorsements. The government is seeking to forfeit certain assets belonging to defendant which were purchased with proceeds of the fraud, including two jet skis, a motorboat, and 31 foot travel trailer, as well as cash.
- In December 2009, a participant in a prescription drug scam was sentenced to 60 months in prison and ordered to pay \$250,828 in restitution for conspiracy to commit mail, wire, and health care fraud. This individual was responsible for financial arrangements in a conspiracy in which he and numerous individuals based in Canada solicited and received money from thousands of elderly American victims on the false promise of receiving free government grants or discount prescription drug coverage through an insurance plan purportedly affiliated with Medicare. The investigation revealed that telemarketers contacted Medicare beneficiaries to get them to enroll in a bogus discount drug benefit program. Some beneficiaries were told that they would lose their Medicare benefit if they

did not enroll. The telemarketers were able to persuade some Medicare beneficiaries to provide their bank account information, after which the individual and his co-conspirators withdrew money from the victims' bank accounts.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

A certain portion of the funds appropriated under HIPAA are, by law, set aside for Medicare and Medicaid activities of HHS/OIG¹³. In FY 2010, the Secretary and the Attorney General jointly allotted \$177.2 million to the HHS/OIG, plus HHS allotted \$1.5 million to OIG to fund additional compliance trainings and a data analysis and mining project. Additionally, Congress appropriated \$29.8 million in discretionary funding for HHS/OIG HCFAC activities.

HHS/OIG participated in investigations or other inquiries that resulted in 1,025 prosecutions or settlements in FY 2010, of which 923, or 90 percent, were health care cases. A number of these are highlighted in the Accomplishments section. In addition, during FY 2010, HHS/OIG excluded a total of 3,340 individuals and entities. Details are below.

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, 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 savings from these joint efforts toward program improvements can be substantial. During FY 2010, HHS/OIG reported that legislative and administrative actions to make funds available for better use resulted in an estimated \$21 billion in health care savings attributable to FY 2010 – \$9.4 billion in Medicare savings and \$11.6 billion in savings to the Federal share of Medicaid.

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>.

¹³ In addition to the funds made available to OIG from the HCFAC account under HIPAA, Congress also provided funds to OIG on a temporary basis specifically for oversight of the Medicaid program. The Deficit Reduction Act of 2005 (DRA, P.L. 109-171) appropriated \$25 million to the OIG for “Medicaid fraud and abuse control activities” for each of fiscal years 2006 through 2010. Also, the Supplemental Appropriations Act of 2008 (Pub. L. 110-252) at § 7001(b) appropriated \$25 million to HHS/OIG “for purposes of reducing fraud and abuse in the Medicaid program.” Finally, the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) at § 5007(b) appropriated \$31.25 million to the HHS/OIG “for purposes of ensuring the proper expenditure of Federal funds under [Medicaid],” available for FYs 2009-2011. Therefore, OIG’s FY 2010 Medicaid-related activities cited throughout this report, including the activities discussed below, may draw on funding from HCFAC as well as other sources.

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 from participation in Medicare, Medicaid, and other Federal health care programs. During FY 2010, HHS/OIG excluded a total of 3,340 individuals and entities. Among these were exclusions based on criminal convictions for crimes related to Medicare and Medicaid (894), or to other health care programs (263); for patient abuse or neglect (247); or as a result of licensure revocations (1,582). 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 2010. Exclusion actions by HHS/OIG included:

- An Ohio chiropractor was excluded for a minimum of 60 years based on his conviction for rape, corruption of a minor, and gross sexual imposition. The Ohio State Chiropractic Board permanently revoked his license, and the State Medical Board of Ohio permanently revoked his license to practice as a physician assistant. In addition, the Ohio Department of Job and Family Services terminated his Medicaid Provider Agreement. He was sentenced to 43 years incarceration.
- The owner of an independent diagnostic testing facility in California was excluded for a minimum of 45 years based on his health-care-related conviction. Over a 4-year period, the owner was involved in a fraud scheme that caused Medicare to pay for tests that were unnecessary or were never performed. As part of the scheme, individuals known as "cappers" were paid cash to recruit Medicare patients to receive services at medical clinics and diagnostic testing facilities owned and operated by the owner and his co-conspirators. He was sentenced to 24 months incarceration and ordered to pay \$11.0 million in joint and several restitution.
- A Virginia midwife was excluded for an indefinite period based on the suspension of her license to practice midwifery by the Virginia Board of Medicine. The Board found that she provided negligent care to two patients during the course of their home births. She allegedly made numerous clinical and professional misjudgments, which resulted in the infants being stillborn.
- A certified alcohol and drug abuse counselor and owner/operator of a counseling center in Kansas was excluded for a minimum of 30 years based on her health care fraud conviction. Between June 2001 and February 2006, the individual, doing business as A New Beginning, submitted materially false and fraudulent claims and caused others to submit materially false and fraudulent claims to Medicaid for community-based drug and alcohol abuse services for 81 children. She was sentenced to 24 months incarceration and ordered to pay \$3.8 million in restitution.

- An owner/operator of a DME company in Florida, K.M. Medical Services, Inc., was excluded for a minimum of 50 years based on his conviction for health care fraud. Between June 2005 and December 2005, he billed Medicare for various health care benefits, items, and services that were not medically necessary or were not provided to beneficiaries. The owner was sentenced to 46 months incarceration and ordered to pay \$668,079 in restitution.
- A previous owner of a Texas DME company was excluded for a minimum of 25 years based on his conviction for aiding and abetting the unlawful obtaining of individually identifiable health information of an individual with the intent to sell, transfer, or use that health information for commercial advantage or personal gain. Over a 2-year period, the owner purchased over 1,000 files from various DME companies that contained Medicare beneficiary information. He sold these beneficiaries' medical information to another owner of several DME companies, who used it to bill Medicare for DME that was not purchased by or delivered to beneficiaries. He was sentenced to 60 months incarceration and ordered to pay \$1.7 million in restitution.

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 Federal 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 continued to pursue its affirmative enforcement actions under these authorities. Examples include:

- In California, Tenet Healthcare Corporation and Tenet HealthSystem KNC, Inc. (d/b/a USC Norris Cancer Hospital) (collectively, "Tenet"), who are currently subject to a 5-year CIA with HHS/OIG, agreed to pay \$1.9 million to resolve their liability under the CMPL. Tenet, pursuant to the CIA's Reportable Event disclosure requirements, revealed to HHS/OIG that between December 2003 and October 2007, it submitted claims not entitled to federal health care program reimbursement for clinical research-related items or services rendered at USC Norris Cancer Hospital. Specifically, Tenet improperly received government reimbursement for: (1) items or services that were paid for by clinical research sponsors or grants under which the clinical research was conducted; (2) items or services intended to be free of charge in the research informed consent; (3) items or services that were for research purposes only and not for the clinical management of the patient; and/or (4) items or services that were otherwise not covered under the CMS Clinical Trial Policy.
- In Illinois, United Shockwave Services, Ltd; United Urology Centers LLC; and United Prostate Centers, LLC (collectively, United) agreed to pay \$7.3 million, along with United Therapies, LLC, enter into a 5-year CIA to resolve their CMP liability. United is a physician-owned enterprise that leases medical equipment and services for the treatment of kidney stones and enlarged prostate glands. The settlement resolves a number of allegations, including that United and certain physician-investors used their ability to control patient

referrals to obtain contract business from hospitals in Illinois, Iowa, and Indiana. Specifically, OIG alleged that United threatened hospitals that it would refer patients to competing hospitals if they did not agree to a contract with United, or promised additional referrals to hospitals that did contract with United. Consequently, if hospitals chose to contract with United over competitors to get more referrals, all claims resulting from that relationship were prohibited by the Anti-Kickback Statute. Furthermore, OIG alleged that certain physician-investor referrals to hospitals that had contracts with United also violated the Stark Law.

- In Missouri, St. John's Regional Medical Center (St. John's) agreed to pay \$274,815 to HHS/OIG to resolve its CMP liability in a self-disclosed improper financial relationship between a wholly owned subsidiary of St. John's and a physician. HHS/OIG contended that the subsidiary allowed the physician, a referral source for St. John's, to be regularly delinquent in rent under a written lease agreement in violation of the Stark Law and Anti-Kickback Statute. St. John's also paid the physician for services without a written contract in place.
- A Florida doctor agreed to pay \$65,000 and enter into a 3-year period of exclusion to resolve his CMP liability for receiving kickbacks from medical device manufacturers. The doctor's potential liability arises from his solicitation and receipt of remuneration in the form of consulting payments from Biomet Orthopedics, Inc. (Biomet), and Zimmer, Inc. (Zimmer), in exchange for using their orthopedic hip and knee products. HHS/OIG alleged that the compensation paid under consulting agreements with Biomet and Zimmer were received, in part, in return for his ordering, or causing to order, Biomet and Zimmer orthopedic products, respectively, to be paid for, in whole or in part, by federal health care programs.
- In California, the former Executive Director of Community Memorial Hospital (CMH), agreed to pay \$64,000 to resolve his liability under provisions of the Stark Law. From May 29, 2002, through September 23, 2003, the individual allegedly orchestrated a scheme involving CMH remunerating doctors and cardiac surgeons for referrals to CMH. In December 2007, CMH agreed to pay the United States over \$1.5 million to resolve CMH's liability for more than 17 different arrangements with physicians and physician family members that allegedly violated the Stark Law and the FCA.

Audits and Evaluations

HHS/OIG conducts numerous 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:

Medicaid Administrative Claims

- Of the \$15.3 million (Federal share) that Missouri claimed in Medicaid administrative costs for the St. Louis Public and Springfield school districts for FYs 2004 through 2006, HHS/OIG found that \$4.2 million was unallowable for Federal reimbursement because the state did not

correctly calculate and claim administrative costs for the School District Administrative Claiming (SDAC) program. In addition, because of errors identified during our review of the St. Louis and Springfield school districts, the other Missouri school districts received \$16.3 million in unallowable Medicaid payments for FYs 2004 through 2006. We set aside for CMS adjudication \$1.5 million for administrative costs claimed for the St. Louis Public and Springfield school districts and \$3.9 million for administrative costs claimed for all other Missouri school districts. The SDAC program permits children to receive health-related services, generally without having to leave school. States may be reimbursed for the administrative activities that directly support identifying and enrolling potentially eligible children in Medicaid. HHS/OIG recommended, among other things, that Missouri refund \$20.5 million to the Federal government for unallowable SDAC expenditures.

Medicaid School-Based Health Services

- HHS/OIG found that Arizona did not always claim Federal reimbursement for Medicaid school-based health services in accordance with Federal and state requirements. Of the 100 sampled student-months from the period January 1, 2004, to June 30, 2006, 46 had 1 or more school-based health services that were not allowable. Based on sample results, HHS/OIG estimated that the state was improperly reimbursed at least \$21.3 million in Federal Medicaid funds. Medicaid pays for medical services provided to children under Part B of the Individuals with Disabilities Education Act of 2004 through a child's individualized education plan. HHS/OIG recommended, among other things, that Arizona refund to the Federal government \$21.3 million for unallowable school-based health services.
- In two reviews, HHS/OIG found that New Jersey's claims for reimbursement of Medicaid school-based health services submitted by its billing agents did not fully comply with Federal and state requirements. During our audit periods, New Jersey contracted with separate billing agents to help administer its Medicaid school-based health services program under contingency-fee-based agreements.

Based on our sample results for claims submitted by the first billing agent for the period July 27, 2003, through October 4, 2006, HHS/OIG estimated that New Jersey was improperly reimbursed \$8 million in Federal Medicaid funds. Of the 100 school-based health claims in our sample, 51 did not comply with Federal and state requirements. Based on our sample results for claims submitted by the second billing agent for the period April 6, 2005, through June 27, 2007, HHS/OIG estimated that New Jersey was improperly reimbursed \$5.6 million in Federal Medicaid funds. For the both billing agents, the claims submitted in error were not (1) provided or supported, (2) in compliance with referral or prescription requirements, (3) in compliance with Federal provider qualification requirements, or (4) documented in the child's plan. HHS/OIG recommended, among other things, that New Jersey refund the overpayments to the Federal government.

Enrollment of Excluded Medicaid Providers

- HHS/OIG examined enrollment information of providers who were excluded by OIG subsequent to their enrollment as Medicaid providers to gather information related to potential weaknesses in states' provider enrollment procedures. Of 188 Medicaid providers from 26 states who had been excluded by OIG subsequent to their enrollment, 8 had disclosed false ownership information at the time of enrollment. Another 8 of the 188 had criminal convictions before they enrolled and committed health care-related crimes after they enrolled. Of the 188 excluded providers, 88 had Federal or state tax liens before or after they enrolled in Medicaid and 24 had a history of tax debt, criminal convictions, or false disclosures before they enrolled. HHS/OIG also found that states impose few enrollment requirements beyond those mandated by Federal regulations.

Medicaid Supplemental Payments

- In a review of Medicaid supplemental rate payments made to a hospital company in Massachusetts, HHS/OIG found that of the \$337 million that Massachusetts claimed during FYs 2004 and 2005, \$11.5 million (\$5.75 million Federal share) was not claimed in accordance with Federal and state plan requirements. HHS/OIG identified an additional \$5.6 million (\$2.8 million Federal share) in supplemental payments to a medical school affiliated with the company on which we were unable to express an opinion. HHS/OIG recommended, among other things, that the state make a financial adjustment of \$11.5 million (\$5.75 million Federal share).

Medicaid Drug Rebates

- HHS/OIG's review of the top 150 brand-name drugs for CY 2007 ranked by Medicaid reimbursement found that 114 had more than 1 version. For 65 of the 114, the prices of the earliest versions of the drugs exceeded their inflation-adjusted prices when the new versions entered the market. HHS/OIG calculated that for CYs 1993–2007, states could have collected about \$2.5 billion in additional rebates for the 65 brand-name drugs if the baseline average manufacturer prices of the new versions had been adjusted (i.e., reduced) to reflect price increases in excess of inflation for the earliest versions. For a manufacturer's covered outpatient drug to be eligible for Federal Medicaid funding, the manufacturer must enter into a rebate agreement that is administered by CMS and pay quarterly rebates to the states.

