
**The Department of Health and Human Services
and
The Department of Justice
Health Care Fraud and Abuse Control Program
Annual Report for Fiscal Year 2013**

February 2014

TABLE OF CONTENTS

	Page
Executive Summary	1
Introduction	3
Monetary Results	5
Program Accomplishments	7
Department of Health and Human Services	
Office of Inspector General	46
Centers for Medicare & Medicaid Services	61
Administration on Community Living	77
Office of the General Counsel	80
Food and Drug Administration Pharmaceutical Fraud Program	83
Department of Justice	
United States Attorneys	86
Civil Division	88
Criminal Division	90
Civil Rights Division	94
Appendix: Federal Bureau of Investigation	99
Return on Investment Calculation	102
Total HCFAC Funding	103
Glossary of Terms	104

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 seventeenth 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 and abuse, and to protect program beneficiaries.

Monetary Results

During Fiscal Year (FY) 2013, the Federal government won or negotiated over \$2.6 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 2013, approximately \$4.3 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 \$4.3 billion, the Medicare Trust Funds³ received transfers of approximately \$2.85 billion during this period, and over \$576 million in Federal Medicaid money was similarly transferred separately to the Treasury as a result of these efforts. The HCFAC account has returned over \$25.9 billion to the Medicare Trust Funds since the inception of the Program in 1997.

Enforcement Actions

In FY 2013, the Department of Justice (DOJ) opened 1,013 new criminal health care fraud investigations involving 1,910 potential defendants. Federal prosecutors had 2,041 health care fraud criminal investigations pending, involving 3,535 potential defendants, and filed criminal charges in 480 cases involving 843 defendants. A total of 718 defendants were convicted of health care fraud-related crimes during the year. Also in FY 2013, DOJ opened 1,083 new civil health care fraud investigations and had 1,079 civil health care fraud matters pending at the end of the fiscal year. In FY 2013, Federal Bureau of Investigation (FBI) health care fraud investigations resulted in the operational disruption of 425 criminal fraud organizations and the

¹ Hereafter, 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.

dismantlement of the criminal hierarchy of more than 115 criminal enterprises engaged in health care fraud.

In FY 2013, HHS' Office of Inspector General (HHS-OIG) investigations resulted in 849 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid; and 458 civil actions, which include false claims and unjust-enrichment lawsuits filed in Federal district court, civil monetary penalties (CMP) settlements, and administrative recoveries related to provider self-disclosure matters. HHS-OIG also excluded 3,214 individuals and entities. Among these were exclusions based on criminal convictions for crimes related to Medicare and Medicaid (1,132) or to other health care programs (311); for patient abuse or neglect (180); and as a result of licensure revocations (1,324). HHS-OIG also issued numerous audits and evaluations with recommendations that, when implemented, would correct program vulnerabilities and save program funds.

Impact of Sequestration

Due to sequestration in 2013, there were fewer resources for DOJ and HHS to fight fraud and abuses against Medicare, Medicaid, and other healthcare programs. A total of \$30.6 million was sequestered from the HCFAC program in FY 2013.

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 2013

**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 2010.⁴ In FY 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act (P.L. 111-148, ACA) 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 2013, the Secretary and the Attorney General certified \$295.1 million in mandatory funding for appropriation to the Account. Additionally, Congress appropriated \$309.1 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 2013. (Separately, the FBI received \$128.1 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 education and guidance regarding complying with current health care law; 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 2013, approximately \$4.3 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 2013	
Department of the Treasury	
Deposits to the Medicare Trust Funds, as required by HIPAA	
Gifts and Bequests	\$95
Amount Equal to Criminal Fines	\$708,406,030
Civil Monetary Penalties	\$14,483,916
Asset Forfeiture	\$30,166,006
Penalties and Multiple Damages	\$1,363,761,885
Subtotal	\$2,116,817,933
Centers for Medicare & Medicaid Services	
HHS-OIG Audit Disallowances – Recovered - Medicare	\$61,717,799
Restitution/Compensatory Damages	\$677,300,987
Subtotal*	\$739,018,786
Grand Total of Amounts Transferred to the Medicare Trust Funds	\$2,855,836,718
Restitution/Compensatory Damages to Federal Agencies	
TRICARE	\$41,597,410
Department of Veterans Affairs	\$40,896,098
HHS-OIG Cost of Audits, Investigations and Compliance Monitoring	\$9,888,585
Office of Personnel Management	\$43,286,981
Other Agencies	\$10,065,851
Centers for Medicare and Medicaid Services	
Federal Share of Medicaid	\$576,540,583
HHS-OIG Audit Disallowances – Recovered - Medicaid	\$431,249,581
Subtotal	\$1,153,525,089
Relators= Payments**	\$324,194,039
TOTAL ***	\$4,333,555,846

* 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 seventeenth year of operation, the Secretary and the Attorney General certified \$295.1 million in mandatory funding as necessary for the Program. Additionally, Congress appropriated \$309.2 million in discretionary funding. Sequestration reductions, as required by law, were taken against the mandatory and discretionary HCFAC accounts. The following chart gives the allocation by recipient:

FY 2013 ALLOCATION OF HCFAC APPROPRIATION				
Organization	Mandatory Allocation⁵	Discretionary Allocation	Funds Sequester	Total Allocation
Department of Health and Human Services				
Office of Inspector General ⁶	197,109,153	29,614,462	(11,503,999)	215,219,616
Office of the General Counsel	8,887,870	0		8,887,870
Administration for Community Living	10,548,259	0		10,548,259
Food and Drug Administration	3,377,220	0		3,377,220
Centers for Medicare & Medicaid Services	12,005,774	249,941,882	(12,598,773)	249,348,883
Unallocated Funding	1,914,767	0	(1,914,767)	0
Subtotal	233,843,043	279,556,344	(26,017,539)	487,381,848
Department of Justice				
United States Attorneys	31,400,000	10,610,752		42,010,752
Civil Division	18,972,139	8,113,000		27,085,139
Criminal Division	1,580,000	6,594,000		8,174,000
Civil Rights Division	2,376,000	1,741,493		4,117,493
Nursing Home and Elder Justice Initiative	1,000,000	0		1,000,000
Justice Management Division	200,000	0		200,000
Department of Justice - Other	5,761,684	2,555,217	(4,618,552)	3,698,349
Subtotal	61,289,823	29,614,462	(4,618,552)	86,285,733
TOTAL⁷	295,132,866	309,170,806	(30,636,091)	573,667,581

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

⁶Total includes \$0.8 million in FY 2013 HCFAC mandatory funding. In addition, HHS-OIG obligated \$17.3 million in funds received as "reimbursement for the costs of conducting investigations and audits and for monitoring compliance plans" as authorized by section 1128C(b) of the Social Security Act, 42 U.S.C. § 1320a-7c(b).

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

ACCOMPLISHMENTS

Overall Recoveries

During this fiscal year, the Federal government won or negotiated approximately \$4.33 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 \$2.85 billion during this period as a result of these efforts, as well as those of preceding years; and another \$576 million in Federal Medicaid money was transferred to the Treasury separately as a result of these efforts.⁸

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

The return-on-investment (ROI) for the HCFAC program over the last three years (2011-2013) is \$8.1 returned for every \$1.00 expended. This is \$2.7 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.

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**

⁸ Note that some of the judgments, settlements, and administrative actions that occurred in FY 2013 will result in transfers in future years, just as some of the transfers in FY 2013 are attributable to actions from prior years.

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 areas such as 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, and 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.

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

- In October 2012, Medicare Fraud Strike Force operations in seven cities led to charges against 91 individuals – including doctors, nurses and other licensed medical professionals – for their alleged participation in Medicare fraud schemes involving approximately \$429.2 million in false billing. The coordinated nationwide takedown encompassed indictments charging more than \$230 million in home health care fraud; more than \$100 million in mental health care fraud and more than \$49 million in ambulance transportation fraud; and millions more in other frauds. HHS also suspended or took other administrative action against 30 health care providers.
- In May 2013, a nationwide takedown by Medicare Fraud Strike Force operations in eight cities resulted in charges against 89 individuals, including doctors, nurses and other licensed medical professionals, for their alleged participation in Medicare fraud schemes

involving approximately \$223 million in false billings. The defendants charged were accused of various health care fraud-related crimes, including conspiracy to commit health care fraud, violations of the anti-kickback statutes and money laundering. The charges were based on a variety of alleged fraud schemes involving various medical treatments and services, primarily home health care, but also mental health services, psychotherapy, physical and occupational therapy, durable medical equipment (DME) and ambulance services. This coordinated takedown was the sixth national Medicare fraud takedown in Strike Force history.

Healthcare Fraud Prevention Partnership (HFPP)

The Healthcare Fraud Prevention Partnership (HFPP) is the groundbreaking public/private partnership between the government and private sector insurance payers. The purpose of the partnership is to exchange data and information between the partners to help improve capabilities to fight fraud, waste and abuse in the health care industry. Current partners include federal (HHS-OIG, DOJ, FBI, CMS), states, private plans and associations. The Partnership's first information sharing study included exchanging codes and code combinations frequently associated with fraud, waste or abuse, as well as fraud schemes and descriptions. Additional studies are underway and the Partnership is poised for the procurement of the data-exchange entity, the Trusted Third Party (TTP), as well as expansion to new partners.

The HFPP is a demonstrated example of effective departmental collaboration between HHS and DOJ, working together to create a strong partnership with the states and private payers to detect fraud, waste, and abuse.

During FY 2013, 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 locations – Miami, FL; Los Angeles, CA; Detroit, MI; Houston, TX; Brooklyn, NY; South Louisiana (South Louisiana and New Orleans, LA)⁹; 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

⁹ While the Strike Force in southern Louisiana started in Baton Rouge, LA, it now operates in New Orleans as well.

resources of the Criminal Division's Fraud Section and the USAOs. Strike Force accomplishments from cases prosecuted in all nine cities during FY 2013 include¹⁰:

- 137 indictments, informations and complaints involving charges filed against 345 defendants who allegedly collectively billed the Medicare program more than \$1.1 billion;
- 234 guilty pleas negotiated and 34 jury trials litigated, with guilty verdicts against 48 defendants; and
- Imprisonment for 229 defendants sentenced during the fiscal year, averaging more than 52 months of incarceration.

In the six and a half years since its inception, Strike Force prosecutors filed more than 788 cases charging more than 1,727 defendants who collectively billed the Medicare program more than \$5.5 billion; 1,137 defendants pleaded guilty and 148 others were convicted in jury trials; and 1087 defendants were sentenced to imprisonment for an average term of approximately 47 months.¹¹

Although multiple factors may be in play, there has been a measurable decrease in Medicare reimbursements for certain medical services that have also been targeted by the Medicare Strike Force. For instance:

Miami: Medicare Payments for DME. The Strike Force initially started in Miami precisely to respond to an epidemic of a particular type of fraud involving claims for DME. The law enforcement activity response to DME fraud in the Miami area was overwhelming. Hundreds of defendants were charged and convicted of DME fraud by the Miami Medicare Fraud Strike Force. Law enforcement prosecution of DME fraud, while diminished from its height, continues.

During this same time period, CMS implemented an aggressive and multifaceted strategy to address DME fraud, waste, and abuse without any loss of access or quality for Medicare beneficiaries. In 2009, CMS began to require DME suppliers to become accredited and possess a surety bond of at least \$50,000. Based upon these new requirements, 10,533 DME suppliers were revoked between October 2009 and December 2009. In addition to those revoked, approximately 1,500 more suppliers voluntarily terminated their enrollment between September 2009 and December 2009, likely to avoid facing revocation actions until they could procure a surety bond or obtain accreditation.¹² Also in 2009, CMS developed the DME Stop Gap Plan. This two year project enhanced detection and prevention in seven high risk states, including Florida, and resulted in the implementation of claims processing edits that denied millions in claims, and the revocation or deactivation of hundreds of providers. Finally, on January 1, 2011, CMS implemented the

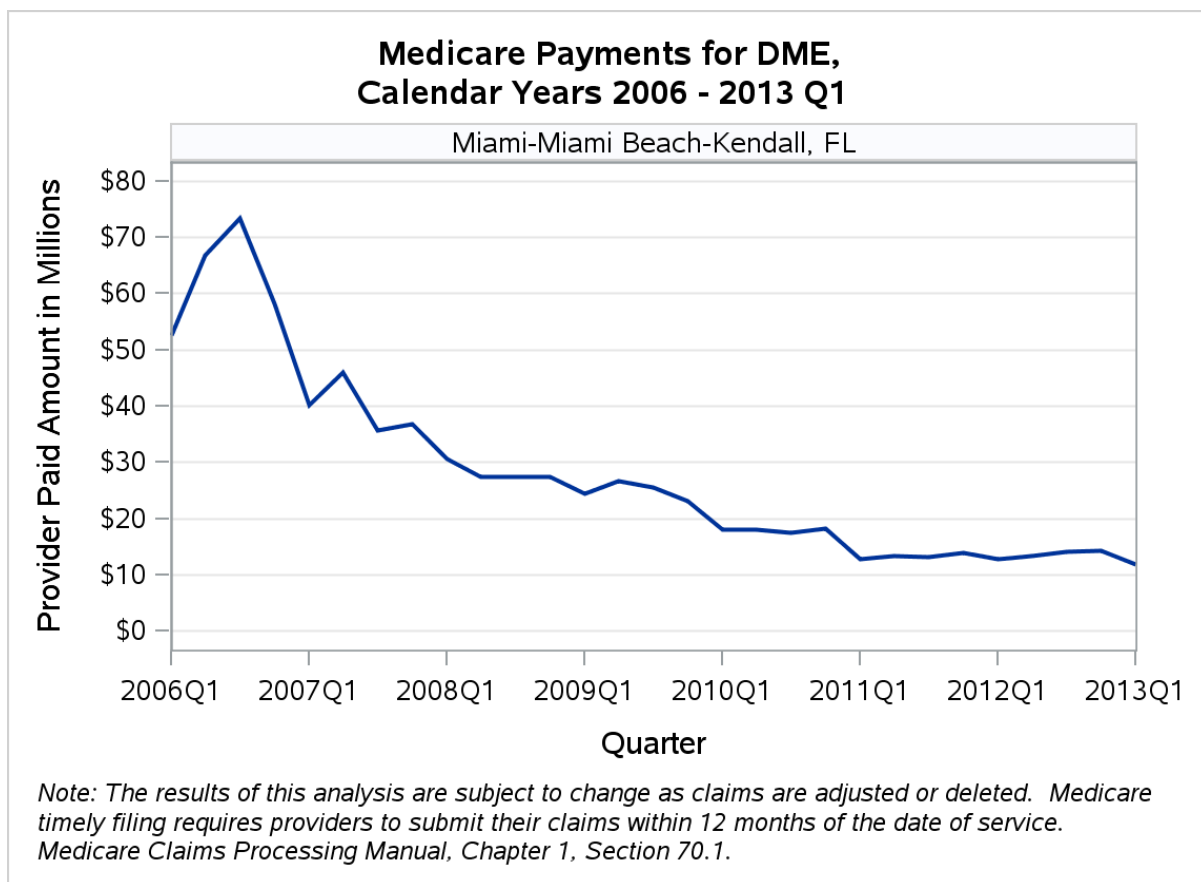
¹⁰ The accomplishments figures presented in the bullets include all reported Strike Force cases handled by DOJ Criminal Division attorneys and AUSAs in the respective USAOs during FY 2013.

