
**The Department of Health and Human Services
and
The Department of Justice
Health Care Fraud and Abuse Control Program
Annual Report for Fiscal Year 2012**

February 2013

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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 sixteenth year of operation, the Program's continued success 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) 2012, the Federal government won or negotiated over \$3.0 billion in health care fraud judgments and settlements², and it attained additional administrative impositions in health care fraud cases and proceedings. As a result of these efforts, as well as those of preceding years, in FY 2012, approximately \$4.2 billion was deposited with the Department of the Treasury and the Centers for Medicare & Medicaid Services (CMS), transferred to other Federal agencies administering health care programs, or paid to private persons during the fiscal year. Of this \$4.2 billion, the Medicare Trust Funds³ received transfers of approximately \$2.4 billion during this period, and over \$835.7 million in Federal Medicaid money was similarly transferred separately to the Treasury as a result of these efforts. The HCFAC account has returned over \$23.0 billion to the Medicare Trust Funds since the inception of the Program in 1997.

Enforcement Actions

In FY 2012, the Department of Justice (DOJ) opened 1,131 new criminal health care fraud investigations involving 2,148 potential defendants. Federal prosecutors had 2,032 health care fraud criminal investigations pending, involving 3,410 potential defendants, and filed criminal charges in 452 cases involving 892 defendants. A total of 826 defendants were convicted of health care fraud-related crimes during the year. Also in FY 2012, DOJ opened 885 new civil health care fraud investigations and had 1,023 civil health care fraud matters pending at the end of the fiscal year. In FY 2012, Federal Bureau of Investigation (FBI) health care fraud investigations resulted in the operational disruption of 329 criminal fraud organizations, and the dismantlement of the criminal hierarchy of more than 83 criminal enterprises engaged in health

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.

³Also known as the Medicare Hospital Insurance (Part A) Trust Fund and the Supplemental Medical Insurance (Part B) Trust Fund.

care fraud.

In FY 2012, HHS' Office of Inspector General (HHS/OIG) excluded 3,131 individuals and entities. Among these were exclusions based on criminal convictions for crimes related to Medicare and Medicaid (912) or to other health care programs (287); for patient abuse or neglect (212); and as a result of licensure revocations (1,463). In addition, HHS/OIG imposed civil monetary penalties against, among others, providers and suppliers who knowingly submitted false claims to the Federal government. HHS/OIG also issued numerous audits and evaluations 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 2012

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 Funds. 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 Funds.

The Act appropriates monies from the Medicare Hospital Insurance 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/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.^{4e} 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) extended permanently the yearly increases to the Account based upon the change in the consumer price index for all urban consumers or CPI-U.

⁴ The CPI-U adjustment in TRHCA did not apply to the Medicare Integrity Program (MIP). Section 6402 of the ACA indexed Medicare Integrity Program funding to inflation starting in FY 2010.

In FY 2012, the Secretary and the Attorney General certified \$294.8 million in mandatory funding for appropriation to the Account. Additionally, Congress appropriated \$309.7 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 2012. (Separately, the FBI received \$136.2 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 Funds for the previous fiscal year under various categories and the source of such amounts; and
- (2) the amounts appropriated from the Trust Funds for such year for use by the Attorney General and the Secretary and the justification for the expenditure of such amounts.

This annual report fulfills the above statutory requirements.

Additionally, this report fulfills the requirement in the annual discretionary HCFAC appropriation (Public Law 112-74 "Consolidated Appropriations Act of 2012") that this report "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."

MONETARY RESULTS

As required by the Act, HHS and DOJ must detail in this Annual Report the amounts deposited to the Medicare Trust Funds and the source of such deposits. In FY 2012, approximately \$4.2 billion was deposited with the Department of the Treasury and CMS, transferred to other Federal agencies administering health care programs, or paid to private persons during the fiscal year. The following chart provides a breakdown of the transfers/deposits:

Total Transfers/Deposits by Recipient FY 2012	
Department of the Treasury	
Deposits to the Medicare Trust Funds, as required by HIPAA	
Gifts and Bequests	\$54
Amount Equal to Criminal Fines	\$1,389,126,761
Civil Monetary Penalties	\$15,766,272
Asset Forfeiture	\$20,370,629
Penalties and Multiple Damages	\$602,272,078
Subtotal	\$2,027,535,794
Centers for Medicare & Medicaid Services	
HHS/OIG Audit Disallowances – Recovered - Medicare	\$89,677,376
Restitution/Compensatory Damages	\$332,565,650
Subtotal*	
Grand Total of Amounts Transferred to the Medicare Trust Funds	\$2,449,778,820
Restitution/Compensatory Damages to Federal Agencies	
TRICARE	\$121,733,571
Department of Veterans Affairs	\$81,149,775
HHS/OIG Cost of Audits, Investigations and Compliance Monitoring	\$11,847,360
Office of Personnel Management	\$157,225,672
Other Agencies	\$3,113,738
Federal Share of Medicaid	\$835,723,125
HHS/OIG Audit Disallowances – Recovered - Medicaid	\$275,559,307
Subtotal	\$1,486,352,548
Relators= Payments**	\$284,539,872
TOTAL ***	\$4,220,671,240

* Restitution, compensatory damages, and recovered audit disallowances include returns to both the Medicare Hospital Insurance (Part A) Trust Fund and the Supplemental Medical Insurance (Part B) Trust Fund.

**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 Funds. These amounts include:

- (1) Gifts and bequests made unconditionally to the Trust Funds, 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 sixteenth year of operation, the Secretary and the Attorney General certified \$294.8 million in mandatory funding as necessary for the Program. Additionally, Congress appropriated \$309.7 million in discretionary funding. The following chart gives the allocation by recipient:

FY 2012 ALLOCATION OF HC FAC APPROPRIATION

Organization	Mandatory Allocation ⁵	Discretionary Allocation	Total Allocation
Department of Health and Human Services			
Office of Inspector General ⁶	196,090,169	29,673,810	225,763,979
Office of the General Counsel	8,887,870	0	8,887,870
Administration for Community Living	10,709,503	0	10,709,503
Food and Drug Administration	3,377,220	0	3,377,220
Centers for Medicare & Medicaid Services	14,530,000	250,442,767	264,972,767
Subtotal	233,594,762	280,116,577	513,711,339
Department of Justice			
United States Attorneys	31,400,000	4,064,433	35,464,433
Civil Division	18,972,139	5,190,085	24,162,224
Criminal Division	3,380,000	5,117,052	8,497,052
Civil Rights Division	3,838,000	1,055,842	4,893,842
Nursing Home and Elder Justice Initiative	1,000,000	0	1,000,000
Federal Bureau of Investigation ⁷	0	3,446,994	3,446,994
Justice Management Division	200,000	0	200,000
Department of Justice - Other	2,434,610	10,799,404	13,233,414
Subtotal	61,224,749	29,673,810	90,898,559
TOTAL⁸	294,819,511	309,790,387	604,609,898

ACCOMPLISHMENTS

⁵ In FY 2007, mandatory funds became available until expended. Discretionary funding is two-year funding.

⁶ In addition, HHS/OIG obligated \$9.4 million in funds received as Areimbursement 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).

⁷ In addition, in FY 2012, the FBI received \$136.2 million in mandatory HIPAA funding.

⁸ Amounts only represent those that are provided by statute, and do not include other mandatory sources or discretionary appropriated sources provided through Departments' annual appropriations.

Overall Recoveries

During this fiscal year, the Federal government won or negotiated approximately \$3.0 billion in judgments and settlements, and it attained additional administrative impositions in health care fraud cases and proceedings. The Medicare Trust Funds received transfers of approximately \$2.4 billion during this period as a result of these efforts, as well as those of preceding years; and another \$835.7 million in Federal Medicaid money was transferred to the Treasury separately as a result of these efforts.⁹

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.

The return-on-investment (ROI) for the HCFAC program over the last three years (2010-2012) is \$7.90 returned for every \$1.00 expended. This is \$2.50 higher than the average ROI for the life of the HCFAC program since 1997. 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 Secretary maintain regular consultation at both senior and staff levels to 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.

⁹ Note that some of the judgments, settlements, and administrative actions that occurred in FY 2012 will result in transfers in future years, just as some of the transfers in FY 2012 are attributable to actions from prior years.

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 Force Teams**, 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 developed training programs to prevent honest mistakes and help stop potential fraud before it happens. This includes CMS compliance training for providers, HHS/OIG's HEAT Provider Compliance Training initiative, on-going meetings at U.S. Attorneys' Offices (USAOs) with the public and private sector, and increased efforts by HHS to educate specific groups – including elderly and immigrant communities – to help protect them. In addition, DOJ conducts, with the support of HHS, a 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 the Secretary promoted several HEAT initiatives during the fiscal year:

- In February 2012, the Medicare Fraud Strike Force attained another milestone with the indictment and arrest of a Texas physician and the office manager of his medical practice, along with five owners of home health agencies (HHA) for their roles in the single largest fraud orchestrated by one doctor in the history of HEAT and the Medicare Fraud Strike Force operation. See the summary included with the Dallas HEAT cases below.

- In May 2012, Medicare Fraud Strike Force teams in 7 cities executed a nationwide operation that resulted in charges against 107 individuals, including doctors, nurses, and other medical professionals, for their alleged participation in Medicare fraud schemes involving approximately \$452 million in false billing. The coordinated operation involved the highest amount of false Medicare billings in a single takedown in the Strike Force's history. As part of the operation, HHS also suspended or took other administrative action against 52 providers.
- From September 27 through September 28, 2012, DOJ hosted a health care fraud training conference for Federal prosecutors, FBI agents, HHS/OIG agents, and others.

In addition to the activities of HEAT, on July 26, 2012, Attorney General Holder and Secretary Sebelius announced the launch of a ground-breaking partnership among the Federal government, State officials, several leading private health insurance organizations, and other health care anti-fraud groups to prevent health care fraud. This voluntary, collaborative arrangement uniting public and private organizations is designed to share information and best practices in order to improve detection and prevent payment of fraudulent health care billings. Its goal is to reveal and halt scams that cut across a number of public and private payers.

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, continue to meet on a periodic basis through numerous local or regional health care fraud working groups and task forces.

In addition, attorneys from HHS/OIG have been detailed to the Fraud Section of the Criminal Division as Special Trial Attorneys and to USAOs as Special Assistant U.S. Attorneys to provide USAOs with additional prosecutorial resources.

During FY 2012, the many significant HCFAC Program accomplishments included the following:

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 nine cities – Miami, FL; Los Angeles, CA; Detroit, MI; Houston, TX; Brooklyn, NY; Baton Rouge, LA; Tampa, FL; Chicago, IL; and Dallas, TX.

Each Medicare Fraud Strike Force team combines the data analysis and administrative action

capabilities of CMS, the investigative resources of the FBI and HHS/OIG, and the prosecutorial resources of the Criminal Division's Fraud Section and the USAOs. Strike Force accomplishments from cases prosecuted in all nine cities during FY 2012 include¹¹:

- 117 indictments, informations and complaints involving charges filed against 278 defendants who allegedly collectively billed the Medicare program more than \$1.5 billion;
- 251 guilty pleas negotiated and 13 jury trials litigated, with guilty verdicts against 29 defendants; and
- Imprisonment for 201 defendants sentenced during the fiscal year, averaging more than 48 months of incarceration.

In the five and a half years since its inception, Strike Force prosecutors filed more than 724 cases charging more than 1,476 defendants who collectively billed the Medicare program more than \$4.6 billion; 918 defendants pleaded guilty and 105 others were convicted in jury trials; and 745 defendants were sentenced to imprisonment for an average term of more than 45 months.¹²

Examples of successful cases initiated or concluded in districts where Strike Force prosecution teams were operational during FY 2012, as well as other successful cases are provided below. Summaries of additional successful prosecutions and settlements follow, organized by fraud type.

Phase 1: Miami (Southern District of Florida)

- In August 2012, the owner and operator of a Miami health care agency pleaded guilty for his participation in a \$42 million home health Medicare fraud scheme. According to plea documents, the defendant conspired with patient recruiters for the purpose of billing the Medicare program for unnecessary home health care and therapy services. The defendant and his co-conspirators paid kickbacks and bribes to patient recruiters in return for these recruiters providing patients and other necessary documentation to the home health care agency for medically unnecessary therapy and home health services for Medicare beneficiaries. The defendant and his co-conspirators also paid kickbacks and bribes directly to physicians in exchange for home health and therapy prescriptions, plans of care, and medical certifications. The defendant used these documents to fraudulently bill the Medicare program for home health care services. The defendant is currently awaiting sentencing.
- In June 2012, an Asheville, N.C. resident pleaded guilty for her role in a health care fraud scheme that resulted in the submission of more than \$63 million in fraudulent claims to Medicare and Medicaid in Miami and Hendersonville, N.C. The defendant, a licensed psychological associate, admitted to participating in a fraud scheme that was orchestrated through a Community Mental Health Center (CMHC) that purported to provide partial

¹¹ The accomplishments figures presented in the bullets include all reported Strike Force cases handled by DOJ Criminal Division attorneys and AUSAs in the respective USAOs during FY 2012.

¹² These statistics are for the period of May 7, 2007, through September 30, 2012.

hospitalization programs (PHPs). Specifically, the defendant and others agreed to fabricate therapy notes and other medical records and to direct other therapists to do the same, all to make it appear as though Medicare beneficiaries received appropriate services.

- In April 2012, the U.S. District Court in Miami sentenced the three owners of a Miami health care agency to 120 months, 87 months and 87 months respectively for their participation in a \$60 million Medicare home health care fraud scheme. The defendants pleaded guilty to one count of conspiracy to commit health care fraud. The defendants admitted that, from about January 2006 to about November 2009, they operated a home health care agency that paid illegal kickbacks to recruiters to obtain Medicare beneficiaries, which they then billed to Medicare for home health care services that were not medically necessary, and in many cases, never provided at all.
- In January 2012, an office administrator at a home health care provider was sentenced to 78 months of incarceration after she pleaded guilty to charges of conspiracy to commit health care fraud. In all, the defendant and two co-conspirators were ordered to pay \$15.3 million, \$118,000, and \$395,000, respectively, in restitution, jointly and severally, for their roles in the fraud scheme. The trio was affiliated with two home health companies that purported to provide home health and physical therapy services to Medicare beneficiaries. The home health companies fraudulently billed Medicare for home health services provided to beneficiaries who were not restricted to their homes and who had no medical need for the services.
- In September 2011, the U.S. District Court in Miami sentenced an owner and operator of a CMHC to 50 years in prison, following his guilty plea to participating in a massive illegal kickback and money laundering scheme that resulted in a \$205 million fraud. In August 2011, a Federal jury in Miami convicted another owner of the same CMHC for her role in the scheme. The owner, convicted at trial, and another owner of the CMHC were each sentenced to 35 years in prison. In June 2012, a Federal jury in Miami convicted five additional defendants, including two doctors, for their roles in the same scheme. The owners/operators of the CMHC paid millions of dollars in illegal kickbacks to owners of Assisted Living Facilities and Halfway Houses to induce them to funnel vulnerable victims, many with Alzheimer or other forms of dementia, to the CMHC. The CMHC performed little or no legitimate mental health services, but submitted \$205 million in claims to Medicare. The convicted defendants are currently awaiting sentencing. To date, the case has resulted in two trials, at which a total of six defendants were convicted. An additional thirteen individuals and the two corporate defendants have pleaded guilty. The convicted defendants include all of the owners and operators of the CMHC, as well as two physicians. The 50-year sentence represents the longest prison sentence in the history of the Medicare Fraud Strike Force.

Phase 2: Los Angeles (Central District of California)

- In June 2012, a Los Angeles physician's assistant who worked at fraudulent medical clinics was convicted of conspiracy, health care fraud, and aggravated identity theft charges in

connection with an \$18.9 million Medicare fraud scheme. The trial evidence showed that between March 2007 and September 2008, the defendants' co-conspirator and others owned and operated several Los Angeles medical clinics established for the sole purpose of defrauding Medicare. These clinics hired street-level recruiters to find beneficiaries willing to provide their Medicare billing information. In exchange, the defendants co-conspirators paid the recruiters cash kickbacks. The clinics then billed Medicare for unnecessary DME for these beneficiaries. Evidence at trial showed that the defendant worked at the clinic and wrote prescriptions for power wheelchairs for beneficiaries he had never examined and who never visited the clinics. In one case, the evidence showed that he wrote a prescription for a beneficiary who suffered from a mental defect and did not have the mental capacity to operate the wheelchair. The physician's assistant is currently awaiting sentencing.

- In January 2012, the U.S. District Court in Los Angeles sentenced a pastor of a now defunct Los Angeles church who owned and operated several fraudulent DME supply companies to 15 years in prison for his role in a \$14.2 million Medicare fraud scheme. In July 2011, a jury found the defendant, his wife, and one of their employees guilty of conspiracy and health care fraud offenses. According to evidence introduced at trial, the husband and wife were pastors at a church in Los Angeles, where they also operated the fraudulent company. They hired several of their parishioners to assist them in running this company and another fraudulent DME supply company. The couple diverted most of this money from the bank accounts of the supply companies to pay for the fraudulent prescriptions and documents which the defendant purchased to further the scheme and to cover the leases on their Mercedes vehicles, home remodeling expenses, and other personal expenses.

Phase 3: Detroit (Eastern District of Michigan)

- In July 2012, the U.S. District Court in Detroit sentenced a Detroit-area rehabilitation agency owner to 84 months in prison for his leading role in a \$3 million Medicare fraud scheme. The defendant was convicted by a Federal jury, following a weeklong trial, of one count of conspiracy to commit health care fraud and six counts of health care fraud. According to evidence presented during the trial, the defendant was the owner of a fraudulent rehabilitation agency in Dearborn, Michigan. Between January 2003 and February 2007, the agency purchased falsified physical and occupational therapy files from more than 30 therapy and rehabilitation companies and used them to fraudulently bill Medicare for more than \$3 million. Four co-defendants in this case pleaded guilty and were sentenced for their role in the same scheme. The rehabilitation facility owner was excluded by OIG for 25 years.
- In May 2012, a Federal grand jury returned an indictment charging a social worker and the owner of an adult day care center and psychotherapy clinic with conspiracy to commit health care fraud for their participation in a \$20 million psychotherapy fraud scheme. In June 2012, the social worker pleaded guilty to conspiracy to commit health care fraud, admitting to owning and running multiple clinics at which services were never performed or were performed by unlicensed staff who were not authorized to perform services reimbursed by Medicare. The staff members also fabricated therapy notes for patients that were never seen and billed Medicare using document templates created by the social worker. In August 2012,

the owner of the adult day care center and psychotherapy clinic pleaded guilty to conspiracy to commit health care fraud and health care fraud with respect to the submission of false psychotherapy claims through her clinic.

- In January 2012, a Detroit-area home health agency owner pleaded guilty for his leading role in a \$13.4 million Medicare home health care fraud and money laundering scheme. The owner, who was charged along with nineteen other defendants in the original and superseding indictments, admitted to paying kickbacks to beneficiaries, billing Medicare for services never rendered and laundering the proceeds of the fraud. Nine defendants charged in the scheme have pleaded guilty, and three are fugitives.
- In January 2012, the U.S. District Court in Detroit sentenced an operator of three medical clinics to 30 months of incarceration and ordered the operator to pay restitution in the amount of \$2.9 million, jointly and severally, for his participation in a multimillion-dollar scheme to defraud Medicare. The clinic operator and his co-conspirators paid Medicare patients to undergo medically unnecessary diagnostic tests at their three clinics. In exchange for illegal kickbacks, the Medicare beneficiaries signed documents indicating they had received the services billed to Medicare. The clinics involved in the fraud scheme subsequently billed Medicare for expensive and medically unnecessary diagnostic tests and diverted the proceeds to the clinic owners and co-conspirators for their personal use. The co-conspirators are awaiting sentencing for their roles in the scheme.
- In November 2011, the two owners of a medical clinic in Michigan were each sentenced to 14 years of incarceration and ordered to pay over \$6 million in restitution, jointly and severally, after they pleaded guilty to charges related to a health care fraud and money laundering scheme. The clinic purported to provide infusion and injection therapy to HIV-positive patients. The owners recruited and paid kickbacks to Medicare beneficiaries and billed Medicare for services not provided, while purchasing only a fraction of the medications billed to Medicare. The owners fled the United States to avoid being apprehended, but were arrested on March 14, 2011, by the Colombian National Police and transferred to the custody of U.S. officials.
- In October 2011, the U.S. District Court in Detroit sentenced the owner of a fraudulent Detroit-area medical clinic to 10 years in prison for his leading role in a \$9.1 million Medicare fraud scheme. The owner was previously convicted by a Federal jury. According to evidence presented at trial, Medicare beneficiaries were not referred to the clinic by their primary care physicians, or for any other legitimate medical purpose, but rather were recruited to come to the clinic through the payment of illegal cash kickbacks. The clinic then billed Medicare for infusions of expensive and exotic medications, purportedly administered to treat HIV and Hepatitis-C. However, the medications were never administered. Once Medicare started paying the co-conspirators, the defendant enlisted a family friend to help him launder the proceeds of the fraud through a shell corporation in Florida. Evidence at trial showed that the shell corporation had no employees, did no research, and was based at the family friend's residence. The family friend, after taking a commission for himself, distributed the laundered proceeds to the defendant, his wife and co-owner, and co-conspirators.

Phase 4: Houston (Southern District of Texas)

- In July 2012, a Federal grand jury returned an indictment charging the owners and employees of a mental health care company, as well as patient recruiters, in an alleged \$97 million Medicare fraud scheme. Four of the defendants are accused of signing admission documents and progress notes certifying that patients qualified for mental health services, when in fact, the patients did not qualify for or need these services. The indictment also alleges that the owners billed Medicare for intensive mental health services when the beneficiaries were actually watching movies, coloring and playing games – activities that are not covered by Medicare. Finally, the owners and another defendant are alleged to have paid kickbacks to group care home operators and patient recruiters in exchange for delivering ineligible Medicare beneficiaries.
- In June 2012, the U.S. District Court in Houston sentenced the former co-owners of a home health care company to 9 years in prison for their participation in a \$5.2 million Medicare fraud scheme. The owners paid co-conspirators to recruit Medicare beneficiaries for the purpose of filing claims with Medicare for care that was medically unnecessary, or not provided. To date, nine individuals, including nurses and patient recruiters, have been sentenced related to the scheme.
- In May 2012 a Federal jury convicted an owner of a DME company in connection with a \$750,000 Medicare fraud scheme. The company purported to provide orthotics and other devices to Medicare beneficiaries. This equipment was medically unnecessary and/or not provided. The defendant awaits sentencing.
- In February 2012, the assistant administrator of a CMHC pleaded guilty to an indictment just 15 days after it was filed. The defendant admitted in his plea that he and others at the CMHC engaged in a scheme to submit over \$116 million in fraudulent claims to Medicare, and to pay kickbacks to patient recruiters and owners of assisted living facilities and group care homes in exchange for the recruiters and owners sending Medicare beneficiaries to the CMHC's partial hospitalization program, which purported to provide intensive mental health services. The CMHC then submitted claims to Medicare for mental health services that were not medically necessary, and in some cases never provided. The assistant administrator is currently awaiting sentencing.
- In February 2012, a Federal jury convicted a patient recruiter for a DME company of health care fraud related to a fraud scheme involving arthritis kits. The defendant operated a call center and hired teenagers to make unsolicited telephone calls to elderly Medicare beneficiaries, asking them if they wanted a free arthritis kit, which included several devices that were billed to Medicare but were not medically necessary or appropriate. Each arthritis kit was billed to Medicare at more than \$3,000. The patient recruiter is currently awaiting sentencing.

Phase 5: Brooklyn (Eastern District of New York)

- In June 2012, a Federal jury convicted a Brooklyn-area doctor who operated a medical clinic in New York for his participation in a scheme to submit approximately \$22.6 million in fraudulent claims to Medicare and numerous private insurance companies. The doctor submitted claims to Medicare and the insurance companies for surgeries that never occurred and services that were not provided. Evidence at trial also showed that the defendant sent letters to his patients asking them to falsely certify in writing that they had received the phony surgeries. The doctor is currently awaiting sentencing.
- In November 2011, a Federal grand jury returned an indictment charging six defendants, including three medical doctors and a chiropractor, for their alleged participation in a fraud scheme at two medical clinics in Flushing. The indictment states that defendants provided a variety of spa services such as massages and facials, while billing Medicare for physical therapy and other services that were medically unnecessary and never provided. The defendants also recruited Medicare beneficiaries to their clinic by offering lunches and dancing classes, in exchange for the beneficiaries providing their Medicare numbers to be billed for medical services that they did not need and never received.
- In November 2011, a Federal grand jury returned an indictment charging a Staten Island osteopathic doctor for participating in a scheme to defraud Medicare of approximately \$13 million. The doctor allegedly billed Medicare for a variety of services she purported to provide – including vitamin infusion therapy, sleep studies, nerve conduction tests and duplex scans – but which were medically unnecessary and never provided. In May 2012, the doctor entered a guilty plea to health care fraud and awaits sentencing.