HHS/OIG did not evaluate the drug manufacturers' bases for developing the new versions of existing drugs identified in this review. Because the Medicaid drug rebate program calculates rebates separately for each version of a drug, manufacturers could develop new versions of existing brand-name drugs solely to avoid paying additional rebates when they substantially increase prices. Without some modification to the rebate law, the risk that manufacturers will take advantage of this potential loophole may increase over time. HHS/OIG recommended that CMS continue to seek legislative authority to modify the present rebate formula calculation to ensure that manufacturers cannot circumvent paying additional rebates by bringing new versions of existing brand-name drugs to market.

Medicaid and CHIP Concurrent Enrollees

- Based on our sample results, HHS/OIG estimated that from April 1, 2007, through March 31, 2008, Florida claimed \$5.3 million in Federal financial participation (FFP) for State Children's Health Insurance Plan (SCHIP) (now known as CHIP) enrollees who were concurrently enrolled in the SCHIP and Medicaid for a total 65,121 enrollment-months. If an individual is eligible for Medicaid, he or she is ineligible for SCHIP. The concurrent enrollments occurred primarily because (1) Medicaid enrollment can be retroactive for up to 3 months, during which time the individual may also have been enrolled in SCHIP, and (2) the State agency's partners did not have adequate internal controls to prevent or correct concurrent enrollments promptly. HHS/OIG recommended, among other things, that the State (1) make a financial adjustment of \$5.3 million for FFP claimed on behalf of concurrent enrollees, (2) make regular financial adjustments in the future to correct FFP claimed on behalf of concurrent enrollees.

Hurricane-Related Uncompensated Care

- HHS/OIG found that Louisiana did not always claim reimbursement for services provided by one hospital in accordance with Federal and state laws and regulations or with the approved provisions of the uncompensated care pool (UCCP) plan. In response to Hurricane Katrina, the Deficit Reduction Act of 2005 (DRA) authorized Federal funding for the total costs of medically necessary uncompensated care furnished to evacuees and affected individuals without other coverage in eligible states. Of the \$3.7 million in costs claimed for services provided to 86 patients, \$3.4 million was unallowable, in part because the state did not have procedures to ensure that it claimed uncompensated care costs only for services covered under the Medicaid plan. HHS/OIG recommended that Louisiana refund to CMS the \$3.4 million in unallowable costs claimed.

Medicare Payment Error Rates

- HHS/OIG conducted a review of a medical review contractor's compliance with the terms of its contract with CMS to perform medical reviews of a subsample of claims from FY 2008 Comprehensive Error Testing (CERT) samples. To help determine the annual Medicare error rate, CMS's CERT contractor conducts medical reviews of a sample of paid claims and in accordance with CMS's written policies. HHS/OIG found that the medical review contractor complied with its CMS contract, but it also found that the medical review contractor's results may not have provided CMS with assurance that the CERT contractor's FY 2008 fiscal intermediaries (FI) and carrier error rates were accurate. The medical review contractor identified enough incorrect determinations by the CERT contractor to warrant further CMS corrective action to improve the Medicare error rate process. HHS/OIG recommended, among other things, that CMS require the CERT contractor to develop a corrective action plan to reduce the number of incorrect determinations.

- Based on a review of the erroneous claims identified by CMS's Medicare CERT contractor for FY 2009, HHS/OIG found that 6 types of health care providers accounted for \$4.4 million, or 94 percent, of the \$4.7 million in improper payments. The provider types were inpatient hospitals, DME suppliers, hospital outpatient departments, physicians, and home health agencies (HHA). Analysis of the erroneous claims also found that 3 types of errors accounted for about 98 percent of the \$4.4 million in improper payments: insufficient documentation, miscoded claims, and medically unnecessary services and supplies. HHS/OIG recommended that, as part of its analysis of the FY 2009 CERT improper payments, CMS use the results of this analysis in identifying (1) the types of payment errors indicative of programmatic weaknesses and (2) any additional corrective actions needed to strengthen the CERT program.

High-Dollar Inpatient and Outpatient Medicare Services

- HHS/OIG issued three reports on high-dollar payments that Medicare FIs made to hospitals for inpatient services claimed under Medicare Part A. High-dollar payments were defined as those that were \$200,000 or more each. CMS contracts with FIs to, among other functions, process and pay Medicare Part A (inpatient) claims submitted by providers.

HHS/OIG found that an FI overpaid Alabama hospitals \$1.5 million for inpatient services during calendar years (CY) 2004 through 2006. Contrary to Federal guidance, hospitals reported excessive units of service and charges that resulted in inappropriate outlier or add-on payments and failed to maintain documentation of all charges filed. In a review of another FI that operates in all states, except New York, HHS/OIG found that of the 520 high-dollar Medicare payments made to hospitals for inpatient services for CYs 2004 through 2006, 42 were appropriate. The 478 remaining payments included net overpayments totaling \$4.7 million, which the hospitals had not refunded before the start of our audit. Contrary to Federal guidance, hospitals inaccurately reported the number of billing units for blood clotting factor, reported incorrect diagnosis and procedure codes, and reported excessive charges that resulted in inappropriate outlier payments. Finally, in a third review, HHS/OIG found that of the 415 high-dollar Medicare Part A payments made to hospitals for inpatient services for CY 2003 through 2005, 306 were appropriate. The remaining payments included net overpayments totaling \$3 million. At the start of our audit, hospitals had not refunded \$1.9 million of these net overpayments. Contrary to Federal guidance, hospitals inaccurately reported the number of billing units of service, reported incorrect procedure codes, and reported excessive charges that resulted in inappropriate outlier payments. In all three reports, HHS/OIG recommended, among other things, that the FIs recover the net overpayments.

- HHS/OIG issued two reports on high-dollar payments made for outpatient services claimed under Medicare Part B. High-dollar payments were defined as payments as those that were \$50,000 or more each. In the first review, HHS/OIG found that that all 46 sampled high-dollar payments (\$50,000 or more) that an FI made to the outpatient departments of hospitals in Virginia and West Virginia during CYs 2003 through 2005 were inappropriate. The 46 payments included overpayments totaling \$3.5 million. Providers received these overpayments by billing for excessive units of service or by billing for the wrong service or procedure. In the second review, HHS/OIG found that of the 104 high-dollar payments made

to hospitals for outpatient services for CYs 2003 through 2005, 27 were appropriate. The 77 remaining payments included overpayments totaling \$6.1 million. HHS/OIG recommended in both reports that the FIs, among other things, recover the net overpayments.

Medicare Payments to Inpatient Rehabilitation Facilities

- In a review of claims submitted by Inpatient Rehabilitation Facilities (IRFs) with dates of service in calendar years 2006 and 2007, HHS/OIG found that IRFs did not receive reduced case-mix-group payments for 113 of 200 sampled claims with patient assessment instruments that were transmitted to CMS's National Assessment Collection Database (the Database) more than 27 days after the beneficiaries' discharges. To administer the prospective payment system, CMS requires IRF's to electronically transmit a patient assessment instrument for each IRF stay to the Database, which the Iowa Foundation for Medical Care (the Foundation) maintains. If an IRF transmits the instrument more than 27 calendar days from (and including) the beneficiary's discharge date, the IRF's payment rate for the applicable case-mix group should be reduced by 25 percent. Based on these sample results, HHS/OIG estimated that FIs made \$20.2 million in overpayments to IRFs during the audit period. The report's recommendations included the following: (1) adjust the 113 sampled claims for overpayments of \$424,000; (2) determine whether any of the \$323,000 potential payment penalty should apply to the 79 sampled claims with modified patient assessment instruments that were transmitted after the 27-day deadline; and (3) immediately reopen the nonsampled claims, review our information on these claims (which have overpayments estimated at \$19.8 million and set-aside payments estimated at \$18.7 million), and recover any overpayments.

Medicare Payments for Interrupted Stays at Inpatient Psychiatric Facilities

- Based on a sample of 100 claims, HHS/OIG estimated that Medicare FIs made \$3.9 million in improper payments to Inpatient Psychiatric Facilities (IPFs) nationwide in CYs 2006 and 2007 for claims on behalf of beneficiaries who had been discharged from another IPF within the prior 3 days. An interrupted stay occurs when a beneficiary is discharged from an IPF and admitted to the same or a different IPF within 3 consecutive days. In such a case, the "readmission" is considered a continuation of the initial stay. CMS provides an exception to the 3-day policy when the beneficiary is admitted to a different IPF within 3 days and the second IPF is unaware of the beneficiary's immediately preceding stay in the first IPF. HHS/OIG recommended, among other things, that CMS instruct its FIs to recover \$19,000 for the 75 sampled claims with payment errors; and that it review our information on the unsampled claims for IPF interrupted stays, which had potential overpayments estimated at \$3.8 million, and work with its FIs to recover any overpayments.

Medicare Outlier Payments to Home Health Agencies

- In this review, HHS/OIG found that Miami-Dade County accounted for more home health outlier payments in 2008 than the rest of the Nation combined. Twenty-three other counties nationwide also exhibited aberrant home health payment patterns similar to that of Miami-

Dade County, but to a lesser extent. HHS/OIG also found that more than 85 percent of home health providers that received outlier payments over \$100,000 per beneficiary were in Miami-Dade County. In addition, 67 percent of home health providers that received total outlier payments over \$1 million were in Miami-Dade County. HHS/OIG recommended that CMS (1) continue efforts to institute a cap on the total outlier payments an individual home health provider may receive annually, (2) review home health providers that show aberrant outlier payment patterns and respond appropriately based on the findings, and (3) continue efforts to strengthen enrollment standards for home health providers to prevent illegitimate home health agencies from obtaining billing privileges.

Inadequately Documented Claims for Power Wheelchairs

- In its review of Medicare claims for power wheelchairs, HHS/OIG found that two out of five claims for standard and complex rehabilitation power wheelchairs did not meet Medicare documentation requirements during the first half of 2007. Power wheelchair claims that did not meet all documentation requirements accounted for \$112 million in improper Medicare payments, out of \$189 million total allowed by Medicare during the 6-month period. Beneficiaries were responsible for paying \$22 million of this amount. Based on the results of the review, HHS/OIG recommended that CMS improve compliance with Medicare's power wheelchair documentation requirements and suggested several methods for improving compliance.

Capped Rental Durable Medical Equipment

- In a study of claims for maintenance and repair costs for capped rental DME, HHS/OIG found that from 2006 to 2008 Medicare erroneously allowed \$2.2 million for unallowable routine maintenance and servicing and nearly \$4.4 million for unallowable repairs. HHS/OIG also found that in 2007, Medicare allowed nearly \$27 million for repair claims for beneficiary-owned capped rental DME that failed to meet payment requirements. Medicare allowed an additional \$29 million (49 percent of all allowed claims) for questionable repair claims for beneficiary-owned capped rental DME in 2007. Additionally, supplier practices adversely affected some beneficiaries with repairs exceeding \$5,000. HHS/OIG recommended that, among other things, CMS implement an edit to deny unallowable claims for routine maintenance and servicing of capped rental and implement an edit to deny claims for repair of beneficiary-rented capped rental DME.

Medicare Payments for Pressure Reducing Support Services

- In a review of suppliers' use of two billing modifiers, HHS/OIG found that in 2007, Medicare Part B paid for 72 percent of all pressure reducing support surface claims containing these modifiers. DME suppliers use these two specific billing modifiers (the GA and GZ modifiers) when they expect that Medicare will deny the claim as not reasonable and necessary. Medicare potentially inappropriately paid \$4.4 million for such claims. These findings, and the additional findings in the report, indicate that Medicare contractors may not have appropriate safeguards in place to pay for Part B claims with these two specific billing

modifiers. The results also demonstrate that suppliers may need further instructions on the appropriate use of these modifiers when they provide upgraded items to beneficiaries.

Medicare Payments for Transforaminal Epidural Injection Services

- Based on a medical review of 433 transforaminal epidural injection services allowed by Medicare in 2007, HHS/OIG found that 34 percent did not meet Medicare requirements, resulting in approximately \$45 million in improper payments. Transforaminal epidural injections are a type of interventional pain management technique used to diagnose or treat pain. Medicare allowed an additional \$23 million in associated facility claims for transforaminal epidural injections performed in error. In addition, services provided in offices were more likely to have a documentation error than those provided in ambulatory surgical centers or hospital outpatient departments. Also, HHS/OIG found that in 2007, 9 of 14 Medicare Part B contractors had a local coverage determination for transforaminal epidural injection services, but reported limited use of other safeguards. Only one contractor enforced all of its local coverage determination requirements with edits. HHS/OIG recommended that, among other things, CMS conduct provider education, directly and through contractors, about proper documentation and strengthen program safeguards to prevent improper payment for transforaminal epidural injection services.

Less-Than-Effective Medicare Part D Drugs

- Of approximately \$115 billion in gross drug costs included in Medicare Part D sponsors' prescription drug event (PDE) data for CYs 2006 and 2007, HHS/OIG found that CMS accepted PDE data totaling \$43.3 million associated with less-than-effective drugs. Pursuant to Federal requirements, Medicare Part D should not have covered these drugs. Less-than-effective drugs are drugs that the FDA approved before 1962 and that FDA subsequently found to be less than effective. CMS's Drug Data Processing System subjects sponsors' PDE data to an edit designed to reject less-than-effective drugs. However, the edit did not identify and reject PDE data for some less-than-effective drugs because the Part D program used an incomplete list of less-than-effective drugs as the basis for the edit. HHS/OIG recommended that CMS determine whether it can impose financial adjustments on sponsors that were paid for furnishing less-than-effective drugs; and help ensure that drugs covered by Medicare Part D comply with Federal requirements by collaborating with FDA to create and maintain a comprehensive list of less-than-effective drugs, regularly disseminating this list to all sponsors, and using this list to reject PDE data for less-than-effective drugs.

Medicare Adverse Events

- HHS/OIG conducted two evaluations examining adverse events at selected hospitals. The term "adverse event" refers to an undesirable event that may cause harm to a patient during the delivery of health care. Studies indicate that adverse events lead to thousands of patient deaths annually and billions of dollars in increased health care costs and lost productivity. HHS/OIG provided CMS with informational copies of our reports, which are considered sensitive and thus are not publicly available.

In the first evaluation, HHS/OIG found only limited public disclosure of information about adverse events among entities reviewed, including state adverse event reporting systems, Patient Safety Organizations (PSO), and CMS. Publicly disclosing adverse event information can educate health care providers about causes of events, compel providers to correct vulnerabilities that lead to adverse events, and assist patients in making decisions about their care. All of the reviewed entities maintain policies, practices, and legal provisions to protect patient privacy. This report examined 17 state adverse event reporting systems, 8 PSOs overseen by the Agency for Healthcare Research and Quality (AHRQ), and CMS regarding its Medicare claims data to analyze policies, practices, and plans for publicly disclosing information about adverse events and protecting patient privacy. Among other things, HHS/OIG found that the more extensive disclosure practices of seven state systems identified in the report can serve as models for other entities.