¹¹ These statistics are for the period of May 7, 2007, through September 30, 2013.

¹² These are national statistics. Miami-specific statistics are not presently available.

competitive bidding program for DME in nine areas, including Miami. Competitive bidding plays an important part in the oversight of the DME benefit. As a new payment methodology and process, DME competitive bidding was devised due to concerns about program integrity. The revisions to program administration and payment established by competitive bidding have resulted in program integrity changes.

Law enforcement activity combined with various measures taken by CMS, which themselves were prompted by enforcement activity, appear to have contributed to even further declines in Medicare payments for DME in Miami over time, as indicated by the chart below. Payments by Medicare for DME in Miami-Dade County¹³ alone hit an all-time high in the third-quarter of 2006, when payments exceeded \$73 million, those payments have decreased over time, and in the first-quarter of 2013 payments were under \$15 million



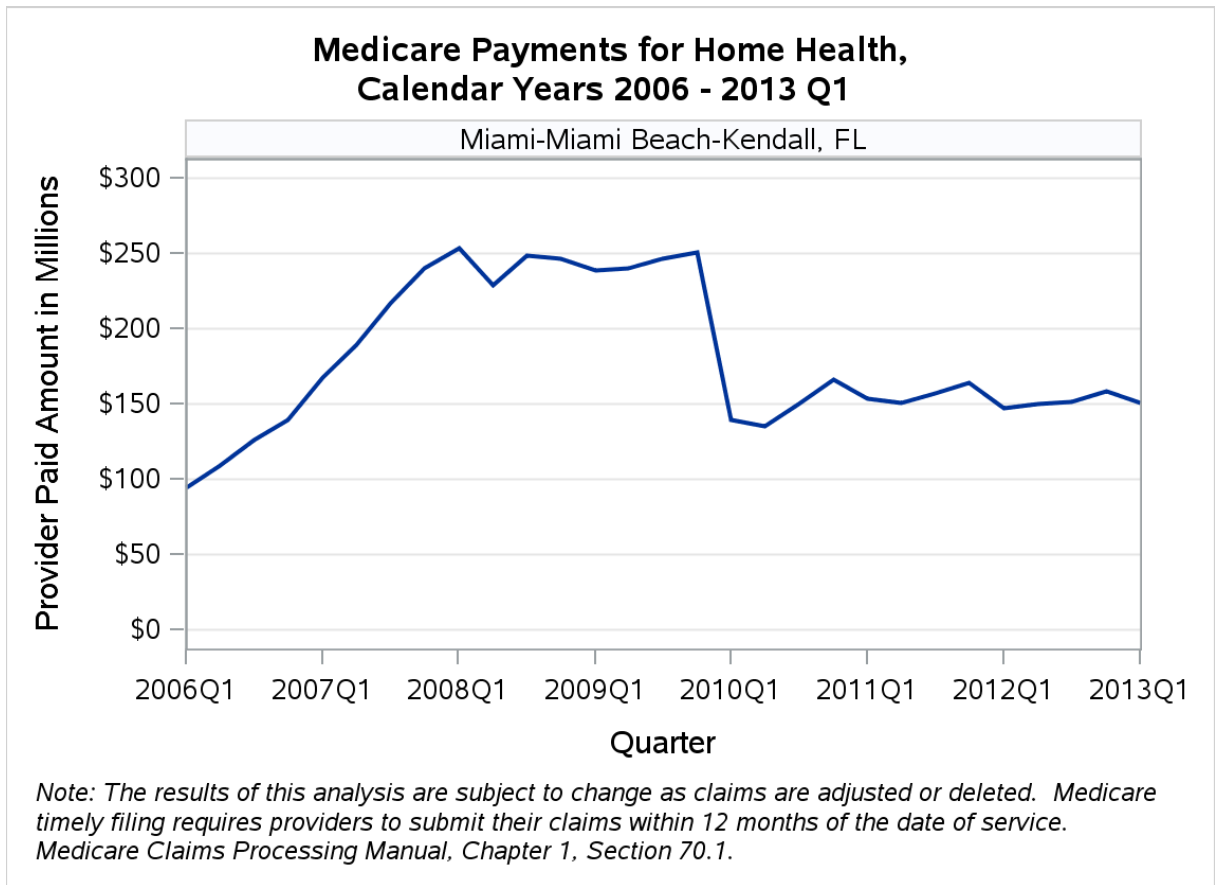
¹³ The charts included in this section were prepared by HHS-OIG’s Consolidated Data Analysis Center (CDAC), which has data available starting in the first quarter of 2006 through the first-quarter of 2013. Core-Based Statistical Areas (CBSAs) are defined by the U.S. Census Bureau. The OIG’s CBSA definitions use the smaller metropolitan division if it exists; the CBSA metro division or CBSA is identified on each chart. The OIG Miami-Miami Beach-Kendall, FL CBSA includes Miami-Dade County.

Miami: Medicare Payments for Home Health. The Miami Medicare Fraud Strike Force began to focus on home health care fraud in 2009. On June 23, 2009, the Strike Force indicted the first large home health care case, *United States v. Zambrana et al.* The *Zambrana* case led law enforcement to discover how criminals operating home health care companies in South Florida were cheating Medicare. To qualify for home health care, which involves a nurse or other skilled medical professional providing services in a beneficiary's home, a beneficiary must be homebound. Medicare makes additional payments, known as outlier payments, to home health providers that supply services to beneficiaries who incur unusually large costs. Criminals in South Florida took advantage of the outlier payment system by falsely claiming that almost every service qualified for an outlier payment. During calendar year 2009, Medicare paid over \$976 million to home health agencies in the Miami area. More than half of these home health payments -- \$558 million -- were for "outliers." Since 2009, the Miami Strike Force has charged over 202 defendants, and convicted 191 for their roles in falsely billing Medicare over \$570 million for home health care services.

Following the issuance of a report by the Inspector General for HHS describing the scheme,¹⁴ CMS put into effect a limit on the percentage of outlier payments that each home health agency can claim to address abuses of these payments. The CMS field office also ran a home health special project in Miami in 2009 and 2010 to identify beneficiaries that were not homebound. As a result of this project, 32 home health agencies had their payments suspended, additional automated payment edits saved \$9.6 million, and \$5.5 million in costs were avoided as a result of the payment suspensions. On July 30, 2013, CMS implemented a temporary enrollment moratorium on new HHAs in Miami-Dade and certain bordering counties to further the fight against fraud in this area.

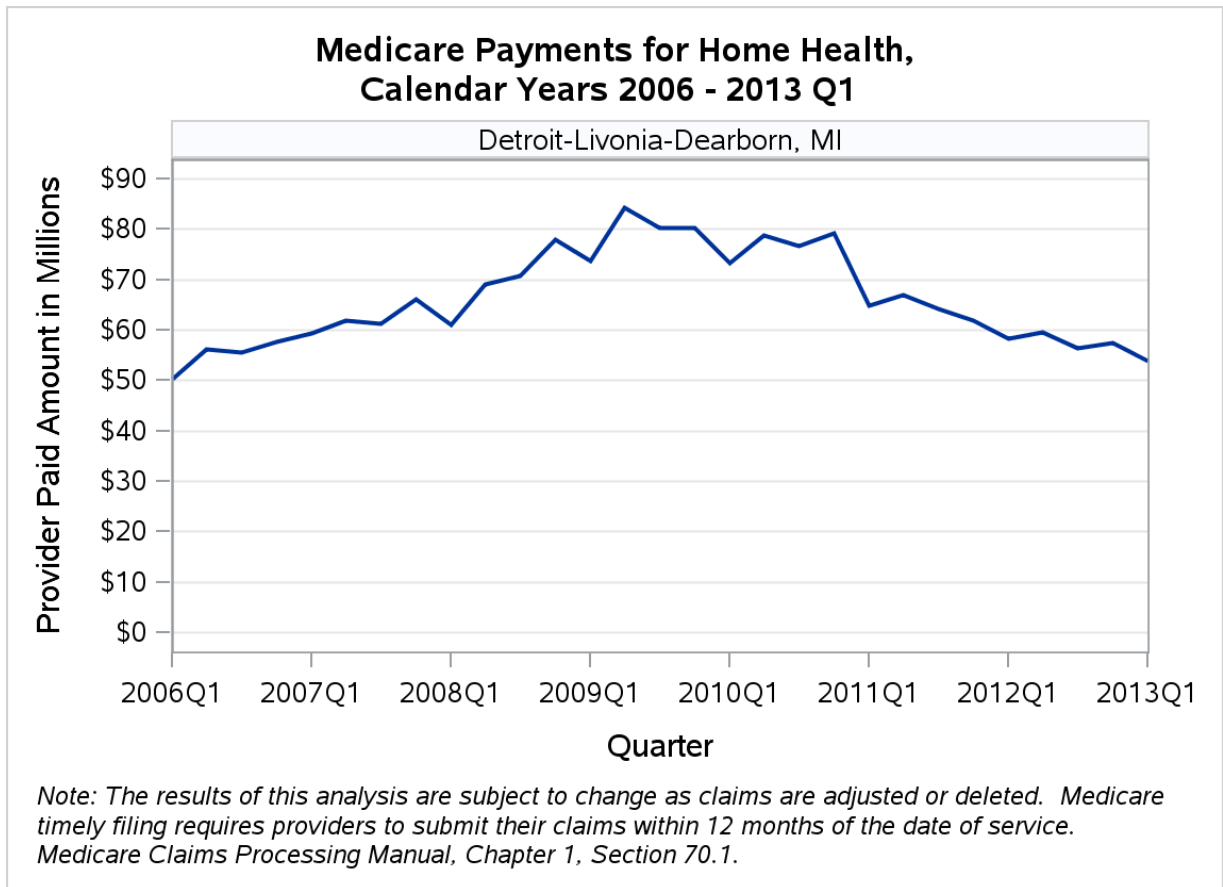
The coordination between the Strike Force and CMS appears to have contributed to a dramatic decline in payment for home health care in Miami and throughout Florida. In 2009, claims to Medicare for home health services in Florida were \$3.4 billion, and Medicare paid approximately \$2.9 billion for home health care services. Just two years later, in 2011, billings to Medicare had dropped precipitously to \$2.3 billion, a difference of \$1.1 billion. Payments by Medicare had dropped to \$2.4 billion, a difference of approximately \$500 million. Payments have essentially flat-lined since that time.

¹⁴ In December 2009, the Inspector General for HHS issued a report entitled "Aberrant Medicare Home Health Outlier Payment Patterns in Miami-Dade County and Other Geographic Areas in 2008." (OEI-04-08-00570). Among other findings, the report concluded that Miami-Dade County accounted for more home health outlier payments in 2008 than the rest of the United States combined.

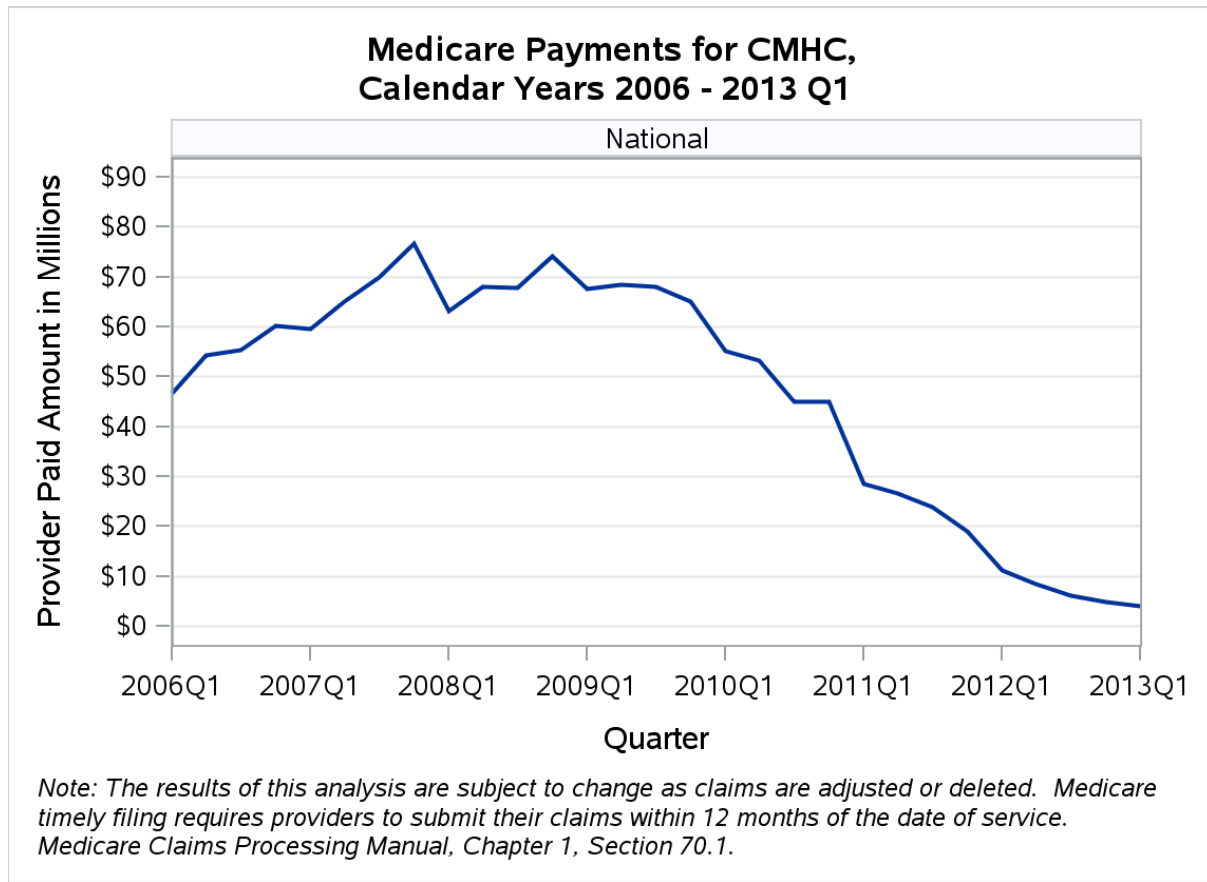


Detroit: Medicare Payments for Home Health. The first large home health care prosecution in Detroit commenced in January 2010 with the indictment of thirteen individuals who participated in a home health care fraud at Patient Choice Home Health Care and All American Home Health Care. Since that time, prosecution of home health care fraud in Detroit has led to the charging of 84 individuals who in aggregate submitted approximately \$150 million in allegedly fraudulent home health care claims to Medicare. To date, the Detroit Strike Force has obtained the conviction of 47 of those individuals. The Strike Force has also coordinated with CMS to ensure that payments are cut off at the earliest possible time. For example, in May 2012, simultaneous with a Detroit Strike Force takedown of home health care fraudsters, CMS suspended payments to 18 associated home health agencies. As shown in the following chart, Medicare payments for home health care services have declined steadily since 2009.¹⁵

¹⁵ The OIG CBSA for Detroit includes only Wayne County.