Phase 6: Baton Rouge (Middle District of Louisiana)

- In August 2012, the U.S. District Court in Baton Rouge sentenced the owner of multiple DME companies that operated in Louisiana to 15 years in prison for his role in three separate Medicare fraud schemes that resulted in more than \$22.5 million in fraudulent billings to Medicare. The defendant, with his wife, owned and operated several DME companies, and was convicted at trial in August 2011 for one scheme and in November 2011 for another. In January 2012 he pleaded guilty for his role in a third conspiracy. The defendant paid kickbacks to recruiters to acquire Medicare beneficiary information, and then fraudulently billed Medicare for DME that was medically unnecessary and, in some cases, never provided. When a claim was denied by Medicare through one of the defendant's companies, it would often be resubmitted through another company. In July 2012, the defendant's wife, a co-conspirator in two of these cases, was sentenced to 7 years in prison.
- In May 2012, a Federal grand jury returned an indictment against seven individuals alleged to have participated in a fraud scheme involving \$225 million in false claims for services purportedly provided at two CMHCs. The case represents the largest CMHC-related scheme

ever prosecuted by the Medicare Fraud Strike Force. The charges are based on allegations that the defendants recruited beneficiaries from nursing homes and homeless shelters, including drug addicted and elderly individuals, and provided them with no services or medically inappropriate services, while billing Medicare for intensive mental health services.

Phase 7: Tampa (Middle District of Florida)

- In May 2012, a Federal grand jury returned an indictment charging the owners of multiple Florida-area physical therapy companies with participating in a scheme to defraud Medicare of approximately \$8.2 million. According to the indictment, the defendants paid patient recruiters to acquire Medicare beneficiary information for purposes of falsely billing Medicare. In addition, upon acquisition of their physical therapy clinics, they also acquired the historical patient records left at the clinic sites, including the names and identification numbers of Medicare beneficiaries. The defendants allegedly allowed others, who owned and operated similarly illegitimate physical therapy clinics in the Southern and Middle Districts of Florida, to submit fraudulent claims for reimbursement to Medicare through their three clinics.
- In October 2011, the U.S. District Court in Tampa sentenced the owner/operator of a fraudulent physical therapy company in Lakeland, Florida to 42 months in prison for his leading role in a scheme to defraud Medicare of \$757,654. The defendant admitted to purchasing a pre-existing physical therapy business and transforming it into a fraudulent enterprise. The defendant and his co-conspirators also paid kickbacks and bribes to Medicare beneficiaries in order to obtain their Medicare billing information and used that information to submit claims to Medicare for physical therapy services that were never provided. The defendant also stole the identities of a physical therapist and Medicare beneficiaries to submit additional false claims to Medicare.

Phase 8: Dallas (Northern District of Texas)

- In February 2012, a Federal grand jury indicted a Dallas-area doctor and owner of an association of health care providers, along with five others, in a \$374 million home health care fraud scheme, the largest fraud case ever indicted in terms of the amount of loss charged against a single doctor. The indictment charges the defendant with fraudulently certifying or directing the certification of more than 11,000 individual patients from more than 500 home health agencies for home health services over five years. These certifications allegedly resulted in more than \$350 million being fraudulently billed to Medicare and more than \$24 million being fraudulently billed to Medicaid.
- In December 2011, four owners of a Dallas home health agency, and one patient recruiter pled guilty to charges related to their participation in a scheme to defraud Medicare and Medicaid of approximately \$1 million. The agency submitted fraudulent claims to Medicare for home health services purportedly provided to Medicare beneficiaries. The defendants falsified Medicare documentation and skilled nursing notes indicating that the patients were homebound and eligible for home health care services. They also falsified time sheets and

patient visit logs for services that were not adequately rendered or were never provided at all, but then billed Medicare as if the services were adequately provided.

- In December 2011, the U.S. District Court sentenced a patient recruiter for a home health agency to 33 months in prison for her role in a scheme to defraud Medicare and Medicaid of approximately \$1 million. This defendant recruited Medicare beneficiaries and agreed to pay patients kickbacks of \$100 per month so that they would continue to use the home health agency. In August 2012, a co-defendant and owner of the home health agency was sentenced to 37 months in prison. This defendant admitted that she submitted fraudulent claims to Medicare for home health services for Medicare beneficiaries who were not homebound and, therefore, ineligible for home health care services.

Phase 9: Chicago (Northern District of Illinois)

- In August 2012, a home health care agency in suburban Chicago, two nurses who are part owners of the company and a third nurse affiliated with them, along with two marketers, were indicted on Federal charges for allegedly participating in a conspiracy to pay and receive kickbacks in exchange for the referral of Medicare patients for home health care services. The part owners of the home health care agency and three other defendants allegedly conspired to pay and receive approximately \$400,000 in kickbacks to themselves, nurses, marketers and others for the referral and retention of Medicare patients that enabled the home health care agency to bill Medicare approximately \$5 million.
- In July 2012, a physician who operated a Chicago area medical clinic was sentenced to 30 months in Federal prison for engaging in a health care fraud scheme between 2007 and July 2010. The defendant was convicted at trial in March 2012 of defrauding Blue Cross Blue Shield of Illinois by submitting false insurance claims for medically unnecessary tests he ordered for patients and using false diagnosis codes to justify those tests.
- In June 2012, the owner of multiple area outpatient surgery centers was arrested on fraud and tax charges in a 19-count indictment alleging that he paid bribes and kickbacks to physicians for patient referrals and filed false Federal income tax returns that understated his income. The defendant was charged with 10 counts of mail fraud, five counts of interstate travel in aid of racketeering, and four counts of filing false income tax returns for the years 2005-08. The indictment seeks forfeiture of at least \$1.8 million in alleged fraud proceeds, or substitute assets, including the defendant's suburban residence and two surgical centers in Chicago.
- In June 2012, 10 defendants, including the owners of two Chicago home health care companies and three physicians, were indicted for allegedly participating in two separate schemes to pay and receive cash kickbacks in exchange for the referral of Medicare patients for home health care services. In one case, the owners of the home health care company, and seven other defendants allegedly engaged in a fraud scheme involving payment of more than \$1.1 million in cash kickbacks to doctors, social workers, and a registered nurse in exchange for the referral of Medicare patients. In the second case, the owner was charged alone with allegedly paying at least \$500,000 in cash kickbacks to doctors in exchange for Medicare

patient referrals.

- In March 2012, two physicians and four registered nurses were among 11 defendants who were added to an indictment against a suburban Chicago man who operated two home health care businesses for allegedly swindling Medicare of at least \$20 million over five years. Nine co-defendants allegedly conspired with the lead defendant to submit millions of dollars in false claims for reimbursement of home health care services purportedly provided to Medicare beneficiaries, which were never provided or were not medically necessary so that they could profit from the fraudulently-obtained funds. These co-schemers allegedly used the proceeds for various purposes, including: using cash to gamble at casinos in the Chicago area and Las Vegas; purchasing automobiles, jewelry and real estate in the United States and the Philippines and, paying kickbacks to others in exchange for patient referrals.

In addition to the Medicare Strike Force matters listed above, our respective Departments successfully pursued the following matters, which are grouped by subject below:

Pharmaceutical and Device Manufacturers and Related Individuals

- In July 2012, GlaxoSmithKline paid \$3 billion, plus interest, to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices. The company pled guilty and paid \$1 billion in fines and forfeitures for misbranding the anti-depressant drugs Paxil and Wellbutrin and for failing to report required information to the Food and Drug Administration (FDA) in connection with the diabetes drug Avandia. GSK also paid \$2 billion to resolve its FCA and civil liability for: (1) promoting the drugs Paxil, Wellbutrin, Advair, Lamictal and Zofran for off-label, non-covered uses and paying kickbacks to physicians to prescribe those drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex; (2) making false and misleading statements concerning the safety of Avandia; and (3) reporting false best prices and underpaying rebates owed under the Medicaid Drug Rebate Program. As part of the settlement, GSK entered into a 5-year CIA (Corporate Integrity Agreement) with HHS/OIG.
- In November 2011, Merck, Sharp & Dohme paid \$950 million to resolve criminal charges and civil claims related to its promotion and marketing of the painkiller Vioxx (rofecoxib). Under the terms of the resolution, Merck pleaded guilty to a one-count information charging a single violation of the Food Drug and Cosmetic Act (FDCA) for introducing a misbranded drug, Vioxx, into interstate commerce and paid a \$32.1 million criminal fine. In addition, Merck paid \$628.3 million to resolve False Claims Act allegations regarding off-label marketing of Vioxx and false statements about the drug's cardiovascular safety.
- In April 2012, McKesson Corporation paid \$190 million to resolve claims that it violated the FCA by reporting inflated pricing information for a large number of prescription drugs, causing Medicaid to overpay for those drugs. McKesson, a large drug wholesaler, reported the inflated pricing data to First DataBank, a publisher of drug prices that are used by most

state Medicaid programs to set payment rates for pharmaceuticals. This settlement resolves claims based on the Federal share of Medicaid overpayments caused by McKesson's conduct.

- In October 2011, Scios, a subsidiary of the pharmaceutical company Johnson & Johnson, pleaded guilty to a violation of the FDCA and agreed to pay a criminal fine in the amount of \$85 million. Scios admitted that it intended Natrecor to be used off-label for infusing chronic (nonacute) congestive heart failure patients on a scheduled, serial basis, even though the company understood that this was not an approved use of the drug.
- In December 2011, GE Healthcare, Inc., (GEHC) paid \$30 million plus interest to resolve allegations that an acquired entity previously known as Amersham Health, Inc., (Amersham) violated the FCA. Specifically, the Government alleged that Amersham knowingly provided false or misleading information to CMS and its contractors from January 2000 through December 2003 regarding Myoview, a radiopharmaceutical product used in certain cardiac diagnostic imaging procedures. In particular, the Government contended that the false and misleading information Amersham provided caused the Medicare program to reimburse certain claims for Myoview at artificially inflated rates.
- In November 2011, Medtronic, Inc., a DME manufacturer, agreed to pay \$23.8 million plus interest to resolve allegations that it violated the FCA. The Government alleged that Medtronic used postmarket studies and device registries as vehicles to pay physicians illegal kickbacks to induce them to implant Medtronic pacemakers and defibrillators. It was also alleged that Medtronic solicited physicians for the studies and registries to convert their business from a competitor's product and persuade physicians to continue using Medtronic products.
- In November 2011, Genentech, Inc. paid \$20 million to resolve allegations that it violated the FCA in connection with an illegal off-label marketing and kickback scheme. In particular, the allegations involved Genentech's marketing of the drug Rituxan, which is used to treat different types of cancer.
- In December 2011, KV Pharmaceutical Company, which was the parent of now-defunct Ethex Corporation, paid \$17 million to resolve FCA allegations that Ethex failed to advise the CMS that two unapproved products did not qualify for coverage under Federal health care programs. In particular, the United States alleges that Ethex misrepresented the regulatory status of both drugs and failed to advise CMS that these unapproved drugs did not qualify for coverage under Federal health care programs.
- In February 2012, Dava Pharmaceuticals Inc. paid \$11 million to settle FCA allegations that it misreported drug prices in order to reduce its Medicaid Drug Rebate obligations. In particular, the settlement resolves allegations that between Oct. 1, 2005 and Sept. 30, 2009, Dava and its corporate predecessors knowingly treated certain of their drugs as "generic" rather than "branded" in order to lower their monthly rebate obligations to the Medicaid program.

- In December 2011, RAM Medical, Inc., a New Jersey distributor of medical devices, pharmaceuticals, food, cosmetics, and miscellaneous commodities, entered a guilty plea to an information charging the company with one count of introducing adulterated medical devices into interstate commerce and one count of introducing misbranded medical devices into interstate commerce. In May, 2012, RAM Medical, Inc. was sentenced to a 36 month term of probation and ordered to pay a \$100,000 fine and \$72,922 in restitution for importing and selling counterfeit and contaminated surgical hernia mesh. RAM Medical purchased overstocked and discounted products from wholesalers and suppliers all over the world and resold these products to distributors and end-users in the United States. Numerous boxes sold included misbranded, counterfeit mesh, as well as adulterated mesh, which contained numerous microorganisms.
- In November and December 2011, four former executives of Synthes or its subsidiaries each pleaded guilty, as responsible corporate officers, to one misdemeanor count of shipping an adulterated and misbranded medical device in interstate commerce. Their terms of imprisonment ranged from 5 months to 9 months of incarceration. In connection with this case Synthes and its former subsidiary, Norian Corporation (Norian) – which develop, manufacture, distribute, market, and sell medical devices – entered into a global resolution with the Government to resolve liability with respect to allegations of conducting unauthorized clinical trials of their Norian XR and Norian SRS medical devices. These devices were allegedly used in surgeries to treat vertebral compression fractures of the spine, a painful condition commonly suffered by elderly individuals. Many of these procedures were performed on Medicare and other Federal health care program beneficiaries, and the procedures were conducted despite a warning on the label for Norian XR against this use and despite serious medical concerns about the safety of the devices when used in the spine.

Hospital

- In March 2012, Beth Israel Medical Center paid over \$13 million to resolve FCA claims that it fraudulently inflated fees for services provided to Medicare patients in order to obtain larger supplemental reimbursement, known as “outlier payments,” that Medicare pays to hospitals and other health care providers in cases where the cost of care is unusually high. In particular, Beth Israel manipulated its fee structure to make it appear as though its treatment of certain patients was unusually costly, when in fact it was not. As a result, Beth Israel obtained millions of dollars in Medicare outlier payments to which it was not entitled during the relevant time period.
- In May 2012, Lenox Hill Hospital paid \$11.8 million to resolve FCA claims that it inflated fees for services provided to Medicare patients in order to obtain larger supplemental reimbursement, known as “outlier payments,” that Medicare pays to hospitals and other health care providers in cases where the cost of care is unusually high. In particular, Lenox Hill raised its room and board charges and manipulated its overall charge structure to make it appear as though its treatment of certain patients was unusually costly, when in fact it was not. As a result, Lenox Hill obtained millions of dollars in Medicare outlier payments to which it was not entitled from February 21, 2002 through August 7, 2003.

- In June 2012, Atlantic Health System, Inc., AHS Hospital Corp. and Overlook Hospital, paid \$8.9 million to settle FCA allegations that they submitted false claims to Medicare for services provided at Overlook Hospital. Overlook Hospital and its owners, AHS Hospital Corp. and Atlantic Health System Inc., allegedly overbilled Medicare for patients who were treated on an inpatient basis when they should have been treated as observation patients or treated on an outpatient basis.
- In February 2012, Rhode Island Hospital agreed to pay \$5.3 million to resolve its liability under the FCA for allegedly submitting improper claims to Medicare and Medicaid. The improper claims sought reimbursement for medically unnecessary overnight stays for patients receiving Gamma Knife stereotactic radiotherapy. From January 1, 2004 through December 31, 2009, overnight hospital admissions were ordered for approximately 260 patients receiving these treatments.
- In June 2012, Christus Spohn Health System Corporation paid \$5.1 million to settle allegations that six of its hospitals in and around Corpus Christi, Texas, violated the FCA by inappropriately admitting patients to inpatient status for outpatient procedures. The government alleged that the hospitals were routinely billing outpatient surgical procedures as if they required an inpatient level of care, which greatly increased the Medicare reimbursement.
- In January 2012, Cayuga Medical Center of Ithaca, New York, paid \$3.5 million to resolve FCA allegations that it submitted false claims to Medicare and Medicaid in connection with improper physician recruitment agreements entered into between Cayuga Medical Center and various medical practices.
- In April, August and November 2011, three Connecticut hospitals paid a total of over \$1.4 million to resolve FCA allegations that the hospitals submitted false claims to Medicare and Medicaid when billing for injections of Lupron, a cancer drug. The hospitals regularly billed the higher-paying, female-related Lupron billing code for its male patients who were being treated for prostate cancer and therefore received substantially higher reimbursement than they should have received. In addition, even after the hospitals realized that they had improperly coded their Lupron injection services and had been overpaid by government health insurance programs, the hospitals never self-disclosed their improper billing to the government or made any attempt to pay the money back to the Medicare and Medicaid programs.
- In October 2011, Gibson Memorial Hospital agreed to pay approximately \$1 million to resolve its civil liability for allegedly violating the FCA. The hospital submitted claims to Medicare and Medicaid for out-patient surgery services that were being provided at a neighboring ambulatory surgery center, not owned by the hospital. The claims falsely stated that the services were being provided at Gibson Memorial Hospital, which resulted in higher Medicare and Medicaid reimbursements. The hospital was also including the costs of these surgeries on its cost reports, even though no costs had been incurred.

- In December 2011, Satilla Health Services, Inc., d/b/a Satilla Regional Medical Center (Satilla) paid \$840,000 to resolve FCA allegations that it submitted claims to Medicare and Medicaid for medically unnecessary and dangerous endovascular procedures performed by a physician for Satilla's heart center that caused serious injury to 37 patients. In addition, Satilla entered into an agreement for its sale to another company, which resulted in a new board of directors, new administrators, and a new compliance program at Satilla.
- In February 2011, fourteen hospitals located in New York, Mississippi, North Carolina, Washington, Indiana, Missouri and Florida paid a total of more than \$12 million to settle FCA allegations that the health care facilities submitted false claims to Medicare. The settlements resolved allegations that these hospitals overcharged Medicare between 2000 and 2008 when performing kyphoplasty, a minimally-invasive procedure used to treat certain spinal fractures that often are due to osteoporosis. In many cases, the procedure can be performed safely as a less costly outpatient procedure, but the government contends that the hospitals performed the procedure on an inpatient basis in order to increase their Medicare billings.

Physicians

- In November 2011, a family practice physician in Michigan was sentenced to 10 years of incarceration and ordered to pay \$5.4 million in restitution for receiving kickbacks and fraudulently billing for diagnostic tests and services that were not medically necessary. The physician ordered unnecessary and actively harmful nuclear stress tests for her patients at a frequency beyond that of any other medical practice in the country. Because each of these tests is the radiation equivalent of at least 80 to 120 chest x-rays and because excess radiation creates a greater risk of cancer, the physician exposed patients to substantial risk.
- In April 2012, a California physician was sentenced to 60 months of probation and ordered to pay over \$1.9 million in restitution, jointly and severally, after pleading guilty to making a false statement to a Government agency. The physician was also excluded by HHS/OIG for a period of 5 years based upon the conviction. According to court documents, the defendants conspired to offer and make payments to Medicare patients in exchange for their Medicare numbers. In addition, the defendants paid "cappers" for the referral of Medicare patients to the various clinics. The defendants then submitted fraudulent claims to Medicare for services that were not performed, were not performed as billed, or were performed by persons other than the provider under whose identification those services were billed. Investigators also believe that the defendants falsely stated that the clinics would be owned and operated by a licensed physician, when in fact the true owner was not a physician. During the course of the investigation, the physician knowingly made false statements to HHS/OIG agents, deliberately trying to conceal his role and relationship to the co-defendants. The true owner was previously sentenced to 3 years and 3 months of incarceration and ordered to pay more than \$2 million in restitution, jointly and severally. This was a joint investigation with the FBI, DOJ, and the Bureau of Medi-Cal Fraud and Elder Abuse (BMFEA).

- In March 2012, a Pennsylvania physician was sentenced to over 7 years in prison for a health care fraud scheme in which he submitted fraudulent claims and caused more than \$1.8 million in payments to be paid by Medicare and 31 other health insurers. A Federal jury had previously convicted the physician of 150 counts of health care fraud, wire fraud, and making false statements in health care matters. He submitted claims for services rendered to patients whom he did not personally see or evaluate. The patients had been seen by other physicians in the office, but the defendant falsified the charts by making notations indicating that he had personally seen and evaluated the patients.
- In December 2011, a Georgia radiologist was convicted following a jury trial, sentenced to 54 months' incarceration, and ordered to pay \$919,000 in restitution for health care fraud, wire fraud, mail fraud, and alteration of records to obstruct an investigation. The defendant submitted bills for radiology services that he did not perform. Non-physician technicians who were not qualified to interpret x-rays and other films had actually performed the services, yet the defendant fraudulently passed off their reports to hospitals as his own. He also instructed employees to alter and destroy records in response to a government subpoena.
- In June 2012, a Colorado neurologist agreed to pay \$747,013 to settle allegations that he submitted improper claims to Medicare. The neurologist performs intraoperative monitoring (IOM) for companies located throughout the United States. IOM involves remote monitoring of a patient's nervous system during surgery. Under Medicare rules, a physician is permitted to bill for the professional component of IOM as a telehealth service, but the physician is required to bill for the actual time spent on a per-hour basis, regardless of the number of cases simultaneously being monitored. The United States alleged that the neurologist routinely conducted multiple IOM services simultaneously in his office and billed Medicare on an hourly basis for each patient he was monitoring concurrently, instead of on an hourly basis overall. Consequently, he billed in excess of 24 hours per day. In addition to the settlement agreement, he agreed to enter into a 5-year Integrity Agreement with OIG.
- In November 2011, a Maryland physician, was sentenced to over 8 years in prison followed by three years of supervised release for six health care fraud offenses in connection with a scheme in which he submitted false claims for inserting medically unnecessary cardiac stents, ordering unnecessary tests, and making false entries in patient medical records, in order to defraud Medicare, Medicaid, and private insurers. The doctor was ordered to pay restitution to Medicare and the other health insurance programs in the amount of \$579,070 and to forfeit \$579,070 as proceeds of the crime.
- In October 2011, 24 defendants were charged in New York in connection with a massive health care fraud. Twenty-two of these defendants – including two general practitioner doctors, one neurologist, and two chiropractors – were charged with participating in fraudulent billing scams that caused no-fault insurance carriers to pay out millions of dollars in reimbursements for medical treatments that were never provided to patients or that were medically unnecessary. Two defendants, operators of a medical supply company, were charged with orchestrating a billing scam in which the defendants forged doctors' signatures

and prescriptions to support fraudulent billing to Medicare and Medicaid for millions of dollars in durable medical equipment, such as motorized wheelchairs, never supplied to patients.

Other Health Care Providers

- In August 2012, a formerly licensed psychologist pleaded guilty to a scheme to defraud Medicare and Medicaid. Between September 2008 and April 2012, the defendant submitted Medicare and Medicaid claims for daily or near daily psychotherapy services to 19 beneficiaries. He billed up to 17 hours per day for 364 days a year and admitted that, based on an estimate of the services he did provide, the amount reimbursed by Medicare and Medicaid for services he did not provide to those 19 beneficiaries was \$1 million. The defendant also admitted that he forged, or caused another person to forge, the signatures of five beneficiaries on patient sign-in sheets. He is subject to a sentence of up to 20 years, a fine of \$500,000, and forfeiture of \$1 million. The defendant has surrendered his license to practice psychology.
- In June 2012, a North Carolina woman was sentenced to 36 months imprisonment and ordered to pay full restitution for her role in a conspiracy to defraud North Carolina Medicaid of \$1.1 million in sham mental and behavioral health services. The woman held herself out to be a provisionally-licensed counselor when, in fact, she was not. Instead, she purchased a fake degree online and failed the licensing test five times. Other Medicaid-approved providers joined the scheme to defraud by agreeing to submit false and fraudulent claims to Medicaid under their provider numbers for services which the unlicensed woman supposedly rendered.
- In April 2012, Tenet Healthcare Corporation, which owns a network of healthcare facilities throughout the nation, paid \$42.75 million to resolve allegations that its inpatient rehabilitation facilities (IRF) unlawfully admitted Medicare patients who did not meet the Medicare standards for IRF admissions. IRFs are designed for patients who require a more intense inpatient rehabilitation program than is generally provided in other settings, such as acute care hospitals or skilled nursing facilities.
- In January 2012, a Maryland podiatrist was sentenced to 54 months of incarceration and ordered to pay \$1.1 million in restitution for his scheme to defraud Medicare Advantage (Medicare Part C) plans. The podiatrist pleaded guilty to fraudulently billing Medicare for services to patients he had never seen. Additionally, he used the names and other personally identifiable information of approximately 200 nursing home patients to submit false claims for podiatry care he never provided.

Pharmacies

- In April 2012, Walgreens, an Illinois-based corporation operating a national retail pharmacy chain, paid the United States and participating states \$7.9 million to resolve allegations that Walgreens violated the FCA. In particular, the settlement resolved allegations that Walgreens offered illegal inducements to beneficiaries of government health care programs, including Medicare, Medicaid, TRICARE and the Federal Employees Health Benefits Program

(FEHBP), in the form of gift cards, gift checks and other similar promotions that are prohibited by law, to transfer their prescriptions to Walgreens pharmacies. The government investigation found that Walgreens had offered government health beneficiaries \$25 gift cards when they transferred a prescription from another pharmacy to Walgreens. The company's advertisements that promoted gift cards and gift checks for transferred prescriptions typically acknowledged that the offer was not valid with Medicaid, Medicare or any other government program. Nevertheless, the government alleged that Walgreens employees frequently ignored the stated exemptions on the face of the coupons and handed gift cards to customers who were beneficiaries of government health programs, in violation of Federal law.

- In October 2011, the controlling member and pharmacist for an Indiana pharmacy, was sentenced to 51 months of incarceration and ordered to pay \$3.5 million in restitution for his role in a health care fraud and money laundering scheme. Between January 2006 and September 2010, the pharmacist used his position at the pharmacy to carry out a scheme to defraud the Indiana Medicaid Program. He entered false prescriptions in the pharmacy's computer billing system which, in turn, billed the Indiana Medicaid Program. This investigation was conducted jointly with the Indiana Medicaid Fraud Control Unit (MFCU).
- In August 2012, a Tennessee pharmacist agreed to plead guilty to defrauding health care benefit programs of more than \$845,000 in a scheme where he mailed misbranded iron sucrose to Kansas dialysis centers. The pharmacist represented to the dialysis centers that he was providing an FDA-approved product, when he was actually providing a product he manufactured, using unapproved chemicals from China. He faces 60 months in prison under the terms of a plea agreement.
- In December 2011, an assistant pharmacist of a Massachusetts pharmacy was sentenced to 12 months and 1 day of incarceration and was ordered to pay restitution in the amount of \$292,635 and \$60,037 to Medicaid and Medicare, respectively, for his role in a health care fraud scheme. The assistant pharmacist and the owner of the pharmacy solicited paper prescriptions from customers in exchange for illegal kickbacks and submitted false claims to Medicare and Medicaid. They targeted customers with HIV/AIDS and/or psychiatric disorders, such as depression and bipolar disorder. The owner was previously convicted on the same charge and sentenced to 15 months of incarceration.