In the second evaluation, HHS/OIG examined 5 methods used in a two-county case study for identifying possible adverse events experienced by Medicare beneficiaries and found that overall, the methods that were reviewed were found to be useful for identifying events that harmed Medicare beneficiaries in hospitals. These methods include: nurse reviews of medical records, interviews of Medicare beneficiaries, two types of analysis of hospital billing data, and reviews of internal hospital incident reports. For hospitalizations with possible events identified by the five screening methods, physicians reviewed medical records to determine whether actual events occurred. However, physician reviewers determined that 62 percent of the possible events identified by the five screening methods were not associated with actual events. HHS/OIG also found that shortcomings in two of the methods have implications for Medicare payments and federal initiatives to identify, track, and monitor events. First, patient diagnosis codes were inaccurate or absent for 7 of the 11 Medicare hospital-acquired conditions (HAC) identified by physician reviewers. Second, reviewed hospitals did not generate incident reports for 93 percent of the events, including some of the most serious events involving death or permanent disability to the patient. Recommendations in the report included that CMS and AHRQ explore opportunities to identify adverse events when conducting medical record reviews for other purposes.

Healthcare Integrity and Protection Data Bank

- In a review of CMS's compliance with Healthcare Integrity and Protection Data Bank (HIPDB) reporting requirements, HHS/OIG found that although CMS took adverse actions, it did not report all of the actions to the HIPDB as required. Federal and state government agencies and health plans are required to report certain adverse actions to the HIPDB. CMS takes several types of adverse actions that are required to be reported to the HIPDB, including revocations and suspensions of laboratory certifications; terminations of providers from participation in Medicare; and imposition of CMPs against all types of providers, managed care plans, and prescription drug plans. CMS failed to report 148 adverse actions imposed against laboratories in 2007 and 30 adverse actions imposed against managed care and prescription drug plans between January 1, 2006, and July 31, 2009. None of the adverse actions against DME suppliers taken after 2008 had been reported to HIPDB at the time of our review; however, as of April 30, 2009, the HIPDB contained 5,125 adverse actions against DME suppliers imposed from 1998–2008. None of the 45 nursing homes terminated from

participating in Medicare from 2004 through 2008 were reported to the HIPDB until 2009, well after the required reporting timeframe. HHS/OIG recommended that CMS report all adverse actions to the HIPDB as required.

Medicare Part D Drug Claims

- HHS/OIG found that Medicare drug plans and enrollees paid pharmacies \$1.2 billion in 2007 for more than 18 million prescription drug claims that contained 527,749 different invalid prescriber identifiers. These invalid identifiers either (1) were not listed as valid identifiers in the National Provider Identifier, DEA number, or Unique Physician Identification Number registries or (2) had been deactivated or retired before January 1, 2006. Our review also revealed that only 10 identifiers accounted for 17 percent of all drug claims with invalid prescriber identifiers in 2007. These drug claims represented \$237 million in payments by Medicare drug plans and enrollees. One of the top ten invalid prescriber identifiers was recorded on almost 1.8 million PDE records for more than 150,000 beneficiaries enrolled with 248 different Medicare drug plan sponsors. Plan sponsors and enrollees paid pharmacies almost \$105 million for drug claims with this single invalid identifier. In addition, 5 of the top 10 invalid prescriber identifiers appeared on individual claims for very expensive drugs, with payment amounts totaling more than \$10,000 per claim.

Medicare Drug Integrity Contractors

- In its review of potential Medicare Part D fraud and abuse incidents identified by Medicare Drug Integrity Contractors (MEDIC) in FY 2008, HHS/OIG found that 87 percent were identified through external sources, such as complaints. The remaining 13 percent of potential fraud and abuse incidents were identified through proactive methods, such as data analysis. Additionally, 96 percent of investigations conducted by MEDICs in FY 2008 involved incidents identified through external sources. Problems with accessing and using data hindered MEDICs' ability to identify and investigate potential fraud and abuse incidents. MEDICs lacked the authority to directly obtain information, such as prescriptions and medical records from pharmacies, pharmacy benefit managers, and physicians. Also, MEDICs may not have been aware of some potential fraud and abuse incidents because plan sponsors are not required to refer them. MEDICs did not have CMS approval to conduct audits of plan sponsors' compliance plans in FY 2008.

Medicare Program Safeguard Contractors

- In its review of Medicare Program Safeguard Contractors (PSCs), HHS/OIG found that of 18 PSCs only 2 were responsible for 62 percent of the \$835 million referred in overpayments to claims processors for collection in 2007. Moreover, the amount of overpayment dollars that PSCs referred for collection was not always related to the size of PSCs' oversight responsibility. PSCs are engaged by CMS to conduct a variety of activities to ensure the integrity of Medicare payments. In addition, while Part B payments represented 29 percent of PSCs' oversight responsibility (\$87 billion of \$296 billion), Part B overpayments accounted for 89 percent of PSCs' overpayment dollars referred for collection (\$747 million of \$835 million). Part A payments represented 71 percent of PSCs' oversight responsibility (\$209

billion of \$296 billion), and Part A overpayments accounted for 11 percent of PSCs' overpayment dollars referred for collection (\$88 million of \$835 million). HHS/OIG recommended that CMS determine why certain PSCs have low levels of overpayment dollars referred for collection and why certain PSCs have low Part A overpayment dollars referred for collection compared with their Part B overpayment dollars referred for collection.

- In a second review of the activities of PSCs, HHS/OIG found that overpayments referred for collection by PSCs in 2007 did not result in significant recoveries to the Medicare program. Only 7 percent (\$55 million) of the \$835 million referred to claims processors had been collected by claims processors as of June 2008. Of the \$55 million collected, 27 percent was for Part A claims; 56 percent was for Part B claims excluding DMEPOS; and 17 percent was for Part B DMEPOS claims. CMS is transitioning PSCs to seven Zone Program Integrity Contractors (ZPIC) and is providing ZPICs an incentive to keep track of the amount claims processors collect on ZPIC overpayment referrals. HHS/OIG recommended, among other things, that CMS regularly collect all necessary information to determine the overpayments PSCs refer to claims processors for collection, the collection status of these overpayments, and the percentage of overpayments in each category of collection status.

Fraud Referrals by Recovery Audit Contractors

- In its review of Medicare Recovery Audit Contractors (RACs), HHS/OIG found that between March 2005 and March 2008, RACs referred two cases of potential fraud to CMS. However, CMS reported that it received no potential fraud referrals from RACs during this period. A 3-year RAC demonstration project conducted from March 2005 through March 2008 was designed to detect and correct past improper payments in the Medicare fee-for-service program and provide information to CMS and to the Medicare claims-processing contractors that could help protect the Medicare trust funds by preventing future improper payments. HHS/OIG recommended the following to CMS: (1) conduct follow-up to determine the outcomes of the two referrals made during the demonstration project, (2) implement a system to track fraud referrals, and (3) require RACs to receive mandatory training on the identification and referral of fraud.

Medicare Part C Marketing

- In its review of the marketing practices of six Medicare Advantage (MA) plan sponsors, HHS/OIG found that each sponsor did not follow at least one of the marketing regulations related to sales agent compensation and qualifications. Five of the selected plan sponsors in our review that employ independent sales agents had compensation practices that resulted in inappropriate financial incentives for sales agents and field marketing organizations (FMO). FMOs typically provide sales agents with enrollment leads and marketing assistance. Five of the six selected plan sponsors also did not ensure that all of their sales agents were qualified under CMS's regulations. We also found that the number and types of beneficiaries' complaints remained unchanged after implementation of sales agent marketing regulations. HHS/OIG recommended that CMS take appropriate action regarding specific instances of misconduct documented in the report, audit plan sponsors, and issue additional guidance and regulations.

Other Fraud and Abuse Prevention Activities

In addition to amounts specifically designated by statute for HHS/OIG activities, OIG was allocated \$1.5 million for Compliance Training and Data Mining Activities.

HHS/OIG is planning a series of compliance training programs that will provide free or low cost, high quality compliance training for providers, compliance professionals, and attorneys in Strike Force cities and elsewhere. These compliance training programs will bring together representatives from OIG and other HHS agencies, DOJ, and MFCUs to address the local provider, legal, and compliance community. The training will focus on methods to identify fraud risk areas and compliance best practices so that providers can strengthen their own compliance efforts and more effectively identify and avoid illegal schemes that may be targeting their communities. \$250,000 has been allocated for Compliance Training activities.

\$1.25 million will support HHS/OIG's enhancement of data analysis and mining capabilities for detecting health care fraud. These expanded capabilities will allow law enforcement officials to use software with predictive and link analysis features to analyze near-time data, allowing them to identify providers that appear to have submitted improper claims, groups that have assumed multiple identities to circumvent fraud detection, and other systemic vulnerabilities. This initiative will assist OIG and its partners in identifying potential fraud with unprecedented speed and efficiency and will result in provider investigations and program improvements at the Federal and state levels. This project supports OIG's core mission of protecting the integrity of HHS programs, and will directly support the HEAT initiative, which relies on near-time data to identify and aggressively prosecute fraud.

Each of these projects will continue into FY 2011 and additional information will be provided in the FY 2011 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 2010, the HHS/OIG, in consultation with DOJ, issued 14 advisory opinions. A total of 233 advisory opinions have been issued during the 14 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 2010, HHS/OIG was monitoring compliance with 285 such agreements.

Office of the Assistant Secretary for Planning and Evaluation

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) was allocated approximately \$1.1 million by HHS during FY 2010. This funding is being used to develop approaches for improving the Department's ability to measure and detect improper payments and fraud.

ASPE is pursuing two areas of research. The purpose of the first research project is to begin the implementation of the determination of a baseline estimate of Medicare fraud. This involves developing and prototyping a methodology to estimate the total amount of fraudulent payments, which consists of the types of fraudulent payments that can be detected within a Comprehensive Error Rate Testing (CERT) framework and other fraudulent payments that can only be estimated via additional information gathering. ASPE currently has a contractor developing the sampling design specifications. This contractor has developed six initial designs and is currently completing detailed sampling specifications. Depending upon the final design, implementation could require examining existing Medicare claims, conducting medical record reviews of these claims, surveying beneficiaries (either in person or via telephone), and conducting on-site provider audits. This project began in FY 2010 and will continue in FY 2011.

The second area of research is undertaking an assessment of the application of pre-payment fraud detection methods to the Medicare program. Current efforts to detect fraud in the Medicare program rely extensively on post-payment claims review, where claims are examined for anomalies and possible fraud after Medicare has paid the provider for the billed service(s). This study will look at pre-payment methods that incorporate sophisticated predictive models to identify claims and providers for further investigation, such as the alternative methods of fraud detection that are currently being employed by commercial insurance carriers. The project will focus on an available pre-payment approach that draws from similar approaches used in the financial services sector to identify potentially fraudulent transactions. This non-parametric predictive modeling approach will combine upwards of 30 separate risk indicators into a single risk score. The resulting scores will then be independently validated by examining beneficiaries' medical claims histories. The objective of this project is to ascertain how well this and other predictive modeling approaches perform in detecting fraud compared to current Medicare control approaches (both pre-payment and post-payment), and what, if any, savings would be realized by implementing a pre-payment approach. This project began in FY 2010 and will continue into FY 2011.

Centers for Medicare & Medicaid Services

In FY 2010, CMS was allocated approximately \$16.5 million by HHS, and appropriated \$251.4 million in discretionary funds by Congress to support a variety of projects related to fraud, waste, and abuse in the Medicare and Medicaid programs. With these funds, CMS has continued to build on existing fraud prevention activities and has increased its efforts to use advanced technology to ensure that accurate payments are made to legitimate providers for appropriate and reasonable services for eligible beneficiaries of the Medicare, Medicaid, and CHIP programs and

to prevent improper payments related to errors, fraud, waste, and abuse. CMS is engaged in many program integrity activities that are beyond the scope of this report because they are not funded directly by the HCFAC Account or discretionary HCFAC funding. For example, Medicare Integrity Program (MIP) activities, such as audit and medical review functions, and Medicaid Integrity program activities are discussed in separate reports.

Affordable Care Act

HCFAC has been a critical component of fraud fighting since its creation in HIPAA. The new authorities granted to HHS and DOJ under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively known as the Affordable Care Act (ACA), will be instrumental in further clamping down on fraudulent activity in the health care sector. For example, the ACA provides CMS with new and enhanced authorities to keep fraudsters out, before they can begin to bill Medicare and Medicaid. The ACA also provides expanded resources and authorities for sharing data across anti-fraud agencies to heighten monitoring and oversight capability, leading to faster identification and eradication of fraudulent activity. In addition, new HCFAC funding provided by the ACA will assist CMS, OIG and DOJ in further developing predictive modeling capacity and enhancing information systems that can improve anti-fraud tracking as well as add to the number of individuals who can perform site visits to ensure legitimacy of providers who seek the privilege of serving Medicare and Medicaid beneficiaries. CMS began implementing new and enhanced authorities provided by the ACA in FY 2010.

Strengthened Program Integrity Activities in Medicare Advantage and Medicare Part D

CMS invested \$158 million in HCFAC discretionary funds to strengthen Medicare Parts C and D oversight. Activities included expanding the scope of MEDICs by adding Part C to their jurisdiction and conducting a comprehensive program assessment to reevaluate its contracting strategy, the structure of the MEDICs, and the manner in which it oversees fraud, waste, and abuse activities. As a result, CMS changed the focus of the MEDIC work from two regional contractors that performed similar duties to a functional contracting approach. One MEDIC focused on contract compliance oversight activities for the entire nation, while the other MEDIC has a national emphasis on fraud, waste, and abuse oversight activities. More specifically, the compliance and enforcement MEDIC was responsible for the following:

- Conducting compliance plan audits;
- Monitoring inappropriate agent/broker activities;
- Interfacing with the State Departments of Insurance;
- Investigating marketing violations;
- Data trending and analysis of compliance issues; and
- Other compliance/enforcement assistance as necessary.