Nationwide: Medicare Payments for Community Mental Health Center (CMHC). Strike Force and CMS activity targeting CMHC fraud began in 2008, accelerated in 2010 and culminated in prosecutions in Miami in 2010 and 2011, the suspension of CMHC providers in Baton Rouge and Houston in 2011, and the prosecution of owners and operators of CMHCs in Baton Rouge and Houston in 2012. The enforcement activity was purposefully aimed at the CMHCs that billed Medicare the most, and were paid the most. The actions correspond to a national decline in CMHC billing to Medicare that has persisted to the present time as indicated in the chart below. Total payments by Medicare to CMHCs, which peaked in 2008 at more than \$70 million per quarter, are now well under \$10 million per quarter, a savings to the Trust Fund exceeding \$60 million per quarter.



Based on these examples, Strike Force and HEAT prevention and enforcement operations appear to have had a real and lasting impact on Medicare payments.

Examples of successful cases initiated or concluded in districts where Strike Force prosecution teams were operational during FY 2013, 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 June 2013 in the Southern District of Florida, the chief executive officer (CEO) of a state-licensed psychiatric hospital and three other hospital executives were convicted at trial in connection with a \$67 million Medicare fraud scheme. This was the first Strike Force case involving charges against executives of a licensed hospital. According to trial evidence, the defendants and their co-conspirators paid illegal bribes and kickbacks to patient brokers in order to obtain Medicare beneficiaries as patients. The defendants then caused the submission of fraudulent Medicare claims for treatments for which these beneficiaries were not eligible. To cover up the fraudulent claims, employees of the hospital falsified patient charts and even administered unnecessary psychotropic medications to make it appear as if Medicare beneficiaries attending the hospital needed intensive mental health services. A fifth defendant, a patient recruiter, had pled guilty

prior to trial. On September 10, 2013, a federal district judge sentenced the CEO to 25 years in prison for her leading role in the fraud, and two other executives to 15 years and 12 years in prison, respectively for their conduct.

- Between October 2012 and July 2013, 11 individuals were convicted, including one at trial, and thirteen were sentenced for their role in a \$63 million health care fraud scheme. On July 17, 2013, a psychiatrist and six additional therapists were also charged in the case, bringing the total number of defendants charged in the case to twenty. According to court documents, the defendants caused the submission of fraudulent claims to Medicare and Medicaid through a company that operated community mental health centers in Miami, FL, and North Carolina. The company paid kickbacks to the owners and operators of assisted living facilities in order to obtain Medicare beneficiaries for purported partial hospitalization program (PHP) services that were unnecessary, and, in many instances, not provided. The scheme operated from 2004 through 2011, and billed Medicare and Florida Medicaid \$63.4 million of which they paid \$28.1 million. All of the sentenced defendants received prison time, ranging from 168 months to 24 months; eight individuals received over five years in prison for their conduct. In addition, defendants were ordered to pay restitution in excess of \$28 million.
- Twelve defendants have been sentenced related to a \$56 million health care fraud scheme. Health Care Solutions Network, Inc. (HCSN), operated community mental health centers (CMHCs) in Florida (HCSN-FA) and North Carolina (HCSN-NC). These CMHCs allegedly provided partial hospitalization program (PHP) services to individuals suffering from mental illness. The clinical director of the PHP at HCSN-FL submitted claims to Medicare under her personal Medicare provider number for individual therapy she purportedly provided, while knowing that HCSN-FL was simultaneously billing for PHP services for the same patients. In addition the defendants paid illegal kickbacks to owners and operators of Miami-Dade County Assisted Living Facilities (ALF) in exchange for referring patients to the HCSN-FL PHP. Many of the ALF referral patients were ineligible for PHP services because they suffered from mental retardation, dementia, and Alzheimer's disease. To date, co-conspirators have been sentenced to a combined 70 years of incarceration and ordered to pay \$186 million in joint and several restitution.
- In April 2013, the owner of a mental health clinic in Miami, FL and three other participants in a \$50 million fraud were sentenced to 30 years in prison, 25 years in prison, 262 months in prison, and 1 year probation following their August 2012 trial convictions. The defendants caused the submission of over \$50 million in false and fraudulent claims to Medicare for purported PHP services at a fraudulent clinic. The defendants paid patient recruiters to refer ineligible Medicare beneficiaries to the clinic for services that were never provided or were not reimbursable under applicable Medicare rules. In December 2012, the former clinical director of the facility was sentenced to 100 months in prison and ordered to pay \$5.6 million in restitution for his role in the offense.
- From October 2012 through January 2013, nine defendants were sentenced and one defendant was convicted at trial in connection with a Medicare fraud scheme involving

over \$205 million in fraudulent billing through a mental health care corporation and related companies. The corporation purported to operate community mental health centers at seven different locations throughout South Florida and Orlando, which purported to provide PHP services. A related company purported to provide diagnostic sleep disorder testing. According to court documents, the corporation paid kickbacks to the owners and operators of assisted living facilities, half-way houses, and patient brokers in exchange for delivering ineligible patients for treatment. In some cases, the patients received a portion of the kickbacks. Throughout the conspiracy, millions of dollars in kickbacks were paid in exchange for Medicare beneficiaries to attend treatment programs at the centers; the companies would then bill Medicare for these medically unnecessary services. To obtain the cash required to support the kickbacks, the co-conspirators laundered millions of dollars of payments from Medicare.

All of the sentenced defendants received a prison sentence, ranging in time from 120 months to 36 months. Additionally, defendants were ordered to pay up to \$87.4 million in restitution.

- In April 2013, a co-owner of Ideal Home Health, Inc., was sentenced to 14 years of imprisonment and ordered to pay \$30 million in restitution after pleading guilty to charges of conspiracy to commit health care fraud and conspiracy to pay health care kickbacks. Ideal Home Health purportedly provided skilled nursing services and home health aide to Medicare beneficiaries. According to the indictment, the co-owner offered and paid kickbacks and bribes to recruiters and its own employees for recruiting Medicare beneficiaries for the purpose of billing Medicare for home health services that were not medically necessary and not provided.
- In October 2012, the owner of a home health agency in Miami was sentenced to 10 years in prison and ordered to pay \$26 million in restitution, joint and several, after pleading guilty to charges of conspiracy to commit health care fraud. The agency, Willsand Home Health Services, Inc. (Willsand), purportedly provided home health care and physical therapy services to Medicare beneficiaries. According to court documents, the owner paid kickbacks to patient recruiters for enrolling Medicare beneficiaries to be placed at Willsand and signed false documents stating that they received home health care services. He also paid kickbacks to physicians in return for signing false prescriptions for these patients. From approximately January 2006 through November 2009, Willsand submitted more than \$40 million in claims to Medicare for home health services it purportedly provided to beneficiaries when, in fact, the patients were not homebound and/or had no medical necessity for the services.
- In February 2013, the co-owner and operator of three Miami, Florida-based pharmacies was sentenced to 168 months in prison, ordered to forfeit over \$23 million, and ordered to pay a \$100,000 fine on his December 2012 guilty plea to conspiracy to pay health care kickbacks and conspiracy to commit health care fraud. According to court documents, from 2007 to September 2012, the defendant paid illegal kickbacks to guarantee a stream

of beneficiary information, which was used to submit false and fraudulent claims by the pharmacies to Medicare and Medicaid.

Phase 2: Los Angeles (Central District of California)

- On October 4, 2012, the U.S. District Court for the Central District of California unsealed an indictment charging four defendants with conspiracy to commit health care fraud, health care fraud, and conspiracy to obstruct a federal auditor. The charges stemmed from a Medicare fraud scheme regarding purported ambulance transportation services involving Alpha Ambulance. According to the indictment, the defendants conspired to defraud Medicare by providing ambulance services to ineligible Medicare beneficiaries. From June 2008 to July 2012, Alpha submitted Medicare claims totaling approximately \$49.3 million for purported ambulance transportation and related services, and Medicare paid Alpha approximately \$13.3 million on those claims. In addition, the indictment alleges that the defendants obstructed a Medicare audit of Alpha's false and fraudulent claims by altering patient files and records that otherwise showed ambulance transportation services provided by Alpha were not medically necessary, and therefore not reimbursable by Medicare.
- A former officer of Fendih Medical Supply, Inc., a medical supply company, was sentenced in September 2013 to serve 51 months in prison for his role in a fraud scheme that resulted in \$1.5 million in fraudulent claims to Medicare. In addition, a physician was sentenced to 27 months in prison for his role in the scheme. In April 2013, a jury in Los Angeles federal court found the two defendants, as well as another health care professional, guilty of conspiracy to pay and receive kickbacks and of conspiracy to commit health care fraud. Trial evidence showed that the owner of the DME company fraudulently billed Medicare for DME that was either never provided to its Medicare beneficiaries or was not medically necessary. The defendant physician provided medically unnecessary power wheelchair prescriptions in exchange for cash kickbacks. This fraud scheme caused the submission of approximately \$1.5 million in false and fraudulent claims to Medicare, of which about \$1 million was paid.
- In July 2013 in the Central District of California, the owner and operator of a DME supply company was convicted in connection with an \$11 million Medicare fraud scheme. The evidence at trial revealed that the defendant submitted false and fraudulent prescriptions for DME by using street-level patient recruiters to find senior citizens with Medicare and Medi-Cal benefits at swap meets and other public places. The recruiters, who were paid about \$600 per beneficiary, would convince the seniors to accept power wheelchairs and other DME that they did not need.

Phase 3: Detroit (Eastern District of Michigan)

- In August 2013, a Michigan oncologist/hematologist was charged with health care fraud in wide-ranging and dangerous fraudulent billing scheme. According to the original complaint and subsequent indictment, the doctor alleged provided chemotherapy and other

medical treatments to patients who did not need the treatments, including patients who were in remission and did not need chemotherapy, and directed his staff to falsify medical documents to justify the treatments. The allegations raised serious health concerns, particularly given the physical effect of chemotherapy and some of the other treatments the doctor administered to his patients. At the time of arrest, the doctor was treating 1,200 patients. The Criminal Division's Fraud Section, working with the U.S. Attorney's Office for the Eastern District of Michigan, undertook a massive and aggressive effort to make sure that victim witnesses received all necessary support in finding new medical care. Between August 2010 and August 2013, the doctor's business, billed Medicare \$225 million and was paid \$91 million. In addition, private insurer Blue Cross/Blue Shield also paid the doctor \$78 million on claims submitted by the practice.

- In May 2013, two health center owners were sentenced on their October 2012 guilty pleas in connection with an over \$13 million Medicare fraud scheme. One owner was sentenced to 100 months in prison and \$5.4 million in restitution, while the other was sentenced to 12 months and one day in prison, and over \$500,000 in restitution. The two defendants were also ordered to forfeit \$40,717. According to plea documents, the two defendants submitted claims through their health clinics for infusion therapy treatments which were never rendered.
- From May 2013 to July 2013, 2 defendants were sentenced and or pled guilty for their involvement in a \$13.8 million home health care Medicare fraud scheme. According to court documents, from June 2009 through September 2011 four companies conspired to defraud Medicare through falsifying documents and submitting fraudulent claims. The two sentenced defendants, the owner/administrator of a home health care company and a physical therapy assistant, were given 30 month and 60 month prison terms, and ordered to pay \$1.7 million and \$1.3 million in restitution, respectively.
- Between December 2012 and April 2013, four individuals— two owners, a marketer and a registered nurse pled guilty for their involvement in a \$24.7 million home health care fraud scheme. According to court documents, the conspirators attempted to defraud Medicare by submitting claims for home health services that were medically unnecessary and/or not provided. The owners oversaw and ran the schemes at multiple home health agencies. The marketer sold the Medicare information of hundreds of Medicare beneficiaries, and the registered nurse fabricated notes and other documentation to give Medicare the impression that she had provided necessary home health care services. In reality, the home health care billed was not needed and/or not provided.

Phase 4: Houston (Southern District of Texas)

- In June 2013, the owner of a DME supply company was sentenced to 97 months in prison and ordered to pay \$2.5 million in restitution as the result of a December 2012 conviction in connection with a \$6.7 million Medicare fraud scheme. According to court documents and trial evidence, the defendant used his company's Medicare provider number to submit

claims to Medicare for DME that was medically unnecessary, and in some cases, never provided.