Clinics

- In June 2012, a man, his sister, and her daughter were all sentenced for their roles in a Medicare fraud scheme. The trio, along with two co-conspirators, fraudulently organized and operated three diagnostic testing clinics in Eastern Michigan. According to court documents, between May 2007 and January 2010, the three clinics submitted false claims to Medicare for medically unnecessary services. The defendants paid drivers to recruit, drive, and pay kickbacks to Medicare beneficiaries to induce them to visit the clinics. The United States alleged that the beneficiaries were recruited from soup kitchens and paid to sign paperwork indicating they had received diagnostic testing, including nerve conduction testing, that was medically unnecessary. The sister was sentenced to 5 years of incarceration and ordered to

pay \$2.9 million in restitution, jointly and severally. She was also excluded by HHS/OIG for a period of 10 years. The man was sentenced to 24 months of incarceration and ordered to pay \$592,813 in restitution, jointly and severally. The daughter was sentenced to 36 months of incarceration. The co-conspirators were each sentenced to 12 months of incarceration and ordered to pay \$2.99 million and \$1.2 million in restitution, respectively, jointly and severally.

- In April 2012, the physician-owner of a medical clinic in the state of Washington and his mother were sentenced on charges of health care fraud and filing false income tax returns. According to court documents, the owner, who was the sole physician for the clinics, used three of the clinics to write a high number of prescriptions to thousands of patients for narcotic pain medications, such as Oxycodone and Methadone, while often providing little or no medical care. His mother served as the business manager and supervisor for the non-medical staff. They collected significant sums for these visits and further inflated the treatment code levels when billing these visits to the health care programs. The physician-owner was sentenced to 12 years and 7 months of incarceration and ordered to pay \$1.28 million in restitution, jointly and severally. His mother was sentenced to 7 years and 3 months of incarceration and ordered to pay \$1.22 million in restitution, jointly and severally. Additionally, the physician-owner and his mother were each excluded by HHS/OIG for a period of 40 years and 30 years, respectively.
- In June 2012, an Asheville, N.C. resident pleaded guilty for her role in a health care fraud scheme that resulted in the submission of more than \$63 million in fraudulent claims to Medicare and Medicaid in Miami, FL and Hendersonville, N.C. The defendant, a licensed psychological associate, admitted to participating in a fraud scheme that was orchestrated through a CMHC that purported to provide partial hospitalization programs (PHPs). Specifically, the defendant and others agreed to fabricate therapy notes and other medical records and to direct other therapists to do the same, all to make it appear Medicare beneficiaries received appropriate services.
- In June 2012, the CEO and founder of a Pennsylvania mental health clinic, was convicted by a jury of 76 counts of health care fraud, aggravated identity theft, distribution of controlled substances, and distribution of controlled substances to minors. The defendant opened the clinic in 2008 and advertised it as a trauma-specific mental health clinic, directed at victims of trauma, children, and members of the military and their families. The defendant falsely portrayed herself as a psychiatrist to the patients of the clinic. Using the prescription pads of two actual psychiatrists, she provided forged prescriptions to the patients at the clinic and medicated the patients whom she purported to be treating. The defendant also wrote prescriptions to children, one as young as four years old. In furtherance of her crime, she also used the name and unique identifying information of an actual psychiatrist to bill insurance companies for patient visits. From February 4, 2009, until the clinic was closed, the defendant submitted thousands of bills to insurance companies, charging them more than \$500,000, as if the patients were being seen by a psychiatrist.
- In October 2011, the owner and operator of a Texas physical therapy facility and his co-conspirators fraudulently used the facility to pay kickbacks to Medicare beneficiaries and

recruiters; provide physical therapy services to Medicare beneficiaries even though it did not employ any licensed or qualified physical therapists; and bill Medicare for physical therapy services that were not rendered. To mask this practice, the facility created false and fraudulent patient files. The owner/operator was sentenced to 27 years and 3 months of incarceration and ordered to pay more than \$30.2 million in restitution, jointly and severally. The co-conspirators were also sentenced in the scheme. One was sentenced to 3 years and 10 months of incarceration and ordered to pay more than \$25.5 million in restitution, jointly and severally. The other was sentenced to 11 years and 3 months of incarceration and ordered to pay more than \$15.6 million in restitution, jointly and severally.

- In November 2011, a facility that treats individuals for lymphatic disorders in New Jersey was ordered to pay \$3 million in restitution after pleading guilty to the submission of false claims by its office manager. Between January 2004 and June 2007, the office manager billed Medicare and Medicaid for services not provided to patients. Specifically, the staff allegedly submitted claims for surgical procedures when, in fact, they had provided physical therapy services, which have a lower reimbursement rate.
- In July 2012, a Miami-area resident and manager of a Detroit-area health clinic and his son and clinic-owner were both sentenced after pleading guilty to charges of conspiracy to commit health care fraud. Between August 2007 and October 2009, the two and their co-conspirators billed Medicare for medically unnecessary tests and services performed by the clinic. The Government contended that they used patient recruiters to offer kickbacks to patients and coach patients to feign symptoms, which were used as justification for the clinic's physicians to order unnecessary diagnostic tests. The father was sentenced to 40 months of incarceration and ordered to pay over \$5.3 million in restitution, jointly and severally. His son was sentenced to 60 months of incarceration and ordered to pay \$6.3 million in restitution, jointly and severally.

Medical Equipment Suppliers

- In April 2012, AmMed Direct, LLC, a durable medical equipment supplier based in Tennessee, paid \$17.5 million to the United States and \$439,003 to the State of Tennessee to settle FCA allegations that it submitted false claims to Medicare and Tennessee Medicaid (TennCare). The United States alleged that AmMed violated the Medicare Cold Call Rule by offering covered supplies, such as diabetes testing supplies, to Medicare beneficiaries who called AmMed to request non-covered supplies, such as diabetes cookbooks, that AmMed advertised as free. The United States also alleged that AmMed unlawfully retained refunds owed to Medicare and TennCare for returned medical supplies.
- In August 2012, the co-owner of two Los Angeles-area health care companies was sentenced to 42 months of incarceration and ordered to pay \$7 million in restitution, jointly and severally, for his conviction stemming from a 9-year Medicare fraud scheme. The individual and a co-defendant were the founders and operators of Prosperity Home Health Services, Inc. (Prosperity), a home health agency, and Caravan Medical Supplies Inc. (Caravan), a DME company. According to court documents, between October 2002 and February 2011, the co-

owner and co-conspirators paid marketers for Medicare beneficiary information and doctors' prescriptions that were acquired fraudulently by the marketers. This information was then used by Prosperity and Caravan to submit false claims to Medicare for services that were not medically necessary or not provided. The co-defendant was previously sentenced to 8 years of incarceration and ordered to pay \$7 million in restitution, jointly and severally. The co-defendant was also excluded by HHS/OIG for a period of 30 years.

- In November 2011, Shield Healthcare, a medical supply company in the Los Angeles area, paid \$5 million to resolve its civil liability under the FCA. From 2003 through 2009, the defendant allegedly submitted fraudulent, inflated claims for payment to California's Medi-Cal program for incontinence supplies, as well as other medical supplies.
- In November 2011, operators and employees of The Mobility Store (TMS), a Houston DME company were sentenced to prison for their roles in fraudulently billing braces to Medicare and Medicaid as orthotic devices. As a result of this scheme, Medicare reimbursed TMS at a rate many times the actual cost of the braces. The four individuals were sentenced to 15 years, 11 years and 3 months, 3 years and 7 months, and 2 years and 9 months of incarceration, respectively, for their roles in the scheme. Additionally, one of the individuals was ordered to pay \$4 million in restitution, jointly and severally, and the other three were each ordered to pay \$8.6 million, jointly and severally.
- In October 2011, the owner/operator of two DME companies that provided oxygen therapy in central and west Florida and two associated managers were sentenced to incarceration and ordered to pay restitution for participating in a scheme to defraud Medicare and Medicaid. Although DME companies are expressly prohibited by Medicare regulations from performing the qualifying tests to establish medical necessity for home oxygen, the owner/operator allegedly instructed his employees to perform such tests; falsify test results; and alter information on office computers, such as the beneficiary's name and the procedure date. The owner/operator was sentenced to 12 years of incarceration and ordered to pay \$7 million in restitution, jointly and severally. The two managers were sentenced to 42 months of incarceration for their roles in the scheme, respectively, and both were ordered to pay \$7 million, jointly and severally, in restitution.
- In March and May 2012, and as part of an organized crime ring takedown, the owner of a Georgia DME company and an associate were sentenced for their roles in a Medicare fraud scheme. According to court documents, the owner stole the identities of hundreds of Medicare beneficiaries and physicians from multiple states and submitted claims to Medicare for medical equipment that was never provided. In addition, his associate engaged in numerous fraudulent financial transactions designed to deliberately conceal the proceeds from the fraudulent claims that were submitted to Medicare. The owner was sentenced to 12 years of incarceration and ordered to pay over \$1.8 million in restitution, jointly and severally, for conspiracy to commit health care fraud and aggravated identity theft. His associate was sentenced to 60 months of incarceration and ordered to pay \$308,963 in restitution, jointly and severally, on charges of money laundering conspiracy. He will be deported after his incarceration. In addition, the owner and associate were each excluded by HHS/OIG for a

period of 20 years and 15 years, respectively. This case was jointly investigated with the U.S. Immigration and Customs Enforcement, the FBI, and the Los Angeles County Sheriff's Office. This investigation has led to more than 35 arrests in connection with this scheme.

- In October 2011, the owner of a California medical supply company was sentenced to 37 months of incarceration and ordered to pay \$576,803 in restitution for one count of health care fraud. Between October 2007 and December 2008, the owner defrauded the Medicare and Medi-Cal programs by paying kickbacks to marketers to solicit beneficiary information with promises of free DME. The owner then sold the beneficiary information to a Medicare billing service, which, in turn, sold some of the information to a fraudulent DME company. The fraudulent company then submitted claims to Medicare falsely representing that it had supplied DME to the Medicare beneficiaries. The owner received the longest possible prison term. In January 2011, the fraudulent company's owner was sentenced to 37 months of incarceration and ordered to pay over \$330,000 in restitution.
- In June 2012, a sales representative for a nationwide supplier of DME, was sentenced to 36 months of probation and ordered to pay \$70,358 in restitution, jointly and severally, after pleading guilty to charges of health care fraud. In order to induce beneficiaries to attend her sales presentations, the sales representative advertised "no cost" custom fit shoes for diabetics and medical equipment for individuals suffering from arthritis. She obtained beneficiaries' Medicare and physician information and then suggested products that could help with their ailments. The sales representative then ordered as many DME products as possible for those beneficiaries without regard to whether they actually requested the products or had a medical need for the equipment. When beneficiaries complained about receiving items that they did not order, she allegedly told them to "keep the products in the closet until you need them." The president of the supplier was previously sentenced to 3 years and 1 month of incarceration and ordered to pay more than \$2.2 million in restitution after pleading guilty to charges of health care fraud, money laundering, and introduction of an adulterated and misbranded medical device into interstate commerce.

Managed Care Organizations

- In August 2012, SCAN Health Plan, a Long Beach-based managed care health plan, paid \$319 million to the Federal government and the State of California to resolve allegations that it received overpayments from Medi-Cal, California's Medicaid program, for services provided to long term care patients. The overpayments to SCAN resulted from two actuarial errors made during the California's rate-setting process. The first error, which spanned the period January 1, 1985 through December 31, 2008, caused Medi-Cal to pay for SCAN's long-term care (LTC) patients, who were generally cared for at home, in the same amount as it would for Medi-Cal fee-for-service LTC patients, who were generally in nursing homes. The amount paid by Medi-Cal for that latter category of nursing home care is much higher than it paid for home care. The second actuarial error, made between July 1, 2001 and December 31, 2007, failed to account for the fact that SCAN's Medi-Cal contract authorized SCAN to terminate the memberships of LTC patients after they had spent a maximum of two months in

a nursing home. Due to this error, Medi-Cal, in effect, kept paying SCAN for certain LTC patients even after SCAN was no longer obligated to provide services to them.

- In April 2012, WellCare, a Florida-based managed care organization, agreed to pay the United States and nine States a total of \$137.5 million to resolve FCA allegations that it (1) falsely inflated the amount it claimed to be spending on medical care in order to avoid returning money to Medicaid and other programs in various states; (2) knowingly retained overpayments it had received from Florida Medicaid for infant care; (3) falsified data that misrepresented the medical conditions of patients and the treatments they received; (4) engaged in certain marketing abuses, including the "cherrypicking" of healthy patients in order to avoid future costs; (5) manipulated "grades of service" or other performance metrics regarding its call center; and (6) operated a sham special investigations unit. WellCare will make payments over a period of three years. In addition to the settlement, WellCare entered into a 5-year CIA with enhanced oversight and reporting obligations.

Nursing Homes

- In August 2012, a nursing home operator in Georgia was sentenced to serve 20 years in Federal prison and ordered to pay \$6.7 million in restitution on charges of conspiring with his wife to defraud the Medicare and Georgia Medicaid programs between July 2004 and September 2007. Medicare and Medicaid paid the operator more than \$32.9 million during that time for food, medical care, and other services for nursing home residents, but evidence presented at trial showed that conditions in the nursing home were so poor that any services provided were of no value. This is the first time that a defendant has been convicted after a trial in Federal court for submitting claims for payment for "worthless services." In addition to the health care fraud conspiracy count, the operator was also convicted of eight counts of failing to pay over \$800,000 in his nursing home employees' payroll taxes to the IRS, and of failing to file personal income tax returns in 2004 and 2005.
- In May 2012, Bethany Lutheran Home, Inc. paid \$675,000 to resolve FCA allegations that from 2002 through 2008, it billed Medicare for medically unnecessary and unreasonable rehabilitation therapy services. Because the daily rate that Medicare paid Bethany Lutheran depended, in part, on the medically unnecessary therapy it provided, Bethany Lutheran billed Medicare at a higher rate than was appropriate.
- In October 2011, Vanguard Healthcare Ancillary Services, LLC; Vanguard Healthcare, LLC; and Vanguard Healthcare Services, LLC (collectively, Vanguard), agreed to pay \$2 million as a part of a settlement agreement to resolve allegations of false claims and illegal kickbacks. Between March 1998 and September 2008, Vanguard allegedly submitted claims to Medicare for enteral (nutrition) therapy goods and services that were also billed to the Tennessee and Mississippi Medicaid programs. Vanguard also allegedly submitted claims to Medicare for certain free items, namely pumps used to deliver nutritional products and intravenous poles used in the administration of enteral therapy that Vanguard had received at no cost from a third party supplier in order to induce referrals. This investigation was conducted jointly with the Tennessee MFCU.

Home Health Providers

- In August 2012, the president and an employee of a home health services supplier in Florida were sentenced for their participation in a multi-million dollar fraud scheme. According to court documents, between February 2005 and April 2011, the president and her co-conspirators paid kickbacks and bribes to patient recruiters in return for the recruiters providing patients to the home health supplier, as well as prescriptions, plans of care (POC), and certifications for medically unnecessary therapy and home health services. Employees of the home health company then falsified patient files for Medicare beneficiaries to appear as though they qualified for the services. The president then used these prescriptions, POCs, and medical certifications to fraudulently bill Medicare for home health care services. The two individuals were sentenced to 9 years and 3 years and 10 months of incarceration, respectively. In addition, the president was ordered to pay \$14 million in restitution, jointly and severally, and the employee was ordered to pay over \$2 million in restitution.
- In August 2012, a private citizen, a representative of an estate, Diversified Health Management Inc. (f.k.a. CareAll Management, LLC), the James W. Carell Family Trust, CareAll, Inc., VIP Home Nursing and Rehabilitation Services LLC, Professional Home Health Care LLC, and University Home Health LLC paid \$9.4 million to settle FCA allegations that the defendants knowingly submitted or caused to be submitted eight false cost reports to Medicare, for cost report years 1999, 2000, and 2001, that concealed the “related party” relationship between the agencies and their management company, resulting in the defendants’ receipt of excessive Medicare reimbursement.
- In February 2012, a personal care attendant and her daughter were sentenced for their roles in a Medicaid fraud scheme. A relative of the pair was a Medicaid beneficiary and received attendant care services from the attendant pursuant to the Medicaid Commerce Waiver Program. An initial investigation by the Pennsylvania MFCU revealed that the beneficiary suffered from ulcers, bed sores, dehydration, and malnutrition and had missed numerous medical appointments. A doctor who examined him in June 2009 recommended that the beneficiary be immediately transported to an emergency room. On a number of the attendant’s timesheets, the attendant’s daughter signed on behalf of the beneficiary, verifying the hours and services provided. Numerous timesheets and claims submitted to Medicaid included hours that the attendant allegedly provided care when in fact the attendant was employed elsewhere or was out of town or when the beneficiary was hospitalized or was in a nursing home. The attendant was sentenced to between 11.5 months to 23 months of incarceration and ordered to pay \$128,000 in restitution. Her daughter was ordered to pay \$38,614 of this amount, jointly and severally with the attendant, and was sentenced to a 7-year term of probation. This was a joint investigation with the MFCU of the Pennsylvania Attorney General’s Office and the Montgomery County District Attorney’s Office.
- In January 2012, the owner/operator of a Minnesota home health facility was sentenced to 24 months of incarceration and ordered to pay \$656,876 in restitution to Medicaid for claims submitted for personal care assistant (PCA) services. Between May 2007 and March 2008,

the owner/operator submitted false claims with respect to the number of PCA service hours provided to Medicaid beneficiaries. The owner/operator also submitted false claims to Medicaid for services that were not rendered, were provided by an unqualified individual, and were not medically necessary. This case was jointly investigated with the Minnesota MFCU.

- In December 2011, Health Care of Virginia, LLC, (HCV), an HHA, was ordered to pay \$323,420 in restitution for health care fraud. The company allegedly submitted claims to the Virginia Medicaid program for services rendered by untrained personal care aides. The investigation indicated that HCV falsified training certificates and patient assessments. Two other defendants pleaded guilty for their roles in the fraud scheme and have been sentenced. This was a joint investigation with the Virginia MFCU.

Other Medicare/Medicaid Matters

- In September 2012, Universal Health Services Inc. (UHS), and its subsidiaries, Keystone Education and Youth Services LLC and Keystone Marion LLC d/b/a Keystone Marion Youth Center agreed to pay over \$6.9 million to resolve allegations that they submitted false and fraudulent claims to Medicaid. Between October 2004 and March 2010, the entities allegedly provided substandard psychiatric counseling and treatment to adolescents in violation of the Medicaid requirements. The United States alleged that UHS falsely represented Keystone Marion Youth Center as a residential treatment facility providing inpatient psychiatric services to Medicaid enrolled children, when in fact it was a juvenile detention facility. The United States further alleged that neither a medical director nor licensed psychiatrist provided the required direction for psychiatric services or for the development of initial or continuing treatment plans. The settlement further resolved allegations that the entities filed false records or statements to Medicaid when they filed treatment plans that falsely represented the level of services that would be provided to the patients. This was a joint investigation with the Virginia MFCU.
- In August 2012, a CFO of a Medicaid contractor agreed to plead guilty to defrauding Kansas Medicaid of more than \$2.1 million for sham consulting fees he had paid to a bogus company he created, and for sports equipment he “donated” to various sports teams he coached. The CFO used the money to build an extravagant home in the country, including a \$70,000 pool. By the terms of the plea agreement the defendant has entered into, he will be sentenced to 36 months incarceration and ordered to pay restitution of over \$2.1 million.
- In June 2012, in Ohio, two leaders of an international ring, which stole identities of doctors and patients in an effort to bill Medicare for more than \$48 million in fraudulent charges, were sentenced to 11 years and 8 years of incarceration, respectively. This case was part of a nationwide sweep in which 73 people were indicted in New York, Georgia, California and New Mexico, for the submission of well over \$100 million in fraudulent claims to Medicare.
- In March 2012, two defendants were convicted of violations of the Controlled Substances Act, and the Money Laundering statute, for their involvement in an illegal Internet pharmacy operation. One defendant owned and operated the illegal Internet pharmacy, Pitcairn, based in

Florida; the other owned and operated the fulfillment pharmacy, Kwic Fill, located in North Carolina, that filled drug orders for Pitcairn and other illegal Internet pharmacies. Pitcairn earned over \$75 million during its four years of operation. Kwic Fill earned over \$4 million in just two months. The pharmacies provided controlled substances to customers solely based on the provision of a credit card number and completion of a 10-question medical questionnaire. The \$75 million in Pitcairn's revenue was laundered through ten different countries, including Switzerland, Liechtenstein, Luxembourg, the Netherlands, Romania, Canada, Panama, the Bahamas, St. Kitts & Nevis, and the Netherlands Antilles. Eight other defendants have entered guilty pleas in this matter. Three additional defendants are set for trial in September 2012.

- In March 2012, a North Carolina woman was sentenced to 54 months incarceration for her role in defrauding Medicaid of \$1.5 million. The woman conspired with other Medicaid approved providers to submit claims for fraudulent services which she allegedly provided. In reality, she did not provide any of the claimed services and merely operated an after school program. She nevertheless sought and obtained Medicaid reimbursement for these services by misrepresenting the nature of the service and the identity of the clinician providing the service. The defendant then spent the proceeds of this fraud on numerous luxury vehicles. She also purchased her residence in North Carolina and a time share in Kissimee, Fla., with the proceeds of her fraud. In announcing the sentence, the judge characterized the "theft of money from a fund for low-income recipients" as appalling and noted that the conduct was "egregious" and "deserving of just punishment." The defendant was ordered to pay \$1.5 million in restitution.
- In December 2011, a Georgia man was sentenced to over 5 years in prison and ordered to pay \$1.0 million for health care fraud and criminal HIPAA violations. The defendant persuaded numerous practicing physicians to bill Medicare, Medicaid, and private insurers under their own provider numbers for allergy-related care provided by him. The defendant had never been licensed in Georgia as a physician, physician assistant, nurse practitioner, or clinical nurse specialist.

Transportation Providers

- In June 2012, Rural/Metro Corporation, Rural/Metro of Central Alabama Inc., and Mercury Ambulance Service paid \$5.4 million to settle FCA claims that the company improperly billed Medicare for payment on ambulance services that were never provided or were medically unnecessary. In particular, the United States alleged that the defendants represented that transported patients were either bed-confined or that transportation by ambulance was, otherwise, medically required. Many of those patients, however, were neither bed-confined nor needed to be moved on stretchers, and did not require ambulance transportation or qualify for ambulance transport under the applicable Medicare requirements.
- In June 2012, the owners and operators of an ambulance and medical transport company in North Carolina entered into a FCA settlement agreement for \$950,178. The settlement resolved allegations that, between January 2002 and October 2006, the owner/operators

submitted Medicare and Medicaid claims for non-emergency ambulance transport for dialysis patients whose transports were not medically necessary because the patients were ambulatory and/or not bed-confined. As part of the settlement, the second owner/operator agreed to an exclusion of 15 years based on her conviction of conspiracy to make false statements relating to health care matters. In the criminal case, she was sentenced to 28 months of incarceration and ordered to pay \$475,089 in restitution. This was a joint investigation with the North Carolina MFCU.

- In November 2011, the president and owner of an ambulance company in Rhode Island was sentenced to 24 months of incarceration and ordered to pay \$704,117 in restitution for health care fraud. Between March and December 2008, the president/owner submitted fraudulent claims to Medicare and Blue Cross and Blue Shield by billing routine dialysis transports as specialty care transports (SCT), even though the ambulance company did not have the proper equipment or personnel to provide SCTs. This upcoded billing, which should have been billed as basic life support, resulted in a higher reimbursement rate. The president/owner also instructed his employees to alter the trip sheets to ensure that the transports qualified as SCTs.

Hospice Providers

- In February 2012, Odyssey Healthcare, Inc., (Odyssey) a subsidiary of Gentiva Health Services, Inc., agreed to pay \$25 million to resolve FCA allegations that between January 2006 and January 2009, it submitted claims for hospice services that were medically unnecessary. The investigation found Odyssey billed Medicare for continuous or crisis care services when the patients were not experiencing a crisis. “Continuous or crisis” care is reimbursed by Medicare at a higher rate than routine care. As part of the settlement, Odyssey entered into a 5-year CIA with HHS/OIG.
- In December 2011, Diakon Lutheran Social Ministries d/b/a Diakon Hospice Saint John (Diakon) paid \$10.6 million to resolve FCA claims that it erroneously submitted claims for Medicare beneficiaries who were not eligible for hospice care during the period from October 1, 2004 to September 30, 2010.
- In June 2012, Hospice Care of Kansas, LLC and its parent company, Voyager HospiceCare, Inc., paid \$6.1 million to resolve allegations that it violated the FCA by submitting claims between January 2004 and December 2008 for ineligible beneficiaries who did not have a terminal prognosis of six months or less.
- In August 2012, Hospice Family Care Inc. (HFC) in Arizona agreed to pay \$3.7 million to resolve its liability for allegations under the FCA. HFC, which was owned by two registered nurses, provided hospice care under Medicare’s hospice benefit. To be eligible for hospice care, the patient’s attending physician and the hospice’s medical director must certify the patient is terminally ill. Medicare reimbursement is based on the level of care provided by the hospice. According to court records, HFC allegedly submitted claims to Medicare for the care of patients who were either completely or partially hospice ineligible or were provided a higher level of hospice care than was necessary or allowable. As part of the agreement, both

nurses agreed to be excluded from participation in Federal health care programs for a period of 7 years.