The benefit integrity MEDIC is responsible for:

- Managing all incoming complaints about Part C and Part D Fraud, Waste, and Abuse (FWA);
- Utilizing new and innovative techniques to monitor and analyze information to help identify potential fraud;
- Working with law enforcement, Medicare Advantage and prescription drug plans, consumer groups and other key partners to protect consumers and enforce Medicare's rules;
- Providing basic tips for consumers so that they can protect themselves from potential scams; and
- Performing proactive research utilizing all available data to find trends in order to ferret out FWA activities.

In addition to the HCFAC resources CMS devoted to the MEDICs to address new complexities facing law enforcement; funding was added to other Part C and Part D oversight functions including contract and plan oversight ; monitoring, plan performance assessment, and surveillance/secret shopper activities; audits of programs; and routine compliance and enforcement tracking. In FY 2010, \$16 million in discretionary funding supported the work being done by the MEDICs. This funding supported the Part C and D anti-fraud efforts conducted by the benefit integrity MEDIC and the data analysis work conducted by Safeguard Services. Approximately \$5 million was allocated to the Program Integrity Technical Assistance contractor. Work performed by this contractor included performance measure development for the MEDIC program, vulnerability analysis of policy and operational processes, and assistance with implementation planning for the Affordable Care Act.

Since their inception, the work of the MEDICs has resulted in thousands of complaints being investigated and over 300 cases being referred to law enforcement for further actions. In 2010 alone, the MEDICs referred 135 cases to Federal law enforcement and 58 Immediate Advisements (inquiries or allegations by beneficiaries or providers concerning potential health care fraud, kickbacks or bribes, a crime by a Federal employee, indications of contractor employee fraud such as altering claims data or manipulating it to create preferential treatment to certain providers, improper preferential treatment in collection of overpayments or embezzlement.)

More specifically, investigators with the benefit integrity MEDIC provided significant assistance that resulted in the indictment of four individuals who had established phantom infusion therapy clinics in Harris County, Texas. On July 2, 2010, an 11 count Federal indictment was unsealed in the Southern District of Texas charging the four individuals with one count of conspiracy to commit health care fraud, five counts of health care fraud and three counts of aggravated identity theft. The phantom clinics submitted claims to Part C plans for \$3.3 million in Medicare treatments, diagnoses, and prescription services that were not rendered. In 2010, the benefit integrity MEDIC referred 10 Immediate Advisements and 4 Referrals to HHS/OIG regarding the infusion therapy fraud scheme.

Established Additional Regional Call Centers and Focused Beneficiary Outreach

South Florida Fraud Hot Line

As part of a two-year infusion therapy demonstration project, CMS established a special fraud hotline in 2007 to protect Medicare beneficiaries in South Florida from fraudulent providers of infusion therapy. As a result of the hotline's success, in FY 2009 CMS expanded the scope of this infusion therapy fraud hotline to handle all Medicare fraud-related calls in South Florida. The fraud hotline number is included on monthly Medicare Summary Notices (MSNs) sent to beneficiaries in Miami-Dade, Broward and Palm Beach counties. This work continued in FY 2010.

Trained, bilingual or trilingual staff fielded and routed calls, as well as acknowledged receipt of complaints in writing. A rapid response team at the ZPIC investigated the highest priority leads received from the fraud hotline within 48 hours of receipt of the call and then collaborated with CMS and/or law enforcement to pursue appropriate follow up action(s). CMS worked with its partners to conduct beneficiary outreach and education to ensure beneficiaries understood the types of fraud that may occur and how to read their MSNs to better detect potential fraudulent billings.

To date the hotline has received more than 29,938 calls leading to 664 new fraud investigations. In addition, the ZPIC has placed 71 providers on prepayment review saving \$3.8 million, revoked/deactivated 59 provider numbers, requested \$15.6 million overpayments, referred 14 cases to law enforcement, and sent 55 Immediate Advisements to the OIG. Law enforcement has seized \$2.8 million in provider bank accounts.

Increased Funding for Program Integrity Demonstrations/Special Initiatives

Durable Medical Equipment Stop Gap Plan

The DME Stop Gap Plan was developed in response to the continued escalation in DME payments, the growth in the number of DMEPOS suppliers, and Congress' postponement of DMEPOS competitive bidding. This two-year project was initiated in FY 2009 to enhance DME fraud, waste and abuse detection and prevention activities in seven high risk states (California, Florida, Illinois, Michigan, North Carolina, New York and Texas), as well as high risk suppliers, ordering physicians, DMEPOS items, and beneficiaries in each area.

Under this project, CMS and its contractors (1) identify and interview or conduct site visits to the: (a) highest paid/highest risk DMEPOS suppliers; (b) highest ordering physicians; and (c) highest utilizing beneficiaries; and (2) identify and scrutinize the highest billed/highest risk DMEPOS equipment and supplies. Based on the findings, autodenial edits and other administrative actions, as appropriate, are initiated.

The first year of the project concluded on September 30, 2010 and the results to date include onsite interviews/reviews of 2,689 high risk providers, suppliers, and beneficiaries; implementation of 9,227 claims processing edits to prevent improper payment (with associated \$17.7 million in denied claims); \$16.4 million in requested overpayments; 759 new investigations opened; and 367 suppliers revoked or deactivated.

Enrollment Special Study

Experts agree that the most effective way to stop fraud is to prevent it before it starts. The traditional manner in which provider enrollment applications are processed does not focus on the potential for fraudulent conduct by those submitting the applications. In high vulnerability areas such as South Florida, where the potential for fraud is the greatest, a more thorough scrutiny of providers/suppliers is necessary before issuing Medicare numbers that enable them to bill Medicare. Focusing resources on the front end of the process helps to significantly reduce or eliminate many of the most common schemes involving sham providers by ensuring providers have been thoroughly evaluated before allowing them to enroll in the Medicare program.

The purpose of this special study is to perform additional fraud, waste and abuse detection, deterrence and prevention activities. Currently in the option year, this one year project began in July 2009 and is based on collaboration between the Medicare Administrative Contractor (First Coast Services, or FCSO) and the Zone Program Integrity Contractor (Safeguard Services, or SGS) for currently enrolled and new Medicare providers in South Florida (Dade/Broward/Palm Beach Counties).

SGS and FCSO worked together to create a Fraud Level Indicator (FLI), which provides a ranking for each provider type that submitted a Medicare enrollment (CMS-855) Form. FCSO scores each provider and those that exceed the threshold for the relevant provider type are referred to SGS to conduct an onsite inspection.

SGS sends a team of investigators and nurses to the provider's location to ensure that the provider is in compliance with Medicare rules and regulations as well as verify that the information provided to CMS/FCSO in the application form is accurate.

The goal of this project is to stop the fraudulent providers from obtaining new Medicare provider numbers, reduce the number of the habitual "bad providers" from re-entering the Medicare system after they have been kicked out in the past, and to stop the pay and chase mentality that has existed in the PSC/ZPIC world in years past.

Through its participation in the project, FCSO has conducted over 4,586 activity checks to verify providers/suppliers operational status, deactivated 260 providers, and revoked 211 providers. Since inception, FCSO saved \$14.9 million from prepayment claim edits and requested over \$140,000 in overpayments. In addition, SGS conducted over 520 on-site investigations resulting in 124 providers being revoked or deactivated. SGS placed 327 providers on prepayment review saving \$7 million and requested \$23 million in overpayments.

Miami Field Office / ZPIC Home Health Project

FY 2010 was the second year of the Home Health project. Results through September 30, 2010, included adding a Fraud Prevention & Early Abatement approach and resulted in 753

beneficiaries being placed on “Not Homebound” edits, 39 beneficiaries being placed on “No Skilled Nursing” edits; and 10 beneficiaries being placed on “No Aide” edits. These edits auto-deny claims for these beneficiaries who were not homebound but for whom claims were submitted as though they were home bound, receiving skilled nursing or receiving other aide. The task order also added a Diabetic Edit approach resulting in 516 diabetic edits as of September 30, 2010. Three additional HHAs were placed on payment suspension in year two bringing the total number of HHs on payment suspicion to 32 for the project. Two additional payment suspension requests were pending as of September 30, 2010. Overpayments calculated to date amount to \$76 million. Edit savings are \$3.7 million year to date and \$9.6 million total to date. Finally, this project resulted in \$2 million in cost avoidance from edits; and \$5.5 million in cost avoidance from monies in payment suspension.

Los Angeles Field Office (FO)/Texas HHA Special Project

There are approximately 2,000 HHAs in the state of Texas. Many of these HHAs have come to rely upon outlier payments, specifically for diabetic beneficiaries, as a predominant part of their overall reimbursement. In an effort to combat home health fraud, waste, and abuse in Texas, the Los Angeles FOs engaged the Zone 4 ZPIC, to address aberrant home health billing. Since September 2009, the Zone 4 ZPIC, in conjunction with the Medicare Administrative Contractor (MAC), has implemented 337 autodenial edits. In addition, the Zone 4 ZPIC added an additional 192 autodenial edits before September 30, 2010. The Zone 4 ZPIC has already imposed 11 payment suspensions, which resulted in a \$1.2 million dollar savings to the Medicare Trust Fund. Overpayments based on post payment review were \$6 million.

Increased Capacity to Identify and Prevent Excessive Payments

Automated Fraud Edits

CMS used automated fraud edits to help prevent payment for improper or fraudulent claims. For example, after uncovering a Medicare infusion scam that involved for-profit clinics and physicians who recruited HIV/AIDS patients for infusion services, paid them kickbacks to come to their clinics, and billed for those services at medically unnecessary frequencies and at lethal dosages, CMS and the Florida PSC (now Zone 7 ZPIC) and Medicare carrier developed and implemented Clinically Unlikely Dosage Edits. These edits auto-deny claims from providers who bill units of medication at lethal dosage amounts. During the time period of June 1, 2005, through June 30, 2010, these edits resulted in denials totaling approximately \$287.6 million. CMS’s Miami FO and the Florida PSC also implemented Beneficiary Auto-denial edits for the top Medicare high volume infusion beneficiaries, which have resulted in denials totaling approximately \$452.4 million in the same time period.

CMS has also implemented Medically Unbelievable Dosage Edits. With these edits, claims from providers who bill units of medication at lethal dosage amounts are automatically denied. CMS has also implemented Beneficiary Autodenial Edits which deny claims for the top 200 Medicare high volume infusion beneficiaries.

Compromised Numbers

CMS contracted with an 8(a) firm in September 2009 to create a national repository of compromised numbers for use by the PSCs, ZPICs and MEDICs. This Compromised Number Contractor (CNC) was also tasked with assisting CMS in developing a national automated database for the compromised numbers that will interface with claims processing so that national edits can be implemented.

To date, the CNC has identified 4,999 compromised providers/suppliers and approximately 266,848 compromised beneficiaries. The CNC provided the updated repository each month to the PSCs/ZPICs/MEDIC and the DMEPOS Pricing, Data Analysis and Coding Contractor, along with associated geomapping analyses to identify “clustering” of compromised numbers. This information was used by the contractors to open investigations and implement claims processing edits. The compromised numbers were also used in national predictive modeling to identify providers/suppliers for investigation. As CMS implements real time analytic tools (see below), the compromised numbers will be one source of valuable data used in the predictive analytics.

Labs & PINs Workgroup

CMS continued to host monthly conference calls for a workgroup comprised of CMS staff nationwide, PSCs and ZPICs, the CNC, and law enforcement, including Assistant United States’ Attorneys, the Federal Bureau of Investigation and HHS/OIG, to share information on “false front” (sham) providers and current fraudulent schemes. Monthly meetings provide invaluable intelligence on geographic shifts and cross-regional schemes.

Workgroup activities resulted in \$133 million in Part B savings through overpayments, administrative actions, and seizures by law enforcement and CMS tasked one PSC to run national claims history for Labs and PINs leads for early identification of potential false provider numbers. For example, in the past 20 months, the workgroup identified 439 false front providers or providers whose identities had been compromised, and approximately 214 were identified prior to any loss of Medicare funds and additional actions were taken against the remaining 225 providers.

Targeted Focus

CMS addressed Medicare “hot fraud” areas with ZPICs and CMS Program Integrity Field Offices. The ZPIC contracting strategy allowed CMS the opportunity to allocate and adjust resources to focus on the highest risk fraudulent activities and geographic areas, particularly fraud, waste, and abuse “hot zones.” Examples include targeted data analysis, site visits to provider locations, beneficiary interviews, and innovative support to law enforcement. The designated Program Integrity FOs in Los Angeles, Miami and New York provided an on the ground presence focused on high risk fraud areas of the country. Together, the Field Offices and ZPICs conducted data analysis to proactively identify targets and to coordinate efforts among various contractors and agencies to identify local, field level issues and vulnerabilities with national or regional impact. All three FOs, which are located in or near the HEAT cites of Miami, Los Angeles and Brooklyn, have staff who are designated CMS Strike Force Liaisons, who then coordinate with law enforcement, facilitate data analysis and expedition suspension requests.

The Miami FO has implemented a comprehensive, multipronged approach to address the varied aspects of health care fraud in South Florida and has provided a testing ground for the efficacy of these efforts on a national level. This initiative focused on intensive provider enrollment screening. CMS also implemented a fraud hotline, follow-up site visits, and prepay review for watch lists providers and suppliers under the South Florida strategy. In addition, CMS instituted a number of targeted efforts in high vulnerability areas such as Miami, Houston, and Los Angeles where there are a large number of beneficiaries and providers/suppliers. CMS and its contractors conducted special projects focused on both high fraud provider/supplier types and high fraud areas of the country. For example, the New York FO led the Medicare 7-State DME Stop Gap Project and the CNC project and participated in the National HEAT Strike Force Data Workgroup to develop data analysis reporting templates

Medicare Secondary Payer Recovery Contractors

The Medicare Secondary Payer (MSP) Recovery Contractor was also partially funded through the use of discretionary HCFAC dollars. This contractor ensures recovery actions are undertaken when Medicare pays for claims where it did not have the primary responsibility to do so. In FY 2010, collections by the MSP Recovery Contractor totaled \$412M.

Enhanced Provider Oversight Efforts

In 2010, CMS invested \$12 million of the HCFAC discretionary funding to enhanced provider oversight activities. CMS has undertaken numerous aggressive actions to tighten the provider enrollment process through a systematic and risk-based application review before enrollment occurs by conducting onsite verifications and by requiring surety bonds.