- In March 2013, a physician was sentenced to 63 months in prison and ordered to pay over \$2.9 million in restitution on his December 2012 conviction of conspiracy to commit health care fraud and several counts of false statements relating to health care matters. Trial evidence showed that the defendant signed plans of care for Medicare beneficiaries who were not under his care and about whose conditions he had no knowledge. Overall, approximately \$17.3 million was paid by Medicare for fraudulent home health care services.
- In March 2013, the owner/operator of an ambulance transport company was convicted on conspiracy to commit health care fraud and health care fraud, in connection with a \$1.7 million Medicare fraud scheme. Trial evidence showed that the defendant and others conspired to enrich themselves by falsifying patient records in order to bill Medicare for ambulance services that were medically unnecessary and not provided.

Phase 5: Brooklyn (Eastern District of New York)

- In October 2012, nine defendants, including the owner and operator of a fraudulent physical therapy clinic in Brooklyn and its medical director, were charged with participating in a \$13 million Medicare fraud scheme. The indictment alleged that the defendants operated a physical therapy clinic in Brooklyn, recruited patients to visit the clinic through the payment of kickbacks and bribes, and billed Medicare for services that were unnecessary and often never provided at all. Between the time of indictment and September 30, 2013, four defendants had pled guilty to participating in the scheme.
- Between October 2012 and July 2013, two physicians and three owners and operators of a fraudulent “medical” clinic pled guilty in connection with an over \$12.6 million Medicare fraud scheme. According to plea documents, these individuals in fact provided a variety of spa services, such as massages, facials, lunches, and dancing classes to Medicare beneficiaries in an effort to induce those beneficiaries into allowing their Medicare numbers to be billed for medical services that were never provided and were not medically necessary.
- In December 2012, a board-certified colorectal surgeon was sentenced to 30 months in prison, ordered to pay over \$1 million in restitution and forfeit over \$1 million on his June 2012 jury conviction on health care fraud and false statements relating to health care matters in connection with a \$22.6 million Medicare scheme. Trial evidence demonstrated that from January 2008 to January 2010, the doctor defrauded Medicare and private insurance companies by billing for surgeries, specifically hemorrhoidectomies, and related medical services that he never provided.

Phase 6: South Louisiana (Middle and Eastern Districts of Louisiana)

- In May 2013, five individuals were indicted in the Eastern District of Louisiana for their role in a home health scheme that billed Medicare \$51 million. The indictment charges an owner, two doctors and two recruiters with conspiracy to commit health care fraud, conspiracy to pay or receive health care kickbacks and health care fraud. The conduct involves billings by three, related home health agencies in Louisiana which obtained patients through paying patient recruiters and billed by services that were not medically necessary and, sometimes, not provided.
- In October 2012, in the Middle District of Louisiana, an executive of a Mississippi corporation that purportedly provided durable medical equipment to Medicare beneficiaries was sentenced to 72 months in prison and ordered to pay \$3 million in restitution on his October 2011 guilty plea in connection with a \$9.1 million Medicare fraud scheme. According to court documents, the defendant admitted that from October 2004 through October 2010, he and others conspired to defraud Medicare through the submission of false and fraudulent claims, and by concealing the submission of those claims and the receipt and transfer of the fraud proceeds. The proceeds were diverted to their own personal use or benefit of others.
- In March 2013, two New Orleans residents, the owner of a home health care company and the director of nursing for the same company, were convicted after a six day trial for their involvement in a scheme that fraudulently billed Medicare \$17.1 million between 2005 and 2011. According to trial evidence, the defendants paid recruiters to obtain Medicare beneficiary information. The owner paid medical doctors to sign referrals and certifications for home health services that were not medically necessary, and the nurse falsified and directed others to falsify certification evaluations and other forms to make it appear that the home health services were medically necessary. The owner was sentenced to 180 months, and the director of nursing was sentenced to 60 months.

Phase 7: Tampa (Middle District of Florida)

Two defendants were indicted on May 7, 2013 on a charge of conspiracy to commit money laundering involving the proceeds of a health care fraud scheme. According to documents filed in the case, the defendants and others conspired to engage in financial and monetary transactions of health care fraud proceeds from Renew Therapy Center of Port St. Lucie LLC (Renew Therapy), a comprehensive outpatient rehabilitation facility. From November 2007 through August 2009, Renew Therapy submitted approximately \$10.5 million in fraudulent claims for reimbursement to Medicare for therapy services that were not legitimately prescribed and not legitimately provided to Medicare beneficiaries. As a result of those fraudulent claims, Medicare deposited approximately \$6.2 million into a Renew Therapy bank account, approximately \$1,847,222 of which was moved through bank accounts and business entities that the defendants controlled. The defendants pled guilty on Oct. 23, 2013 and Oct. 24, 2013.

Phase 8: Dallas (Northern District of Texas)

- In February 2013, the husband and wife owners/operators of a home health care agency were each sentenced to 37 months in prison and ordered to pay over \$850,000 on their December 2011 guilty pleas to conspiracy to commit health care fraud. According to court documents, the couple along with a second couple owned a home health care agency that provided care to Medicare and Medicaid beneficiaries. The couple admitted to conspiring with others to defraud Medicare by submitting fraudulent claims home health services on behalf of patients who were ineligible for the services. They also falsified documentation indicating that patients were home bound and eligible for home health services, when in fact they were ineligible, and paid kickbacks to a patient recruiter to recruit Medicare patients so that the agency could increase its Medicare billing and revenue.
- In October 2012, the owner and operator of a home health services company pled guilty to conspiracy to commit health care fraud, in connection with a home health care scheme that billed over \$350 million to Medicare and \$24 million to Texas Medicaid. According to the court documents, the defendant admitted to directing others to recruit Medicare beneficiaries from Dallas, Texas neighborhoods for home health services they did not need and for which they did not qualify.

Phase 9: Chicago (Northern District of Illinois)

- In September 2013, the owner of numerous outpatient surgery centers and other healthcare-related businesses in Illinois and Indiana, pleaded guilty in the U.S. District Court for the Northern District of Illinois to honest services fraud and tax fraud. The charges stem from a healthcare bribery scheme that included the defendant paying cash to physicians in exchange for the physician referring his patients to or conducting surgeries at the defendant's outpatient surgery centers, rather than at a hospital or competitor surgery center. The indictment, returned by the grand jury in June 2012, alleges that the defendant paid hundreds of thousands of dollars to different physicians, in exchange for the referrals the physicians made to the defendant's facilities, and that the bribery arrangement was not disclosed to the patients, thereby depriving patients of the right to the honest services of their physician. The indictment further alleged that, to obtain cash to pay bribes to doctors, the defendant engaged in a tax fraud scheme with another individual that consisted of the defendant giving Individual A over \$2 million in checks written from defendant's healthcare businesses, which were deducted as business expenses, in exchange for which Individual A gave the defendant cash in an amount approximately equal to about 70% of the value of the checks.
- On October 3, 2012, a grand jury returned an indictment charging a Chicago-area dermatologist, with defrauding Medicare and private health insurance companies by submitting false claims for hundreds of patients resulting in millions of dollars of losses. The doctor falsely diagnosed patients with actinic keratosis, or sun-induced skin lesions that have the potential to become cancerous, and then billed Medicare, Blue Cross Blue Shield of Illinois, Aetna, and Humana for treatments that were ineffective and falsely

documented. Between 2003 and 2010, the doctor allegedly falsely documented patients' charts to support medically unnecessary, cosmetic treatments that he ordered. In some instances, he falsely documented the removal of more than 1,000 lesions from patients over several years of treatment, according to the indictment. Trial is scheduled for February 2014.

- In September 2013, the owner of numerous outpatient surgery centers and other healthcare-related businesses in Illinois and Indiana, pleaded guilty in the U.S. District Court for the Northern District of Illinois to honest services fraud and tax fraud. The charges stem from a healthcare bribery scheme that included the defendant paying physicians cash in exchange for the physician referring his patients to or conducting surgeries at the defendant's outpatient surgery centers, rather than at a hospital or competitor surgery center. The indictment, returned by the grand jury in June 2012, alleges that the defendant paid hundreds of thousands of dollars to different physicians, in exchange for the referrals the physicians made to the defendant's facilities, and that the bribery arrangement was not disclosed to the patients, thereby depriving patients of the right to the honest services of their physician. The indictment further alleged that, to obtain cash to pay bribes to doctors, the defendant engaged in a tax fraud scheme with another individual that consisted of the defendant giving Individual A over \$2 million in checks written from defendant's healthcare businesses, which were deducted as business expenses, in exchange for which Individual A gave the defendant cash in an amount approximately equal to about 70% of the value of the checks.

This case is one of the first in which a healthcare bribery scheme has been charged as honest services fraud under 18 U.S.C. §§ 1341 and 1346, premised upon the defendant (as a third-party) causing a breach of the physician's duty of care and disclosure to a patient. Also representing a departure from ordinary charging theories in healthcare fraud cases, the indictment included Travel Act allegations, *see* 18 U.S.C. § 1951, premised on the defendant causing the travel of patients across state lines and the use of the interstate mail with intent to facilitate commercial bribery in violation of Illinois law. The defendant's sentencing is scheduled for January 2014.

- In 2013, five of ten defendants charged in two separate indictments with conspiracy to violate the Medicare anti-kickback statute pled guilty, including a Doctor who admitted to receiving approximately \$324,000 in cash kickbacks in exchange for Medicare patients referrals to Grand Home Health Care, Inc. In all, ten individuals, including the owners of two home health care agencies and three physicians, were charged in two indictments with conspiracy to violate the Medicare anti-kickback statute. The charges stemmed from kickback schemes in which the owners of the two home health care agencies paid cash kickbacks to physicians and other health care professionals in exchange for the referral of Medicare patients. According to the indictments, from 2005 through 2011, the owners of Grand Home Health Care, Inc. paid over \$1.1 million in cash kickbacks to approximately twenty doctors, nurses, social workers, and other health care professionals in exchange for the referral of Medicare patients to Grand. During this period, Medicare paid Grand more than approximately \$8.3 million on claims for patients illegally referred to Grand in

exchange for kickbacks. During this same time period, the owner of Romyst Home Health, Inc. paid approximately \$500,000 in cash kickbacks to several doctors in exchange for the referral of Medicare patients to Romyst. Medicare paid Romyst more than approximately \$11.7 million on claims for patients illegally referred to Romyst in exchange for kickbacks.

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 May 2012, Abbott Laboratories pleaded guilty and in October 2012 was sentenced to pay \$1.5 billion (including a criminal fine and forfeiture totaling \$700 million and federal and state civil settlements totaling \$800 million) to resolve criminal and civil liability arising from the company's off-label promotion of the prescription drug, Depakote. In particular, Abbott pleaded guilty to misbranding Depakote by promoting the drug to control agitation and aggression in elderly dementia patients and to treat schizophrenia when neither of these uses was FDA approved. In an agreed statement of facts filed in the criminal action, Abbott admitted that from 1998 through 2006, the company maintained a specialized sales force trained to market Depakote in nursing homes for the control of agitation and aggression in elderly dementia patients, despite the absence of credible scientific evidence that Depakote was safe and effective for that use. Moreover, this settlement resolved FCA allegations that Abbott misled doctors about the safety and efficacy of Depakote for off-label indications, encouraged physicians to circumvent regulations designed to prevent the use of unnecessary drugs in nursing homes, and paid kickbacks to doctors and long-term care pharmacies to prescribe and/or recommend Depakote. As part of this resolution, Abbott also is now subject to court-supervised probation and reporting obligations for Abbott's CEO and Board of Directors.
- In December 2012, Amgen Inc. paid \$762 million to resolve criminal and civil FCA liability arising from the improper marketing of certain drugs and biologics. The company pleaded guilty to a misdemeanor and paid \$150 million combined criminal fine and forfeiture for misbranding the anemia drug Aranesp. In addition, the company paid \$612 million to resolve FCA allegations that Amgen (1) promoted Aranesp and two other drugs that it manufactured, Enbrel and Neulasta, for off-label uses and doses that were not approved by the FDA and not properly reimbursable by federal insurance programs; (2) offered illegal kickbacks to a wide range of entities in an effort to influence health care providers to select its products for use, regardless of whether they were reimbursable by federal health care programs or were medically necessary; and (3) engaged in false price reporting practices involving several of its drugs. As part of the criminal and civil resolutions, Amgen also executed a Corporate Integrity Agreement (CIA) with HHS-OIG.
- In May 2013, Ranbaxy Laboratories Limited (Ranbaxy) and its subsidiary, Ranbaxy USA, Inc., paid a total of \$500 million to resolve criminal and civil liability relating to the manufacture and distribution of certain adulterated drugs made at two of Ranbaxy's

manufacturing facilities in India. The settlement included \$350 million to resolve FCA allegations that Ranbaxy manufactured, distributed, and sold drugs whose strength, purity, or quality differed from the drug's specifications or that were not manufactured according to the FDA-approved formulation. In addition, Ranbaxy USA pleaded guilty to three felony Food, Drug, and Cosmetic Act (FDCA) counts, and four felony counts of knowingly making material false statements to the FDA. Under the plea agreement, the company will pay \$150 million in fines and forfeitures.