- In December 2011, Hospice Home Care, Inc., (HHC) agreed to pay \$2.7 million to resolve its liability under the FCA for allegedly submitting false claims to Medicare. Between January 2002 and December 2004, HHC allegedly billed Medicare for general inpatient services when the patients received only routine care, which has a lower reimbursement rate.

Other Schemes

- In March 2012, LifeWatch Services, Inc. paid \$18.5 million to resolve allegations that it violated the FCA by submitting false claims to Medicare for heart monitoring services that were not eligible for reimbursement.
- In July 2012, NextCare, Inc, an Arizona-based company, agreed to pay \$10 million to settle Federal and state allegations that it submitted false claims to Medicare, TRICARE and the FEHBP, as well as the Medicaid programs of Colorado, Virginia, Texas, North Carolina and Arizona, for unnecessary allergy, H1N1 virus and respiratory panel testing. The United States also contended that NextCare inflated billings for urgent care medical services in the years under review.
- In February 2012, Accela Medical LLC, a laboratory established to bill Medicare for diagnostic testing services, and six other defendants (Western Slope Laboratory, Coventry Diagnostics LLC, Performance Labs, Inc., and individual defendants) paid \$5.4 million to resolve FCA claims that they fraudulently secured a provider number for McCormick, who had been excluded from the Medicare program, to further the scheme. The United States further contended that the defendants billed Medicare for quantitative opiate tests that were never performed. A non-party investor in defendant Coventry Diagnostics separately paid the United States \$400,000 in Medicare funds he had received from Coventry.
- In December 2011, February 2012, and June 2011, three individuals were sentenced to 7 years, 5 years and 3 months, and 2 years and 6 months of incarceration, respectively. Between December 2007 and February 2008, these co-conspirators laundered fraudulent proceeds from five pharmacies and DME companies. One individual was charged with 15 counts of money laundering and 2 counts of structuring to avoid reporting requirements and was ordered to pay \$250,000 in restitution following his jury trial conviction. After the convictions of these individuals and with cooperation from other defendants, the owner of the pharmacies and DME companies was indicted for allegations of crimes, including health care fraud and aggravated identity theft.
- In November 2011, a private citizen was sentenced to 7 years and 2 months of incarceration for possession with intent to distribute, as well as for distributing the Schedule II drug Oxycodone. The individual was part of a fraud scheme that entailed obtaining paper Oxycodone prescriptions from a local physician who prescribed the controlled substances to

Medicare and Medicaid beneficiaries, despite lack of medical necessity. He then assisted in filling the prescriptions and trafficking the drugs to street dealers.

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/OIG.¹³ In FY 2012, the Secretary and the Attorney General jointly allotted \$196.1 million to HHS/OIG. Additionally, Congress appropriated \$29.7 million in discretionary funding for HHS/OIG HCFAC activities.

HHS/OIG conducted investigations or other inquiries that resulted in 1,145 prosecutions or settlements in FY 2012, of which 1,047, or 91 percent, were health care cases. A number of these are highlighted in the Accomplishments section. In addition, during FY 2012, HHS/OIG excluded a total of 3,131 individuals and entities, the details of which are below.

In FY 2012, HHS/OIG continued to staff and support Medicare Strike Force operations worked in conjunction with DOJ Criminal Division's Fraud Section, local USAOs, the FBI, and State and local law enforcement agencies. HHS/OIG has assigned agents to Strike Forces in Miami, New York City, Houston, Tampa, Detroit, Los Angeles, Baton Rouge, Dallas, and Chicago. HHS/OIG has supported Strike Force operations by providing investigative, analytic, and forensic resources. These Strike Forces have effectively investigated and prosecuted 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. The continued support of Medicare Strike Force operations is a top priority for HHS/OIG.

Program Savings

Frequently, investigations, audits, and evaluations reveal vulnerabilities or incentives for questionable or fraudulent 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 2012, HHS/OIG reported that legislative and administrative actions to make funds available for better use resulted in an estimated \$8.5 billion in health care savings attributable to FY 2012 – \$8 billion in Medicare savings and \$525 million in savings to the Federal share of Medicaid.

Additional information about savings achieved through such policy and procedural changes may

¹³ In addition to the funds made available to OIG from the HCFAC account under HIPAA, Congress has provided funds to OIG specifically for oversight of the Medicaid program. The Deficit Reduction Act of 2005 (DRA, P.L. 109-171), and the Supplemental Appropriations Act of 2008 (Pub. L. 110-252) at § 7001(b) each appropriated funding for Medicaid-related oversight efforts. Therefore, OIG's Medicaid activities cited throughout this report may have drawn from these funding sources, in addition to HCFAC.

be found in the HHS/OIG Semiannual Report, on-line at <http://oig.hhs.gov>.

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 2012, HHS/OIG excluded a total of 3,131 individuals and entities. Among these were exclusions based on criminal convictions for crimes related to Medicare and Medicaid (912) or to other health care programs (287); for patient abuse or neglect (212); or as a result of licensure revocations (1,463). 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 2012.

Exclusion actions by HHS/OIG included:

- Texas – In September 2012, a nurse was excluded from participation in Federal health care programs for a period of 60 years after she was sentenced to life in prison without parole for capital murder. In April 2008, the nurse worked at a dialysis center in Lufkin, Texas, which serviced Medicare beneficiaries. During the time of her employment, the facility experienced an unusual rate of patients suffering cardiac arrest while undergoing dialysis. According to court records, on April 28, 2008, two patients witnessed the nurse draw bleach into a syringe and inject it into the dialysis lines of patients at the dialysis center, causing the patients to suffer distress and respiratory arrest. It was determined that at least five patients died and five others suffered cardiac arrest that did not result in death due to the nurse injecting bleach into their dialysis lines or directly into their bloodstream.
- Iowa – In December 2011, a certified medication aide at a residential facility was excluded for 20 years for his conviction on two counts of dependent adult abuse. He sexually exploited two dependent adults and caused them to suffer mental injuries and increased symptoms regarding their mental health problems. The medication aide also has a prior criminal history that includes convictions for driving with a suspended license; assault with intent to cause pain or injury; theft in the fifth degree; driving while barred – habitual offender; and possession of a controlled substance.
- Florida – In December 2011, the owner of durable medical equipment companies was excluded for 95 years on the basis of his conviction of health care fraud and conspiracy to commit health care fraud. From 2002 to about August 2004, the owner and his co-conspirators submitted false Medicare claims on behalf of the companies, seeking reimbursement for DME that was neither ordered by a physician nor provided to the beneficiary. The court ordered him to pay \$35.1 million in restitution and to serve 168 months of incarceration.
- Ohio – In January 2012, a pediatrician was excluded for 50 years on the basis of his conviction of unlawful sexual conduct with a minor, bribery, complicity to deception to obtain dangerous drugs, and compelling prostitution. From about March 1992 to about December 2008, this physician provided prescriptions for controlled substances or money to patients in

return for sexual favors. The court sentenced him to 13 years of incarceration. The Ohio State Board of Medicine permanently revoked his license to practice medicine.

- California – In June 2012, the former medical doctor of a famous pop singer was excluded for a minimum period of 50 years based on his conviction for involuntary manslaughter. According to court documents, the doctor's actions included administering Propofol, an anesthetic drug used to induce and maintain anesthesia to the singer on a nightly basis for over 2 months. On June 25, 2009, he administered Propofol, along with another drug to the singer and then abandoned him. When he directed his attention back to his patient, he found that he was no longer breathing. It is alleged that the doctor waited at least 20 minutes prior to summoning emergency personnel. In November 2011, a jury convicted him of involuntary manslaughter for his actions. He was sentenced to 4 years of incarceration, ordered to pay \$101,827,871 in restitution, and ordered to cease and desist from practicing medicine in the State of California.
- Arizona – In May 2012, an Arizona medical doctor specializing in pediatrics was excluded indefinitely based on the revocation of his license by the Arizona Medical Board. According to court records, an FBI agent from the Innocent Images Unit signed into a file sharing program on the internet and came into contact with a person later identified as this physician, who was sharing approximately 10,000 files. The files contained multiple images of child pornography. After being charged with distributing child pornography in interstate commerce, the Medical Boards of California and Texas revoked the physician's license to practice medicine in their States. On September 2010, while on house confinement, the physician removed his electronic monitoring unit and absconded. He remains a fugitive.

Other Administrative Enforcement Actions – Civil Monetary Penalties

HHS/OIG has the 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 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:

- Mississippi – OIG reached settlements with eight physicians who allegedly violated the Civil Monetary Penalties Law (CMPL) by causing the submission of false claims to Medicare from physical medicine companies. Specifically, the physicians reassigned their Medicare payments to various physical medicine companies in exchange for medical directorship positions. The companies then falsely billed Medicare using the physicians' reassigned provider numbers as if the physicians had personally rendered the services or directly supervised individuals rendering the services. The eight physicians have collectively paid \$604,874 to resolve their CMPL liability. Several owners and operators of the physical medicine companies were criminally prosecuted in Federal court for their roles in these schemes.

- New Jersey – In December 2011, Sandoz Inc. (Sandoz), a pharmaceutical manufacturer, agreed to pay \$230,000 to resolve its potential liability under the CMPL. Specifically, the Government contended that Sandoz failed to timely submit pricing data required under the Medicaid Drug Rebate Program.
- Georgia – In October 2011, Piedmont Hospital (Piedmont) agreed to pay \$50,000 to resolve its potential liability under the Emergency Medical Treatment and Active Labor Act (EMTALA). The Government alleged that Piedmont failed to provide an appropriate medical screening exam and stabilizing treatment for an individual who presented to Piedmont’s emergency department for evaluation and treatment of an emergency medical condition. The individual made repeated requests for treatment for approximately 8 hours without success. The individual left Piedmont, went to another hospital, and was diagnosed and treated for deep vein thrombosis and pulmonary embolus.
- Tennessee – In December 2011, Vanderbilt University Medical Center (Vanderbilt) agreed to pay \$45,000 to resolve its potential liability under EMTALA. The Government alleged that Vanderbilt refused to accept the appropriate transfer of a 66-year-old patient suffering from a large subdural hematoma on the brain with a midline shift. The patient, who had an unstable emergency medical condition that required the specialized capabilities available at Vanderbilt, died a few hours later at another hospital. The neurosurgeon on call at Vanderbilt agreed to pay \$35,000 to resolve his potential liability as a responsible physician under EMTALA for refusing to accept an appropriate transfer of an individual with an unstable emergency medical condition that required the services of a neurosurgeon.
- Massachusetts – In April 2012, Baypointe Rehabilitation and Skilled Care Center, a nursing home, agreed to pay \$351,255 to resolve its liability under the CMPL. Baypointe employed an excluded nurse as its Assistant Director of Nursing from January 2006 through July 2009. OIG excluded the nurse after the Mississippi Board of Nursing revoked her license following a positive pre-employment drug test. The Government contended that Baypointe should have known that the nurse was excluded.

Audits and Evaluations

Every year, HHS/OIG conducts a substantial number 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 those completed in FY 2012 were:

Medicaid Drugs

- HHS/OIG found that states could better approximate pharmacies’ invoice prices of drugs by developing separate reimbursement methodologies for major categories of drugs (single-source drugs, brand-name multiple-source drugs, and generic multiple-source drugs). Numerous OIG reviews have found that the basis that states historically used for Medicaid drug reimbursements did not represent pharmacies’ actual costs to acquire drug

ingredients (invoice prices) and as a result, states often have over-reimbursed pharmacies for those costs. This review evaluated the relationships between three recognized pricing benchmarks and pharmacy invoice prices for Medicaid-reimbursed drugs and found variations depending on whether the drugs were brand-name or generic. HHS/OIG recommended that CMS share the results of this review with states to use when considering changes to their pharmacy reimbursement methodologies, including those for major categories of drugs.

- HHS/OIG found that neither CMS nor the 14 state agencies that it reviewed had adequate controls to ensure that all drug expenditures complied with Federal requirements. Federal Medicaid funding is generally available for covered outpatient drugs if the drug manufacturers have rebate agreements with CMS and pay rebates to the states. The agreements require manufacturers to provide a list of all covered outpatient drugs to CMS quarterly. However, manufacturers did not always provide information timely. In addition, HHS/OIG found that the states generally did not use the quarterly Medicaid drug tapes (quarterly listings) to determine whether a drug was eligible for coverage and did not contact CMS to determine whether a drug was eligible for coverage if the drug was not on the tapes. HHS/OIG recommended that CMS instruct states to ensure compliance with Federal requirements, appropriately report terminated drug expenditures to states, and require that states use the reports to ensure compliance. CMS should also work with manufacturers to ensure that they collect and submit complete and accurate information and take appropriate action if they are not timely in providing the information.

Medicaid Personal Care Services

Medicaid reimburses for personal care services, which are generally furnished to individuals residing in their homes and not residing in hospitals, nursing facilities, intermediate care facilities for the mentally retarded, or institutions for mental diseases. Further, Medicaid beneficiaries are authorized for personal care services by a physician in accordance with a plan of treatment or with a service plan approved by each state. Other requirements may also apply based on state regulations.

- HHS/OIG found that New Jersey improperly claimed an estimated \$145 million in Federal Medicaid reimbursement for PCS. Types of deficiencies in the claims reviewed included lapses relating to: authorizations, in-service education for personal care attendants, nursing supervision, documentation of services, nursing assessments, and certification of personal care attendants by the New Jersey Board of Nursing. New Jersey did not effectively monitor the PCS program for compliance with Federal and State requirements. HHS/OIG recommended that the state refund \$145 million to the Federal government and improve its monitoring of the PCS program to help ensure compliance with Federal and state requirements.
- HHS/OIG found that New Mexico improperly claimed about \$889,000 in Federal reimbursement for PCS provider Ambercare that did not always comply with certain Federal and state requirements. The deficiencies included lapses with attendant training,

lack of support for the number of units claimed for attendant services, and prior approval for PCS provided by a legal guardian. HHS/OIG recommended that New Mexico refund \$889,000 to the Federal government and ensure that PCS providers maintain evidence that they comply with Federal and State requirements.

- HHS/OIG found that New Mexico did not always ensure that PCS provider Coordinated Home Health's (Coordinated's) claims for Medicaid personal care services complied with certain Federal and state requirements. Based on sample results, HHS/OIG estimated that Coordinated improperly claimed at least \$11 million (Federal share) for personal care services during the period October 1, 2006, through September 30, 2008. Of the 100 claims in the sample, 54 complied with requirements, but 46 did not. Three of the 46 claims were partially allowable. The 46 claims contained a total of 60 deficiencies, including insufficient attendant qualifications. HHS/OIG recommended, among other things, that the state refund to the Federal government the \$11 million paid to Coordinated for unallowable personal care services.
- For the period October 1, 2006, through September 30, 2008, HHS/OIG estimated that New Mexico paid PCS provider Heritage Home Healthcare (Heritage) approximately \$4.5 million for personal care services claims that did not always comply with certain Federal and State requirements. Of the 100 claims in the random sample, 36 did not comply with these requirements. The deficiencies included insufficient attendant training, missing prior approval for services, and unsupported units of service claimed. HHS/OIG recommended, among other things, that the state refund to the Federal government the \$4.5 million paid to Heritage for unallowable personal care services.
- On the basis of sample results, HHS/OIG estimated that the Missouri Department of Social Services (State agency) claimed \$26.7 million (Federal share) in reimbursement for Medicaid personal care services that did not comply with Federal and State requirements. In addition, the state agency claimed \$213,000 (Federal share) for personal care services that were not supported by the claim data because the State agency did not have procedures to maintain that supporting documentation. Of the 100 grouped line items in our sample, 50 complied with Federal and state requirements. HHS/OIG recommended, among other things, that the State agency refund \$26.9 million to the Federal government.

Medicaid Continuing Day Treatments

- HHS/OIG found that more than half of the claims for continuing day treatment (CDT) services that it reviewed did not comply with one or more of New York State's requirements for payment, resulting in unallowable Federal reimbursements estimated at about \$84.4 million. CDT is a form of clinic services performed by non-hospital providers that New York includes among its licensed outpatient programs. Providers did not properly document the type of CDT services billed, recipients' clinical progress, and/or recipients' contacts with outpatient program staff. Although the State conducts periodic onsite monitoring, its monitoring program did not ensure that providers complied

with all state requirements. HHS/OIG recommended that the State refund \$84.4 million to the Federal government, work with the State Office of Mental Health to issue guidance to the provider community regarding State requirements for claiming Medicaid reimbursement for CDT services, and work with the state office to improve its monitoring of the CDT program to ensure compliance with State requirements.

Medicaid Transportation Services

States are required to ensure necessary transportation for Medicaid beneficiaries to and from providers. Pursuant to New York State regulations, nonemergency medical transportation (NEMT) services may be delivered through the use of an ambulance, an ambulette, a taxicab, or livery service. However, prior authorization must be obtained; a medical practitioner's order justifying the beneficiary's use of NEMT services must be documented in the beneficiary's medical record; and a transportation provider must notify the New York Department of Motor Vehicles within 10 days of the date on which an ambulette driver commences employment.

- HHS/OIG found that New York improperly claimed an estimated \$13.5 million in Federal Medicaid reimbursement for NEMT services. The deficiencies occurred because New York State's policies, procedures, and mechanisms for overseeing the Medicaid program did not ensure that providers complied with Federal and state requirements for ordering, documenting, providing, and claiming such services. HHS/OIG recommended that the state refund \$13.5 million to the Federal government; strengthen policies and procedures to ensure compliance with requirements for ordering, documenting, and claiming NEMT services; and require the New York State social services districts to strengthen their quality assurance mechanism to ensure that NEMT services are properly provided.
- HHS/OIG found that during a 1-year period, New York improperly claimed Federal reimbursement for almost 1 million NEMT claims for services in New York City. We set aside for further analysis additional New York City NEMT claims that may also have been noncompliant. New York's policies and procedures did not ensure that providers complied with Federal and state requirements for ordering, documenting, and claiming NEMT services, and New York City's social services district's quality assurance mechanism did not ensure that NEMT services were properly provided. HHS/OIG recommended that the state refund an estimated \$17 million to the Federal government; resolve \$2.9 million set aside for further analysis; and strengthen policies, procedures, and quality controls.

Medicaid Managed Care

- HHS/OIG found that 11 excluded providers enrolled in 4 of 12 Medicaid managed care entities (MCE) provider networks. Only providers enrolled in the 12 selected MCEs were reviewed; additional excluded individuals may be employed by providers enrolled in the 663 MCEs not included in this study. States may benefit from sharing information regarding the failures that led to the inclusion of these few excluded providers in MCE provider networks. For example, two MCEs explained that excluded providers had joined their

MCE networks through their acquisition of other MCEs or the providers had simply not been removed from the enrollment data when their last contracts expired or were terminated. This report also describes the safeguards MCEs use to identify excluded providers. HHS/OIG recommended that CMS periodically remind states of their obligation to ensure that no excluded providers receive Medicaid payments.

- Medicaid MCE reported to HHS/OIG that they took steps to oversee fraud and abuse safeguards, but they remain concerned about the prevalence of fraud. CMS, states, and Medicaid MCEs expressed that services billed but not rendered are their primary concern with respect to fraud and abuse in Medicaid managed care. Other concerns include rendering services that are not medically necessary, upcoding by providers, questionable beneficiary eligibility, and prescription drug abuse by beneficiaries. All MCEs in our sample reported taking steps to meet Federal program integrity requirements. HHS/OIG recommended that CMS require that state contracts with MCEs include a method to verify with beneficiaries whether they received services billed by providers. HHS/OIG also recommended that CMS update guidance to reflect concerns expressed by MCEs and States.

Medicaid Contractors

The Deficit Reduction Act (DRA) of 2005 established the Medicaid Integrity Program as the first comprehensive effort by CMS to fight fraud, waste, and abuse within Medicaid. CMS defined three types of Medicaid Integrity Contractors to perform the program integrity activities listed in the DRA: Review MICs, Audit MICs, and Education MICs. Review MICs review State Medicaid claims data and identify potential overpayments. Audit MICs conduct audits of providers and identify actual overpayments. Education MICs educate providers and beneficiaries on program integrity issues. During FY2012, HHS/OIG conducted two reviews of activities conducted by Audit and Review MICs.

- HHS/OIG found that Review MICs completed 81 percent of their assignments; however, they had limited involvement in recommending specific audit leads and identifying potential fraud. Further, because data were missing or inaccurate, Review MICs were hindered in their ability to accurately complete data analysis assignments. States invalidated more than one-third of sampled potential overpayments from assignments, mainly because data were missing or inaccurate. As a result, some of Review MICs' data analyses may not lead to recoveries. HHS/OIG recommended that CMS improve the quality of data that Review MICs can access for conducting data analysis and require Review MICs to recommend specific audit leads.
- HHS/OIG found that the performance of Audit MICs was hindered because audit targets were poorly identified. Audit targets were misidentified because of data problems and because State program policies were applied incorrectly. Of the 370 audits assigned to Audit MICs, 81 percent of audits either did not or are unlikely to identify overpayments. Only 11 percent of assigned audits were completed with findings of \$6.9 million in overpayments, \$6.2 million of which resulted from seven completed collaborative

audits. HHS/OIG recommended that CMS increase collaboration among Audit and Review MICs, CMS, and States to improve target selection.

Medicaid Administrative Claims

- HHS/OIG found that for FYs 2005 and 2006 New Jersey's Medicaid Administrative Claim (MAC) did not comply with Federal requirements for claiming costs associated with the administration of the state Medicaid plan. Specifically, Maximus Inc. (Maximus), the contractor that computed the MAC, included unallowable salaries and operating costs in the cost pool used to compute the MAC, resulting in a claim for \$22.2 million (\$11.1 million Federal share) in excess Medicaid administrative costs. HHS/OIG recommended, among other things, that the state refund \$22.5 million to the Federal government.
- HHS/OIG found that for FY 2007 New Jersey's MAC did not comply with Federal requirements. Specifically, the state agency's contractor, Maximus, included unallowable costs in the cost pool used to compute the MAC, resulting in a claim for \$10 million (\$5 million Federal share) in excess Medicaid administrative costs. However, HHS/OIG was unable to express an opinion on the allowability of the remaining \$15.9 million (\$8 million Federal share) claimed on the State agency's MAC. HHS/OIG recommended, among other things, that New Jersey refund \$5 million to the Federal government and work with CMS to determine what portion of the remaining \$8 million in Medicaid administration costs claimed for FY 2007 was allowable under Federal requirements.

Medicaid Waiver Programs

- HHS/OIG found that for calendar years 2005 through 2007 New Jersey claimed Federal Medicaid reimbursement for some Community Care Waiver (CCW) program services that did not comply with certain Federal and state requirements. HHS/OIG estimated that, as a result, the State improperly claimed \$60.7 million in Federal Medicaid reimbursement. The CCW program allows the state agency to claim Medicaid reimbursement for home and community-based services (HCBS) provided to individuals with intellectual and developmental disabilities. Without HCBS, these individuals would require institutionalization in an Intermediate Care Facility for the Mentally Retarded (ICF/MR). HHS/OIG recommended, among other things, that the state refund \$60.7 million to the Federal government.
- Based on sample results, HHS/OIG estimated that New Jersey improperly claimed approximately \$2.7 million in Federal Medicaid reimbursement for CCW program services provided by Bancroft NeuroHealth (Bancroft) that did not comply with certain Federal and state requirements during calendar years 2005 through 2007. The claims for unallowable services were made because: Bancroft and the State's Division of Developmental Disabilities (the division) did not ensure that they only claimed for documented, allowable CCW program services; the division did not ensure that CCW

program services were provided only to beneficiaries with completed and approved individual habilitation plans; and the division did not ensure and document that all beneficiaries were assessed and certified to require an ICF/MR level of care. HHS/OIG recommended, among other things, that New Jersey refund \$2.7 million to the Federal government.

- The New York State Department of Health (DOH) claimed Federal Medicaid reimbursement for some Office for People With Developmental Disabilities (OPWDD) waiver program services provided by New York City providers that did not comply with certain Federal and State requirements. Based on sample results, HHS/OIG estimate that DOH improperly claimed \$7.8 million in Federal Medicaid reimbursement for OPWDD waiver program services during calendar years 2006 through 2008. The claims for unallowable services were made because DOH and OPWDD's policies and procedures for overseeing and administering the waiver program were not adequate to ensure that providers claimed reimbursement only for services actually provided and maintained all the required documentation to support services billed; and OPWDD waiver program services were provided only to beneficiaries pursuant to written plans of care. HHS/OIG recommended, among other things, that DOH refund \$7.8 million to the Federal government.

Medicaid Fraud Control Units

HHS/OIG is responsible for overseeing the activities of all Medicaid Fraud Control Units (MFCUs or Units). As part of this oversight, HHS/OIG conducts periodic onsite reviews of the Units. These reviews describe the Units' caseload and assess their performance; identify any opportunities for improvement and instances of noncompliance with laws, regulations, and policy transmittals; and identify noteworthy practices.

- In its review of the New York MFCU, HHS/OIG found, among other things, that from fiscal years 2008 to 2010 the Unit filed criminal charges against more than 400 defendants, obtained over 400 convictions, and was awarded more than \$750 million in recoveries. However, the Unit did not establish annual training plans for each of the three professional disciplines (auditors, investigators, or attorneys) and provided limited training opportunities to staff. The Unit also lacked policies and procedures to reflect many of its current practices, and its case files lacked consistency and uniform supervisory reviews. At the same time, the review found no evidence of significant noncompliance with applicable laws, regulations, or policy transmittals. HHS/OIG recommended that the New York MFCU, among other things, establish annual training plans and increase the number of training opportunities available to staff, ensure that its memorandum of understanding, policies, and procedures reflect current practices, and ensure that its case files are maintained with greater consistency and reviewed more frequently.