For example, in some of our special oversight activities and projects, enrollment applications for specific supplier types were evaluated and assigned a Fraud and Abuse Indicator of Risk (FAIR) of high, medium, or low based on potential fraud risk to the program. In assessing the FAIR, factors such as experience as a DMEPOS supplier, experience with other payers, prior Medicare experience, and geographic area were considered. The level of screening used for an applicant depended on the fraud score. Those applicants with a high or medium FAIR received at least one unannounced site visit to verify compliance with the supplier standards. DMEPOS suppliers that were not in compliance with one or more of the supplier standards had their billing number revoked. The enhanced review of applications for new DMEPOS supplier billing numbers helps to prevent non-compliant providers from ever entering the program.

CMS also continued to implement DMEPOS Accreditation Standards which ensure DMEPOS suppliers meet CMS's supplier quality standards. All DMEPOS suppliers were required to comply with the CMS quality standards in order to receive Medicare Part B payments and to retain a supplier billing number starting on October 1, 2009. A supplier billing number is not issued to any non-accredited supplier, thus any non-accredited supplier cannot receive nor maintain any Medicare billing privileges. CMS also implemented additional supplier standards for all DMEPOS suppliers, including hours of operation, physical space and access, obtaining oxygen from state licensed suppliers in states that license, and requiring documentation on ordering and referring of DMEPOS supplies.

CMS has established a surety bond requirement for all DMEPOS suppliers that went into effect on October 2, 2009. Provider numbers cannot be issued or renewed unless the supplier obtains and maintains a surety bond on a continuous basis. The surety bond requirement for DMEPOS suppliers is expected to:

- Limit the Medicare program risk to fraudulent DMEPOS suppliers;
- Ensure that only legitimate DMEPOS suppliers are enrolled or are allowed to remain enrolled in the Medicare program;
- Provide Medicare with the time necessary to determine if a DMEPOS supplier is acting in good faith;
- Ensure that the Medicare program recoups erroneous payments from fraudulent or abusive billing practices by allowing CMS or its designated contractor to seek payments from a surety up to the penal sum; and
- Ensure that Medicare beneficiaries receive products and services that are considered reasonable and necessary from legitimate DMEPOS suppliers.

The combined impact of the surety bond and accreditation efforts in 2009 was substantial. During the first quarter of FY 2010, CMS revoked over 10,000 suppliers as a result of failure to meet the more stringent enrollment criteria and another 6,000 suppliers have voluntarily withdrawn from the program rather than be held accountable to the new standards.

All of these program integrity efforts will work in tandem with CMS' DMEPOS Competitive Bidding Program that has now been implemented and which strengthens Medicare by taking an important step towards paying appropriately for medical equipment and supplies. Competitive bidding reduces out-of-pocket costs for consumers and is estimated to save the Medicare program billions over 10 years. Importantly, DME competitive bidding helps to prevent Medicare fraud. All suppliers in the program must be licensed, meet strict quality and financial standards, and be accredited by a national accreditation organization. A reduction in excessive payment amounts makes competitively bid items less attractive targets for fraud and abuse.

Measured Error Rate

Payment Error Rate Measurement (PERM)

The PERM program was developed to comply with the requirements of the Improper Payments Information Act of 2002 (IPIA), which requires HHS to annually produce national level error rates for Medicaid and CHIP. The IPIA was later amended by the Improper Payments Elimination and Recovery Act of 2010 (IPERA) in order to strengthen improper payment programs and reduce improper payment amounts by \$50 million by 2012. CMS uses Federal contractors to measure Medicaid and CHIP error rates in a subset of States every year. In 2006, CMS measured the fee-for-service component of Medicaid. Starting in 2007, PERM was expanded to measure error rates for fee-for-service, managed care, and eligibility in both the Medicaid and CHIP programs.

HHS calculated and is reporting the three-year weighted average national error rate that includes data from FYs 2008, 2009, and 2010. This three-year rolling error rate is 9.4 percent or \$22.5 billion. The weighted national error components rates are as follows: Medicaid FFS: 4.4 percent; Medicaid managed care: 1.0 percent; and Medicaid eligibility: 5.9 percent. Further evaluation of the error rates shows that the vast majority of Medicaid errors were due to cases reviewed for eligibility that were either not eligible or undetermined, followed by diagnosis coding errors and insufficient documentation errors in the fee-for-service medical review.

HHS reported in the *FY 2009 Agency Financial Report* a two-year weighted average national error rate for Medicaid that included data from 2008 and 2009. The two-year average national Medicaid error rate was 9.6 percent. The weighted national error component rates were: Medicaid fee-for-service: 5.7 percent; Medicaid managed care: 1.5 percent; and Medicaid eligibility: 4.9 percent.

Importantly, CMS noted instances where some States' policies were in conflict with the resulting measurements. One of these instances was in the review of eligibility cases. In some cases, policy and operational differences among states may affect the degree to which states and providers can obtain documentation to validate payments and eligibility decisions. States that have simplified eligibility documentation rules through use of self-declaration and passive renewal often found it harder to obtain necessary documentation for PERM reviews, which led to more undetermined cases that were treated as errors for PERM. To address this issue, one of the requirements Congress included in the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) is that the payment error rate determined for a State should not take into account payment errors resulting from the state's verification of an applicant's self-declaration or self-certification of eligibility if the State process for verifying an applicant's self-declaration or self-certification was approved by CMS. CMS anticipates errors will decrease in the future due to this important policy change.

CMS is currently measuring cycles that will be reported in 2011 and 2012. CMS expects the error rates for Medicaid will decline in future years through program maturation and corrective action initiatives implemented at the State and Federal levels.

As a result of the President's Executive Order on Reducing Improper Payments, the PERM program has added several new requirements including reporting on the Treasury payment accuracy website and reporting comprehensive improper payment measurement and reduction activities to HHS/OIG.

The PERM final rule (75 FR 48816) was published on August 11, 2010 and was effective September 10, 2010. This final rule implements provisions from the Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009 with regard to the PERM program. Section 601 of CHIPRA prohibits HHS from calculating or publishing any national or State-specific error rates for CHIP until six months after the new PERM final rule is effective. HHS will begin CHIP error rate measurement in 2010 with the results being published in November 2012. There was no CHIP error rate calculated or published in 2010, and HHS will not calculate or publish a CHIP error rate in 2011.

Further Development of Near-Real Time Data Analysis Tool

The One Program Integrity (One PI) data project was developed to provide a fully integrated searchable database of all Medicare paid claims. One PI is comprised of analytic tools that will be used to perform data analysis across a centralized Integrated Data Repository (IDR), which does include data from Medicare Parts A, B, and D. The IDR currently houses Part A and B claims data dating back to January 1, 2006 and prescription drug event records dating back to January 1, 2006. CMS will continue to add additional data streams and reference data to the IDR. The availability of a centralized source for accessing the tremendous volume of data on claims, providers, and beneficiaries will enable consistent, reliable, and timely analyses. This will in turn improve the ability to detect fraud, waste, and abuse in the Medicare and Medicaid programs. CMS will continue to add additional data streams, such as standardized Medicaid data across multiple states, and reference data to the IDR.

The Center for Program Integrity (CPI) was created by Secretary Sebelius in April, 2010, to give new focus to antifraud activities in CMS. CPI brings together the Medicaid and Medicare Program Integrity Groups for the first time. Working with the related components of CMS, CPI is coordinating and consolidating program integrity policies and activities. A major initiative of CPI is leveraging innovative technology and techniques to better identify excessive payments early. In FY 2010, CPI initiated several pilot projects to demonstrate the capabilities and gather knowledge for potential broader implementation.

Predictive Modeling

To prevent excessive payments before they are made, CPI began moving toward using predictive modeling techniques (similar to those currently used in the financial sector) to identify high-risk claims for further review prior to payment. CPI has implemented several pilot projects to develop and test predictive models to determine their efficiency (e.g., probability of false positives). Many of these models will be tested with near real-time data in order to ensure that they are effective at identifying high-risk claims. Analyses are specifically underway in the areas of home health, durable medical equipment, and compromised beneficiary and provider numbers. Results from such analyses will be evaluated internally or referred to appropriate contractors for investigation; when confirmed, the results from predictive analytics will provide the basis for administrative actions by CMS and, when appropriate, referral to OIG and DOJ. The long-term plan is to use these models for prepayment risk scoring to identify claims for further review. The sophisticated analytics will move CMS toward its goal of preventing inappropriate payments before they are made.

Advanced Investigative Tool

CPI worked with the Recovery Accountability and Transparency Board to pilot the use of a fraud detection tool that links publicly available data sources in order to conduct network analysis for specific Medicare providers. The pilot involved identifying and analyzing a group of providers that are considered high-risk for potential fraud. The providers were those: 1) most frequently reported by beneficiaries as potentially fraudulent through 1-800-MEDICARE; or 2) screened as high risk in the high fraud area of South Florida. This type of tool may be useful in reviewing

high-risk providers prior to Medicare enrollment. Preliminary results of the pilot were positive and the more extensive use of such tools in enrollment screening is being considered.

Funded Medicaid/CHIP Financial Management Project

Under this project, funding specialists, including accountants and financial analysts, worked to improve CMS's financial oversight of the Medicaid and CHIP programs. Through the continued efforts of these specialists, CMS identified and resolved \$1.7 billion of approximately \$5.8 billion in cumulative questionable costs in FY 2010.

Furthermore, an estimated \$204 million in questionable reimbursement was actually averted due to the funding specialists' preventive work with states to promote proper state Medicaid financing. The funding specialists' activities included reviews of proposed Medicaid state plan amendments that related to reimbursement; development of financial management reviews; research regarding state Medicaid financing policy and practices; collaboration with states to resolve the Medicaid and CHIP portions of the A-133 "Single State" audits; and identification of sources of the non-Federal share of Medicaid program payments to ensure proper financing of Medicaid program costs.

National and Regional Fraud Summits

On January 28, 2010 HHS and DOJ leadership joined private sector leaders, law enforcement personnel, and health care experts for a landmark National Summit on Health Care Fraud. The summit was the first national gathering on health care fraud between law enforcement and the private and public sectors. The National Fraud Summit featured discussions of innovative ways to eliminate fraud and abuse in the U.S. health care system. It laid the groundwork for an open dialogue among stakeholders in the private and public sectors to discuss innovative ways to eliminate fraud within the U.S. health care system. On June 8, 2010 a nationwide series of regional fraud prevention summits as part of a multi-faceted effort to crack down on health care fraud summits was initiated. Summits were held on July 16, 2010, in Miami; on August 26, 2010, in Los Angeles; on November 5, 2010, in New York, and on December 16, 2010 in Boston. \$2 million in HCFAC funds were used to fund these regional fraud summits and also to underwrite the Fraud Prevention Campaign described below. DHHS has a strong commitment to partnering with the private sector so we can mutually learn from best practices. We intend to move forward from the Fraud Prevention Summits to further collaboration and learning and increase focus on anti-fraud activities across the nation.

Fraud Prevention Campaign

A Fraud Prevention Campaign was launched in January 2010 to increase public awareness about Medicare's fight against fraud. The main goal of the campaign is to inform beneficiaries about how to prevent, identify, and report Medicare fraud and raise awareness of the government's robust crackdown resulting from the passage of the Affordable Care Act. Federal, state and local partners, beneficiaries, providers, and other interested parties are joining forces for the Fraud

Prevention Campaign initiative to discuss innovative ways to eliminate fraud within the U.S. health care system, as well as develop strategies aimed at changing the behaviors.

The national paid advertising buy was targeted to Medicare beneficiaries and was designed to educate Medicare beneficiaries about the importance of keeping Medicare information private and where to go for help if fraud is suspected. The paid advertising referred beneficiaries to 1-800-MEDICARE or www.stopmedicarefraud.gov for help. The paid advertising plan ran nationally on network news, national cable, and national print. An estimated 95 percent of Adults over age 55 were exposed to the fraud message an average of 8.35 times.

Administration on Aging

In FY 2010, the Administration on Aging (AoA) was allocated \$3.8 million in HCFAC funding by HHS to support infrastructure, technical assistance and the other Senior Medicare Patrol (SMP) program support and capacity-building activities designed to enhance the effectiveness of state-wide SMP programs. SMP is funded from a separate Congressional appropriation. These dollars support SMP programs that 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 HHS/OIG's Deputy Inspector General for Evaluation and Inspections, dated May 19, 2010, 4,444 active volunteers served the 55 SMP projects during 2009. These volunteers performed an essential function of this program, contributing close to 122,410 hours in efforts to share the SMP message of fraud awareness and prevention within the senior community.

Of the \$3.8 million in HCFAC dollars given to AoA, \$500,000 was used specifically 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.

Of this \$500,000, AoA used \$165,000 to develop SMP Fraud Prevention Public Service Announcements (PSAs), and to provide media toolkits, training and support for SMPs to ensure effective use, placement and response to the PSA. Public awareness campaign fact sheets and supporting materials have been developed and training webinars for SMPs have been planned.

Additionally, AoA plans to use \$335,000 received in FY 2010 to provide additional Hispanic Outreach by working with The National Hispanic SMP (NHSMP) in FY 2011. The NHSMP will work with AoA to develop a SMP Training Manual for Hispanic Volunteers across the country and to conduct a targeted Volunteer Outreach Program and Outreach and Communications Campaign in South Florida.

The key to the campaign will be linguistic, cultural and age-appropriate strategies for reaching this population. The educational campaign will be carried out with media that are shown to reach

Hispanic adults, and educational efforts carried out by people that the Hispanic older adults trust, including Hispanic community-based organizations and members of the local community who are their neighbors and friends. This project is founded on the idea that fighting Medicare fraud in the Hispanic community requires as high a level of cultural competency as that employed by the criminals - the winner will be determined by who is able to gain the trust and confidence of the community. AoA will use this program targeted to South Florida to learn more about National SMP strategies that may be effective nationally in the Hispanic community.

Outreach to senior consumers is a key element of the SMP program. During 2009, SMP projects held 5,684 community education events reaching close to an estimated 1.5 million people, and conducted over 311,000 media outreach activities to increase beneficiary awareness about issues related to Medicare and Medicaid integrity. During this period, 33,855 one-on-one counseling sessions were held with or on behalf of a beneficiary on a variety of issues related to potential Medicare or Medicaid fraud, error or abuse. In addition, over 217,000 beneficiaries were educated through close to 7,200 group educational sessions conducted by SMP programs in local communities.