- In July 2013, Wyeth Pharmaceuticals Inc. pleaded guilty and paid a total of \$490.9 million to resolve its criminal and civil liability arising from the unlawful marketing of the prescription drug Rapamune for uses not approved as safe and effective by the FDA. In particular, Wyeth pleaded guilty to a criminal information charging it with a misbranding violation under the FDCA. The resolution included a criminal fine and forfeiture totaling \$233.5 million. In addition, Wyeth paid \$257.4 million to resolve FCA allegations that it promoted Rapamune for unapproved uses, some of which were not medically accepted indications and, therefore, were not covered by Medicare, Medicaid and other federal health care programs. These unapproved uses included non-renal transplants, conversion use (switching a patient from another immunosuppressant to Rapamune) and using Rapamune in combination with other immunosuppressive agents not listed on the label.
- In December 2012, Sanofi-Aventis U.S., Inc. and Sanofi-Aventis U.S. LLC, subsidiaries of international drug manufacturer Sanofi (collectively, Sanofi), agreed to pay \$109 million to resolve FCA allegations that they provided physicians with free units of Hyalgan, a knee injection, to induce them to purchase and prescribe the product in violation of the Anti-Kickback Statute. The settlement also resolved allegations that Sanofi submitted false average sales price (ASP) reports for Hyalgan that failed to account for the free units distributed contingent on Hyalgan purchases. The Government alleged that the false ASP reports, which were used to set reimbursement rates, caused Government programs to pay inflated amounts for Hyalgan.
- In October 2012, Boehringer Ingelheim Pharmaceuticals Inc. paid \$95 million to resolve FCA allegations relating to the improper promotion of the stroke-prevention drug Aggrenox, the chronic obstructive pulmonary disease (COPD) drugs Atrovent and Combivent, and the hypertension drug Micardis. Boehringer promoted each of the drugs for uses that were not medically accepted indications and were not covered by federal health care programs. Specifically, the settlement resolves allegations that Boehringer promoted Aggrenox for certain cardiovascular events such as myocardial infarction and peripheral vascular disease; that Combivent was marketed for use prior to another bronchodilator in treating COPD; and that Micardis was marketed for treatment of early diabetic kidney disease. As part of the resolution, Boehringer entered into a CIA with HHS/OIG.
- In December 2012, Wyeth Pharmaceuticals Inc. (acquired by Pfizer in October 2009) agreed to a \$55 million civil disgorgement settlement to resolve civil FDCA allegations that it illegally introduced and caused the introduction into interstate commerce of a

misbranded drug, Protonix, between February 2000 and June 2001. Protonix is a proton pump inhibitor (“PPI”) that was used by physicians to treat various forms of gastro-esophageal reflux disease (“GERD”). Wyeth sought and obtained approval from the FDA to promote Protonix for short-term treatment of erosive esophagitis—a condition associated with GERD that can only be diagnosed with an invasive endoscopy. However, Wyeth allegedly promoted Protonix for all forms of GERD, including symptomatic GERD, which is far more common and can be diagnosed without an endoscopy.

- In May 2013, C.R. Bard, Inc. paid \$48.26 million to resolve FCA allegations that it paid illegal kickbacks in the form of grants and rebates to doctors and/or hospitals to solicit business from those providers in violation of the Anti-kickback Statute. The hospitals purchased Bard’s brachytherapy seeds, the doctors surgically implanted the seeds in prostate cancer patients, and the hospitals then falsely billed Medicare for those seeds in claims the government alleged were rendered false by Bard’s illegal kickback conduct. As part of the resolution, Bard also paid \$2.2 million pursuant to a Non-Prosecution Agreement to resolve a related criminal investigation.
- In December 2012, Healthpoint Ltd. agreed to pay \$48 million to resolve allegations that it caused false claims to be submitted to Medicare and Medicaid for an unapproved drug, Xenaderm, which was ineligible for reimbursement by those programs. The complaint alleged that Healthpoint’s business strategy was to market new prescription drug products modeled after drug products that were on the market before October 1962, in order to avoid the time, effort, and expense of obtaining FDA approval. The complaint further alleged that at no time prior to its introduction of Xenaderm into the market did Healthpoint complete any double-blind placebo-controlled clinical studies that established the safety and effectiveness of Xenaderm. Notwithstanding the lack of FDA approval, the government alleges, Healthpoint actively promoted Xenaderm as a prescription drug that, unlike non-prescription skin ointments such as Vaseline, was “Medicaid reimbursed” and thus cost nursing homes nothing to administer to Medicaid patients.
- In March 2013, Par Pharmaceutical Companies Inc. (Par) pleaded guilty and paid a total of \$45 million to resolve its criminal and civil FCA liability arising from the company’s promotion of its prescription drug Megace ES for uses not approved as safe and effective by the FDA and not covered by federal health care programs. In particular, Par pleaded guilty to a criminal misdemeanor for misbranding Megace® ES and paid a fine and forfeiture totaling \$22.5 million. Moreover, Par paid an additional \$22.5 million to resolve civil allegations that, by promoting the sale and use of Megace® ES for uses that were not FDA-approved and not covered by federal health care programs, Par caused false claims to be submitted to these programs. The government further alleged that Par deliberately and improperly targeted sales to elderly nursing home residents with weight loss, whether or not such patients suffered from AIDS, and launched a long-term care sales force to market to this population. As part of the criminal and civil resolution, Par entered into a CIA with HHS-OIG.

- In May 2013, ISTA Pharmaceuticals, Inc. pleaded guilty and paid a total of \$33.5 million to resolve its criminal and civil FCA liability arising from the company's promotion of its prescription drug, Xibrom. In particular, ISTA pled guilty to conspiring to introduce a misbranded drug into interstate commerce and conspiracy to pay illegal remuneration in violation of the federal Anti-Kickback Statute. Under the terms of the plea agreement, ISTA paid \$18.5 million, including a criminal fine of \$16,125,000 for the conspiracy to introduce misbranded Xibrom into interstate commerce, \$500,000 for the conspiracy to violate the Anti-Kickback Statute, and \$1,850,000 in asset forfeiture associated with the misbranding charge. In addition, ISTA also paid \$15 million to resolve FCA allegations that ISTA promoted the sale and use of Xibrom for certain uses that were not FDA-approved and not covered by the federal health care programs, including prevention and treatment of cystoid macular edema, treatment of pain and inflammation associated with non-cataract eye surgery, and treatment of glaucoma.
- In April 2013, Amgen Inc. paid \$24.9 million to settle FCA allegations that it violated the Anti-Kickback Statute. In particular, the government alleged that Amgen paid kickbacks to long-term care pharmacy providers Omnicare Inc., PharMerica Corporation and Kindred Healthcare Inc. in return for implementing "therapeutic interchange" programs that were designed to switch Medicare and Medicaid beneficiaries from a competitor drug to Aranesp. The government alleged that the kickbacks took the form of performance-based rebates that were tied to market-share or volume thresholds. The government further alleged that, as part of the therapeutic interchange program, Amgen distributed materials to consultant pharmacists and nursing home staff encouraging the use of Aranesp for patients who did not have anemia associated with chronic renal failure.
- In July 2013, a bio-pharmaceutical company based in Ventura County, California paid \$14.99 million to settle FCA allegations that it knowingly paid unlawful remuneration to oncology practice groups and doctors in order to induce them to prescribe a cancer-treatment drug to beneficiaries of federally funded health care programs, in violation of the Anti-Kickback Statute. The remuneration included directing data purchase agreements for prescription information to the oncology practice groups.
- In December 2012, Victory Pharma, Inc. (Victory) paid \$11.4 million to resolve federal civil and criminal liability arising from its marketing of the pharmaceutical products Naprelan, Xodol, Fexmid, and Dolgic. Under the agreement, Victory entered into a deferred prosecution agreement and paid a criminal forfeiture of \$1.4 million to resolve federal Ant-Kickback Statute allegations, and paid \$9.9 million to resolve federal FCA allegations. The settlement resolves allegations that Victory engaged in a scheme to promote its drugs by paying kickbacks to doctors to induce them to write prescriptions for Victory's products, including tickets to sporting events; concerts and plays; spa, golf and ski outings; dinners at expensive restaurants. The settlement also resolves allegations that Victory improperly used paid preceptorships to induce doctors to prescribe Victory's products.

- In July 2013, Mallinckrodt, Inc., a pharmaceutical manufacturer, agreed to pay \$3.5 million to settle allegations that it made improper payments to physicians and, as a result, caused the submission of false claims to Medicare and Medicaid for various drugs.

Hospitals

- Fifty-five hospitals located throughout 21 states paid a total of over \$34 million to resolve FCA liability related to claims for kyphoplasty, a minimally-invasive procedure used to treat spinal compression fractures. In many cases, kyphoplasty can be performed safely and effectively as an outpatient procedure without any need for a more costly inpatient hospital admission. The settlements resolve allegations that the hospitals knowingly billed Medicare for medically unnecessary admissions for kyphoplasty procedures in order to increase their profits and circumvent lower outpatient reimbursement rates.
- In August 2013, Shands Teaching Hospital & Clinics Inc., Shands Jacksonville Medical Center Inc. and Shands Jacksonville Healthcare Inc. (collectively, Shands Healthcare), paid the government and the state of Florida a total of \$26 million to settle FCA allegations that six of its health care facilities submitted false claims to Medicare, Medicaid and other federal health care programs for inpatient procedures that should have been billed as outpatient services.
- In April 2013, Intermountain Health Care Inc. paid \$25.5 million to settle claims that it violated the Stark Statute and the FCA by engaging in improper financial relationships with referring physicians. These improper financial relationships included employment agreements under which the physicians received bonuses that improperly took into account the value of some of their patient referrals and office leases and compensation arrangements between Intermountain and referring physicians that violated other requirements of the Stark Statute. These issues were disclosed to the government by Intermountain.
- In December 2012, American Sleep Medicine, LLC (ASM), agreed to pay \$15.3 million to resolve allegations that it violated the FCA. ASM operates 19 sleep diagnostic centers throughout the United States. ASM allegedly submitted claims to Medicare and other federal health care programs for sleep diagnostic services that were not eligible for payment because the diagnostic tests were performed by individuals who lacked the required license, certification, or credentials. Between January 2004 and December 2011, ASM submitted nearly 20,000 claims for reimbursement. In addition to the monetary agreement, ASM entered into a CIA with HHS/OIG.
- In July 2013, Sound Inpatient Physicians Inc., a nationwide hospitalist firm, paid \$14.5 million to settle allegations that it overbilled Medicare and other federal health care programs. The agreement resolves allegations that the firm upcoded Evaluation & Management services rendered to inpatients. The parent company bills on behalf of the providers for the professional services, while the physicians are being paid a flat salary.

- In May 2013, Adventist Health System/West, dba Adventist Health, and its affiliated hospital, White Memorial Medical Center, paid \$14.1 million to settle FCA allegations that Adventist Health violated the Anti-Kickback Statute and Stark Statute by improperly compensating physicians who referred patients to the White Memorial facility by transferring assets, including medical and non-medical supplies and inventory, at less than fair market value.
- In January 2013, Cooper University Hospital agreed to pay \$12.5 million to settle allegations that it created a fraudulent advisory board in an effort to induce referrals to its cardiology department. The hospital recruited local outside primary care physicians and non-invasive cardiologists to serve on a sham advisory board. The physicians were paid approximately \$18,000 a year to attend four meetings. However, these meetings were largely marketing affairs and there was little evidence of any services being provided by the physician members. In addition to the monetary settlement, the hospital enacted and agreed to maintain a number of corporate reforms designed to enhance accountability, training, and other aspects of its compliance operations.
- In June 2013, the Chief Financial Officer of a hospital in California was sentenced to 8 months of home confinement and ordered to pay \$10.6 million in restitution after pleading guilty to charges of conspiracy to pay kickbacks for patient referrals and other related crimes. According to court documents, the CFO oversaw the issuance of checks to companies owned by co-conspirators for the referral of recruited beneficiaries admitted to the hospital. The hospital executed sham “consultant” contracts with these companies to conceal the kickback payments. The hospital then billed Medicare and Medi-Cal for hospital stays and related services provided to the recruited beneficiaries, including admissions that were medically unnecessary. Medicare and Medicaid paid the hospital more than \$10.5 million in reimbursement for these false claims.
- In November 2012, Morton Plant Health Care, Inc. and its affiliated hospitals, all part of the BayCare Health System, paid the United States \$10.1 million to settle FCA allegations of improperly billing for certain interventional cardiac and vascular procedures as inpatient care when those services should have been billed as less costly outpatient care or as observational status.
- In November 2012, Freeman Health System paid \$9.3 million to resolve FCA allegations that it knowingly provided incentive pay to physicians in a manner that violated the Stark Law. In particular, the government alleged that Freeman provided incentive pay to 70 physicians employed at clinics operated by the health system based on the revenue generated by the physicians’ referrals for certain diagnostic testing and other services performed at the clinic.
- In July 2013, Dubuis Health System and Southern Crescent Hospital for Specialty Care, Inc. (Southern Crescent) paid \$8 million to settle allegations that they knowingly kept patients hospitalized beyond the time considered to be medically necessary in order to

increase their Medicare reimbursement and to maintain Southern Crescent's classification as a long-term acute care facility.

- In July 2013, Beth Israel Deaconess Medical Center (BIDMC) paid \$5.3 million to settle civil allegations that it violated the FCA by improperly admitting patients and then billing for inpatient stays with respect to services that should have been provided in an outpatient setting, resulting in overpayment by Medicare for unnecessary hospital stays.
- In February 2013, St. Joseph's Medical Center paid \$4.9 million to resolve the hospital's civil liability to the United States under the FCA for admitting patients to the hospital unnecessarily from 2007 to 2009. More specifically, the hospital voluntarily disclosed that it admitted patients for short stays (typically one or two days) that were not warranted by the patient's medical condition, and thereby generated a larger reimbursement than was medically necessary for each patient.
- In April 2013, St. Vincent Healthcare and Holy Rosary Healthcare (collectively, the Hospitals) agreed to pay \$3.9 million to resolve allegations under the Stark law. These Montana Hospitals self-disclosed that, between July 2003 and December 2010, they paid certain employed physicians incentive compensation that was based, in part, on the volume or value of referrals made to the Hospitals. More specifically, the physician formula for compensation included inappropriate revenue related to such designated health services as EKG and EMG services at the Hospitals. In addition, the Hospitals identified numerous arrangements or contracts it held with independent physicians or physician groups that the Government contended violated the Stark Law. These arrangements or contracts included violations relative to expired or unsigned contracts, unwritten agreements, untimely payment of rent under lease terms, and potential deviations from fair market value rental charges.
- In January 2013, EMH Regional Medical Center (EMH) paid \$3.8 million and North Ohio Heart Center Inc. (NOHC) paid \$541,870 to resolve allegations that they submitted false claims for medically unnecessary cardiac procedures. In particular, the government alleged that between 2001 and 2006, EMH and NOHC performed angioplasty and stent placement procedures on patients who had heart disease but whose blood vessels were not sufficiently occluded to require the particular procedures at issue.
- In July 2013, University Medical Center (UMC), doing business as University of Louisville Hospital, paid \$2.8 million to settle FCA allegations that it may have violated federal law concerning the relationships it had with certain health care providers. University of Louisville Hospital operates a separate fast track unit within the emergency department to address non-urgent care. This in-house immediate care center, FirstCare, is staffed by UMC-employed physician assistants (PAs) and nurse practitioners (NPs) under the direction of the Department of Emergency Medicine physicians – who in turn operate as University Emergency Medicine Associates (UEMA). From January 1, 2006 through December 31, 2010, the salaries and benefits paid to FirstCare PAs and NPs were claimed on UMC cost reports filed with Medicare. At the same time, UEMA physicians generally

treated the FirstCare PAs and NPs as their own employees including, to various degrees, billing and collecting from Medicare for their professional services. The United States contended that UMC provided an improper benefit to UEMA in violation of the FCA and other federal law.