Quality of Care

- HHS/OIG found that State survey and certification agencies' (State agencies) responses to allegations of serious harm to hospital patients were generally timely. However, State agencies often missed opportunities to incorporate patient safety principles. In addition, CMS often failed to inform the Joint Commission concerning complaints about the hospitals it accredits, thereby impeding the Joint Commission's oversight. Together, five types of in-hospital adverse events represented half or more of the complaints in our sample: sexual assault, medication error, physical abuse by hospital staff, restraint problems, and suicide. Investigations into these types of events led to most of the citations issued. State agencies conducted the investigations on behalf of Medicare. The hospitals' corrective actions resulted largely in training, coupled with policy and process changes. HHS/OIG recommended that CMS require that State surveys evaluate compliance with quality improvement requirements, ensure that States monitor hospitals' corrective actions, amend guidance on State agency disclosure of the nature of complaints to hospitals, and improve communication with accreditors.

Medicare-Medicaid Data Matching

- The Medicare-Medicaid Data Match program (Medi-Medi program) enables program safeguard contractors and participating Federal and State government agencies to collaboratively analyze billing trends across the Medicare and Medicaid programs to identify potential fraud, waste, and abuse. Participation is optional. In its review of this program, HHS/OIG found that the Medi-Medi program produced limited results and few fraud referrals. In addition, during 2007 and 2008, the program – in which 10 states had chosen to participate – received \$60 million in appropriations and it avoided and recouped \$57.8 million. Also, of the \$46.2 million total in Medicare and Medicaid expenditures recouped through the program during 2007 and 2008, more than three quarters, \$34.9 million, was recouped for Medicare. HHS/OIG recommended that CMS reevaluate the goals, structure, and operations of the Medi-Medi program to determine what aspect of the program, if any, should be part of CMS's overall program integrity strategy.

Medicare Physician Services

- Two reviews of paid claims for cardiovascular and musculoskeletal surgeries in 2007 revealed that Medicare's payment methodology often did not reflect the actual number of evaluation and management (E/M) services actually provided to beneficiaries, resulting in wasteful spending. The physician fee schedule includes global surgery fees for the surgical service and the related preoperative and postoperative E/M services provided during the global surgery period. In determining a global surgery fee, CMS estimates the number of E/M services that a physician provides to a typical beneficiary during the global surgery period and compensates physicians regardless of the E/M services actually provided. For the two types of surgeries, Medicare paid an estimated \$63 million in E/M services that were not provided in 2007. HHS/OIG recommended that CMS adjust the estimated number of E/M services within cardiovascular and musculoskeletal global

surgery fees to reflect the actual number of such services being provided to beneficiaries or use the results of this audit during the annual update of the physician fee schedule.

Comprehensive Outpatient Rehabilitation Facilities

- HHS/OIG found that 18 of the 101 South Florida Comprehensive Outpatient Rehabilitation Facilities (CORF) included in its analysis were not operational. Ten of the 18 CORFs were not at the locations on file with CMS and 8 were not open during business hours. Medicare allowed \$2.2 million in 2010 for services billed by these nonoperational CORFs. This HEAT initiative review was limited to determining whether the CORFs were operational. In prior reviews at three South Florida CORFs, HHS/OIG estimated that each audited CORF received between \$720,000 and \$1.6 million for services that did not meet Medicare reimbursement requirements. HHS/OIG recommended that CMS continue to periodically conduct unannounced site visits to CORFs and implement additional program safeguards for CORFs.

Community Mental Health Centers

- HHS/OIG found that in 2010 approximately half of CMHCs met or exceeded thresholds that indicated unusually high billing for at least one of nine questionable billing characteristics. Approximately one-third of these CMHCs had at least two of the characteristics. Additionally, approximately two-thirds of CMHCs with questionable billing were located in eight metropolitan areas. Finally, 90 percent of CMHCs with questionable billing were located in states that do not require CMHCs to be licensed or certified. During 2010, 206 CMHCs received an estimated \$218.6 million for providing PHP services to approximately 25,000 Medicare beneficiaries with mental disorders. Past OIG studies have found vulnerabilities in Medicare payments to CMHCs for PHPs. HHS/OIG recommend that CMS increase its monitoring of CMHCs' Medicare billing and fraud prevention controls; enforce the requirement that certifying physicians be listed on the PHP claims submitted by CMHCs; finalize and implement the proposed conditions of participation for CMHCs; and review and take appropriate action against CMHCs with questionable billing identified in the report.

Medicare Outpatient Services

- HHS/OIG's review of outpatient line items for which Medicare payments significantly exceeded billed charges revealed frequent errors, including incorrect units of services, incorrect codes, billing for unallowable services, and inadequate supporting documentation, causing Medicare to overpay for the services. Billed charges are the prices that a provider sets for its services. These reviews focused on billings in which Medicare's payments significantly exceeded billed charges. Millions of dollars in overpayments have occurred in part because key Medicare systems (the Fiscal Intermediary Standard System and the Common Working File (CWF)) did not have sufficient edits in place during the audit periods to prevent or detect the overpayments. For the 18 reviews conducted of Medicare payment contractors, HHS/OIG identified

nearly \$67 million in overpayments. HHS/OIG recommended that Medicare's payment contractors recover the identified overpayments, implement suggested system edits, and use the results of our audits in provider education activities.

Medicare Home Health Agencies

Medicare beneficiaries who are generally confined to their homes may be eligible to receive certain medical services at home. Home health services include part-time or intermittent skilled nursing care, as well as other skilled care services, such as physical, occupational, and speech therapy; medical social work; and home health aide services. The services are provided by certified HHAs.

- In a review of HHAs compliance with data reporting requirements, HHS/OIG found that HHAs did not properly submit required Outcome and Assessment Information Set (OASIS) data for six percent of claims filed in 2009, which represented over \$1 billion in Medicare payments. Among other important uses, states use OASIS data in the survey and certification of HHAs, which ensures that HHAs are meeting all conditions of participation required by Medicare. CMS holds states accountable for ensuring that HHAs submit timely and accurate OASIS data; however, it does not provide guidance on how states should oversee this process. HHS/OIG recommended that CMS identify all HHAs that failed to submit OASIS data and apply its two-percent payment reduction authority, establish and implement enforcement actions for late submission of the data, and develop clear guidelines that delineate expectations regarding data accuracy and timeliness.
- In a review of the availability of intermediate sanctions, CMS issued a Notice of Proposed Rulemaking (NPRM) in 1991 to implement intermediate sanctions for HHAs found to be noncompliant with Medicare's conditions of participation; however, CMS did not issue a final rule and withdrew the NPRM in August 2000. CMS said that legislative changes and other demands impeded promulgation of a final rule. Intermediate sanctions, such as civil money penalties, payment suspensions, and appointments of temporary management, will provide CMS with important tools to enforce compliance. HHS/OIG concluded that CMS should make HHA intermediate sanctions a high priority and complete their implementation as soon as possible. Most recently, CMS published a new NPRM on July 13, 2012, which proposes to implement intermediate sanctions for HHAs effective January 1, 2013.
- In a review of HHAs' compliance with documentation requirements, HHS/OIG found that HHAs usually documented Medicare's coverage requirements in beneficiaries' medical records. However, for the claims reviewed, HHS/OIG also found that 22 percent were in error, resulting in \$432 million in improper payments. This review, which examined the medical records supporting a sample of HHAs' claims to Medicare, showed that HHAs' records nearly always documented the information necessary to demonstrate compliance with key Medicare coverage requirements – that beneficiaries were homebound, needed skilled nursing care or therapy services, and were under the care of a physician. However,

other HHS/OIG reviews and investigations, as well as joint efforts between the HHS and DOJ, have demonstrated that home health is an area at increased risk for fraud. HHS/OIG concluded that further reviews beyond the medical records are needed to determine whether beneficiaries are actually eligible, services are furnished, and Medicare requirements for payment are met.

Medicare Contractors

- HHS/OIG found that the workload data that CMS uses to oversee Zone Program Integrity Contractors (ZPICs) were not accurate or uniform, and inaccuracies and lack of uniformity in the ZPICs' data prevented a conclusive assessment of ZPICs' activities. ZPICs are the contractors that perform benefit integrity work for Medicare Parts A and B. The inaccuracies and lack of uniformity in ZPICs' data resulted from system issues in CMS's Analysis, Reporting, and Tracking System (CMS ARTS); ZPIC reporting errors; ZPICs' interpretations of workload definitions; and inconsistencies in requests for information reports. ZPICs' performance evaluations contained few workload statistics, and data access issues affected ZPICs' program integrity activities. These conditions are serious obstacles to CMS's oversight of ZPIC operations and effectiveness. HHS/OIG recommended that CMS clarify definitions in CMS ARTS, perform a timely review of data in CMS ARTS, use and report ZPIC workload statistics in ZPIC evaluations, and ensure that ZPICs have access to necessary data.
- HHS/OIG found that CMS had not resolved, or taken significant action to resolve, 77 percent of vulnerabilities that its Medicare benefit integrity contractors reported in 2009. The estimated impact of vulnerabilities, such as those in claims coding and provider identifiers was at least \$1.2 billion. Only two of the vulnerabilities reported in 2009 had been resolved as of January 2011. Although CMS has procedures to consistently track and review vulnerabilities, it lacks procedures to ensure that vulnerabilities are resolved. HHS/OIG recommended that CMS determine the status of all unresolved vulnerabilities and take action to address them, require contractors to report monetary impact, and ensure that vulnerabilities are resolved by establishing formal written procedures.
- HHS/OIG found that, as of October 2010, Medicare had not recovered the majority of overpaid amounts OIG identified in audit reports during FYs 2007 and 2008 and the first 6 months of FY 2009. Collection efforts were obstructed by time constraints imposed by the statute of limitations. Also, Medicare contractors lacked adequate guidance for collecting overpayments and CMS did not have an effective system for monitoring contractors' collection efforts. We identified inaccuracies and could not verify the \$84.2 million that CMS reported collecting. HHS/OIG recommended, among other things, that CMS collect sustained amounts related to OIG recommendations made after the audit period and verify that the \$84.2 million reported as collected has actually been collected.
- In a July 2012 report, HHS/OIG found that ZPIC offerors (companies that submit proposals for ZPIC contracts) and their subcontractors often had business and contractual

relationships with CMS and with other offerors, but rarely considered them to be actual conflicts of interest. Conflicts of interest could introduce bias, which in turn could influence ZPICs' efforts to reduce fraud, waste, and abuse in the Medicare program. Offerors, subcontractors, and CMS identified 1,919 business and contractual relationships as possible conflicts and 16 as actual conflicts. However, descriptions of the conflicts of interest presented were often unclear and some did not distinguish actual conflicts from possible conflicts. In addition, some ZPIC offerors and their subcontractors failed to provide all the requisite information regarding financial interests in other entities. HHS/OIG recommended that CMS provide clear guidance to offerors and subcontractors regarding which business and contractual relationships should be identified as actual or possible conflicts and develop a formal, written policy outlining how conflict of interest information provided by offerors should be reviewed by CMS staff.

Medicare Advantage Organizations

- In two reports, HHS/OIG found that two Medicare Advantage (MA) organizations were overpaid in 2007 because the diagnoses and/or supporting documentation that they submitted to CMS for use in CMS's risk score calculations did not always comply with Federal requirements. CMS uses risk scores to adjust the monthly capitated payments to MA organizations for the next payment period. The first MA organization, which was overpaid an estimated \$115.4 million, did not have written policies and procedures for obtaining, processing, and submitting diagnoses to CMS and its practices were not effective in ensuring that the diagnoses it submitted to CMS complied with Federal requirements. For the second MA organization, which was overpaid and estimated \$18.2 million, the documentation submitted did not support the diagnoses, was incomplete or missing, or the diagnoses were unconfirmed, causing CMS's risk scores to be invalid. HHS/OIG recommended that the two organizations refund to the Federal government overpayments identified for sampled beneficiaries and work with CMS to determine the correct contract level adjustment for the projected overpayments.

Medicare Part D

- In a review of Part D billing by retail pharmacies, HHS/OIG found that over 2,600 pharmacies nationwide had questionable billing, indicating vulnerabilities in the oversight of the Part D program. These pharmacies had extremely high billing for at least one of eight measures. They represented 4 percent of all retail pharmacies nationwide. Together, they billed \$5.6 billion to Part D in 2009. Many billed for extremely high dollar amounts or numbers of prescriptions per beneficiary or per prescriber. Many also billed for high percentages of Schedule II or III controlled substances. HHS/OIG recommended, among other things, that CMS strengthen the Medicare Drug Integrity Contractors' monitoring of pharmacies and ability to identify pharmacies for further review; provide additional guidance to sponsors on monitoring pharmacy billing; require sponsors to refer potential fraud and abuse incidents that may warrant further investigation; and develop risk scores for pharmacies.

Medicare Error Rates

CMS's Comprehensive Error Rate Testing (CERT) program contractors collect and review documents supporting claims for payment, identify improper payments, and calculate a national Medicare fee for service error rate. HHS/OIG found the following issues in current CERT practices.

- HHS/OIG found that a CERT contractor's error rate calculations did not account for pending appeals. If the CERT statistical contractor had included overturned CERT claim payment denials in its error rate calculations, it would have decreased the estimated value of reported errors for FYs 2009 and 2010 by approximately \$2 billion each year. CMS could improve the accuracy of the reported estimate of improper payment error rates by including an adjustment for overturned CERT claim payment denials. HHS/OIG recommended that CMS improve the accuracy of the reported estimate of improper payment error rates by including an adjustment for overturned CERT claim payment denials.
- HHS/OIG found that the necessary documentation required for the CERT contractors to conduct claims reviews was not provided by the cutoff date for the error rate calculation. The submission of this documentation to the CERT contractor upon initial claim review and before the cutoff date would have reduced the estimate of improper payments for FY 2010 by almost \$1 billion. HHS/OIG recommended that CMS should continue to educate providers on the documentation required, assess the improper payments and overturned denials of claim payments to identify the population of providers that would benefit from additional requests for medical records, and ensure that the CERT documentation contractor continues following established procedures in seeking signature attestations.

Other Fraud and Abuse Prevention Activities

HHS/OIG's HEAT Provider Compliance Training initiative (HEAT PCT), launched in 2011, provided free, high-quality compliance training for providers, compliance professionals, and attorneys in Strike Force cities and elsewhere, and online. During FY 2011, HEAT PCT, which included presenters from HHS/OIG, CMS Regional Offices, CMS Program Integrity, USAOs, and state Medicaid Fraud Control Units, held sessions in Houston, Tampa, Kansas City, Baton Rouge, Denver, and Washington, D.C., training a total of 737 in-person attendees. In addition, the final HEAT PCT session in Washington, D.C., was webcast live to 2,335 participants. HHS/OIG developed comprehensive training materials to accompany HEAT PCT, and those materials are now available online at no charge, together with sixteen video modules dividing the webcast by subject area. HEAT PCT continues to reach the health care community with HHS/OIG's message of compliance and prevention via a series of twelve free, downloadable video and audio podcasts, which were rolled out during FY 2012. The podcasts summarize a range of compliance topics covered in the HEAT PCT initiative materials.

HCFAC funding also supported HHS/OIG's continued enhancement of data analysis and mining

capabilities for detecting health care fraud, including tools that allow for complex data analysis. OIG continues to use data mining, predictive analytics, trend evaluation, and modeling approaches to better analyze and target the oversight of HHS programs. Analysis teams use near-time data to examine Medicare claims for known fraud patterns, identify suspected fraud trends, and to calculate ratios of allowed services as compared with national averages, as well as other assessments. When united with the expertise of OIG agents, auditors, and evaluators, as well as our HEAT partners, HHS/OIG's data analysis fosters a highly effective combination of technologies and traditional skills to the fight against fraud, waste, and abuse.

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 AKS, the CMP laws, or the exclusion provisions. During FY 2012, the HHS/OIG, in consultation with DOJ, issued 19 advisory opinions and two modifications of advisory opinions. A total of 276 advisory opinions have been issued during the 16 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 or supplier 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 2012, HHS/OIG was monitoring compliance with 214 such agreements.

OIG Round Tables

On February 23, 2012, HHS/OIG convened a Pharmaceutical Compliance Roundtable. The Roundtable provided an opportunity for OIG to discuss with compliance professionals in the pharmaceutical industry their experiences under CIAs and with various types of compliance activities. Forty-two compliance officers and other compliance professionals from 23 pharmaceutical manufacturers currently under CIAs attended the day-long event. One goal of the event was to identify compliance measures that the participants have found to be effective. A publicly-available report about the Roundtable shared the participants' insights with others in and beyond the pharmaceutical industry.

Also, on August 7, 2012, HHS/OIG held a roundtable meeting titled "Focus on Compliance: The Next Generation of CIAs." The roundtable included representatives from 32 companies that have entered into CIAs since 2009. The companies represented included hospitals, ambulance companies, medical device manufacturers, physician practices, laboratories, home health agencies, and skilled nursing facilities. The purpose of the roundtable was to solicit feedback

from the company representatives regarding their current compliance best practices and their efforts to implement the requirements of their CIAs. The OIG will provide a summary of the roundtable in a whitepaper that will be posted on the OIG's website.

Centers for Medicare & Medicaid Services

In FY 2012, CMS was allocated approximately \$14.5 million by HHS, and appropriated \$250.4 million in discretionary funds by Congress to support a variety of projects related to fraud, waste, and abuse in the Medicare and Medicaid programs and the Children's Health Insurance Program (CHIP). With these funds, CMS is building on existing fraud prevention activities and new advanced technology to ensure that accurate payments are made to legitimate providers for appropriate and reasonable services for eligible beneficiaries of the federal health care programs. CMS has also 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. Medicare Fee-for-Service error rate measurement, activities and Recovery Audit activities are discussed in separate reports, and CMS will submit a combined Medicare and Medicaid Integrity Program report to Congress later this year.

CMS has taken four major approaches to fraud prevention and organizing its key anti-fraud, waste, and abuse activities:

1. Prevention
2. Detection
3. Transparency and Accountability
4. Recovery

1. Prevention

The Affordable Care Act (ACA)

The new authorities granted to HHS and CMS under ACA have been instrumental in clamping down on fraudulent activity in the health care sector. CMS has begun to implement these authorities and published one final rule on provider identification numbers and a Notice of Proposed Rule-Making on reporting and returning overpayments.

In FY 2012, CMS implemented ACA authorities to keep fraudulent providers and suppliers out of Medicare and Medicaid. CMS published a Final Rule entitled "Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements" (CMS-6010-F) on April 27, 2012. This rule finalized ACA provisions that were addressed in a May 5, 2010 interim final rule. It requires all providers of medical or other items or services and suppliers that qualify for a National Provider Identifier (NPI) to include their NPI on all enrollment applications for Medicare and Medicaid programs and on all claims for payment submitted under those programs. In addition, it requires physicians and other professionals who are permitted to order and certify covered items and services for Medicare beneficiaries to be enrolled in Medicare. Finally, it

establishes document retention and provision requirements on providers and supplier that order and certify items and services for Medicare beneficiaries.

CMS also published a NPRM entitled “Medicare Program; Reporting and Returning of Overpayments” on February 16, 2012. This proposed rule would require providers and suppliers, who receive funds under Medicare, to report and return overpayments 60 days after the later of the date that the overpayment was identified, or the date that any corresponding cost report is due.

The Fraud Prevention System

The Fraud Prevention System (FPS) was launched on June 30, 2011 pursuant to the Small Business Jobs Act of 2010. While the development of the FPS is not directly funded by HCFAC, many activities in this report both support and rely on the FPS. The FPS analyzes all Medicare fee-for-service claims using risk-based algorithms developed by CMS and the private sector, prior to payment, allowing CMS to take prompt action where appropriate. CMS uses the FPS to target investigative resources to suspect claims and providers, and swiftly impose administrative action when warranted. The system generates alerts in priority order, allowing program integrity analysts to further investigate the most egregious, suspect, or aberrant activity. CMS and our program integrity contractors use the FPS information to stop, prevent, and identify improper payments using a variety of administrative tools and actions, including claim denials, payment suspensions, revocation of Medicare billing privileges, and referrals to law enforcement.

Automated Provider Screening

To strengthen and help implement the new provider enrollment requirements under the ACA, CMS launched the Automated Provider Screening (APS) system in December 2011. The APS is designed to verify the data submitted on enrollment applications against independent commercial and health care data to establish eligibility for enrollment into Medicare. It assesses risk of potential fraud of each individual and organization, and returns the results and supporting data to a web-based user interface accessible to CMS and its designees. In FY 2012 CMS began the process of screening all 1.5 million Medicare-enrolled providers through the new Automated Provider Screening (APS) system which identifies ineligible providers and suppliers prior to enrollment or revalidation to verify the data in the Provider Enrollment, Chain and Ownership System (PECOS). This baseline screen of existing Medicare enrollments enables CMS to quickly identify ineligible and potentially fraudulent providers within existing enrollments. This process was followed by nightly screens of updated enrollments and new applications in a pilot with three Medicare Administrative Contractors in June 2012. The integration of this automated provider screening tool with the enrollment data in PECOS and the claims data in the Fraud Prevention System (FPS) will improve CMS’ ability to screen and identify questionable entities efficiently, and lead to cost-avoidance and increased savings for Medicare.

Provider Screening Lab

CMS worked with a national health research organization managing a Federally Funded Research and Development Center to establish the Provider Screening Lab. The lab tests concepts for new provider screening data sources, methodologies, and associated algorithms. To date, the lab has

provided analytic support to develop approximately 59 criteria to assess provider eligibility and potential risk as part of effective provider screening. A variety of CMS data sets, such as Provider Enrollment, Chain and Ownership System (PECOS), the Federal Investigations Database (FID), the Compromised Numbers Checklist (CNC), and the Medicare Exclusion Database (MED) were used in the development of these criteria; External data have also been used for criteria around criminal, financial and identity verification. CMS is continuously evaluating additional data sources to develop new criteria for use in the provider screening solution.

Revalidation Project

In FY 2012, CMS embarked on an ambitious project to revalidate the enrollments of all existing 1.5 million Medicare suppliers and providers by 2015 under the new ACA screening requirements. Since March 25, 2011, CMS enrolled or revalidated enrollment information for approximately 409,150 Medicare providers and suppliers under the enhanced screening requirements of the ACA. These efforts will ensure that only qualified and legitimate providers and suppliers can provide health care items and services to Medicare beneficiaries.

The FPS, APS, and other enrollment enhancements promote synergy in CMS program integrity activities. For example, based on FPS leads, CMS identified specific providers and suppliers as top priorities for revalidation. As a result of the screening performed as part of revalidation, CMS has moved to revoke and deactivate the billing privileges and enrollment records of providers and suppliers that do not meet Medicare enrollment requirements. The first phase of revalidation led to 17,620 deactivations of provider practice locations for non-response to the revalidation request, as of September 1, 2012. The second phase of revalidation has resulted in the deactivation of 21,114 provider enrollments records for non-response and 6,630 revocations after it was determined the providers were not properly licensed in the state in which they were enrolled, as of September 1, 2012.¹⁴ These initiatives complement the traditional program integrity work and additional provider enrollment enhancements that CMS performs.

One Program Integrity

In FY 2012, CMS made improvements and changes to the One Program Integrity (One PI), CMS' centralized portal that provides CMS contractors and law enforcement with a single access point to Medicare data as well as analytic tools to review the data. CMS moved from an integration contractor to a system support contractor while continuing to enhance the existing analytic tools. One PI users now have access to the CMS Integrated Data Repository (IDR) as the basis of their data analytics. The IDR contains a comprehensive and accurate set of Medicare provider, beneficiary and claims data for Medicare Parts A, B, and D back to January 2006. One PI improves CMS' ability to detect fraud, waste, and abuse with consistent, reliable, and timely analytics.

¹⁴ We note that the first and second phase revalidation results are preliminary results as deactivated providers could reactivate over time with updated practice information or after showing evidence of proper licensing.

Over the last 12 months, CMS has expanded the IDR to include shared systems data, providing access to Part B and Part B-DME claims data from both before and after final payment has been made. This access allows ZPICs to perform pre-payment analytics on historical data and develop models that can be applied in the FPS. With shared systems history going back to FY 2006, ZPICs will also be able to improve their analytics for post-payment detection of fraud, waste, and abuse. Part A data from the shared systems will be added in the near future.

The new system support contract includes onsite training at ZPICs sites, which began in July of 2012, and is scheduled to occur at one ZPIC each month into calendar year 2013. This training will be replaced by web-based training once the new modules are completed in 2013.

Next Generation Desktop

The Next Generation Desktop (NGD) was developed to provide single access point that interacts with all Medicare claims processing systems and multiple other government data sources. NGD has been adapted for law enforcement purposes, providing investigators the ability to examine all claims associated with a specific provider tax ID or a Medicare beneficiary. CMS implemented enhancements to the Next Generation Desktop in September of 2012. These enhancements are a result of collaboration between CMS, National Government Services (NGS), the NGD contractor, and Medicare Administrative Contractor (MAC), with specific requests from law enforcement for enhanced views of provider data. CMS and NGS developed tailored training material for law enforcement partners and have scheduled four 3-day training sessions in FY 2013. CMS anticipates training up to 100 or more individuals in FY 2013.

Compromised Number Checklist

In January 2010, CMS developed its first national database of compromised Medicare beneficiary and provider ID numbers called the Compromised Number Checklist (CNC). This database is populated by monthly submissions from program integrity contractors. The purpose of the CNC is to share compromised ID numbers and any associated corrective actions that have been taken. CMS uses this national CNC database to enhance efforts detecting and preventing fraud and abuse in Medicare.