As a result of educating beneficiaries, the projects received over 60,000 inquiries in 2009 from or on behalf of beneficiaries and resolved over 99 percent of the inquiries during this period. In addition, as a result of educational efforts, SMP projects received 3,052 complex issues—i.e., beneficiary complaints requiring further research, assistance, case development and/or referral. While the SMP program staff was able to resolve 2,588 complex issues for beneficiaries during 2009, an additional 966 of these issues, with an estimated dollar value of \$3.8 million, were referred to law enforcement, CMS integrity contractors, state Medicaid Fraud Control Units, or other entities for further action. During this period, HHS/OIG documented that almost \$565,000 in healthcare expenditures were avoided and over \$214,000 in Medicare, Medicaid and other savings resulted from actions taken by the SMP program.

Since the program's inception, the program has educated over 3.84 million beneficiaries in group or one-on-one counseling sessions and has reached almost 24 million people through community education outreach events. While SMPs make numerous referrals of potential fraud to CMS program integrity contractors, there is no mechanism for tracking the actions (investigation, prosecution, collection) required to realize actual savings to the government as a result of these referrals. Therefore, it is not possible to directly track the outcome of most of the cases reported and dollars recovered as a result of SMP program activities. Moreover, the impact of the SMP program's primary activities - education of beneficiaries to prevent health care fraud—is difficult to measure and impossible to quantify in dollars and cents. As HHS/OIG indicated in the May 2010 report:

“We continue to emphasize that the number of beneficiaries who have learned from the Senior Medicare Patrol Projects to detect fraud, waste, and abuse and who subsequently call the OIG fraud hotline or other contacts cannot be tracked. Therefore, the projects may not be receiving full credit for savings attributable to their work. In addition, the projects are unable to track substantial savings derived from a sentinel effect, whereby fraud and errors are reduced in light of Medicare beneficiaries scrutiny of their bills.”

AoA recognizes the importance of measuring the value of the SMP program impact to the fullest degree possible. Toward that end, AoA has recently initiated a first-ever SMP program evaluation that will assess the adequacy of current SMP performance measures, and seek to determine the most appropriate measures of SMP program value (benefits, results and impact), including return on investment.

Despite the factors that have limited AoA's ability to quantify the value of the SMP program in preventing, identifying and reporting health care fraud, it must be noted that the OIG has documented over \$105.9 million in savings attributable to the program as a result of beneficiary complaints since its inception in 1997.

Office of the General Counsel

In FY 2010, the Office of the General Counsel (OGC) was allocated approximately \$8.7 million in HCFAC funding by HHS to supplement OGC's efforts to support program integrity activities. OGC's efforts in FY 2010 focused heavily on program integrity review, in which OGC reviews CMS' programs and activities in order to strengthen them against potential fraud, waste, and abuse. OGC also continued to expand its litigation role in order to assist in the recovery of program funds. During FY 2010, OGC was involved in a wide range of HCFAC efforts that resulted in Government recoveries of over \$1.2 billion in judgments, settlements, or other types of recoveries, savings, or receivables described elsewhere in this report.

The Affordable Care Act: The ACA significantly amends existing anti-fraud statutes. These provisions establish fundamental expectations for compliance, disclosure, transparency, and quality of care, and are matched by corresponding enforcement provisions. Some specific provisions of the ACA that particularly support HCFAC priorities and goals amend the Anti-Kickback Act provider/supplier Medicare and Medicaid enrollment requirements, overpayment provisions to specifically invoke the FCA, and create a statutory disclosure protocol for violations of the physician self-referral prohibitions known as the "Stark Law." During FY 2010, OGC spent significant time and resources working with CMS and Congress to review and implement the program integrity provisions of the ACA. As new programs from the ACA were implemented, OGC was involved in working with the relevant agencies to ensure that program integrity issues were reviewed and resolved and assisted the agencies in addressing program integrity and compliance problems as they occur.

HEAT: During FY 2010, OGC was involved in HEAT initiatives and worked closely with other HEAT members to combat fraud, waste and abuse in the Medicare and Medicaid programs by providing advice on the myriad legal issues presented as the Government works to initiate innovative anti-fraud programs in various hotspots throughout the country. OGC's involvement in HEAT included advising CMS on provider and supplier revocations, payment suspensions and recoupments that arise from the initiative (as they arose, in addition to criminal and civil fraud prosecutions) and defending the administrative appeals that resulted. OGC continued to assist DOJ in prosecuting those seeking to defraud Medicare and Medicaid and defend any Federal court challenges that are brought as a result of this initiative.

FCA and Qui Tam Actions: OGC assisted DOJ in assessing *qui tam* actions filed under the FCA

by interpreting complex Medicare and Medicaid rules and policies in order to help DOJ focus on those matters which were most likely to result in a recovery of money for the Government. When DOJ filed or intervened in a FCA matter, OGC provided litigation support, including interviewing and preparing witnesses and responding to requests for documents and information. In FY 2010, OGC participated in FCA and related matters that recovered over \$1.07 billion for the Government. The types of FCA cases in which OGC participated included: drug pricing manipulation; illegal marketing activity by pharmaceutical manufacturers that resulted in Medicare and Medicaid paying for drugs for indications that were not covered; underpayment of rebates to state Medicaid programs; physician self-referral and Anti-Kickback Statute violations; and provider upcoding and outlier cases. OGC also assisted DOJ in an emerging workload of cases involving alleged fraud in Medicare Part D, the Medicare prescription drug program.

Provider/Supplier Suspensions and Enrollment Revocations or Denials: Suspensions play a critical role in protecting against the abuse of program funds because they provide a source from which CMS can obtain recoupment after a final overpayment has been determined. Suspensions can also prevent improper payment from being made, thus avoiding the need to “chase” down these funds later. OGC advised CMS on whether to suspend payments to Medicare providers and suppliers and defended the suspensions when challenged. During FY 2010, OGC attorneys were involved in a myriad of suspension and recoupment actions, totaling over \$43 million, many of which involved fraudulent billings and different segments of the health care industry, including DME suppliers, ambulance companies, physicians, infusion clinics, therapists, home health agencies, and diagnostic testing facilities. OGC also represented CMS when a provider or supplier appealed CMS’ denial of enrollment or revocation. During FY 2010, OGC represented CMS in numerous appeals before the Departmental Appeals Board (DAB) and typically resolved these cases without formal hearings. OGC also continued to advise CMS on the interpretation of enrollment regulations and reviewed proposed enrollment rules and manual changes.

Medicare Prescription Drug Program (Part D) & Medicare Advantage Program (Part C) Compliance: OGC continued to provide extensive advice to CMS on a variety of Part D and Medicare Advantage-related contract compliance issues, including identifying enforcement options against sponsors that are noncompliant or violate program rules, such as Marketing Guidelines. OGC reviewed compliance-related correspondence that CMS issued to Part D sponsors and MA plans in the form of warning letters, corrective action plan letters, intermediate sanction and CMP notices and non-renewal or termination notices. One example of OGC’s work in this area in FY 2010 involved the termination of a Part D plan sponsor. OGC advised CMS on the possible termination action, as well as other potential penalties that could apply to this sponsor’s misconduct. OGC is defending the termination in the administrative appeal process and OGC worked closely with DOJ to defend against the sponsor’s federal lawsuit and subsequent federal appeal.

Civil Monetary Penalties: CMS has the responsibility for administering numerous CMP provisions enacted by Congress to combat fraud, waste, and abuse by enforcing program compliance and payment integrity. During FY 2010, OGC provided legal advice to CMS regarding the development and imposition of CMPs and defended CMS in numerous administrative appeals and judicial litigation resulting from these cases, recovering or establishing the right to recover over \$13 million in CMPs.

Petitions for Remission: OGC collaborated with Federal law enforcement, including the FBI, the USAOs, the Secret Service, U.S. Postal Service, and the U.S. Marshal's Service in filing petitions for remission directed to recover assets subject either to administrative forfeiture by Federal law enforcement or civil judicial forfeiture by DOJ. Each petition set forth the background of the fraudulent scheme, the history of Medicare's payments, and how the fraudulently induced payments could be traced to the seized assets. During FY 2010, OGC petitioned these agencies to recover funds in both criminal and civil litigation matters in which Medicare was a victim of fraud involving about \$1 million seized by law enforcement agencies.

Regulatory Review and Programmatic Advice: During FY 2010, OGC advised CMS in developing draft regulations related to compliance and appeals in a proposed rule for the Medicare Parts C and D programs. OGC also advised CMS regarding a variety of contract compliance, immediate sanction and civil money penalty issues, and assisted CMS with a variety of law enforcement inquiries related to Parts C and D. Further, OGC advised CMS regarding the development and finalization of the appeals process for Part C routine audit data validation initiative and reviewed Part D licensure waiver issues.

Medicaid Integrity: OGC saw increased involvement in FY 2010 in Medicaid integrity issues as CMS devoted more resources to financial reviews and oversight and as States continued to present innovative proposals to reconfigure their programs and to draw down federal financial participation at or beyond the margins of the regular Medicaid program. OGC also saw a significant increase in the provision of legal advice to CMS regarding proposed disallowances, many resulting from increased audit scrutiny of state Medicaid expenditures and the filing of Medicaid disallowance appeals before HHS' DAB. In FY 2010, OGC continued to see an increase in disallowances taken in instances where a State received a settlement, often from a pharmaceutical manufacturer, under its State false claims act law or a State consumer protection or fraud law and did not properly pay the Federal government its fair share of the recovery. During FY 2010, OGC was successful in securing over \$150 million in Medicaid program savings.

Physician Self-Referral: OGC provided valuable assistance to CMS in navigating the complexities of the Stark physician self-referral law. In FY 2010, OGC reviewed and offered extensive comments on recent Stark regulations and their implementation, successfully defended regulatory challenges to controversial new provisions in the Stark Law and anti-markup rules, and reviewed several draft Stark advisory opinions. In addition, OGC has reviewed various payment or coverage rules and suggested modifications necessary to avoid implicating, or to conform the regulation to, the Stark law.

Medicare Secondary Payer (MSP) Workload: OGC's efforts to recover conditional payments by Medicare that are the primary responsibility of other payers directly supports the HCFAC statutory goal of facilitating the enforcement of all applicable legal remedies for program fraud and abuse. During FY 2010, OGC has been successful in establishing the right to recover over \$15 million for Medicare under the MSP program. Recent statutory changes to the MSP law have strengthened and expanded OGC's efforts in this area – to the benefit of the Medicare Trust Fund – including substantial CMPs for failure to report.

Bankruptcy Litigation: OGC protected Medicare funds when providers sought bankruptcy protections by asserting CMS' recoupment rights to collect overpayments, arguing to continue suspension or termination actions against debtors, seeking adequate assurances from the bankruptcy court that CMS' 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. In FY 2010, OGC vigorously asserted CMS' interests in numerous bankruptcy and receivership actions involving hospitals, nursing homes and nursing home chains, negotiated agreements to recover overpayments, and aggressively advanced the use of Medicare's recoupment authority, collecting or establishing the right to collect over \$12.8 million in overpayments involving bankrupt providers.

Denial of Claims and Payments: CMS and its contractors engaged in various activities and initiatives to detect and prevent abusive and fraudulent billing practices. These measures included provider and beneficiary education, use of claim sampling techniques and a more rigorous scrutiny of claims with increased medical review. In FY 2010, OGC played a major role in advising CMS regarding the development and implementation of these types of program integrity measures and defended CMS in litigation brought by providers and suppliers who challenged these efforts. OGC continued to aggressively defend CMS and its contractors in cases seeking damages for the alleged wrongful denial of claims, for being placed on payment suspension and for not being granted extended repayment plans.

Food and Drug Administration Pharmaceutical Fraud Program

In FY 2010, the Food and Drug Administration (FDA) was allocated \$1.7 million in HCFAC funding by HHS for the FDA Pharmaceutical Fraud Pilot Program (PFPP). The PFPP has enhanced the health care fraud-related activities of FDA's Office of Criminal Investigations (OCI) and the Office of the General Counsel, Food and Drug Division (OGC). OCI, with the support of OGC, investigates criminal violations of the FDCA, the Prescription Drug Marketing Act, the Federal Anti-Tampering Act, and related Federal statutes.

The PFPP is designed to detect, prosecute, and prevent pharmaceutical, biologic, and medical device fraud. The PFPP focuses on fraudulent marketing schemes, application fraud, clinical trial fraud, and flagrant manufacturing-related violations for biologics, drugs, and medical devices. The early detection and prosecution of fraudulent conduct furthers FDA's public health mission and helps reduce health care costs and deter future violators. As described below, the PFPP has identified, in a relatively short time, several alleged pharmaceutical fraud schemes through various avenues including enhanced intra-agency coordination. PFPP is pursuing all available criminal and civil remedies to punish and deter such conduct.

The PFPP gathers information from sources inside and outside FDA to detect and prosecute pharmaceutical fraud cases by focusing on marketing, clinical trial, and application fraud. The PFPP anticipates that some of these schemes will involve the promotion of drugs and medical devices for uses not approved or cleared by FDA, also known as "off-label promotion." Other cases involve marketing schemes that knowingly overstate the effectiveness or minimize the risk of a medical product. FDA also hopes to detect schemes involving clinical trials and the

submission of false or fraudulent FDA approval applications to prevent the distribution of drugs, biologics, and medical devices that do not meet FDA standards.

Status of FY 2010 HCFAC Program

FDA received approval for the PFPP in FY 2010 and has hired or is in the process of hiring the approved complement of personnel.

The FDA PFPP has developed investigative leads from within FDA's Center for Drug Evaluation and Research. Developing additional investigative leads relating to biologics and medical devices is expected through future increased coordination with FDA's Center for Biologics Evaluation and Research and FDA's Center for Devices and Radiological Health. In addition, FDA has identified and is monitoring various other available sources of information for indications of fraudulent medical product schemes, such as government and public internet sites.

FDA has established the ground-work for coordination and communication between criminal investigators, regulatory components of FDA and the United States Attorney's Offices investigating PFPP-identified health care fraud investigations. FDA has developed procedures to investigate suspected fraudulent schemes that risk the public's health, schemes involving regulated products that thus defraud health benefit programs.

FDA Criminal Investigators are providing support for fraud investigations initiated as a result of the PFPP research and case development. FDA Criminal Investigators are working with the United States Attorney's Offices to investigate these cases and pursue criminal and civil remedies and monetary recoveries. OGC is providing direct legal support for both criminal and civil cases initiated as a result of the PFPP program.

FDA also has established a training plan to further implement the PFPP. This includes instruction of OCI's field office supervisors, who manage the criminal investigators assigned to PFPP investigations, on the internal and external protocols of the program.