- In October 2012, Wyoming Medical Center (WMC) paid \$2.7 million arising from the alleged submission of fraudulent claims to Medicare. More specifically, the settlement resolved allegations that WMC submitted higher-paying inpatient reimbursement claims to Medicare for (a) procedures that had been performed in an outpatient setting, (b) hospital stays where there was no record of a physician ordering inpatient-level care, and (c) services provided to patients who did not meet requirements for inpatient admission. The United States also settled allegations that WMC prolonged inpatient hospital admissions without medical necessity in order to qualify patients for Medicare-covered, long-term care at a skilled nursing facility. In addition to the settlement agreement, WMC agreed to enter into a 5-year CIA with HHS-OIG.

Physicians

- In February 2013, an individual and his two companies (identified as Wasserman), paid \$26.1 million to resolve FCA allegations that he and his company violated the Anti-Kickback Statute by accepting free pathology services from Tampa Pathology Lab (“TPL”) for biopsy specimens they sent to the lab. The government also alleged that Wasserman billed Medicare for medically unnecessary skin repair procedures and for evaluation and management services that he did not perform. In addition to paying the settlement amount, the individual agreed to a five-year voluntary exclusion from participation in any federal health care programs as part of the resolution.
- In July 2013, the United States District Court for the District of Columbia granted the United States’ motion for partial summary judgment against a Doctor and his two companies, Ishtiaq Malik M.D., P.C. and Advanced Nuclear Diagnostics, for submitting false nuclear cardiology claims to federal and state health care programs and awarded over \$17 million in damages and penalties. The United States alleged that the doctor and his companies violated the FCA by double-billing multi-day nuclear stress test studies, billed for services that were already included in the payment for these tests, and billing for services not rendered.
- In December 2012, a California physician was sentenced for his role in a hospital fraud scheme to 1 year and 1 day in prison and ordered to pay \$11 million in restitution. He previously pleaded guilty to conspiracy to receive kickbacks. According to court documents, Tustin Hospital paid marketers to recruit patients and drive them from “Skid Row” around Los Angeles, past other hospitals, to be admitted to its facility. The physician admitted these patients and then he and the hospital billed Medicare for inpatient services, even if the services were not medically necessary. The physician admitted that many of the recruited patients had been coached to recite false symptoms, and that he falsified medical records to justify the admission of some patients. On

average, he admitted approximately 60 patients per month to the hospital, even though some did not require hospitalization.

- In July 2013, Jackson Cardiology Associates (JCA) and its owner paid \$4 million to resolve FCA allegations that JCA's owner and certain JCA cardiologists performed medically inappropriate cardiac procedures, including invasive catheterizations at Allegiance Health. Specifically, the government alleged that JCA's owner ordered catheterizations for patients based on findings from nuclear stress tests that he improperly read as positive. The government found that three-quarters of these patients had no significant heart blockages. These catheterizations involve snaking a hollow tube into the heart through an incision in the patient's groin.
- In August 2013, Imagimed LLC and its former owners and former chief radiologist paid \$3.57 million to resolve FCA allegations that they submitted false claims for magnetic resonance imaging (MRI) services. In particular, the government alleged that the defendants submitted claims to Medicare, Medicaid and TRICARE for MRI scans performed with a contrast dye without the direct supervision of a qualified physician. Since a potential adverse side effect of contrast dye is anaphylactic shock, federal regulations require that a physician supervise the administration of contrast dye when it is used for an MRI. The government also alleged that Imagimed submitted claims for services referred to Imagimed by physicians with whom Imagimed had improper financial relationships in violation of the Stark Law and the Anti-Kickback Statute.
- In June, 2013, an oncologist and his wife paid \$3.1 million to resolve FCA allegations that they jointly defrauded Medicare, Tricare, and other federal programs by overbilling for medication and services and/or billing for medication and services not provided.
- In December 2012, an Illinois physician was sentenced to 10 years in prison and ordered to pay \$2.9 million in restitution after being convicted on charges of health care fraud and fraud of visas, permits, or other documents. The physician was the manager and co-owner of House Call Physicians, LLC, a suburban home health care provider. According to court documents, the physician directed House Call Physicians to bill Medicare for: (a) services that were not medically necessary, including uncomfortable nerve conduction tests; (b) services purportedly provided by physicians when, in fact, they were performed by physician assistants; and (c) services performed by a podiatrist with a suspended license. Two other defendants were sentenced to 6 months and 18 months of incarceration, respectively. The two were also, respectively, fined \$20,000 and ordered to pay \$791,095 in restitution. After completing his sentence, the physician, a Canadian citizen who was not authorized to work in the United States, will be surrendered to the Department of Homeland Security for a deportability determination.
- In November 2012, a Michigan physician was sentenced to 5 years of incarceration and ordered to pay \$2.9 million in restitution after being convicted on charges of health care fraud and conspiracy to commit health care fraud. The physician was an obstetrician/gynecologist who served as a general practitioner for three clinics operating in

the same location: Blessed Medical Clinic, Alpha and Omega Medical Clinic, and Manuel Medical Clinic. According to evidence presented at trial, the physician joined a conspiracy to bill Medicare for medically unnecessary neurological tests. Some of the tests involved sending an electrical current through the arms and legs of the patients. Clinic employees, who lacked any meaningful training, administered the diagnostic tests. Patients were recruited with prescriptions for controlled substances, cash payments, and fast food.

- In July 2013, Northwestern University agreed to pay \$2.93 million to resolve FCA allegations of grant fraud by one of its cancer center physician researchers. The physician was the principal investigator on several National Institutes of Health (NIH) grants related to cancer research. Instead of using the funds as the grants required, he allegedly spent the money on family trips, meals, and hotels for himself and friends. He also charged “consulting fees” to the grants which went to unqualified friends and family members, including his brother and cousin. Northwestern additionally allowed the researcher to subcontract work under the grants without following NIH guidelines. A civil suit against the individual doctor is proceeding.
- In April 2013, the owner of Winnetka Medical Group, a cosmetic health care clinic, pled guilty to health care fraud and was sentenced to 42 months in prison and was ordered to make full restitution. The defendant billed Medicare, Anthem Blue Cross, and Blue Shield of California for three unusual and high-paying procedures, even though he lacked the equipment necessary to perform them. The defendant even billed Medicare for 26 patients who were already dead on the date he claimed to have performed the procedures. In total, the defendant submitted approximately \$7.5 million in fraudulent claims to Medicare and was paid over \$3 million.
- In May 2013, Las Vegas Urology, LLP agreed to pay \$1 million to settle allegations that it submitted false claims to federal health care programs. An investigation of the practice’s billing and medical records showed that it had billed for intra-abdominal pressure testing that had never been performed and upcoded its billings for cystourethroscopies, consultations, and ultrasound tests. In addition to the settlement agreement, the practice has entered into a three-year CIA with HHS/OIG.
- In January 2013, a Missouri psychotherapist was sentenced to 36 months’ imprisonment and ordered to pay \$1 million in restitution for health care fraud. The defendant also agreed to surrender his psychotherapy license. Between September 17, 2008 and April 5, 2012, the defendant submitted Medicare and Medicaid claims for daily or near daily psychotherapy services to 19 beneficiaries for which he was paid \$1.3 million. Although the defendant provided some services for most of the beneficiaries, he admitted that he never saw them more than once a week. The defendant further admitted that he forged, or caused another person to forge, the signatures of five the beneficiaries on patient sign-in sheets in order to obtain payments.

Other Health Care Providers

- In May 2013, U.S. Renal Care, Inc. paid \$7.3 million to resolve FCA allegations that Dialysis Corporation of America, which U.S. Renal acquired in June 2010, submitted false claims to Medicare for more Epogen, an intravenous drug commonly given to dialysis patients, than it actually administered.
- In October 2012, Westchester County Health Care Corporation (WCHCC) agreed to pay \$7 million to resolve alleged FCA violations. WCHCC operates the freestanding mental health facility Westchester Behavioral Health Center (BHC). WCHCC allegedly submitted false certifications to Medicaid stating that claims for services at BHC complied with applicable regulations. However, WCHCC allegedly knew or should have known that: (1) many of the claims lacked the required supporting documentation, and (2) many of the services either did not meet the minimum duration requirements and/or were provided by staff who lacked proper certification. BHC also allegedly billed Medicaid for psychiatric services without creating or maintaining treatment plans and progress notes.
- In October 2012, the owner/operator of a halfway house was sentenced to 4 years and 3 months of imprisonment and ordered to pay \$2.4 million in restitution after pleading guilty to charges of conspiracy to receive and pay health care kickbacks. According to court documents, the owner/operator accepted kickbacks to send Medicare beneficiaries who resided at the half-way house to American Therapeutic Corporation (ATC) for partial hospitalization services. Investigators believe that these services were not medically necessary and were not provided at ATC. ATC then billed Medicare for these services.
- In October 2012, the owner of Gideon's Gate, a provider of tutoring and day care services, was sentenced to 6 years and 8 months of incarceration and ordered to pay more than \$1.9 million in restitution after pleading guilty to health care fraud charges. The owner admitted that she executed a scheme to file more than 2,400 illegitimate reimbursement claims for psychological services that she never performed. The owner conspired with another defendant, who owned the company Primeway. Primeway's owner had a welfare-to-work contract to train Medicaid recipients to become certified nursing assistants. Primeway's owner provided the Medicaid recipients' personal identifiers to the owner of Gideon's Gate, who then back billed these recipients to Medicaid for mental health services that were not rendered. The owner of Primeway previously pleaded guilty to charges of receiving an illegal kickback from a health care program and was sentenced to 5 years of probation and assessed a \$2,000 fine.

Pharmacies

- From August, 2011 through July, 2013, twenty-six defendants have been convicted for their roles in a widespread scheme to defraud Medicare and Medicaid of nearly \$58 million. According to the indictment, a licensed pharmacist owned or controlled 26 pharmacies in Michigan. The pharmacist concealed his ownership and control over many of his pharmacies through the use of straw owners. He offered and paid kickbacks, bribes,

and other inducements to providers in exchange for them writing fraudulent prescriptions for patients with Medicare, Medicaid, and private insurance and directing the patients to fill their prescriptions at one of his pharmacies. In September 2013, the pharmacist was sentenced to 17 years in prison and ordered to pay \$18.9 million in restitution, joint and several. His co-conspirators were sentenced between February and May 2013 to a combined 19 years in prison and ordered to pay more than \$8.4 million in restitution, joint and several. Nineteen additional defendants are awaiting sentencing.

- In June 2013, Omnicare, Inc. paid \$17.2 million to settle FCA allegations that it paid kickbacks to obtain pharmacy contracts in violation of the federal Anti-Kickback statute. The settlement addressed false claims allegedly made to the Medicaid programs of Missouri, Illinois, and Florida.
- In October 2012, RxAmerica LLC., a wholly owned subsidiary of CVS Caremark Corporation, paid \$5.25 million to resolve FCA allegations that it made false submissions to CMS regarding prices for certain generic prescription drugs used for Plan Finder, a web-based tool offered by CMS to assist participants to choose a Part D plan that minimized their out-of-pocket costs by estimating prescription drug prices for each Medicare Part D plan that the beneficiary considered for enrollment. As a result of the false submissions, the government alleged that RxAmerica received Medicare Part D payments for claims for the covered drugs at prices that in some cases were significantly higher than the pricing data RxAmerica submitted to CMS for use on Plan Finder.
- In November 2012, two HHS-OIG Most Wanted Fugitives were captured and later pled guilty to charges related to health care fraud. In April 2013, the first was sentenced to 4 years and 9 months of incarceration and ordered to pay \$4.4 million in restitution, joint and several, while the second sentenced to 2 years and 6 months of incarceration and ordered to pay \$845,000 in restitution. The two owned and operated pharmacies in Miami. According to court records, the two owners/operators and their co-conspirators were involved in a Medicare scheme in which kickbacks and bribes were paid to patient recruiters and beneficiaries for prescriptions that were then used to submit fraudulent claims to Medicare. An employee, who also participated in the scheme, was sentenced to 3 years and 10 months of incarceration and ordered to pay \$4.4 million in restitution, joint and several.
- In August 2013, National Respiratory Services (NRS), a mail-order/closed door pharmacy which supplied compounded inhalation drugs to patients, pled guilty to health care fraud for billing for compounded medications as if they were non-compounded, commercially manufactured FDA-approved drugs. The compounded medications were most often sub-potent, super-potent, and in some cases non-sterile. As a result of the conduct, the government paid NRS over \$2 million dollars. The two NRS pharmacists, the minority owner, and the majority owner pled guilty to a FDA misbranding violation and were sentenced to one year probation. The vice-president of operations pled guilty to felony misbranding, felony adulteration, health care fraud, and mail fraud. The defendants must pay restitution jointly and severally in the amount of \$2 million.