The compromised numbers are updated on a monthly basis. In FY 2012, as part of its refinement of and assignment of risk assessment indicators to the CNC database, CMS and the PSCS/ZPICs and MEDIC have removed some providers and beneficiaries whose identifiers were closely linked to compromised providers or beneficiaries but were not themselves compromised. This refinement process has reduced the number of providers from approximately 5,000 to 2,185, and reduced the number of beneficiaries from approximately 284,000 to 226,000.

SAS Statistical Programming License

CMS established an analytics lab to develop and test new models for the FPS using SAS statistical programming software to analyze claims data to identify aberrant billing patterns and program vulnerabilities. As of the end of FY 2012, CMS has added 31 new models to the FPS,

and 29 additional models were under active development for future integration in the FPS. Going forward, CMS will develop models on a continuous basis.

The Command Center

In FY 2012, CMS established the Command Center to improve health care fraud detection and investigation, drive innovation, and help reduce fraud and improper payments in the Medicare and Medicaid programs. The Command Center provides the advanced technologies and collaborative environment for a multi-disciplinary team of experts and decision makers to more efficiently coordinate policies and case actions, reduce duplication of efforts, and streamline fraud investigations for more immediate administrative action.

CMS anticipates that the Command Center collaborative activities will help increase CMS' ability to take administrative actions, such as revoking Medicare billing privileges and payment suspensions, more quickly and efficiently. From the opening of the Command Center on July 31, 2012 through September 27, 2012 the Command Center conducted 22 missions and identified 223 action items that will lead to improvements in the fraud prevention and detection process. Missions are facilitated collaboration sessions that bring together experts from various disciplines to improve the processes for fraud prevention in Medicare and Medicaid. Approximately 290 experts met during this period representing policy analysts, investigators, lab modelers, FBI, OIG, ZPICS, field office staff, clinicians, Contracting Officer Representatives (CORs), and other CMS staff.

DME Initiatives

CMS has undertaken a comprehensive strategy to address program integrity concerns with durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers:

- DMEPOS Enrollment Requirements: In the February 2, 2011 final rule, CMS assigned newly enrolling DMEPOS suppliers to the high level of screening. As a result, such suppliers are subject to an announced or unannounced site visit prior to the approval of their application. Newly enrolling DMEPOS suppliers will also be subject to a FBI criminal history record check once CMS completes the procurement of an FBI-approved channeler. Enrolled DMEPOS suppliers are assigned to the "moderate" screening level, and are also subject to an announced or unannounced site visit prior to the approval of their revalidation.
- DMEPOS Surety Bond: Since 2009, CMS has required DMEPOS suppliers to post surety bonds prior to enrollment. CMS also implemented DMEPOS Accreditation Standards, which have been in effect since October 1, 2009. Supplier numbers cannot be issued or renewed unless the supplier - assuming it does not otherwise qualify for an exception under 42 CFR § 424.57(d)(15) - obtains and maintains a surety bond of at least \$50,000 and meets the accreditation standards on a continuous basis.

CMS finalized its DMEPOS surety bond collection procedures in January 2012. CMS has

thus far collected approximately \$263,000 in DMEPOS supplier overpayments from sureties. The DME MACs are continuing to make requests for payments from sureties, and CMS expects more overpayments to be collected as a result. In addition, CMS has recouped approximately \$65,000 in overpayments from suppliers immediately after their debts were referred to their respective sureties for payment. In many cases, once suppliers learn that their debt has been sent to their surety for collection, they proceed to pay back the debt themselves. This is an encouraging sign that the surety bond collection process is spurring DMEPOS suppliers to satisfy their debts earlier than would otherwise have been the case.

- DMEPOS Swipe Card Pilot: The DMEPOS Swipe Card pilot was designed in part to assess the effectiveness of new regulatory requirements as a result of the Affordable Care Act, Section 6406. Physicians and other suppliers that participated in the pilot on a voluntary basis used swipe magnetic cards (similar to credit cards), and entered a code into existing credit card terminals when placing or filling DMEPOS orders. CMS, through its contract with National Government Services (NGS), extracted the DMEPOS data from the financial network, and used the data to confirm that the orders were appropriately initiated and filled.

The Swipe Card pilot began in early 2011 with a series of meetings to plan out the issuing of swipe cards to providers and suppliers in the Greater Indianapolis area and concluded in FY2012. CMS found that the voluntary nature of the pilot led to low participation, and that a significant number of providers do not have swipe terminals in their office. CMS is evaluating these results to identify opportunities for future pilots.

Fraud Prevention Campaign

In FY 2012, CMS worked with the Assistant Secretary for Public Affairs (ASPA) to expand the Fraud Prevention Campaign, which was launched in January 2010 to increase public awareness about Medicare's fight against fraud. HCFAC funding in FY 2012 – supported by FY 2011 HCFAC dollars — was used to support outreach to inform Medicare beneficiaries how to prevent, detect and report Medicare fraud.

Outreach included a national television campaign featuring a “cracking-down” spot, print, and digital advertising as well as targeted in-language advertising. In-language advertising included print and radio advertising in Russian in New York, in Armenian in Los Angeles and in Spanish in Miami. The national television advertising delivered an estimated 140,580,420 impressions. The digital advertising delivered an additional 11.1 million views of the “cracking-down” spot.

Medicaid and CHIP Business Information Solutions (MACBIS)

The Medicaid and CHIP Business Information Solutions (MACBIS) is a CMS enterprise-wide initiative to modernize and transform the information and data exchanges with States and other key health reform stakeholders in order to ensure we have high performing Medicaid and CHIP programs. This initiative creates a more robust and comprehensive information management

strategy for Medicaid and CHIP. We have designed a “transformed data state” that will, for the first time, integrate Medicaid and CHIP program, operational, quality, and performance data. Specifically, the data will be used to support detection of fraudulent patterns in State Medicaid programs as well as comparative analytics across state lines.

The accomplishments for FY 2012 include:

- MACBIS – Completed Medicaid & CHIP enterprise data work resulting in an expanded data dictionary.
- TMSIS – Completed and evaluated an 11-State pilot to test an expanded operational data set (Transformed MSIS); developed a plan to launch a national implementation of TMSIS in 2014.
- MACPro – Collected business requirements to complete system development to adjudicate a limited set of Medicaid and CHIP plans and waiver actions for January 2013 implementation. Subsequent phases will cover the remaining actions for full implementation by 2016.
- Information Technology Support – Integrated MACBIS processes into CMS’s enterprise shared services efforts including, master data management, identity management, and portal development.

2. Detection

Strengthened Program Integrity Activities in Medicare Advantage and Medicare Part D

In FY 2011, CMS established a contract for Medicare Advantage (Part C) and Medicare Prescription Drug (Part D) outreach and education. This contractor is responsible for coordinating all Part C and Part D program integrity outreach activities for all stakeholders, including plan sponsors and law enforcement. In addition, this contractor supports compliance audits and fraud audits.

CMS continued to fund the Program Integrity Technical Assistance contractor to support Part C and Part D program integrity strategy, ROI methodology, performance measure database maintenance, development of program risk assessment processes, and other technical assistance as requested. CMS also contracted with the Compliance and Enforcement Medicare Drug Integrity Contractor (MEDIC) to conduct ad-hoc studies and analysis with a special focus on select geographic areas.

Additionally, CMS continued to invest HCFAC discretionary funds to strengthen Medicare Part C and Part D oversight. CMS contracts with the MEDICs for all Medicare Advantage and Part D program integrity work, including:

- Managing all incoming complaints about Part C and Part D fraud, waste, and abuse;
- Utilizing new and innovative techniques to monitor and analyze information to help identify potential fraud;

- Working with law enforcement, MA, and prescription drug plans, consumer groups, and other key partners to protect consumers and enforce Medicare's rules;
- Providing basic tips for consumers on how to protect themselves from potential scams;
- Identifying program vulnerabilities; and
- Performing proactive research utilizing all available data to find trends in order to ferret out fraud, waste, and abuse activities.

As of May 2012, the national benefit integrity MEDIC received approximately 348 actionable complaints (within the MEDIC's scope) per month; processed 27 requests for information from law enforcement per month; and referred an average of 34 cases to law enforcement per month.

In addition to the work of the MEDICs, CMS enhanced other Part C and Part D oversight functions in FY 2012: to address new complexities facing law enforcement, contract and plan oversight functions, monitor plan performance assessment and surveillance/secret shopper activities, audit programs, and conduct routine compliance and enforcement tracking. Also in FY 2012, CMS conducted 33 program audits of sponsoring organizations and tested for compliance with program requirements relating to Part D formulary and benefit administration, Part C and D organizational/coverage determinations, appeals, and grievances, part C Access, Enrollment/Disenrollment, Late Enrollment Penalty (LEP), independent agent and broker oversight, and compliance program effectiveness. These audits covered programs that accounted for 27 percent of all MA and Prescription Drug Plan contracts and 28 percent of all beneficiaries enrolled as of September 2012.

CMS also strengthened program integrity in MA and Part D through marketing surveillance activities and compliance actions based on surveillance activities:

Marketing Surveillance Activities

In FY 2012, CMS conducted many marketing surveillance activities, such as secret shopping and examining newspaper ads for unreported marketing events and content. These activities have improved plan sponsor oversight of marketing activities and lessened incidents of agent/broker marketplace misconduct.

For the 2012 Annual Enrollment Period (AEP), CMS conducted 1,661 secret shopping events. Secret shopping is the undercover surveillance of formal, public MA and Part D plan marketing events to ensure agents and brokers are providing accurate information to Medicare beneficiaries and are in compliance with CMS marketing rules for Parts C and D. Of the 1,661 shops, almost 80 percent had no validated deficiencies and were considered entirely compliant with Medicare regulations. The percentage of plan sponsors with no validated deficiencies improved from 2011 to 2012, with 31 of 84 plan sponsors (36.9 percent) having no deficiencies notes from events shopped (from 18.7 percent plan sponsors in 2011). This improvement demonstrates a continued increase in compliance likely due, in part; to CMS' market surveillance efforts. CMS estimates that over 850,000 beneficiaries who attended marketing events during the 2012 AEP were protected by CMS' marketing surveillance efforts this year.

Unreported Marketing Events

The unreported marketing events initiative was an effort to determine if plan sponsors appropriately reported and represented their sales events activity to CMS. The CMS contractor reviewed daily and weekly print publications in U.S. domestic markets nationwide, including advertisements from Armenian, English, Korean, Mandarin, Russian and Spanish publications. None of the reviewed Armenian or Russian publications contained Medicare marketing events. Each of the remaining language publications advertised marketing events that were not properly reported to CMS in a timely manner.

Under CMS' direction, the surveillance contractor reviewed 9,714 unique events (derived from 2,162 Medicare advertisements in 579 newspapers) collected from October 24, 2011 through December 29, 2011 from a total of 86 plan sponsors. Results by plan sponsor included: 42 plan sponsors (approx. 49 percent) submitted all clipped marketing events to CMS; an additional 41 plans (approx. 4 percent) submitted at least 95 percent of clipped marketing events to CMS ; and 3 plan sponsors (approx. 4 percent) failed to submit at least 5 percent of their clipped events. These three plan sponsors were issued notices of non-compliance for their failure to submit at least 95 percent of all of their events to CMS.

Compliance Actions Based on Surveillance Activities

CMS may issue the following types of letters to sponsors who have had deficiencies related to our surveillance. They include Technical Assistance Letters (which are not formal compliance letters), Notices of Non-Compliance, Warning Letters, and Ad-hoc Corrective Action Plans (CAPs). Listed below are the compliance actions taken for each primary surveillance activity.

Compliance Actions

Compliance Action	Secret Shopping Events*	Unreported Marketing Events
Technical Assistance Letter*	105	0
Notice of Non-compliance	12	3
Warning Letter with Business Plan	1	0
Ad-hoc CAP	0	0
Total Letters Issued	118	3

**Totals include results from both AEP and post-AEP shopping.*

**Technical Assistance Letters were sent to plan sponsors that were shopped, but either did not meet the minimum number of shops, no matter how many deficiencies were found, or had minimal findings.*

Medicare Advantage Encounter Data Processing System Contract

The Medicare Advantage (MA) Encounter Data Processing System (EDPS) is currently being

developed out of guidance published in the final FY 2009 inpatient prospective payment system (IPPS) rule. In that rule, CMS revised regulations to clarify that CMS has the authority to require MA organizations to submit encounter data for each item and service provided to MA plan enrollees. Consistent with this authority, CMS is requiring MA organizations to submit encounter data for dates of service January 3, 2012 and later. MA plans are required to submit data for all institutional, professional and DME services provided to MA plan enrollees on or after that date.

What program needs will EDPS be addressing? Over the past several years there has been dramatic growth in the Medicare Advantage program. Today, one-fourth of Medicare beneficiaries are enrolled in Medicare Advantage plans. CMS pays Medicare Advantage organizations approximately \$145 billion per year for the care provided to these 13 million beneficiaries. To date, however, CMS has not had detailed information on the care we are purchasing. This is because Medicare Advantage organizations are paid a fixed amount (monthly capitation) per beneficiary and, therefore, do not bill CMS for each service provided. Encounter data will provide CMS with information that is equivalent to the information provided on a FFS claim record. The diagnosis data provided on these claims will be used to risk adjust payments and, as a result, CMS will need complete encounter data records for the MA population being served. Sampling is not an option for processing the approximately 330 million encounter data claims any more than it would be for processing Medicare FFS claims.

To better ensure that CMS is a more prudent purchaser, earlier this year the agency launched an initiative to collect encounter data from Medicare Advantage organizations. Essentially the encounter data are “no pay” claims that detail each item and service provided to enrollees of Medicare Advantage organizations. CMS can collect and process these data for an estimated average annual cost of \$25 million. These records are comparable in format and detail to claims submitted to the MACs by FFS providers.

How will CMS use the data collected by EDPS? CMS will be able to use encounter data to make more accurate risk adjusted payments, recognize cost efficiencies, better assess the value of what we are purchasing for beneficiaries, and more closely monitor fraud, waste and abuse in the MA program. For example, using encounter data, CMS will be able to compute quality metrics, such as hospital readmission rates, for Medicare Advantage as a whole, as well as for individual Medicare Advantage organizations.

In addition, using procedure and diagnosis information for each health care service provided, CMS will shadow price each encounter using FFS payment rules. This will allow CMS to conduct cost comparisons against FFS relative to the actual services used.

Under the new EDPS system, MA plans face significant differences from the current Risk Adjustment Processing System. Most notably, data collection changes from 5 data elements currently collected to all of the required data elements on the HIPAA 5010 version of the X12 standards. The collection of MA encounter data is expected to provide CMS with a complete picture of MA member utilization and will provide CMS the ability to perform, such as:

- Encounter data can be utilized to identify provider types and facilities with increased fraudulent or incorrect billing to Medicare.
- Claims, where Medicare is the secondary payer, can be analyzed focusing on coordination of benefits, employer group health plans, or other government issued benefits.
- CMS can utilize analysis of DME data, and make cost comparisons by region and location of DME service provider or supplier to determine that diagnostic, procedural and costs patterns are appropriate. Careful analysis of the DME fee schedule will be employed to ascertain accurate payment reimbursement methods.

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 program and CHIP. In FY 2012, through the continued efforts of these specialists, CMS removed an estimated \$895 million (with approximately \$451 million recovered and \$444 million resolved) of approximately \$7.8 billion identified in questionable Medicaid costs.

Furthermore, an estimated \$128 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.

HHS/OIG Hotline Database

CMS and its contractor use the OIG Hotline database to perform program integrity activities. Specifically, the contractor currently receives and processes the complaints OIG receives through its TIPS Hotline and uploads them to the OIG Hotline database for review by the MACs. The complaints from both the OIG Hotline and 1-800-Medicare have been in two separate databases and followed two distinct processes for resolution. These processes will improve as we consolidate and integrate all the complaints received by OIG and 1-800-MEDICARE. The CMS contractor is coordinating this effort with the OIG, ECM and NGD. CMS and the OIG anticipate implementing the new process by December 2012.

3. Transparency and Accountability

Measured Error Rate - Payment Error Rate Measurement (PERM)

The Improper Payments Information Act (IPIA) of 2002, amended by the Improper Payments Elimination and Recovery Act of 2010 (IPERA), requires each agency to periodically review

programs it administers, identify programs that may be susceptible to significant improper payments, estimate the amount of improper payments, submit those estimates to Congress, and report on actions the Agency is taking to reduce improper payments.

The Medicaid program and CHIP have been identified as at risk for significant erroneous payments. To comply with the IPIA and IPERA, CMS established the Payment Error Rate Measurement (PERM) to estimate improper payment error rates in Medicaid and CHIP. The error rates are based on reviews of the fee-for-service (FFS), managed care, and eligibility components of Medicaid and CHIP in the fiscal year under review. CMS uses federal contractors to measure Medicaid and CHIP error rates using a 17-state rotation so that each state is reviewed once every three years. After several years of development, piloting and implementing the PERM error rate was published for the first time in FY 2008.

HHS calculated, and is reporting in the FY 2012 Agency Financial Report, the three-year weighted average national Medicaid error rate that includes the rates reported in fiscal years 2010, 2011, and 2012. This three-year rolling national error rate is 7.1 percent or \$19.2 billion in estimated improper payments and has decreased from FY 2011 (8.1 percent or \$21.9 billion). The weighted national error components rates are as follows: Medicaid FFS, 3.0 percent; Medicaid managed care, 0.3 percent; and Medicaid eligibility, 4.9 percent. The most common cause of errors in fee-for-service claims is lack of sufficient documentation to support the payment. The vast majority of the eligibility errors were due to beneficiaries found to be ineligible or whose eligibility status could not be determined.

Section 601 of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) prohibited HHS from calculating or publishing any national or state-specific error rates for CHIP until six months after a new PERM final rule was effective. In addition, Section 205(c) of the Medicare and Medicaid Extenders Act of 2010 exempted HHS from reporting a 2011 CHIP improper payment rate. On August 11, 2010, as part of enhanced efforts to reduce improper payments in federal programs, HHS issued the final regulations that fully implemented improvements to the PERM program. Therefore, HHS commenced CHIP error rate measurement in 2011 and is reporting the single-year FY 2012 national CHIP error rate in the FY 2012 Agency Financial Report. The FY 2012 national CHIP error rate is 8.2 percent or \$0.7 billion in estimated improper payments. The national component error rates are as follows: CHIP FFS – 6.9 percent; CHIP managed care – 0.1 percent; and CHIP eligibility – 5.8 percent. The most common causes of errors are due to beneficiaries found to be ineligible. Other errors are due to policy violations, payments made for non-covered services, and no documentation.

CMS is currently measuring cycles that will be reported in 2013 and 2014. CMS expects the error rates to decline in future years through program maturation and corrective action initiatives implemented at the state and Federal levels.

As a result of the Executive Order 13520—Reducing Improper Payments and Eliminating Waste in Federal Programs, the PERM program has added several new requirements including reporting error rate information on the Treasury improper payment dashboard – PaymentAccuracy.gov — and annually reporting comprehensive improper payment measurement and reduction activities to

HHS/OIG.

Error Rate Measurement and Increased Accountability in Medicare Advantage (Part C) and Medicare Prescription Drug Benefit Program (Part D)

In compliance with IPIA, CMS has implemented a systematic plan regarding improper payments for Part C and Part D programs. Unlike Medicare fee-for-service, CMS makes prospective, monthly per-capita payments to Part C organizations and Part D plan sponsors. Each per-person payment is based on a bid amount, approved by CMS, that reflects the plan's estimate of average costs to provide benefit coverage to enrollees. CMS risk-adjusts these payments to take into account the cost associated with treating individual beneficiaries based on health status. In addition, certain Part D prospective payments are reconciled against actual costs, and risk-sharing rules set in law are applied to further mitigate plan risk.

The Part C payment error estimate reported for FY 2012 (based on calendar year CY 2010) is 11.4 percent, or \$13.1 billion. The Part C payment error estimate has remained relatively constant compared to FY 2011 of 11.0 percent. The FY 2012 Part C payment error estimate presents the combined impact on Part C payments of two sources of error: Part C payment system error and the Risk Adjustment Error. Most of the Part C payment error is driven by errors in risk adjustment data (clinical diagnosis data) submitted by Part C plans to CMS for payment purposes. Specifically, the Risk Adjustment Error estimate reflects the extent to which diagnoses that plans report to CMS are not supported by medical record documentation. In an effort to improve the Part C error rate, CMS has implemented contract-specific Risk Adjustment Data Validation (RADV) audits designed to recover overpayments to Part C plans, and to provide outreach and education to plans. Further, CMS has initiated outreach and education efforts for physicians/providers for FY 2012.

On February 24, 2012, HHS released the *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits*. The notice clarifies the final audit methodology that will be implemented for audited contracts going forward. Calendar year 2011 is the first year that CMS will conduct payment recovery based on extrapolated estimates. CMS expects to audit about 30 MA contracts each year.

Additionally, the CY 2007 contract-level RADV audits are in the final stages. In FY 2012, CMS conducted payment recovery (at the beneficiary level) from five of the contracts involved in the CY 2007 RADV pilot audits totaling \$3.5 million.

The Part D payment error estimate reported for FY 2012 (based on CY 2010) is 3.1 percent, or \$1.59 billion. The FY 2012 Part D error estimate presents the combined impact on Part D payments of five sources of error: Part D payment system error; payment error related to low income subsidy status; payment error related to incorrect Medicaid status; payment error related to prescription drug event data validation; and payment error related to direct and indirect remuneration.

Probable Fraud Measurement Pilot

While CMS calculates improper payments error rates in Medicare and Medicaid as described above, there is no reliable estimate of the amount of fraud in the Medicare program. Documenting the baseline amount of fraud in Medicare is of critical importance, as it allows officials to evaluate the success of ongoing fraud prevention activities. In collaboration with the HHS Office of the Assistant Secretary for Planning and Evaluation, CMS developed the methodology for the first nationally representative estimate of the extent of probable fraud in the Medicare fee-for-service program in FY 2011. In FY 2012, CMS developed the measurement tools for the pilot, and collaborated with government partners, including ASPE, on the strategy for implementation.

This project will estimate probable fraud within the area of Home Health Agencies (HHAs) to pilot test the measurement approach and calculate a service-specific estimate. This pilot is measuring “probable fraud” rather than “fraud” because “fraud” is a legal determination that CMS cannot make on its own. A review panel of experienced health care analysts, clinicians, policy experts, and fraud investigators will review all collected data and determine if there is sufficient evidence to warrant a referral to law enforcement. After the completion of this pilot, CMS will assess the value of expanding the measurement to other areas of health care. CMS will begin collecting data on probable fraud and have an estimate of probable fraud within HHAs in 2013.

Fraud Summits

Since June 8, 2010 when President Obama announced a nationwide series of regional fraud prevention summits as part of a multi-faceted effort to crack down on health care fraud, HHS has a strong commitment to partnering with the private sector to exchange information on best practices. The seventh fraud prevention summit was held in Chicago on April 4, 2012 highlighting the new high-tech war against health care fraud being jointly fought by HHS and DOJ. FY 2010 HCFAC funds totaling \$1 million were used to fund these regional fraud summits and also to underwrite the Fraud Prevention Campaign in both FY 2011 and FY 2012.

4. Recovery

Field Offices

CMS has been placing resources in Medicare “hot fraud” areas with ZPIC and CMS program integrity field offices. The ZPIC contracting strategy aligns the anti-fraud contractors with the Medicare Administrative Contractor (MAC) zones. Additionally, the designated program integrity field offices are located in or near the HEAT cities of Miami, Los Angeles, and Brooklyn, and provide a CMS presence in high risk fraud areas of the country. Together, the field offices and ZPICs conduct data analysis to proactively identify targets and to coordinate efforts among various contractors and agencies to identify local issues and vulnerabilities with national or regional impact. All three field offices have staff that are designated CMS Strike Force Liaisons, who coordinate with law enforcement, facilitate data analysis, and expedite suspension

requests.

Enrollment Special Study

The Enrollment Special Study is a project designed to stop fraudulent providers from obtaining new Medicare provider numbers, reduce the number of habitual “bad providers” from re-entering the Medicare system after they have been kicked out, and shift from the pay and chase approach that has existed in years past. In this project, site visits are conducted prior to enrollment, and providers are targeted for a closer review. The project is limited to Community Mental Health Centers (CMHCs), Comprehensive Outpatient Rehabilitation Facilities, and Independent Diagnostic Testing Facilities in South Florida. Once the MAC conducts a site visit, it assesses the provider’s individual risk. If the provider appears to be suspect or pose an elevated risk of fraud, the provider is referred to the ZPIC for investigation and administrative action, as appropriate. This project began as a one year project in July 2009 and has been extended due to its success.

As of July 31, 2012, First Coast Service Operations, Inc. (FCSO), a MAC, has conducted 15,826 activity checks to verify providers/suppliers operational status; deactivated 576 practice locations and revoked 736 providers’ billing privileges. Since inception, FCSO has saved over \$42 million through prepayment review. In addition, as of July, 14, 2012, SafeGuard Services (SGS), the ZPIC, conducted 1,296 on-site investigations resulting in 605 requests for provider revocation or deactivation. SGS placed 618 providers on prepayment review resulting in savings of \$18.7 million.

South Florida Fraud Hot Line

CMS also continued a successful initiative aimed at increasing fraud reporting in South Florida. As part of a two-year infusion therapy demonstration, 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.

Trained, bilingual, or trilingual staff fielded and routed calls, and 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 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 detect potential fraudulent billings.

As of August 31, 2012, the hotline has received more than 86,535 calls leading to 954 new fraud investigations. In addition, the ZPIC has placed 191 providers on prepayment review saving \$14 million, revoked or deactivated 157 provider numbers, referred 42 cases to law enforcement, and sent 133 Immediate Advisements to the HHS/OIG. Additionally, law enforcement has seized \$3 million in provider bank accounts.