Through its PFPP, as a result of HCFAC funding, FDA has opened, within a relatively short time, criminal investigations that FDA continues to investigate, including:

- two off-label promotion matters involving different manufacturers of brand name prescription drugs;
- a third pharmaceutical manufacturer for various violative promotional issues including but not limited to overstatement of efficacy claims, omission of material facts, and promotion of unapproved uses;
- two matters involving manufacturing fraud associated with current Good Manufacturing Practice issues, one which also involves potential application and promotional fraud;
- a clinical trial fraud matter where study documents are alleged to have been falsified by a study coordinator;
- a Contract Research Organization company that reportedly falsified study documents related to research studies conducted for pharmaceutical manufacturers; and

- a Contract Testing Laboratory company that allegedly falsified data used to support multiple drug applications

Assistant Secretary for Public Affairs

In FY 2010, the Assistant Secretary for Public Affairs (ASPA) was allocated \$690,894 in HCFAC funding by HHS to produce a series of live, remote events to promote the awareness of healthcare fraud issues before national and regional public and law enforcement audiences. Local and regional audiences, as well as the national press, are key targets for the messages to be presented. Funding for this project is a direct result of feedback given at the National Fraud Summit; it addresses multiple workgroup recommendations that more be done to raise the public awareness of how health care fraud can be prevented. While funding was allocated to ASPA in FY 2010, these events will occur, and the funds will be obligated, in FY 2011.

In FY 2011, ASPA will produce six to eight events spanning approximately six months. These events will include presentations with distinguished speakers and panel discussions. Additionally, the events will be webcast live and involve a press conference for press to ask questions of administration officials.

ASPA will seek to maximize health care fraud awareness through the internet, including blogs; multi-media viewership, including downloads of any webcasts; podcasts; and other outreach mediums. Additionally, in order to measure the results of this project, a base metric will be gathered, tracked, and analyzed through the use of focus groups, surveys and other awareness measures, and the volume of calls to the fraud phone line. ASPA expects this campaign to create an improved awareness of fraudulent practices and to decrease incidents of fraud.

THE DEPARTMENT OF JUSTICE

United States Attorneys

In FY 2010, the USAOs were allocated approximately \$42.9 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 district resources to combating health care fraud and abuse in 2010, 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. Each district has a designated Criminal Health Care Fraud Coordinator and a Civil Health Care Fraud Coordinator. Civil and criminal 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, although civil cases 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. USAOs also handle most criminal and civil appeals at the federal appellate level.

USAOs play a major role in health care fraud enforcement by bringing criminal and affirmative civil cases to recover funds wrongfully taken from the Medicare Trust Fund and other taxpayer-funded health care systems as a result of fraud, waste, and abuse. Civil and criminal AUSAs litigate a wide variety of health care fraud matters, including false billings by doctors and other providers of medical services, overcharges by hospitals, Medicaid fraud, and kickbacks to induce referrals of Medicare or Medicaid patients, fraud by pharmaceutical and medical device companies, and failure of care allegations against nursing home owners. The Medicare Fraud Strike Forces are currently operating in seven districts. Each district has dedicated several AUSAs and support personnel to this important initiative, along with Criminal Division attorneys who support these cases. New Special Focus Teams, consisting of additional AUSAs, paralegals, and auditors, have been established in three districts and are focusing on pharmaceutical and device fraud. The teams have created a training and mentoring program to increase the capacity of other districts to successfully litigate these complex health care fraud cases. Finally, several of the USAOs partner with the Civil Division in the Elder Justice and Nursing Home Initiative to address elder abuse and neglect.

In addition to the positions funded by HCFAC, the Executive Office for United States Attorneys' Office of Legal Education (OLE) 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 2010, OLE offered an Affirmative Civil Enforcement (ACE) Seminar, which included training on health care fraud, and was attended by over 100 AUSAs and DOJ trial attorneys. In addition, an ACE Conference, with a heavy concentration on health care fraud issues, was offered for paralegals, auditors and investigators. Many of our attorneys, investigators, auditors and

paralegals serve as faculty at these OLE trainings, and also participate in other federal, state and private healthcare fraud seminars.

Criminal Prosecutions

In FY 2010, the USAOs received 1,116 new criminal matters involving 2,095 defendants, and had 1,787 health care fraud criminal matters pending¹⁴, involving 2,977 defendants. The USAOs filed criminal charges in 488 cases involving 931 defendants, and obtained 726 federal health care fraud related convictions.

Civil Matters and Cases

In FY 2010, the USAOs had opened 942 new civil health care fraud investigations. At the end of FY 2010, the USAOs had 1,130 civil health care fraud investigations pending.

Civil Division

In FY 2010, the Civil Division was allocated approximately \$26.9 million in HCFAC funding to support civil health care fraud litigation (this amount includes \$1 million allotted for the Elder Justice and Nursing Home Initiative).

The Civil Division recovers money on behalf of defrauded federal health care programs including Medicare, Medicaid, TRICARE, and the Federal Employees Health Benefits Program. The Civil Division, working closely with USAOs, HHS/OIG and other law enforcement agencies, has recovered over \$1 billion almost every year since 2000 and \$2.5 billion in FY10 alone.

In recent years, pharmaceutical fraud cases have constituted a significant part of the Civil Division's efforts, together with United States Attorneys throughout the country, to combat health care fraud. These cases are commonly nationwide in scope, both legally and factually complex, and routinely require the dedication of significant resources. Moreover, these cases are important as they involve schemes that cost federal payers billions of dollars and affect public health. For example, the Allergan, Novartis, and AstraZeneca cases cited earlier in this report all arose from allegations that those pharmaceutical manufacturers marketed their drugs for uses that the FDA had not found to be safe or effective and thereby caused federal payers to pay for those unapproved uses. Those cases resulted in civil recoveries of \$225 million, \$237 million, and \$520 million, respectively. Moreover, in addition to the pharmaceutical fraud cases, the Civil Division pursues a wide array of cases that protect both the public fiscal and public health. For example, Omnicare (the nation's largest supplier of pharmaceutical products to long term care facilities) paid \$98 million to resolve allegations pursued by the Civil Division and the United States Attorney in Massachusetts that it solicited and received kickbacks from certain pharmaceutical manufacturers in order to market their drugs to elderly nursing home patients.

¹⁴ When 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.

Likewise, FORBA, a dental management company that managed the Small Smiles chain of dental clinics, paid \$24 million to resolve allegations pursued by the Civil Division and several United States Attorneys that it caused bills to be submitted to Medicaid for medically unnecessary dental services provided to children.

In addition to the matters highlighted above, Civil Division personnel investigate and litigate against the full spectrum of Medicare and Medicaid providers and suppliers, such as hospitals, physicians, skilled nursing facilities, and pharmaceutical and device manufacturers for overcharging the government for health care services or goods, or, for billing for goods and services that were either not provided or not medically necessary. Oftentimes, these allegations are linked to allegations that the doctors and others were paid kickbacks or other remuneration to induce referrals of Medicare or Medicaid patients in violation of the Anti-Kickback Statute and Physician Self-Referral laws. Through its Office of Consumer Litigation, the Civil Division investigates both criminal and civil violations of the Food, Drug, and Cosmetic Act. The Civil Division also investigates allegations of drug price manipulation and illegal marketing activity that cause the Medicare and Medicaid programs to pay for drug uses that were neither approved by the FDA nor supported by medical literature.

In addition to its recovery efforts, the Civil Division actively provides training and guidance on health care fraud matters generally and pharmaceutical and device fraud specifically. Likewise, the Civil Division regularly provides speakers and trainers to health care fraud conferences organized by other law enforcement organizations such as the National Association of Medicaid Fraud Control Units, National Health Care Anti-Fraud Association, and assorted Medicare contractor entities.

The Elder Justice and Nursing Home Initiative, which is housed in the Civil Division, continues to coordinate and support law enforcement efforts to combat elder abuse, neglect, and financial exploitation. The Initiative supports law enforcement efforts by maintaining an information bank of Elder Justice related materials (including briefs, opinions, indictments, plea agreements, subpoenas templates); funding medical reviewers, auditors, and other consultants to assist DOJ attorneys and AUSAs in their nursing home and/or long term care facility cases; hosting quarterly teleconferences with DOJ attorneys and AUSAs across the country to discuss issues or developments in connection with our nursing home and failure of care cases; and coordinating nationwide investigations of skilled nursing facilities. Moreover, starting this fiscal year, the Initiative began assembling an elder justice team to be comprised of a lead attorney and an investigative staff. This team will help AUSAs to triage and investigate failure of care allegations, to develop new investigative leads, and to litigate, if necessary. In addition to supporting law enforcement efforts, the Initiative continues to fund research projects awarded by the Office of Justice Programs, National Institute of Justice, to study the abuse, neglect and exploitation of elderly individuals and residents of residential care facilities.

Lastly, the Civil Division works closely with the Office of Inspector General, Office of Counsel, in all settlements of health care fraud allegations in order to ensure that the administrative remedies possessed by HHS are appropriately considered and to enable the negotiation of compliance terms that diminish the risk that the offending conduct will be repeated.

Criminal Division

In FY 2010, the Criminal Division was allocated \$6.9 million in HCFAC funding to support criminal health care fraud litigation and interagency coordination, which is carried out primarily by two sections with the Criminal Division: the Fraud Section and the Organized Crime and Racketeering Section (OCRS).

The Fraud Section

The Fraud Section initiates and coordinates complex health care fraud prosecutions and supports the USAOs with legal and investigative guidance and training, and trial attorneys to prosecute health care fraud cases. Beginning in March 2007, the Criminal Division's Fraud Section working with the local USAOs, the FBI and law enforcement partners in HHS/OIG, and state and local law enforcement agencies launched the Medicare Fraud Strike Force in Miami-Dade County, Florida, to prosecute individuals and entities that do not provide legitimate health care services, but exist solely for the purpose of defrauding Medicare and other Government health care programs. Since 2007, DOJ and HHS have expanded the Strike Force to seven cities. In FY 2010, the Fraud Section continued to provide attorney staffing, litigation support, as well as leadership and management oversight for numerous Strike Force prosecutions in each of the seven cities. A summary of the Fraud Section's key litigation accomplishments in FY 2010 follows:

- Opened or filed 27 new health care fraud cases involving charges against 131 defendants who collectively billed the Medicare and Medicaid programs more than \$208 million;
- Obtained 95 guilty pleas and litigated 12 jury trials, winning guilty verdicts against 18 defendants.¹⁵
- Prison sentences imposed in the Section's health care fraud cases during the year averaged more than 43 months; and
- Court-ordered restitution, forfeiture and fines exceeded \$78 million.

Fraud Section attorneys staffed and coordinated most of the Division's health care fraud litigation through the existing Medicare Fraud Strike Force teams in Miami, Los Angeles, Detroit, and Houston, and by implementing the new Strike Force phases in Brooklyn, Baton Rouge, and Tampa during FY 2010. Section attorneys coordinated two major multi-district Strike Force arrest takedowns carried out during the fiscal year and handled several of the investigations and indictments that were filed in these operations.

On December 15, 2009, Fraud Section and federal prosecutors from three USAOs charged 30 people in Brooklyn, Detroit, and Miami for their alleged roles in schemes to submit more than \$61 million in false Medicare claims. On July 16, 2010, Fraud Section attorneys and federal prosecutors from five USAOs charged 94 people for their alleged participation in schemes to collectively submit more than \$251 million in false claims to the Medicare program in the largest federal health care fraud takedown in U.S. history. More than 360 law enforcement agents from

¹⁵ Fraud Section attorneys litigated twelve of the eighteen Medicare Fraud Strike Force trials during FY 2010. Several of these trials were summarized previously in the "Medicare Fraud Strike Force" section of this report.

the FBI, HHS/OIG, multiple Medicaid Fraud Control Units, and other state and local law enforcement agencies participated in the arrests and searches in Miami, New York, Baton Rouge and Detroit. Four defendants were also charged in Houston for their alleged roles in a fraudulent DME scheme.

In addition to health care fraud litigation, the Fraud Section also provided legal guidance to FBI and HHS/OIG agents, health program agency staff, AUSAs and other Criminal Division attorneys on criminal, civil and administrative tools to combat health care fraud; provided advice and written materials on patient medical record confidentiality and disclosure issues, and coordinated referrals of possible criminal HIPAA privacy violations from the HHS Office for Civil Rights; monitored and coordinated DOJ responses to legislative proposals, major regulatory initiatives, and enforcement policy matters; reviewed and commented on health care provider requests to the HHS/OIG for advisory opinions, and consulted with the HHS/OIG on draft advisory opinions; worked with CMS to improve Medicare contractors' fraud detection, referrals to law enforcement for investigation, and case development work; and prepared and distributed to all USAOs and FBI field offices periodic summaries of recent and significant health care fraud cases.

The Organized Crime and Racketeering Section (OCRS)

The Criminal Division's Organized Crime and Racketeering Section (OCRS) supports investigations and prosecutions of fraud and abuse targeting the 2.8 million private sector health plans sponsored by employers and/or unions, including schemes by corrupt entities that sell insurance products. Such private sector group health plans are the leading source of health care coverage for individuals not covered by Medicare or Medicaid. OCRS also provides strategic coordination in the identification and prosecution of domestic and international organized crime groups engaged in sophisticated frauds posing a threat to the health care industry.

OCRS provides litigation support and guidance to AUSAs and criminal investigative agencies to combat corruption and abuse of employment based group health plans covered by the Employee Retirement Income Security Act. For example, one OCRS attorney provided substantial litigation support in the prosecution of a scheme to deprive private sector workers on Federal and state construction projects in New York of their health and other employment benefits guaranteed under prevailing wage laws.

OCRS attorneys also provide health care fraud and abuse training and legal guidance to AUSAs and to criminal investigators and agents of the Department of Labor's Employee Benefits Security Administration and Office of Inspector General. The Section drafts and coordinates criminal legislative initiatives affecting employee health benefit plans and reviews and comments on legislative proposals affecting employment based health benefit plans.

OCRS attorneys provide litigation support and advice in the investigation and prosecution of health care fraud perpetrated by domestic and international organized crime groups through the long-standing Organized Crime Strike Force Units located within various United States Attorneys' Offices. In February 2010, the lead defendant in a racketeering prosecution of La Cosa Nostra associates of the Bonanno crime family was sentenced to 151 months in prison and

\$140,000 in restitution for a scheme to defraud Medicare. That case was prosecuted by the Organized Crime Unit in Fort Lauderdale, Florida.