Clinics

- In May 2013, a captured HHS-OIG Most Wanted Fugitive was sentenced to 9 years and 1 month of incarceration and ordered to pay more than \$26 million in restitution, joint and several, after pleading guilty to charges of conspiracy to commit health care fraud and money laundering. According to court documents, as an employee of a provider of physical therapy services, he signed his name on patient files as the provider of such services, including blank treatment data forms, progress notes, and daily physical therapy records. However, he was not licensed, trained, or otherwise qualified to provide physical therapy to patients. This individual was arrested by Nigerian authorities in 2011 and extradited back to the United States in June 2012 to face health care fraud charges.
- In November 2012, a Miami man was sentenced to 12 years and 7 months of incarceration and ordered to pay \$11 million in restitution after pleading guilty to charges of conspiracy to commit health care fraud and to pay health care kickbacks, health care fraud, payment of health care kickbacks, and money laundering. The man was the president and co-owner of Research Center of Florida, Inc., a purported medical clinic. He paid more than \$2.3 million to fraudulent companies controlled by outside patient recruiters who paid cash to Medicare beneficiaries to attend Research Center as purported patients. Between October 2003 and November 2004, Research Center submitted claims to Medicare for nearly \$21 million, almost exclusively for the purported treatment of HIV-positive Medicare beneficiaries and for the administration of prescription drugs. Co-conspirators were previously sentenced to 6 years and 6 months and 5 years and 10 months of incarceration, respectively, and ordered to pay \$14 million in restitution, joint and several, for their roles in the scheme. Two other defendants were sentenced to 3 years and 10 months and 6 years and 6 months of incarceration, respectively, and ordered to pay \$10.9 million in joint and several restitution.
- In June 2013, the part-owner and medical biller for the Advanced Clinics was sentenced to serve twelve months and one day in federal prison for her role in a health care fraud scheme. The defendant was also ordered to pay a \$1.89 million fine, restitution of \$120,689 and a refund of \$1 million. The majority of patients of the Advanced Clinics were injured United States Postal Service workers receiving medical benefits under the U.S. Department of Labor, Office of Workers' Compensation Program (DOL-OWCP). The defendant fraudulently billed DOL-OWCP for services not rendered, double billed, and unbundled billing codes to obtain higher reimbursements. The defendant personally received over \$4.4 million from the Advanced Clinics.
- In July 2013, Health Guard Inc. and its owner, a unlicensed diagnostic technician, pled guilty to health care fraud, and currently awaits sentencing. Patients went to Health Guard Inc. for medical tests that were not performed or were medically unnecessary. Patients were moved between other commonly owned health care clinics to Health Guard Inc. to repeatedly perform the same unnecessary tests. Five other clinics and their owners have already been sentenced for the same activity. If the patients refused the diagnostic tests at

Health Guard Inc., prescriptions for narcotic drugs were withheld. Thereafter, bills for the unnecessary services were submitted to Medicare and Medicaid.

- In March 2013, the medical director of a clinic in Long Beach, California, was sentenced to 42 months' imprisonment and ordered to pay \$2.9 million in restitution for issuing bogus prescriptions that led to fraudulent Medicare claims of over \$3 million. The doctor and his co-schemers recruited Medicare patients for office visits that typically included unnecessary tests and procedures. The medical director, who was a doctor, also generated fraudulent prescriptions for medical equipment, power wheel chairs and enteral nutritional supplies, prescriptions that were sold to medical supply companies that used the fraudulent documents to bill Medicare for millions of dollars of unnecessary and undelivered medical supplies. Nearly all of the wheelchair prescriptions signed by the doctor were written for people who could walk. As a result of the fraudulent conduct involving the defendant and his co-schemers, \$5.6 million in fraudulent claims were submitted to Medicare, which paid approximately \$2.97 million. The defendant was convicted following a jury trial in March 2012.
- In July 2013, the owner of two "false front" healthcare clinics operating in Houston, Texas and Euless, Texas was sentenced to 120 months imprisonment and ordered to pay over \$2 million in restitution, jointly and severally with four codefendants. Along with the owner, the clinics were operated by the codefendants who were unlicensed physicians and physician's assistants. These unlicensed employees traveled to Medicare beneficiaries homes to conduct medical examinations. In addition to conducting medical examinations, the unlicensed employees would falsify orders for medical testing in order to make the patient files look legitimate. These tests were never ordered and never administered. The owner of the clinic purchased fake results and subsequently billed Medicare for millions of dollars in phony home visits and fake medical tests.
- In May 2013, a Florida woman was sentenced to 10 years in prison following her conviction for conspiracy to commit health care fraud through several physical and occupational therapy clinics she owned in the Miami area. The owner of the clinics defrauded the Medicare Part A program by falsely billing over \$20 million in therapy services that were never rendered. As part of the scheme, patients were recruited and paid kickbacks for allowing their Medicare eligibility to be misused. Clinic employees would rotate the patients, many of whom lived hours away from Miami, through the various clinics in an effort to spread out the fraudulent billing and avoid detection. Eight other employees and therapists at the clinics were convicted and received sentences ranging from two to five years of imprisonment. Collectively, the defendants were ordered to repay almost \$14 million in restitution. The owner of the clinics forfeited approximately \$200,000 in cash, along with various real properties and personal items seized at the time of her arrest.

Medical Equipment Suppliers

- In November 2012, Orthofix International NV paid \$30 million to settle FCA allegations that it paid illegal kickbacks to spinal surgeons to induce them to use the company's products. In particular, the government alleged that Blackstone Medical Inc., a subsidiary of Orthofix, paid kickbacks to spinal surgeons in a number of forms, including sham consulting agreements, sham royalty arrangements, sham research grants, travel and entertainment. As part of the settlement, Orthofix entered into a CIA with HHS/OIG.
- In May 2013, an owner/operator of several durable medical equipment (DME) companies in Nevada was sentenced to 4 years and 3 months of incarceration and ordered to pay over \$12 million in restitution after pleading guilty to charges of health care fraud and tax evasion. According to the indictment, the owner/operator paid marketers in Southern California to obtain patients for her various DME companies. The marketers provided patients with money in exchange for their Medicare information, which was used to bill Medicare for items not provided. The owner/operator also forged or caused to be forged prescriptions and falsified or caused to be falsified certificates of medical necessity to make it appear as if a physician had ordered a product for her customers. She then submitted and caused to be submitted false claims to Medicare for DME that was not medically necessary, was not provided to her customers, and was not prescribed by a physician.
- In March 2013, a California DME company owner and operator was sentenced to 156 months imprisonment and ordered to pay \$8.2 million in restitution, jointly and severally, after a jury convicted her of multiple counts of health care fraud and anti-kickback violations. At trial, the government presented evidence that the defendant paid marketers to recruit Medicare beneficiaries to seek expensive DME, such as motorized wheel chairs, that they did not need. The defendant or the marketers she relied on, often paid doctors to write the fraudulent prescriptions. The defendant would then submit the false claims to Medicare. Over the course of the scheme, defendant submitted over \$16 million in fraudulent claims to Medicare, of which Medicare paid over \$8 million. Other defendants included a marketer, who was sentenced to 41 months imprisonment, as well as a cooperating marketer who received a time served sentence and a cooperating doctor who received a 36-month period of probation.
- In July 2013, TranS1, Inc. (now known as Baxano Surgical, Inc.) paid \$6 million to resolve FCA allegations that the company caused health care providers to submit false claims to federal health care programs for surgical procedures involving the company's AxiaLIF System. Specifically, the settlement resolves allegations that TranS1 (1) improperly counseled physicians and hospitals to inflate reimbursement by using incorrect and inaccurate codes intended for more invasive spine fusion surgeries; (2) provided improper remuneration in violation of the Anti-Kickback Statute; and (3) promoted unapproved uses that were not covered by federal health care programs.

- In April 2013, the owner/operator of a DME company in New York was sentenced to 12 years of imprisonment and ordered to pay \$4.4 million in restitution for her role in a scheme to defraud Medicare by billing for DME that she did not provide. Through the DME company, the owner/operator and her husband fraudulently billed the accounts of nursing home residents from over 15 New York area nursing homes for DME that was never ordered or provided. According to court documents, the owner/operator entered these nursing homes falsely presenting herself in many roles, including physician, nurse practitioner, and wound care expert. She then stole original medical records, as well as altered and manufactured records, in an effort to justify medical billing. Investigators believe that her husband fled the country and remains a fugitive.
- In June 2013, the owner/operator of a DME company in Louisiana was sentenced to 8 years and 1 month of incarceration and ordered to pay \$2.5 million in restitution after being convicted on charges of health care fraud. According to the indictment, the owner/operator submitted approximately \$467,000 in claims to Medicare for DME purportedly prescribed by a doctor in Houston, Texas. However, the doctor never prescribed any of the DME for which he billed Medicare. He also submitted more than \$6.7 million in claims to Medicare for DME that was not medically necessary, and in some cases, was never provided.
- In June 2013, a DME business owner was sentenced to 70 months of imprisonment and ordered to pay \$1.9 million in restitution, after pleading guilty to conspiracy to commit health care fraud and aggravated identity theft. According to court documents, the DME company owner created several different companies and submitted more than 1,500 false and fraudulent claims to Medicare for DME including power wheelchairs, power pressure reducing air mattresses and knee orthosis. The defendant submitted claims using the identities of Medicare beneficiaries for DME that was not medically necessary.
- In October 2012, the co-owner of a Florida DME company was sentenced to 11 years and 3 months of incarceration and ordered to pay \$1.7 million in restitution, joint and several, after pleading guilty to charges of conspiracy to commit health care fraud. The DME company, MA Medical Supply, Inc., paid beneficiaries for allowing them to use their information to create false and fraudulent prescriptions for DME and medical services that were either not rendered or were unnecessary. From January 2006 through July 2011, MA Medical Supply submitted \$4 million in false and fraudulent claims to Medicare. In addition, the co-owner and his co-conspirators caused the submission of false and fraudulent claims and prescriptions to Medicare through several pharmacies. From approximately April 2009 through January 2012, Medicare paid more than \$16 million to these pharmacies based on claims for medical benefits, primarily prescription drugs, which, in turn, were never actually received by the beneficiaries.

Nursing Homes

- In March 2013, Grace Healthcare LLC and its affiliate Grace Ancillary Services LLC (collectively, "Grace") paid \$2.7 million, plus interest, to resolve FCA allegations that

they knowingly submitted or caused the submission of false claims to Medicare and Medicaid for medically unreasonable and unnecessary rehabilitation therapy. In particular, the government alleged that in ten nursing home facilities where Grace provided physical, occupational, and speech therapy, Grace pressured therapists to increase the amount of therapy provided to patients in order to meet targets for Medicare revenue that were set without regard to patients' individual therapy needs and could only be achieved by billing for a large amount of therapy per patient.

- In February 2013, Fairfax Nursing Center, Inc. and its owners paid \$700,000 to resolve FCA allegations that they provided excessive, medically unnecessary, or otherwise non-reimbursable physical, occupational, and speech therapy services to 37 Medicare beneficiaries.

Home Health Providers

- In April 2013, a Miami man was sentenced to 168 months for his role as one of the owners of a Miami-Dade home health agency which submitted approximately \$45 million in false claims to Medicare, causing Medicare to pay the agency approximately \$30 million. Almost all of these claims were for providing twice daily insulin injections to purportedly homebound diabetic patients. The investigation revealed that the agency used the services of dozens of patient recruiters who were paid \$1,500 per month for each patient that they provided to the agency. Investigation revealed that almost all of these patients were not homebound and many of them were not insulin dependent diabetics. During the course of this investigation, a total of thirty two defendants pled guilty and four were found guilty after trial. These defendants included patient recruiters, office employees, and registered nurses.
- In December 2012, a Miami man was sentenced to 120 months in prison for his role in a home health care fraud scheme in which he submitted and caused the submission of approximately \$5.3 million in false claims to Medicare. The defendant recruited individuals so that he could secretly control three separate home health agencies in Miami-Dade County. The defendant would purchase the companies for cash, and within a few weeks of purchasing the companies he used stolen Medicare beneficiary information to submit claims for services that were never actually rendered to Medicare beneficiaries. The defendant was a former drug trafficker who served nine years in prison from 1999 through 2006.
- Nine defendants were sentenced in April and May of 2013 for their roles in a home health care fraud scheme. According to court records, the president of Safe Home Health Care Agency, Inc., a Miami-based business that purportedly provided home health services to Medicare beneficiaries, and several co-conspirators allegedly offered and paid kickbacks and bribes to patient recruiters in return for referring beneficiaries to Safe Home to serve as patients. Beneficiaries also received kickbacks for agreeing to serve as patients of Safe Home. Safe Home received \$9.5 million in reimbursements from these false claims. The

nine defendants were sentenced to a combined 16 years and 2 months in prison and ordered to pay more than \$5.8 million in restitution, joint and several.

- In February 2013, two owners of a home health company, Alliance Home Health, each received a sentence of 37 months and were ordered to pay over \$800,000 in restitution for a conviction on one count of conspiracy to commit health care fraud. They were also permanently excluded from the program. Another owner also received the same sentence in August 2012, and a marketer for the company received a 27 month sentence. The owners of Alliance and the marketer sought out Medicare beneficiaries for home health care, regardless of homebound status and paid the beneficiaries \$100 each month to use Alliance services.
- In July 2013, a New Jersey physician and the founder and owner of Visiting Physicians of South Jersey, a provider of home-based physician services for seniors, was sentenced to 24 months in prison and ordered to pay more than \$1 million in restitution and forfeiture for charging Medicare for lengthy visits that her elderly patients did not receive. The physician admitted to lying in Medicare billings about the amount of face-to-face time she spent with her elderly and disabled patients, which led to her receiving at least \$511,068 in criminal profits. The physician was, for the period January 1, 2008 through October 14, 2011, the highest billing home health care provider of all of the 24,000 doctors in New Jersey.
- In April and June 2013, respectively, a Florida woman and a registered nurse were sentenced after pleading guilty to conspiring to pay and receive illegal health care kickbacks and paying kickbacks in connection with the a home health agency they operated. The woman was sentenced to 70 months imprisonment and ordered to pay more than \$5 million in restitution, jointly and severally. The registered nurse was sentenced to 97 months imprisonment and ordered to pay more than \$22,000 in restitution, jointly and severally. According to court documents, the defendants paid kickbacks to patient recruiters to obtain Medicare beneficiaries to serve as patients of a home health agency they operated. The defendants also paid bribes to doctors who prescribed the home health services for the beneficiaries. In a little more than two years of operation, Medicare paid the defendant's home health agency more than \$11 million dollars, most of which was tied to kickbacks. In addition to these two defendants, seven patient recruiters were convicted in this indictment.
- In August 2013, the owner of a network of Michigan health care companies was sentenced to 4 years in prison, paid a \$1 million civil FCA settlement, and agreed to a 20-year exclusion from federal health care programs in connection with pervasive kickback and upcoding schemes at his physical therapy clinics, medical offices, and home health care agency. This sentence followed the convictions and sentencings of eight other individuals: two physicians, three physician assistants, two practice administrators, and a biller, who participated in these schemes. According to court documents in the criminal case and a parallel civil case against 25 defendants, the defendants paid or received illegal kickbacks in exchange for referring Medicare and Medicaid patients for physical therapy,

electrodiagnostic testing, and home health care services. The illegal payments were made in cash and checks disguised as bonuses, mileage reimbursements, and payments for medical director and consulting services that were never performed. At least one of the affiliated health care companies also allegedly engaged in upcoding by fraudulently billing for high-level office visits, among other things. To date, the Government has obtained over 7 years in total prison sentences in these cases, collected \$1.1 million in related civil settlements, and OIG has imposed 40 years in total exclusions from federal health care programs.