DME Stop Gap Plan

The DME Stop Gap Plan was developed in response to the escalation in DMEPOS fraud and the delay in implementation of DMEPOS competitive bidding. This two-year project was initiated in FY 2009 to enhance detection and prevention activities in connection with fraud, waste and abuse in DMEPOS in seven high risk states (California, Florida, Illinois, Michigan, North Carolina, New York and Texas). The project is intended to address fraud involving high risk suppliers, ordering physicians, DMEPOS items, and beneficiaries in each area.

Under this project, CMS and its contractors first identify and then interview or conduct site visits to the highest paid and highest risk DMEPOS suppliers ordering physicians, and utilizing beneficiaries. These visits and interviews allow CMS to identify and scrutinize the highest billed and highest risk DMEPOS equipment and supplies.

Based on the findings, administrative actions, as appropriate, are initiated. The second year of the project concluded on September 30, 2011 and the results to date include onsite interviews/reviews of 5,371 high risk providers, suppliers, and beneficiaries; implementation of 15,470 claims processing edits to prevent improper payment (with associated \$36.4 million in denied claims); \$69 million in requested overpayments; 1,240 new investigations opened; and 479 suppliers revoked or deactivated.

As a result of the DME Stop Gap project CPI has decided to incorporate lessons learned from the DME Stop Gap into the routine DME workload for all ZPICs.

Defending Medical Review Decisions at Administrative Law Judge (ALJ) Hearings

In FY 2011, CMS was awarded HHS Wedge funding to hire additional Contractor Medical Directors (CMDs) to support CMS anti-fraud and error rate reduction efforts by defending decisions at the ALJ. The funding was provided to the MACs in FY 2012. As a result, there are now Medical Directors dedicated to serving as expert witnesses at appeal hearings.

This project supports agency administrative actions by ensuring there are adequate CMDs that can serve as expert witnesses for the agency at the ALJ level. In a pilot program, CMS had previously had success with reducing the overturn rate on appeals by having a physician participate at the ALJ level.

Administration for Community Living

In FY 2012, the Administration for Community Living (ACL) via the Administration on Aging (AoA) was allocated \$3.378 million in HCFAC funding by HHS to support infrastructure, technical assistance, and the other Senior Medicare Patrol (SMP) program support. In addition to this funding, ACL was allocated \$7.331 million for capacity-building activities designed to enhance the effectiveness of state-wide SMP programs. During FY 2010 and FY 2011, CMS had provided this capacity funding to ACL for the SMP projects. In FY 2012, the funding came

directly to ACL. The base SMP project grant is funded from a separate Congressional appropriation.

SMP Project Activities and Outcomes

ACL funds 54 SMP statewide projects (each state, Guam, Puerto Rico, Virgin Islands and D.C.) with funds authorized in the Older American Act and the HCFAC Wedge. SMP projects recruit and train senior volunteers to educate their peers on how, as beneficiaries, they can detect and prevent fraud, waste and abuse in Medicare.

In FY 2012 ACL received the aforementioned \$7.3 million in additional HCFAC funds to continue the expanded funding of statewide SMP projects that began in FY 2010 and continued in FY 2011. This additional funding has allowed SMP's to target their expansions in large states with high instances of fraud.

According to the most recent annual performance report from HHS/OIG's Deputy Inspector General for Evaluation and Inspections, dated June 21, 2012, 5,671 active volunteers served SMP projects during 2011. This represents a 14 percent increase in the number of volunteers from that of 2010. These volunteers performed an essential function of this program, contributing 88,169 hours in efforts to educate beneficiaries about how to prevent and detect Medicare and Medicaid fraud within local communities.

Outreach to senior consumers is a key element of the SMP program. During 2011, SMP projects held 8,800 community outreach education events reaching close to an estimated 1.67 million people, and were responsible for over 592,000 media airings to increase beneficiary awareness about issues related to Medicare and Medicaid integrity. During this period, 66,303 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 431,000 beneficiaries were educated through 11,109 group educational sessions conducted by SMP programs in local communities.

SMP projects nationwide resolved 77,367 inquiries for information or assistance in 2011 from or on behalf of beneficiaries. This included receipt of 2,077 complex issues—i.e., beneficiary complaints requiring further research, assistance, case development, and/or referral. SMP projects reported that 1,415 complex issues were resolved for beneficiaries during 2011, while 819 complex issues with an estimated dollar value of over \$5.3 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 \$247,850 in health care expenditures were avoided and nearly \$33,000 in Medicare, Medicaid and other savings resulted from actions taken by the SMP program.

Since the program's inception, the program has educated over 4.7 million beneficiaries in group or one-on-one counseling sessions and has reached nearly 27 million people through community education outreach events. While SMPs make numerous referrals of potential fraud to CMS program integrity contractors, it is still difficult to measure the outcome of these cases without a

tracking mechanism. Therefore, we have no measure of these outcomes, though we anticipate that they would demonstrate an additional benefit of the SMP program’s ability to detect and prevent fraud and abuse in the Medicare program. In addition, 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 June 2012 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.”

ACL recognizes the importance of measuring the value of the SMP program impact to the fullest degree possible. Toward that end, in 2012, ACL contracted for the first-ever SMP program evaluation that will assess the national design and implementation of the SMP program, the adequacy of current SMP performance measures, and seek to determine the most appropriate measures of SMP program value (benefits, results and impact). The contract was awarded in September 2012 and will continue for 15 months.

In addition, during FY 2012, ACL and HHS/OIG continued a collaborative effort to help ensure SMP referrals of beneficiary complaints of potential fraud are received by law enforcement in a timely fashion. This has included development of processes for SMP referral of beneficiary complaints to the HHS/OIG hotline, including mechanisms for capturing outcomes related to these referrals. In addition, a workgroup between ACL and HHS/OIG meets regularly to review potential fraud cases for submission to the OIG hotline.

Despite the factors that have limited ACL’s ability to quantify the value of the SMP program in preventing, identifying, and reporting health care fraud, the OIG has documented close to \$106 million in savings attributable to the program as a result of beneficiary complaints since its inception in 1997.

SMP Infrastructure and Program Support

National Consumer Protection Technical Resource Center

The Center, established October 1, 2003, provides technical assistance, support and training to the SMP projects, ensuring a fully consolidated national approach to reaching Medicare and Medicaid beneficiaries. The goal of the Center is to provide professional expertise and technical support, serve as an accessible and responsive central source of information, and maximize the effectiveness of the SMP projects in healthcare integrity outreach and education. The Center has been instrumental in supporting ACL efforts to forge national visibility for the SMP program.

National Hispanic SMP Project Grant

In September 2008, AoA awarded an initial three-year grant to the National Hispanic Council on Aging for the development and implementation of a National Hispanic SMP (NHSMP) Program. The problem of health care fraud and abuse becomes even more challenging to address with hard-to-reach populations, particularly those with cultural and language barriers. The NHSMP project also promotes collaborations among key community players in order to promote the prevention, detection and reporting of fraud within the Hispanic community. The NHSMP program is working to create a model to provide technical assistance to SMP projects who work with Hispanic populations so that they can expand their reach to Hispanic older adults.

Office of the General Counsel

In FY 2012, the Office of the General Counsel (OGC) was allocated approximately \$8.9 million in HCFAC funding by HHS to supplement OGC's efforts to support program integrity activities. OGC's efforts in FY 2012 focused heavily on program integrity review, in which OGC reviews CMS' programs and HCFAC 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 2012, OGC was involved in a wide range of HCFAC efforts that resulted in Government recoveries of over \$2.8 billion in judgments, settlements, or other types of recoveries, savings, or receivables described elsewhere in this report.

The Affordable Care Act

The ACA significantly amended existing anti-fraud statutes. These provisions established 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 include amending Medicare and Medicaid provider/supplier enrollment requirements, overpayment provisions to specifically invoke the FCA, strengthening the anti-kickback statute, and creating a statutory disclosure protocol for violations of the physician self-referral prohibition known as the "Stark law." During FY 2012, OGC spent significant time and resources working with CMS to implement program integrity provisions in the ACA. As new ACA programs were implemented, OGC worked 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 occurred.

HEAT

During FY 2012, 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 continued to assist DOJ in pursuing both criminal and civil cases involving individuals and entities seeking to defraud the Medicare and Medicaid programs and to defend any Federal court challenges that are brought as a result of HEAT initiatives. OGC's involvement in HEAT also included advising CMS on provider and supplier revocations, payment suspensions, recoupments, and defending the administrative appeals that resulted.

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 assist DOJ in discerning which allegations were program violations and should be pursued and 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 2012, OGC participated in FCA and related matters that recovered over \$2.6 billion for the government. The types of FCA cases that OGC participated included: drug pricing manipulation; illegal marketing activity by pharmaceutical manufacturers that resulted in Medicare and Medicaid paying for drugs for indications not covered; underpayment of rebates to state Medicaid programs; physician self-referral violations; and provider up coding cases.

Provider/Supplier Suspensions and Enrollment Revocations or Denials

Suspensions play a critical role in protecting against the abuse of program funds. OGC advised CMS on whether to suspend payments to Medicare providers and suppliers and defended the suspensions when challenged. In FY 2012, OGC attorneys were involved in a myriad of suspension and recoupment actions, which involved fraudulent billings and different segments of the health care industry: 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 a denial of enrollment or revocation. In FY 2012, OGC represented CMS in appeals before the Departmental Appeals Board (DAB) and often 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 (Part C) Compliance

During FY 2012, OGC continued to provide extensive advice to CMS on a variety of Part D and MA-related contract compliance issues, including identifying enforcement options against sponsors that are noncompliant or violate program rules, such as the 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 sanctions, CMP notices, and non-renewal or termination notices.

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. In FY 2012, OGC provided legal advice to CMS regarding the development and imposition of CMPs and defended CMS in many administrative appeals and judicial litigation resulting from these cases, recovering or establishing the right to recover over \$4.5 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 2012, OGC petitioned these agencies to recover funds in both criminal and civil litigation matters in which Medicare was a victim of fraud involving about \$5.4 million seized by law enforcement agencies.

Regulatory Review and Programmatic Advice

In FY 2012, OGC advised CMS on 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. OGC also provided extensive legal counsel to CPI on a proposed rule implementing new section 1128J(d) of the Social Security Act (SSA), which requires providers and suppliers to report and return overpayments within 60 days of identifying them.

Medicaid Integrity

Continuing recent trends, OGC saw continued increasing involvement in FY 2012 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.

Physician Self-Referral

OGC provided valuable assistance to CMS in navigating the complexities of the Stark physician self-referral law. In FY 2012, OGC reviewed several draft Stark advisory opinions as well as various payment or coverage rules and suggested modifications necessary to avoid implicating, or to conform the regulation to, the Stark law. In addition, OGC has been instrumental in advising CMS on the newly established (by the ACA) voluntary Self Referral Disclosure Protocol, under which providers of services and supplies may self-disclose actual or potential violations of the physician self-referral statute. OGC has advised CMS on how to implement this new provision, how to apply the protocol, and how to resolve the specific disclosures (now over 100) that CMS has received.

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 2012, OGC has been successful in establishing the right to recover over \$17 million for Medicare under the MSP program. Recent statutory changes implementing reporting requirements to the MSP law have

strengthened and expanded OGC's efforts in this area – to the benefit of the Medicare Trust Funds – including substantial CMPs for failure to report.

Bankruptcy Litigation

OGC protected Medicare funds when providers sought bankruptcy protections by asserting CMS' recoupment and set-off rights to collect overpayments. In FY 2012, OGC asserted CMS' interests in numerous bankruptcy and receivership actions involving physicians, hospitals, independent diagnostic test facilities, DME suppliers, nursing homes, and nursing home chains. Further, OGC negotiated agreements to recover overpayments, and advanced the use of Medicare's recoupment and set-off authority, collecting or establishing the right to collect over \$4.9 million in recoveries 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 2012, 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 2012, the FDA was allocated \$3.4 million in HCFAC funding by HHS for the FDA Pharmaceutical Fraud Program (PFP). The PFP has enhanced the health care fraud-related activities of FDA's Office of Criminal Investigations (OCI) and the Office of the General Counsel (OGC) Food and Drug Division. OCI, with the support of OGC, investigates criminal violations of the Food, Drug, and Cosmetic Act (FDCA), the Prescription Drug Marketing Act, the Federal Anti-Tampering Act, and related Federal statutes.

The PFP is designed to detect, prosecute, and prevent pharmaceutical, biologic, and medical device fraud. The PFP gathers information from sources inside and outside FDA and focuses on fraudulent marketing schemes, application fraud, clinical trial fraud, and flagrant manufacturing-related violations related to 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 PFP has identified multiple alleged medical product fraud schemes through various avenues.

Since the inception of the PFP, OCI has opened a total of forty-two criminal investigations. In FY 2012, FDA's second full fiscal year of HCFAC Program activity, OCI, through its PFP,

opened seventeen criminal investigations, described below:

- Two investigations involving allegations of promotional violations including minimization of risk and/or off label promotion of two drugs by different manufacturers. One investigation involves the promotion of a drug for conditions not indicated in the drug's labeling. The other investigation involves allegations of deceptive marketing practices regarding the safety of a drug product.
- One investigation involving allegations of promotional violations involving multiple medical devices by a manufacturer. In this investigation, it is alleged that the manufacturer was aware of defects and repeated failures of the devices and failed to provide safety information to the FDA, doctors and patients.
- One investigation involving allegations of off-label promotion, clinical trial and application fraud and insurance billing matters regarding a medical device. The device is allegedly being promoted off-label and being used in a clinical trial without an investigational device exemption for a condition that falls outside the cleared indication for use.
- Thirteen investigations involving allegations of clinical trial fraud and/or application fraud. These investigations consist in part of individuals suspected of falsifying clinical trial data, forging signatures of clinical investigators, and enrolling ineligible subjects in clinical trials.

In regards to judicial action, one of the PFP clinical trial fraud investigations has resulted in the convictions of two individuals. The investigation revealed that a physician and a clinical research coordinator conducting clinical trials of biological product intended to treat allergies enrolled ineligible participant in the clinical trial, falsified records of physical examinations, and made false statements to the FDA about the study. Both were charged with conspiracy, mail fraud, and falsifying information required by the FDA. The defendants each received 12 months probation and were ordered to pay restitution in the amount of \$36,040. OCI forwarded information about the convictions to FDA's Office of Enforcement for consideration of appropriate administrative remedies to prevent the defendants from conducting additional clinical investigations.

In addition to these investigative activities, FDA conducted a three day training session in late June 2012 for criminal investigators and supervisors covering PFP-related topics. Instruction provided included legal training by the Office of General Counsel on the Federal Food, Drug, and Cosmetic Act in areas relevant to PFP cases, investigative scenario training on clinical trial fraud investigations, case presentations on successful prosecutions involving off-label promotion and other fraud schemes involving both drugs and medical devices. The training also provided background on OCI's participation in the HCFAC Program and resources available to assist in investigations being conducted under the PFP.

THE DEPARTMENT OF JUSTICE

United States Attorneys

In FY 2012, the United States Attorney's Offices (USAOs) were allocated approximately \$35.4 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 2012, 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 the civil referrals are sometimes handled jointly with the Civil Division's Commercial Litigation Branch (Fraud Section). 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 in the Frauds Section. 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 Funds 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 physicians and other providers of medical services, overcharges by hospitals, Medicaid fraud, kickbacks to induce referrals of Medicare or Medicaid patients, fraud by pharmaceutical and medical device companies, home health and hospice fraud, and failure of care allegations against nursing home owners. Working closely with their partners in the Civil Division, several civil health care fraud AUSAs have focused their efforts on pharmaceutical fraud, resulting in significant recoveries including: \$3.0 billion from GlaxoSmithKline, and \$950 million from Merck, Sharp and Dohme. Most of the civil settlements, including these settlements were part of a global resolution, which also addressed the criminal liabilities, resulting in criminal pleas, as well as significant fines and forfeitures. The criminal portion of these investigations and resolutions was handled by criminal health care fraud AUSAs, often working with their counterparts at the Consumer Protection Branch of the Civil Division. These global settlements resolved allegations including, reporting of false and inflated drug prices, manufacturing and distributing adulterated drugs, off-label marketing and kick-backs. These cases are detailed earlier in this report.

Several of the USAOs have dedicated significant resources to investigate fraud perpetrated on our most vulnerable citizens. To this end, the USAOs have partnered with Civil Frauds in the Elder Justice and Nursing Home Initiative to address elder abuse and neglect. As a result of USAO efforts, the owner and operator of three nursing homes was sentenced to serve 20 years in Federal

prison on charges of conspiring with his wife to defraud the Medicare and Georgia Medicaid programs by billing them for “worthless services” in the operation of three nursing homes. This is the first time that a defendant has been convicted after a trial in Federal court for submitting claims for payment for worthless services. The defendant was also ordered to pay \$6.7 million in restitution to Medicaid and Medicare

The USAOs partner with the Criminal Division in the Strike Forces, which are currently operating in nine USAOs across the country. Each USAO has dedicated several AUSAs and support personnel to work with Criminal Division attorneys in this important initiative. The MFSFs use data analysis to identify high-billing levels in health care hot spots so that emerging or migrating schemes can be targeted. The significant successes of the MFSFs have been detailed earlier in this report.

Special Focus Teams, consisting of criminal and civil AUSAs, paralegals, and auditors, are operational in three districts and focus on pharmaceutical, biologics, and medical device fraud. The teams have contributed significantly to the success of the pharmaceutical investigations and recoveries this year. To increase the capacity of other districts to successfully litigate these complex health care fraud cases, the Special Focus Teams have organized monthly training Webinars and serve as advisors for the USAO community in the various complex areas of health care fraud.

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 2012, OLE offered a Health Care Fraud Seminar, which 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 USAO attorneys, investigators, auditors, and paralegals serve as faculty at these OLE trainings, and also participate in other Federal, state, and private health care fraud seminars.

Criminal Prosecutions

In FY 2012, the USAOs received 1,131 new criminal matters involving 2,148 defendants, and had 2,032 health care fraud criminal matters pending,¹⁵ involving 3,410 defendants. The USAOs filed criminal charges in 452 cases involving 892 defendants, and obtained 826 Federal health care fraud related convictions.

Civil Matters and Cases

In FY 2012, the USAOs had opened 885 new civil health care fraud investigations. At the end of FY 2012, the USAOs had 1,023 civil health care fraud investigations pending.

¹⁵ 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.

Civil Division

In FY 2012, the Civil Division received approximately \$25.1 million in HCFAC funding to support the health care fraud activities of the Commercial Litigation Branch's Fraud Section and the Consumer Protection Branch. This amount also included funding to support the Department of Justice's Elder Justice and Nursing Home Initiative.

The Commercial Litigation Branch's Fraud Section

The Civil Division's Commercial Litigation Branch (Fraud Section) investigates health care fraud allegations and brings actions under the FCA to recover money on behalf of defrauded Federal health care programs including Medicare, Medicaid, TRICARE, and the FEHBP. The Fraud Section works closely with the Consumer Protection Branch, USAOs, HHS/OIG, state Medicaid Fraud Control Units and other law enforcement agencies. As a result of these efforts, the Fraud Section has obtained settlements and judgments of over \$1 billion almost every year since 2000 and over \$3 billion in FY 2012 alone.

The Fraud Section investigates and resolves matters against a wide array of health care providers and suppliers. Matters involving pharmaceutical and device manufacturers are among the most complex and resource intensive cases handled by the Fraud Section. These matters commonly involve nationwide conduct, raise legally and factually complicated issues, and demand significant resources to investigate, resolve, and litigate, if necessary. Many of these cases, including the GlaxoSmithKline matter discussed above and in greater detail below, involved allegations that the pharmaceutical manufacturer improperly promoted its drug for uses not approved by the FDA and thereby caused Federal health care programs to pay for drugs for unapproved and non-covered uses. Other cases involved allegations that the manufacturer provided false and misleading information about their products, or else paid kickbacks to physicians to prescribe their products. Lastly, some of these matters alleged drug pricing manipulation by pharmaceutical manufacturers in order to lower their month rebate obligations to the Medicaid program. In all, the Fraud Section recovered more than \$2 billion in matters involving pharmaceutical and medical device manufacturers.

The Fraud Section also investigated and resolved several matters involving hospice and hospital providers in FY12. For example, Odyssey Healthcare paid \$25 million to resolve FCA allegations that it submitted claims for medically unnecessary "continuous home care" services that were intended for patients who are experiencing an acute crisis and whose symptoms could only be controlled at home through the provision of skilled nursing services. Likewise, the Fraud Section resolved several hospital matters involving allegations that the hospitals overbilled Medicare by treating patients on an inpatient basis when they should have been treated as observation patients or treated on an outpatient basis.

In addition to its investigative responsibilities, the Fraud Section plays a critical role supporting and providing guidance to its health care fraud partners. It regularly provides training and guidance to AUSAs and agents on the FCA and health care fraud issues. The Section works closely with HHS/OIG, Office of General 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. The Section also collaborates with and counsels CMS and HHS/OIG on interagency initiatives and proposed rules and regulations.

The Elder Justice and Nursing Home Initiative, which is housed in the Civil Division, coordinates and supports 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. 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.

The Consumer Protection Branch

The Consumer Protection Branch (CPB) investigates and prosecutes manufacturers and individuals who are illegally promoting and distributing unapproved, misbranded, and adulterated drugs and devices in violation of the FDCA. CPB works closely with the Commercial Litigation Branch's Fraud Section, the USAOs, and the FDA on a wide variety of health care fraud matters. In recent years, CPB has convicted dozens of companies and individuals. The prosecutions resulted in significant jail terms and fines, penalties, and forfeitures totaling in the billions of dollars.

In the area of pharmaceutical and device fraud, CPB coordinates complex investigations with districts nationwide, staffing the cases directly as well as providing assistance to USAOs. Because these investigations are complicated, both legally and factually, they demand significant resources. The recent prosecution of GlaxoSmithKline ("GSK"), a major pharmaceutical company, is an example of the sort of complex health care fraud investigation the Consumer Protection Branch handles with its investigative partners. GSK agreed to plead guilty and pay \$3 billion to resolve criminal and civil liability arising from the company's unlawful promotion of its drugs Paxil and Wellbutrin, its failure to report certain safety data for its drug Avandia, and its civil liability for alleged false price reporting practices. As part of the global resolution—the largest combined health care fraud recovery in a single global resolution in U.S. history—GSK pled guilty to three misdemeanor violations of the FDCA. One of the criminal charges involved the off-label promotion of Paxil, which had been approved only for patients over the age of 18, and which, since 2004, like other antidepressants, included on its label a "black box warning" stating that antidepressants may increase the risk of suicidal thinking and behavior based on short-term studies in patients under age 18. CPB and the USAO developed evidence showing that GSK prepared, published and distributed a misleading medical journal article that misrepresented that a clinical trial of Paxil demonstrated efficacy in the treatment of depression in patients under age

18, when the study failed to demonstrate efficacy. At the same time, GSK did not make available data from two other studies in which Paxil also failed to demonstrate efficacy in treating depression in patients under 18. The evidence also showed that GSK sponsored dinners, lunches, spa programs and similar activities to promote the use of Paxil in children and adolescents. GSK agreed to plead guilty to misbranding Paxil with false and misleading labeling regarding the use of Paxil for patients under 18.

In addition to prosecuting major pharmaceutical companies for health care offenses, CPB prosecutes smaller-scale, yet equally dangerous schemes involving drug compounding and drug diversion. For example, in FY 2012, CPB prosecuted ApothéCure, and its principal, Gary Osborn, who were convicted of misdemeanor misbranding under the Food, Drug, and Cosmetic Act. ApothéCure purchased raw active pharmaceutical ingredients for use in the manufacture of prescription drugs. Three patients who received injections from lots shipped from the company's pharmacy died from colchicine toxicity, as some of the vials were super-potent, containing 640 percent of the level of compounded colchicine declared on the drug's label. ApothéCure and Osborn pled guilty and each was fined \$100,000.

CPB has also taken the lead in investigating and prosecuting drug diversion schemes, in which prescription drugs are removed from lawful channels of distribution and then reintroduced into the marketplace for sale to consumers. In such schemes, prescription drugs at issue are often stolen from warehouses or cargo trucks or repackaged and resold from boxes of free samples. Drugs diverted from lawful channels of distribution may not have been properly labeled and stored, which allows for contamination, or they could be expired. In FY2012, CPB and the USAO prosecuted Altec Medical and William Rodriguez for their role in a drug diversion scheme. Altec paid Rodriguez approximately \$55 million for prescription drugs that it knew had been diverted from lawful channels of drug wholesale distribution. The diverted drugs were a wide variety of expensive branded products, including HIV medications, atypical antipsychotics, diabetes medications (including insulin products, which need to be refrigerated, and were not refrigerated while they were being diverted) and cholesterol medications. Altec pled guilty, was fined \$2 million, and was ordered to forfeit an additional \$1 million; Rodriguez pled guilty, was sentenced to 120 months' imprisonment, and ordered to forfeit \$55 million. A second co-conspirator received a sentence of probation of one year.

CPB has also been a leader in investigating and prosecuting Internet pharmacies, which is, in many ways, the leading edge of health care fraud in the United States. The Internet now provides an avenue for the illegal dissemination of prescription drugs and controlled substances for drug abusers and others who divert drugs. Website owners often hire doctors and pharmacists who are willing to authorize and dispense prescriptions based on an online questionnaire, without any legitimate doctor-patient relationship, thereby permitting these websites to operate as online "pill mills." CPB prosecutes those who unlawfully distribute prescription drugs and controlled substances over the Internet. As a result of its leadership in this area, CPB is now a primary source for legal advice to prosecutors around the country pursuing such cases.