Under the International Organized Crime Initiative commenced in 2009, OCRS monitors trends in the targeting of health care by international organized criminal groups and assists in the coordination of multi-district health care fraud investigations. Through the International Organized Crime Intelligence and Operations Center (IOC-2), OCRS provides training and organizes case coordination meetings for multi-district organized crime investigations of health care fraud. The threat posed by international organized crime groups targeting Medicare and Medicaid was emphasized by the racketeering indictment in September 2010 of members of an international organized crime enterprise allegedly involved in sophisticated and wide-ranging money making criminal schemes which defrauded the health care system. The leadership of the organization was based in Los Angeles and New York with members and associates located throughout the United States and in Armenia. They are alleged to have perpetrated a large-scale, nationwide scam that fraudulently billed Medicare for more than \$100 million of medical treatments that were unnecessary or never performed using a series of phantom clinics. One of the defendants charged with racketeering is alleged to be a “Vor,” a term translated as “Thief-in-Law” and refers to a member of a select group of high-level criminals from Russia and the countries that have been part of the former Soviet Union, including Armenia. This case is being prosecuted by the Organized Crime Unit of the United States Attorney’s Office in the Southern District of New York.

Civil Rights Division

In FY 2010, the Civil Rights Division was allocated approximately \$4.4 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 2010 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 six health care facilities in five states during FY 2010. 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 2010, the Section opened or continued formal investigations, entered remedial agreements, or monitored existing remedial agreements regarding 71 health care facilities in 25 states, the District of Columbia, the Territory of Guam, and the Commonwealth of Puerto Rico.

The Section found that conditions and practices at five state facilities for persons with mental illness, and three state facilities for persons with intellectual and developmental disabilities violate the residents' Federal constitutional and statutory rights. Those facilities are: Rosewood Center in Owings Mills, Maryland; W.A. Howe Developmental Center in Tinley Park, Illinois; Clyde L. Choate Developmental Center in Anna, Illinois; and five Georgia facilities for persons with mental illness, including Georgia Regional Hospital in Savannah; East Central Regional Hospital in Augusta; Central State Hospital in Milledgeville; Southwestern State Hospital in Thomasville; and, West Central Georgia Regional Hospital in Columbus.

In Fiscal Year 2010, the Section commenced investigations of five facilities for person with intellectual and developmental disabilities in Arkansas, including Alexander Human Development Center; Arkadelphia Human Development Center; Booneville Human Development Center; Jonesboro Human Development Center; and, Southeast Arkansas Human Development Center, and two publicly operated nursing facilities, LaSalle Nursing Home in Ottawa, Illinois and Casa del Veterano in Juana Diaz, Puerto Rico.

The Section entered settlement agreements to resolve its investigation of one state operated facility for persons with mental illness. That facility is: Kings County Hospital Center in Brooklyn, New York.

In addition, the Section filed an amended complaint in United States v. Georgia (N.D. Ga.) regarding conditions at Georgia Regional Hospital in Atlanta; Georgia Regional Hospital in Savannah; Northwest Georgia Regional Hospital in Rome; East Central Regional Hospital in Augusta; Central State Hospital in Milledgeville; Southwestern State Hospital in Thomasville; and, West Central Georgia Regional Hospital in Columbus.

The Section continued its investigations of ten residential facilities for persons with intellectual and developmental disabilities: 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; Bellefontaine Developmental Center, in St. Louis, Missouri; Northwest Habilitation Center, in St. Louis, Missouri; Rosewood Center in Owings Mills, Maryland; Clyde L. Choate Developmental Center, in Anna, Illinois; Howe Developmental Center, in Tinley Park, Illinois; and, Central Virginia Training Center in Lynchburg, Virginia. The Division also continued its investigations of seven facilities for persons with mental illness, including Oregon State Hospital, in Salem,

Oregon; Delaware State Psychiatric Center in New Castle, Delaware; Ancora Psychiatric Hospital in Winslow, New Jersey; and, four facilities in North Carolina, including John Umstead Hospital in Butner; Dorothea Dix Hospital in Raleigh; Cherry Hospital in Goldsboro; and Broughton Hospital in Morgantown. The Section also continued its investigations of William F. Green State Veterans' Nursing Home in Bay Minette, Alabama and Maple Lawn Nursing Home in Palmyra, Missouri. In some of these matters, the Section is reviewing voluntary compliance to improve conditions.

The Section monitored the implementation of remedial agreements for 23 facilities for persons with intellectual and developmental disabilities: 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; 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; Oakwood Community Center in Somerset, Kentucky; Beatrice State Developmental Center, in Beatrice, Nebraska; Lubbock State Supported Living Center, in Lubbock, Texas; Denton State Supported Living Center, in Denton, Texas; Abilene State Supported Living Center, in Abilene, Texas; Austin State Supported Living Center in Austin, Texas; Brenham State Supported Living Center, in Brenham, Texas; Corpus Christi State Supported Living Center, in Corpus Christi, Texas; El Paso State Supported Living Center, in El Paso, Texas; Lufkin State Supported Living Center, in Lufkin, Texas; Mexia State Supported Living Center, in Mexia, Texas; Richmond State Supported Living Center, in Richmond, Texas; Rio Grande State Supported Living Center, in Harlingen, Texas; San Angelo State Supported Living Center, in Carlsbad, Texas; San Antonio State Supported Living Center, in San Antonio, Texas. It also monitored the implementation of remedial agreements regarding community placements from facilities for persons with intellectual and developmental disabilities in Indiana, Puerto Rico, and Washington, D.C.

The Section also monitored the implementation of remedial agreements regarding 15 state-operated residential facilities for persons with mental illness: Guam Mental Health Unit in the Territory of Guam; Vermont State Hospital, in Waterbury, Vermont; Metropolitan State Hospital, in Norwalk, California; Napa State Hospital in Napa, California; Atascadero State Hospital, in Atascadero, California; Patton State Hospital, in Patton, California; St. Elizabeth's Hospital, Washington, D.C.; 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 Hospital, in Columbus, Georgia; East Central Georgia Regional Hospital, in Augusta, Georgia; and Connecticut Valley Hospital, in Middletown, Connecticut.

In addition, the Section continued its monitoring of seven nursing facilities, including Reginald P. White Skilled Nursing Facility, in Meridian, Mississippi; Mercer Geriatric Center, in Trenton, New Jersey; C.M. Tucker Nursing Care Center, in Columbia, South Carolina; Tennessee State Veterans' Homes, in Murfreesboro and Humboldt, Tennessee; Ft. Bayard Medical Center, in Ft. Bayard, New Mexico; and, Laguna Honda Hospital and Rehabilitation Center, in San Francisco, California.

Federal Bureau of Investigation Mandatory Funding & Discretionary 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 2010, \$126,258,242.”

In FY 2010, the FBI was allocated \$130.2 million in funding, including \$126.3 million from HIPAA and \$3.9 million from discretionary HCFAC, for health care fraud enforcement. This yearly appropriation is used to support 769 positions (460 Agent, 309 Support). The number of pending investigations has shown steady increase from 591 pending cases in 1992 to 2,584 cases through the 3rd quarter of FY 2010. FBI-led investigations resulted in 648 criminal health care fraud convictions and 889 indictments and informations being filed through the 3rd quarter of FY 2010. Through July of FY 2010, FBI HCF fraud investigations resulted in the operational disruption of 163 criminal fraud organizations, and the dismantlement of the criminal hierarchy of more than 60 HCF criminal enterprises.

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 HHS/OIG, the FDA, the 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, 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 high priority within the FBI 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 disruption, dismantlement and prosecution of criminal organizations.

During FY 2010, the FBI initiated the Home Health Agency Fraud Initiative. The overall goal of this program is to develop intelligence, identify fraudulent providers, and target physicians who

exploit this care system for financial gain. The initiative utilizes data analysis, sophisticated and advanced investigative techniques, and traditional investigative strategies to identify and target perpetrators of home health care fraud. The FBI maintained a national initiative addressing DME fraud, one of the most pervasive targets of health care fraudsters. In addition, during FY 2010, the FBI realigned existing initiatives into National Focus Threats, to provide a mechanism to allocate investigative and analytical/intelligence resources against significant health care fraud schemes involving Infusion Therapy, Staged Accident, and Internet Pharmacy.

In FY 2010 the FBI continued to staff and support DOJ Medicare Strike Force operations in Miami, New York City, Houston, Tampa, Detroit, Los Angeles, and Baton Rouge. These task force operations are comprised of agencies that include the United States Attorney's office, state prosecutor/Attorney General offices, the Internal Revenue Service – Criminal Investigative, HHS/OIG, state health care fraud investigative agencies, and local law enforcement personnel. Entering the final quarter of FY 2010, the FBI has finalized plans to deploy additional resources to Strike Force locations, as well as increase investigative personnel in future Strike Force locations.

In FY 2010, the FBI aggressively expanded its involvement in *qui tam* investigations involving major pharmaceutical manufacturers. High-profile *qui tam* investigations, such as the \$2.3 billion Pfizer criminal/civil settlement, the \$126 million Omnicare civil settlement, and the recently announced \$600 million Allergan criminal/civil settlement required a significant dedication of FBI investigative resources. These investigations involve violations of the FCA, and include kickbacks, off-label marketing, misbranding, and the submission of fraudulent/false claims to Medicare and Medicaid.

The FBI has teamed with DOJ, the United States Attorneys, and HHS/OIG to expand training in the priority threat areas of health care fraud. Training was expanded to include the involvement of traditional organized crime and extraterritorial groups in health care fraud schemes, with joint training sessions addressing common health care fraud activity, identity theft, money laundering, and criminal enterprise targeting. The FBI training program in health care fraud focuses on the development of human capital capable of adapting to emerging threats and fraud schemes. Training also included innovative methods of employing sophisticated and advanced investigative techniques against organized criminal enterprises engaged in defrauding United States government sponsored health care programs. In FY 2010, more than 400 FBI health care fraud investigators and analysts received training, and the FBI conducted a wide range of training for external audiences involved in the investigation of health care fraud matters.

Funding received by the FBI is used to pay direct and indirect personnel-related costs associated with the 769 funded positions. Funds not used directly for personnel matters are used to provide operational support for major health care fraud investigations, national initiatives, training, specialized equipment, expert witness testimony, and Strike Force operations.

Corrections to the FY 2009 HCFAC Report

1. On page 5 of the FY 2009 HCFAC report, the line “Restitution/Compensatory Damages was overstated by \$30,442,595. In addition, the Federal Share of Medicaid amount of \$440,955,428 was included in the line “Restitution/Compensatory Damages”, and should have been included in the section titled “Restitution/Compensatory Damages to Federal Agencies”.
2. On page 27 of the FY 2009 HCFAC report, it was stated that the Condell Health Network “admitted in the settlement agreement to leasing medical office space at rates below fair market value; giving improper loans to physicians; and providing hospital reimbursement to doctors who performed patient services without required agreements.” While this sentence accurately describes the covered conduct, the Condell Health Network did not admit to the allegations.

Return-on-Investment Calculation

- The Return-on-Investment (ROI) for the HCFAC program is calculated by dividing the total monetary results to the Federal government (not including relator payments) by the annual appropriation for the HCFAC Account in a given year.
- The monetary results include deposits and transfers to the Medicare Part A Trust Fund and the Treasury, as well as restitution and compensatory damages to Federal agencies.
- The HCFAC Account is made up of three funding sources: mandatory funding for HHS and DOJ, including HHS/OIG, appropriated through Section 1817(k) (3) (A) of the Social Security Act; mandatory funding for FBI activities appropriated through Section 1817(k) (3) (B) of the Social Security Act; and discretionary funding for the HCFAC Account appropriated through the annual Labor-HHS-Education appropriation. FBI mandatory HIPAA funding is included in ROI calculations given the important role the FBI plays in achieving the monetary results reflected in the HCFAC annual report and because that statute states that the funds are for the same purposes as the funds provided for HHS and DOJ under the Social Security Act, even though FBI spending and monetary results are not required to be reported, per the statute.
- While all mandatory HCFAC Account funding is included in the ROI calculation of this report, only certain portions of discretionary HCFAC funding is included. All discretionary HCFAC funding for HHS/OIG and DOJ are included in the HCFAC report ROI since they spend their discretionary funding on the same types of activities that they support with mandatory funding. Only the portion of CMS Medicare discretionary HCFAC funding that supports law enforcement is included in the HCFAC report ROI. The remainder of CMS's HCFAC Medicare discretionary funding supports activities in the Medicare Integrity Program (MIP) that are included in the MIP ROI, which is calculated separately and outside of the HCFAC report. All discretionary Medicaid Integrity program funding is included in a separate Medicaid Integrity Program ROI published in a separate report.

Glossary of Terms

The Account - The Health Care Fraud and Abuse Control Account

ACA – Affordable Care Act

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

ASPA – Assistant Secretary for Public Affairs (HHS)

AUSA - Assistant United States Attorney

CERT - Comprehensive Error Rate Testing

CHIP - State Children's Health Insurance Plan

CIA - Corporate Integrity Agreement

CMP - Civil Monetary Penalty

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

CNC – Compromised Number Contractors

CPI – Center Program Integrity

CPI-U – Consumer Price Index – Urban Consumers

CRIPA - Civil Rights of Institutionalized Persons Act

CY – Calendar Year

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

DOJ - The Department of Justice

DRA - Deficit Reduction Act of 2005

EOUSA - Executive Office for the United States Attorneys

FBI - Federal Bureau of Investigation

FCA - False Claims Act

FDA - Food and Drug Administration

FDCA – Food, Drug, and Cosmetic Act

FI – Fiscal Intermediaries

FLI – Fraud Level Indicator

FY – Fiscal Year

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

HEAT - Health Care Fraud Prevention & Enforcement Action Team

HHA – Home Health Agency

HHS - 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

HIV - Human Immunodeficiency Virus

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

MEDIC - Medicare Drug Integrity Contractors

MFCU – Medicaid Fraud Control Unit

OCRS - Organized Crime and Racketeering Section

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

PERM - Program Error Rate Measurement

PFPP – Pharmaceutical Fraud Pilot Program

The Program - The Health Care Fraud and Abuse Control Program

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

SMP - Senior Medicare Patrol

TRHCA - Tax Relief and Health Care Act

USAO - United States Attorney's Office

ZPIC - Zone Program Integrity Contractor