In addition, CPB provides expertise and guidance in the prosecution of those selling counterfeit drugs—which are often sold online and are a growing problem in the United States and abroad.

In addition to advising USAOs on this issue, CPB also serves on the Attorney General's Task Force on Intellectual Property, which has made it a priority to improve law enforcement with respect to counterfeit products, such as drugs and devices, which threaten the public health and safety.

Criminal Division

In FY 2012, the Criminal Division was allocated \$8.5 million in HCFAC funding to support criminal health care fraud litigation and interagency coordination, which is carried out primarily by the Fraud Section and, to a lesser extent, the Organized Crime and Gang Section (OCGS).

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 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 nine cities. In FY 2012, the Fraud Section continued to provide attorney staffing, litigation support, and leadership and management oversight for numerous Strike Force prosecutions in eight of the nine cities. A summary of the Fraud Section's key litigation accomplishments in FY 2012 follows:

- Filed 136 new health care fraud cases involving charges against 110 defendants who collectively billed the Medicare and Medicaid programs more than \$1.3 billion;
- Obtained 99 guilty pleas and litigated 10 jury trials, winning guilty verdicts against 21 defendants;¹⁶
- Secured prison sentences in health care fraud cases averaging more than 56 months; and
- Secured court-ordered restitution, forfeiture and fines exceeding \$373 million.

Fraud Section attorneys staffed and coordinated the Division's health care fraud litigation through the existing Medicare Fraud Strike Force teams in Miami, Los Angeles, Detroit, Houston, Brooklyn, Baton Rouge, Tampa, and Dallas.¹⁷

Section attorneys coordinated a major multi-district Strike Force arrest takedown during the fiscal year and handled many of the investigations and indictments that were filed in these operations.

¹⁶Fraud Section attorneys litigated 9 of the 13 Medicare Fraud Strike Force trials during FY 2012. Several of these trials were summarized previously in the "Medicare Fraud Strike Force" section of this report.

¹⁷The U.S. Attorney's Office for the Northern District of Illinois implemented the Strike Force in Chicago and is providing management and oversight for Strike Force prosecutions in that district.

On May 2, 2012, Fraud Section and USAO Strike Force prosecutors in seven cities executed a nationwide operation that resulted in charges against 107 individuals, including doctors, nurses, and other medical professionals, for their alleged participation in Medicare fraud schemes involving approximately \$452 million in false billing. The coordinated operation involved the highest amount of false Medicare billings in a single takedown in Strike Force history.

Of particular note during the FY2012, the Fraud Section prosecuted one of the largest criminal health care fraud cases in history, involving American Therapeutic Corporation (ATC). Fraud Section attorneys tried two cases involving executives, physicians, and others involved in a \$205 million fraud at ATC. As part of that prosecution, during the fiscal year, Fraud Section attorneys obtained three of the longest prison sentences ever handed down in health care fraud prosecutions for the three owners and operators of ATC – one sentence of 50 years and two sentences of 35 years. In addition to the six defendants convicted at trial, Fraud Section attorneys obtained guilty pleas from an additional thirteen individuals and the two corporate defendants, including ATC itself.

In February 2012, Fraud Section attorneys, in conjunction with attorneys from the local United States Attorney's Office, obtained an indictment against a Dallas-area doctor and owner of an association of health care providers, along with six others, in a \$374 million home health care fraud scheme, the largest fraud case ever indicted in terms of the amount of loss charged against a single doctor. The indictment charges the defendants with fraudulently certifying or directing the certification of more than 11,000 individual patients from more than 500 home health agencies for home health services over five years. These certifications allegedly resulted in more than \$350 million being fraudulently billed to Medicare and more than \$24 million being fraudulently billed to Medicaid.

In addition to Medicare Fraud Strike Force cases, the Fraud Section handles other types of complex criminal health care fraud litigation. Often, such cases are handled in a parallel manner by Fraud Section prosecutors along with DOJ Civil Division attorneys and/or AUSAs from the USAOs.

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. From September 27 through September 28, 2012, the Fraud Section hosted a two-day health care fraud training conference for approximately 175 Federal prosecutors, FBI agents, HHS/OIG agents, and others. The Fraud Section also 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 Gang Section (OCGS)

The Criminal Division's Organized Crime and Gang Section (OCGS) supports investigations and prosecutions of fraud and abuse targeting the 2.5 million private sector health plans sponsored by employers and/or unions, as well as investigations and prosecutions of health care frauds perpetrated by domestic and international organized crime groups. OCGS is also working to improve 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.

In FY 2012, OCGS increased the number of attorneys assigned to health care fraud prosecutions despite substantial budget limitations restricting its available resources. In this fiscal year, two attorneys have worked with the Organized Crime Strike Force in Philadelphia on cases involving Medicare fraud. One OCGS attorney partnered with an AUSA in the prosecution of a hospice co-owner for conspiring to defraud Medicare by submitting \$14.3 million in fraudulent medical claims for hospice services provided to patients who did not receive services or were ineligible. This attorney is also prosecuting a doctor for the receipt of more than \$200 in kickbacks for Medicare and Medicaid patient referrals to the hospice. A second OCGS attorney is prosecuting the operator of an ambulance service company, indicted in June 2012, for submitting more than \$5.4 million in false claims to Medicare for medically unnecessary transportation of patients by ambulance.

A third OCGS attorney teamed with the OC Strike Force Chief in the Southern District of Florida in the prosecution of a health care fraud perpetrated by a Eurasian organized crime group alleged to have significant ties to Russia and Armenia. This criminal conspiracy was indicted in February 2011 as part of a multi-district crackdown on activities of Armenian Power, an international organized crime group. The health care fraud schemes in Miami involved chiropractic clinics that allegedly paid individuals to refer "patients" of staged accidents. The clinics then billed private automobile insurance carriers for treatments that were either not medically necessary or were not provided. Two defendants were convicted of health care fraud conspiracy in October 2011.

Finally, a fourth OCGS attorney is prosecuting an acting boss of a La Cosa Nostra crime family for an alleged embezzlement from a health plan operated by Teamsters unions in Philadelphia.

Private sector employment-based group health plans are the leading source of health care coverage for individuals not covered by Medicare or Medicaid. OCGS attorneys routinely provide litigation support and advice to AUSAs and criminal investigative agencies to combat corruption and abuse of such private employment-based group health plans covered by the Employee Retirement Income Security Act (ERISA). OCGS attorneys provide considerable support to investigations of fraud schemes by corrupt entities that sell unlicensed health insurance products and fraud schemes by corrupt employers that cheat workers out of health benefits required by the prevailing wage laws and regulations. In addition, OCGS attorneys regularly 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. Such guidance and training has covered prosecutions involving

abuses targeting private sector employee health plans subject to ERISA, health plans sponsored by labor organizations, and multiple employer welfare arrangements. OCGS drafts and reviews criminal legislative proposals affecting employee health benefit plans.

OCGS also provides legal guidance to prosecutors and required approvals in the use of the Racketeer Influenced and Corrupt Organizations (RICO) statute in prosecutions of Medicare or Medicaid fraud or private sector health care frauds. For example, OCGS reviewed and approved a RICO indictment submitted by the Organized Crime Strike Force in the Eastern District of New York in which defendants allegedly operated medical clinics to generate medical claims for treatments that were never performed or not medically needed. The indictment, which was returned in February 2012, charged that defendants operated nine clinics which billed private automobile insurance companies for \$279 million in unnecessary and excessive medical treatments claimed to be the result of automobile accidents, including physical therapy, acupuncture, pain management, psychological services, X-rays, MRIs and other services. The indictment was believed to be the largest single no-fault insurance fraud ever charged and the first case of its kind to allege violations of the RICO statute.

Civil Rights Division

In FY 2012, the Civil Rights Division was allocated approximately \$4.8 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 and service systems. The Division conducts investigations to eliminate abuse and grossly substandard care in public, Medicare and Medicaid funded long-term care facilities. Consistent with the Supreme Court's decision in Olmstead v. L.C., 527 U.S. 581 (1999), the Division has also undertaken initiatives to eliminate the needless institutionalization of individuals who require health care supports and services.

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 Disability Rights Section of the Civil Rights Division has primary enforcement authority for the Americans with Disabilities Act (ADA). Title II of the ADA authorizes investigation of allegations of discrimination by public entities against individuals with disabilities, including discrimination in the form of needless institutionalization of persons who require health care supports and services. *See* Olmstead v. L.C., 527 U.S. 581 (1999). Title II also authorizes the initiation of civil action to remedy discrimination in violation of the ADA. Both the Special

Litigation Section and the Disability Rights Section have undertaken initiatives to combat the unjustified institutionalization of persons with disabilities.

The Special Litigation and Disability Rights Sections work collaboratively with the USAOs and HHS.

Fiscal Year 2012 Accomplishments

Special Litigation Section staff conducted preliminary reviews of conditions and services at 19 health care facilities in 16 states during Fiscal Year 2012. The task in preliminary inquiries is to determine whether there is sufficient information supporting allegations of unlawful conditions and needless institutionalization to warrant formal investigation under CRIPA and/or the ADA. 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 Fiscal Year 2012, the Section opened or continued formal investigations, entered remedial agreements, or monitored existing remedial agreements regarding 62 health care facilities in 19 states, the District of Columbia, and the Commonwealth of Puerto Rico.

The Section found that conditions and practices at 12 state facilities for persons with intellectual and developmental disabilities and/or mental illness violate the residents' statutory rights. Those facilities are: Boswell Regional Center, in Magee, Mississippi; Ellisville State School, in Ellisville, Mississippi; Hudspeth Regional Center, in Pearl, Mississippi; Southern Mississippi Regional Center, in Long Beach, Mississippi; Mississippi Adolescent Center, in Brookhaven, Mississippi; North Mississippi Regional Center, in Oxford, Mississippi; Mississippi State Hospital, in Whitfield, Mississippi; South Mississippi State Hospital, in Purvis, Mississippi; Central Mississippi Residential Center, in Newton, Mississippi; East Mississippi State Hospital, in Meridian, Mississippi; North Mississippi State Hospital, in Tupelo, Mississippi; and the Specialized Treatment Center, in Gulfport, Mississippi.

In Fiscal Year 2012, the Section entered into a court-enforceable settlement agreement to resolve its investigations of Central Virginia Training Center, in Lynchburg, Virginia and Virginia's state-wide system for serving individuals with disabilities. Pursuant to the Agreement, Virginia will create a total of approximately 4,200 home and community-based waivers for people who are on waitlists for community services and individuals transitioning from institutional settings over a ten year period. Virginia also will provide support services to an additional 1,000 people to enable them to stay in their home or their family's home, rather than face institutionalization. Further, Virginia will create a comprehensive community crisis system to divert individuals from unnecessary institutionalization or other out-of-home placements. The Agreement also requires the Commonwealth to create a comprehensive quality and risk management system to ensure that community-based services are safe and effective.

The Section moved to intervene in two Olmstead actions. The Section moved to intervene in Lynn v. Lynch, (D. N.H.), a proposed class action involving claims under the ADA that the State of New Hampshire failed to provide adequate community-based services to persons with mental

illness, unnecessarily segregating them in institutions and placing them at risk of unnecessary and more costly institutionalization. The case will go to trial in 2014. Separately, in Steward v. Perry, (W. D. TX.), the court granted the Section's intervention motion in a proposed class action involving ADA claims that the State of Texas fails to provide adequate community-based services to persons with intellectual disabilities residing in nursing homes.

The Section continued its investigations of 10 residential facilities for persons with intellectual and developmental disabilities, including: Northwest Habilitation Center, in St. Louis, Missouri; Bellefontaine Habilitation Center, in St. Louis, Missouri; Sonoma Developmental Center, in Eldridge, California; Lanterman Developmental Center, in Pomona, California; Clyde L. Choate Developmental Center, in Anna, Illinois; and, five Arkansas facilities, including: Arkadelphia Human Development Center, in Arkadelphia, Arkansas; Alexander Human Development Center, in Alexander, Arkansas; Booneville Human Development Center, in Booneville, Arkansas; Jonesboro Human Development Center, in Jonesboro, Arkansas; and Southeast Arkansas Human Development Center, in Warren, Arkansas.

The Section also continued its investigations of three facilities for persons with mental illness, including: Ancora Psychiatric Hospital, in Hammonton, New Jersey; Oregon State Hospital, in Salem and Portland, Oregon; and Kingsboro Psychiatric Center, in Brooklyn, New York.

The Section also continued its investigations of two nursing facilities: Maple Lawn Nursing Home, in Palmyra, Missouri; and Casa del Veteranos, in Juana Diaz, Puerto Rico.

The Section monitored the implementation of remedial agreements for 17 facilities for persons with intellectual and developmental disabilities: Beatrice State Developmental Center, in Beatrice, Nebraska; Woodbridge Developmental Center, in Woodbridge, New Jersey; Clover Bottom Developmental Center in Nashville, Tennessee; Greene Valley Developmental Center in Greeneville, Tennessee; 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. These remedial agreements include the provision of adequate community supports and services. The Section also litigated the issue of whether the closure of Arlington Developmental Center in Memphis, Tennessee should result in the dismissal of its case involving the facility and community services for individuals with intellectual and developmental disabilities in West Tennessee; a ruling is forthcoming.

The Section also monitored the implementation of remedial agreements regarding 18 state-operated residential facilities for persons with mental illness: Metropolitan State Hospital, in Norwalk, California; Patton State Hospital, in San Bernardino, California, Atascadero State

Hospital, in Atascadero, California; Napa State Hospital, in Napa, California; Kings County Hospital Center, in Brooklyn, New York; Delaware State Psychiatric Center, in New Castle, Delaware; Georgia Regional Hospital, in Atlanta, Georgia; Georgia Regional Hospital, in Savannah, 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; St. Elizabeth's Hospital, in Washington, D.C.; Connecticut Valley Hospital, in Middletown, Connecticut 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. These remedial agreements include the provision of adequate support and services to enable individuals to live successfully in the community.

In addition, the Section continued monitoring of remedial agreements at two nursing facilities: William F. Green State Veterans' Nursing Home, in Bay Minette, Alabama; and Ft. Bayard Medical Center, in Ft. Bayard, New Mexico.

In August 2012, the Disability Rights Section entered a comprehensive, eight-year settlement agreement with the State of North Carolina resolving the Section's Olmstead investigation of North Carolina's mental health service system, which currently serves thousands of individuals with mental illness in large institutional settings known as adult care homes. The Agreement, which is court-enforceable, will expand access to community-based supported housing – integrated housing that promotes inclusion and independence and enables individuals with mental illness to participate fully in community life. Pursuant to the Agreement, North Carolina will provide community-based supported housing to 3,000 individuals unnecessarily segregated in, or at risk of entry into, adult care homes. The Agreement will also ensure that thousands of people with mental illness have access to critical community-based mental health services such as Assertive Community Treatment (ACT) teams, and will expand integrated employment opportunities for individuals with mental illness by providing supported employment services to 2,500 individuals.

The Section also commenced two statewide Olmstead investigations in FY 2012. In Oregon, the Section conducted an extensive nine-month investigation of the state's employment service system for individuals with intellectual and developmental disabilities, which is funded in significant part through Medicaid home and community-based waivers pursuant to Section 1915(c) of the Social Security Act. Following the investigation, in June 2012, the Division issued a Letter of Findings stating that Oregon was violating Title II of the ADA and Olmstead by unnecessarily segregating individuals with disabilities in sheltered workshops when such individuals can and want to work in more integrated supported employment settings. Negotiations with the state to resolve these allegations are ongoing.

The Section also conducted an investigation of the State of Florida regarding allegations that Florida unnecessarily segregates children with disabilities in private nursing facilities, when such children could be served in more integrated, community-based settings. In September 2012, the Section issued a Letter of Findings notifying the State of the Section's findings that the State violates the ADA by planning, structuring and administering its system of care for children with

disabilities in a manner that causes hundreds of children with disabilities to be unnecessarily institutionalized in nursing facilities, and places many other children with complex medical conditions at risk of such institutionalization.

The Section also engaged in ongoing settlement discussions with the State of New York regarding the state's administration of its mental health service system, which relies on large, private, institutional adult homes in New York City to house individuals with mental illness who can and should be residing in more integrated community settings. The Section also continued its ongoing investigation of the State of New York regarding the placement of children with disabilities at certain restrictive out-of-state facilities.

The Division filed ten statements of interest or *amicus* briefs in litigation raising issues of needless institutionalization in California, the District of Columbia, Florida, New Hampshire, Oregon, and Pennsylvania. These briefs have addressed a wide range of issues, including unnecessary institutionalization of individuals in state-run and private institutions and cuts to community services placing individuals at risk of unnecessary, and more costly, institutionalization.

Federal Bureau of Investigation

In FY 2012, the FBI was allocated \$136.2 million in funding, including \$131.8 million from HIPAA and \$3.4 million from discretionary HCFAC, to support the facilitation, coordination and accomplishment of the goals of the HCFAC Program. This yearly appropriation was used to support 798 positions (478 Agent, 320 Support). In FY 2012, the FBI initiated 817 new health care fraud investigations and had 2,835 pending investigations. Investigative efforts produced 1,096 criminal health care fraud convictions and 909 indictments and informations. In addition, investigative efforts resulted in the operational disruption of 329 criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 83 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. Each of the 56 FBI field offices has personnel assigned specifically to investigate health care fraud matters. With national health care expenditures projected to exceed \$2.8 trillion dollars in FY 2012, it is especially important to coordinate all investigative efforts to combat the significant fraud and abuse within the health care system.

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, state Medicaid Fraud Control Units, and other state and local agencies. On the private side, the FBI is actively involved in the Fraud Prevention Partnership, an effort to exchange facts and information between the public and private sectors in order to reduce the prevalence of health care fraud. These efforts will enable members to share successful anti-fraud practices and effective methodologies and strategies for detecting and preventing health care fraud. In addition, the FBI maintains significant liaison with private insurance national groups, such as the National Health Care Anti-Fraud Association, the National Insurance Crime Bureau, other professional associations, and private insurance investigative units.

Health care fraud investigations are considered a high priority within the FBI White Collar Crime Program. 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 threats through coordinated initiatives, task forces, working groups, and undercover operations. These activities identify and pursue investigations against the most egregious offenders, which included criminal enterprises and other crime groups.

In an effort to ensure sufficient FBI HCF resources are dedicated to address priority threats within the health care system for which the FBI has primary responsibility, the FBI established national priorities. During FY 2012, the FBI's top HCF Program National Priorities were Government Sponsored and Private Insurance Programs. Accordingly, approximately 85 percent of FBI cases primarily involve these programs. The FBI also investigated violations involving drug diversion, Internet pharmacy, and other investigations that did not include billings to government sponsored or private insurance programs.

A review of the threats to the health care system reveals that many schemes target multiple FBI HCF Program National Priority areas, and individual schemes may have considerable impact on the health care system. In response to these threats the FBI has enhanced its focus on threats to government sponsored and private insurance programs associated with Large Scale Conspiracies and Major Providers, in addition to combating traditional provider fraud.

Large scale conspiracies include criminal enterprises and other crime groups involving significant losses, or potential losses, to health care benefit programs. The criminal activity of these groups can cross multiple Federal districts and have included the sharing/selling of beneficiary information, the sharing/selling of referring provider identifiers, and kickback schemes involving invoices, referrals, and medical services/products. It is not unusual for more complex large scale conspiracies to conduct other criminal activity in addition to health care fraud. The potential extent of this type of criminal activity is noted in several investigations that each involved hundreds of millions of dollars and included numerous providers conspiring together to defraud health plans. An example of these types of cases was the American Therapeutic Corporation (ATC) investigation in which kickbacks were made to halfway houses and assisted living facilities for patient referrals. ATC billed the Medicare program for intensive mental therapy. The therapy was either not rendered, or rendered to some degree to patients who cannot benefit from this form of therapy, and therefore, was medically unnecessary. The FBI is committed to addressing this type crime problem through the disruption, dismantlement and prosecution of those involved in criminal enterprises and other organized criminal activities.

Major Providers can include companies, corporations, hospitals, provider groups, and other groups able to significantly bill, or effect billing, to health care benefit programs. The related schemes are frequently complex and challenging to identify. A principal source of referrals on these schemes is the filing of *qui tams*. In FY 2012, the FBI continued to aggressively expand its involvement in major provider/*qui tam* investigations. Examples of significant major provider investigations for FY 2012 included the GlaxoSmithKline LLC agreement to plead guilty and pay \$3 billion to resolve its criminal and civil liabilities and the Merck, Sharp and Dohme agreement to pay \$950 million to resolve criminal charges and civil claims. In addition to the work completed at the field office level, and in response to this substantial and increasing threat, the FBI has established a centralized squad to provide investigative assistance on these types of cases nationwide. The FBI coordinates this effort with the DOJ, HHS/OIG, and FDA.

In FY 2012, the FBI continued to staff and support Medicare Strike Force operations worked in conjunction with DOJ Criminal Division's Fraud Section, local USAOs, HHS/OIG, and state and local law enforcement agencies. The FBI has assigned agents to Strike Forces in Miami, New York City, Houston, Tampa, Detroit, Los Angeles, Baton Rouge, Dallas, and Chicago. In addition to funding agent resources, the FBI funded undercover operations expenses, financial and investigative analysis support, offsite and evidence storage locations, and other investigative costs. These Strike Forces have effectively investigated and prosecuted individuals and entities that do not provide legitimate health care services, but exist solely for the purpose of defrauding Medicare and other Federal government health care programs. The continued support of Medicare Strike Force operations is a top priority for the FBI.

In addition to its investigative efforts, the FBI actively provides training and guidance on health care matters. The FBI has teamed with the DOJ, the United States Attorneys, HHS, and private insurance organizations to provide training in the priority threat areas of health care fraud. Funded training has included innovative methods of employing advanced investigative techniques, basic HCF training for FBI special agent and professional staff newly assigned to HCF, and sessions on new and current HCF trends and issues. FBI personnel training opportunities included sessions offered by other government agencies and the private sector. In FY 2012, more than 400 FBI health care fraud investigators and analysts received training. FBI personnel also conducted a wide range of training for external audiences, including personnel involved in the investigation of health care fraud matters and industry representatives.

Funding received by the FBI is used to pay direct and indirect personnel-related costs associated with the 798 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.

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 (not including portions of CMS funding dedicated to the Medicare Integrity Program, listed in the table on page 95).
- 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 CMS Medicaid Integrity program funding is included in a separate Medicaid Integrity program ROI published in a separate report.

Total Health Care Fraud and Abuse Control Resources

The table below sets forth HCFAC funding, by agency, for health care fraud and abuse control activities in FY 2012. The FBI also receives a stipulated amount of HIPAA funding for use in support of the Fraud and Abuse Control Program, which is shown below. Separately, CMS receives additional Mandatory Resources under the Medicare Integrity Program (section 1817(k)(4) of the Social Security Act). The inclusion of the activities supported with these funds is not required in this report, and this information is included for informational purposes.

Since 2009, Congress has also appropriated annual amounts to help carry out health care fraud and abuse control activities within DOJ and HHS. Those amounts are set forth as Discretionary Resources in the table below and the results of the efforts supported with these funds are contained within this report.

Mandatory Resources	Fiscal Year 2012
Office of Inspector General	\$196,090,169
Health and Human Services Wedge ¹	\$37,504,593
Medicare Integrity Program ²	\$863,128,689
<i>MIP/Medicare (non-add)</i>	<i>\$796,734,174</i>
<i>Medi-Medi (non-add)</i>	<i>\$66,394,515</i>
Department of Justice Wedge ¹	\$61,224,749
Federal Bureau of Investigation ³	\$131,871,557
Subtotal, Mandatory HCFAC	\$1,289,819,757
Discretionary Resources	
Office of Inspector General	\$29,673,810
CMS Program Integrity	\$250,442,817
<i>Medicare Program Integrity (Non-Add)</i>	<i>\$219,463,429</i>
<i>Medicaid Program Integrity (Non-Add)⁴</i>	<i>\$30,979,388</i>
Department of Justice	\$29,673,810
Subtotal, Discretionary HCFAC	\$309,790,437
Grand Total, HCFAC	\$1,599,610,194

¹ The HHS and DOJ Wedge funds are divided among multiple agencies within HHS and DOJ. Page 7 of this report includes the allocations of the HHS and DOJ Wedge by agency or activity.

² Medicare Integrity Program (MIP) and Medi-Medi fund fraud prevention and detection activities within Medicare and Medicaid, which are not included in this report to Congress. There is another mandatory report due to Congress in April regarding MIP activities.

³ The FBI receives funding annually to conduct anti-fraud activities authorized by HIPAA. This funding is included in the HCFAC ROI calculation for this report.

⁴ This is not to be confused with the Medicaid Integrity Program authorized in the Deficit Reduction Act of 2005, which receives funding separately from the HCFAC account.

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

ACL – Department of Health and Human Services, Administration for Community Living

ASPA – Assistant Secretary for Public Affairs (HHS)

AUSA - Assistant United States Attorney

CHIP - Children’s Health Insurance Program

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

CRIPA - Civil Rights of Institutionalized Persons Act

CY – Calendar Year

DME - Durable Medical Equipment

DMEPOS – Durable Medical Equipment Prosthetics, Orthotics, and Supplies

DOJ - The Department of Justice

FEHBP – Federal Employee Health Benefits Program

FBI - Federal Bureau of Investigation

FCA - False Claims Act

FDA - Food and Drug Administration

FDCA – Food, Drug, and Cosmetic Act

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

MEDIC - Medicare Drug Integrity Contractors

MFCU – Medicaid Fraud Control Unit

OCGS - Organized Crime and Gang Section

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

PERM - Program Error Rate Measurement

PFP – 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

USAO - United States Attorney=s Office

ZPIC - Zone Program Integrity Contractor