- In July 2013, the president of a D.C.-based home health care provider was sentenced to 8 months incarceration, to be followed by 4 months home detention, after pleading guilty to one count of falsification of records in connection with an HHS audit. The defendant's company, which provided home healthcare services, was asked by auditors to produce plans of care for 62 patients who had received home health care services from her company. In total, Medicare and D.C. Medicaid had paid nearly \$1.9 million in federal funds to the defendant's company for the services these patients had already supposedly been provided. The company lacked the requisite plans of care for these individuals. Rather than admitting that the company lacked the necessary documentation, the defendant and employees of the company devised and implemented a plan to fabricate the plans of care. After creating plans of care for the patients who had already received this nearly \$1.9 million in services, the defendant and others had a doctor sign the plans and then the documents were backdated to dates prior to the services. This doctor, who was the medical director, was sentenced to two years of probation after pleading guilty to one count of making a false writing in connection with this audit.

Other Medicare/Medicaid Matters

- In December 2012, Orthofix, Inc. pled guilty to a one count felony information charging obstruction of a health care audit. In addition, the company agreed to a \$42 million civil and criminal global resolution in connection with a number of practices, including falsification of certificates of medical necessity and kickbacks. The case also resulted in a number of criminal convictions of Orthofix employees, six of whom were sentenced or charged during FY 2013, including three Territory Managers, a Vice President of Sales, and a Regional Manager. A Virginia physician was also indicted in June 2013 for making false declarations to a grand jury in Boston. Her trial has not yet been scheduled.
- In January 2013, American Sleep Medicine LLC paid \$15.3 million to resolve FCA allegations that it billed Medicare, TRICARE, and the Railroad Retirement Medicare Program for sleep diagnostic services that were not eligible for payment. In particular, the government alleged that although federal regulations require that initial sleep studies must be conducted by technicians who are licensed or certified by a state or national credentialing body as sleep test technicians, American Sleep submitted claims for diagnostic testing services that were performed by technicians who lacked the required credentials or certifications.

- In April 2013, the California Rural Indian Health Board Inc., a nontribal entity and grantee of the HHS Substance Abuse and Mental Health Services Administration, agreed to a settlement worth over \$5.1 million to resolve an FCA lawsuit filed by the United States. The lawsuit involved the entity's administration of a grant to provide services to Native American tribes. The United States alleged that the entity eliminated the substance abuse screening and assessment required of certain program applicants, and instructed the service providers to pay for prohibited expenses with the federal grant funds. The entity agreed to pay \$532,000 and relinquish federal grant funds valued at over \$4.6 million.
- In December 2013, two Regional Vice-Presidents employed with Humana Inc. will be sentenced for their roles in a kickback scheme involving Humana's Medicare Advantage and prescription drug plan. As a result of their conduct, each received a kickback payment of approximately \$2 million dollars. The two defendants entered guilty pleas to violation of the Travel Act and the state commercial bribery statute in January and February 2013, respectively. Each defendant has been ordered to pay \$100,000 in restitution to Humana and \$900,000 in forfeiture.
- In January 2013, a California university paid \$925,000 to resolve allegations that its medical center sought Medicare reimbursement for liver transplants and related services when its liver transplant program failed to comply with federal requirements regarding surgeon staffing.

Hospice Providers

- In March 2013, Hospice of Arizona L.C., along with a related entity, American Hospice Management LLC, and their parent corporation, American Hospice Management Holdings LLC, paid \$12 million to resolve FCA allegations that they submitted or caused the submission of false claims to the Medicare program for ineligible hospice services. In particular, the government alleged that Hospice of Arizona and its related entities engaged in certain practices that resulted in the admission of ineligible patients or inflated bills, including pressuring staff to find more patients eligible for Medicare, adopting procedures that delayed and discouraged staff from discharging patients from hospice when they were no longer appropriate for such services, and not implementing an adequate compliance program that might have addressed these problems. As part of the settlement, American Hospice Management Holdings has agreed to enter into a CIA with HHS-OIG.

Other Schemes

- In November 2012, a Washington, D.C., woman was sentenced to 6 years and 3 months of incarceration and ordered to pay \$3.1 million in restitution after being convicted of charges related to health care fraud. According to the indictment, the woman was part owner and chief executive officer of the Health Advocacy Center, Inc. (HAC), which purportedly was an advocate for improving health care delivery to the community. She was also the owner of Sheridan Rehabilitative and Wellness Centers, Inc., which purportedly provided rehabilitative services to the mentally and physically disabled

community. Around October 2002, HAC entered into an agreement with DC Medicaid to provide health care services to District of Columbia Medicaid beneficiaries. The woman's employees transported many of these patients to HAC, where they often slept, watched television, and occasionally received drug and alcohol counseling. From these visits, the woman submitted more than \$6 million in claims to DC Medicaid for manual therapy services, despite the fact that: 1) she did not maintain progress notes and related documentation for the purported manual therapy and other services, 2) she frequently billed for services for which HAC lacked the medical equipment to perform, and 3) she frequently billed for more than 24-hours of services for a single patient in a given day.

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 2013, the Secretary and the Attorney General jointly allotted \$197 million to HHS/OIG. Additionally, Congress appropriated \$30 million in discretionary funding for HHS/OIG HCFAC activities. Of these amounts, over \$11 million was sequestered in FY 2013 and thus unavailable to OIG to fight fraud and abuse in Medicare and Medicaid.

In FY 2013, HHS/OIG investigations resulted in 849 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid; and 458 civil actions, which include false claims and unjust-enrichment lawsuits filed in Federal district court, civil monetary penalties (CMP) settlements, and administrative recoveries related to provider self-disclosure matters. In addition, during FY 2013, HHS/OIG excluded a total of 3,214 individuals and entities, the details of which are below.

In FY 2013, 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, South Louisiana, 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. For FY 2013, potential savings from legislative and administrative actions that were

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.

supported by HHS/OIG recommendations were estimated by third parties, such as the Congressional Budget Office or actuaries within HHS, to be \$19.4 billion – \$18.54 billion in Medicare savings and \$834 million in savings to the Federal share of Medicaid.

Additional information about savings achieved through such policy and procedural changes may be found in the HHS/OIG fall Semiannual Report to Congress, 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 2013, HHS/OIG excluded a total of 3,214 individuals and entities. Among these were exclusions based on criminal convictions for crimes related to Medicare and Medicaid (1,132) or to other health care programs (311); for patient abuse or neglect (180); or as a result of licensure revocations (1,324). 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 2013. Exclusion actions by HHS/OIG included:

- Florida – In February 2013, the owner and operator of a pain clinic, was excluded for a minimum period of 50 years based on his conviction for conspiracy to possess with intent to distribute oxycodone and oxymorphone and conspiracy to commit health care fraud. From November 2007 to about September 2011, he owned and operated the pain clinic for the purpose of obtaining false prescriptions for these drugs for beneficiaries of the Medicare, Medicaid, and private insurance plans and he would offer inducements to beneficiary recruiters so they would bring beneficiaries to his pain clinic. The court sentenced the owner/operator to more than 16 years of incarceration and ordered him to pay \$15 million in restitution.
- Pennsylvania – In January 2013, an osteopath was excluded for a minimum period of 20 years based on his drug trafficking conviction. Between September 2000 and March 2010, the osteopath and others distributed controlled substance prescription diet drugs outside of professional practice. This included more than 1.5 million doses of a substance that contained phendimetrazine and more than 2.5 million doses of a substance that contained phentermine. The court sentenced him to 2 years and 10 months of incarceration. The Pennsylvania State Board of Osteopathic Medicine revoked his license to practice.
- Kansas – In December 2012, a licensed practical nurse was excluded for a minimum period of 10 years based on her conviction on charges of consumer product tampering and adulteration of a drug. During the course of her employment, the nurse would steal morphine from a particular patient at the facility where she worked. To conceal her behavior, she added tap water to the patient's medication bottle and then placed the bottle back on the medication cart to dispense to the patient. The court sentenced her to 3 years of incarceration. In addition, the Kansas State Board of Nursing permanently revoked her license to practice nursing.

- Florida – In August 2013, a chiropractor, was excluded for a minimum period of 40 years based on his convictions for health care fraud, conspiracy to illegally distribute and dispense and cause to be distributed and dispensed schedule III and IV controlled substances, and aiding and abetting transactional money laundering. The chiropractor billed and caused bills to be sent to Medicare, Medicaid, and private insurers for services that were rendered by him or his staff as though they were medical doctors. In actuality, he used the name of a medical doctor to fraudulently bill for services that were never performed or provided by the medical doctor. In addition, he used the names and DEA numbers of medical doctors to illegally prescribe controlled substances to patients with no legitimate doctor-patient relationship. As a result of these crimes, the chiropractor was sentenced to 15 years and 8 months of incarceration and ordered to pay more than \$2 million in restitution. The Florida Board of Chiropractic Medicine ordered the voluntary relinquishment of his license to practice.
- Louisiana – In August 2013, an individual who was the owner, manager, and technician of several medical clinics was excluded for a minimum period of 25 years based on his conviction. The owner and his co-conspirators were involved in a scheme to defraud Medicare and Medicaid through fraudulent billing for diagnostic tests that were not medically necessary or not performed. Based on this scheme, he was convicted on charges of conspiracy to commit health care fraud and conspiracy to commit money laundering and was sentenced to 4 years and 1 month of incarceration and ordered to pay more than \$6 million in restitution, joint and several. The owner was also excluded from participation in Medicaid by the Louisiana Department of Health and Hospitals.
- Kentucky – In August 2013, a registered nurse was excluded for a minimum period of 20 years based on her reckless homicide conviction. The nurse entered the room of a patient with a cigarette lighter, which started a fire on the patient's bedding. Because he was in a complete vegetative state, the patient was unable to escape and he died as a result. The court sentenced the nurse to 5 years of incarceration. In addition, the Kentucky State Board of Nursing revoked her license to practice.
- Florida – In August 2013, a medical doctor was excluded for a minimum period of 10 years based on his conviction for conspiracy to knowingly and willfully dispense and cause to be dispensed schedule IV controlled substances. From about January 2004 to about February 2008, the doctor conspired with others to dispense controlled substances that involved a mixture and substance containing methadone. Investigators believe that the use of these substances resulted in one or more deaths. The doctor was sentenced to 12 months of incarceration followed by 12 months of home detention.

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 proscribed in statute. HHS/OIG has continued to pursue its affirmative enforcement actions under these authorities. Examples

include:

- South Carolina – In January 2013, Heritage Medical Partners agreed to pay \$170,260 to resolve allegations that, from April 2008 through December 2008, Heritage violated the CMP Law by requesting that its 5,474 patients who were Medicare beneficiaries pay a \$50 administrative fee. Heritage told these Medicare beneficiaries that “the Federal Government (Medicare) continue[s] to increase the amount of paperwork we’re required to fill out to assure you receive the benefits to which you’re entitled” and that Heritage instituted the fee as partial compensation for the time the “physician and staff spend assuring [patients] receive prescription renewals quickly [and] maximum benefits from Medicare. . .” HHS/OIG alleged that a portion of the \$50 constituted payment for Medicare services that are covered and reimbursed by Medicare and constituted a request for payment other than copayments or coinsurance, which violated Medicare assignment regulations. Heritage agreed to return the money it collected to patients and pay a penalty to HHS/OIG.
- Illinois – In November 2012, ForTec Medical, Inc.; ForTec Litho, LLC; ForTec Litho Florida, LLC; ForTec Litho Central, LLC; and ForTec Litho NY, LLC (collectively, ForTec), agreed to pay \$126,249 to resolve their liability under the CMPL for offering remuneration in exchange for referrals. From 2006 through 2011, ForTec allegedly provided customers, including physicians, with an all-expense paid trip to the Masters Golf Tournament in Augusta, Georgia. Invitations to these trips were extended to physicians based on their use of ForTec’s products and services and the potential for additional business from those physicians.
- New Mexico – In December 2012, University of New Mexico Hospital (UNMH) agreed to pay \$30,000 to resolve its liability under the patient dumping statute. UNMH allegedly failed to provide an adequate medical screening examination and failed to stabilize a suicidal patient when it did not prevent the suicidal patient from hanging himself in the hospital. The patient came to the emergency room experiencing suicidal ideations and was placed in an observation room, but he was not provided a medical screening examination for 7 hours. During this time, the patient used his shoelaces to hang himself from an air vent in the observation room. The patient was found still alive by a security employee. UNMH then treated and admitted the patient. UNMH self-reported the incident to the State.
- Illinois – In October 2012, University of Chicago Medical Center (UCMC) agreed to pay \$50,000 to resolve its liability under the patient dumping statute. UCMC allegedly failed to provide appropriate medical screening and stabilizing treatment within its capabilities to a male patient who arrived at their emergency department complaining of severe jaw pain as a result of a physical assault. The results of a CT scan taken by UCMC revealed injuries that he needed corrective surgery. However, UCMC did not provide further treatment and discharged the patient with instructions to go to another hospital for further care.
- Massachusetts – In May 2013, Trustees of Tufts College and Tufts University School of Dental Medicine (TUSDM) agreed to pay \$841,120 for allegedly violating the CMP Law. TUSDM submitted claims to Medicare for various services from four of their clinics. However, HHS/OIG alleged that these claims were improper because the services were

provided by dentists who were not credentialed by Medicare or the services were not supported by sufficient medical record documentation.

- Georgia – In May 2013, C.F. Health Management, Inc., d/b/a Gainesville Pain Management (GPM), and its physician agreed to pay \$1.5 million for allegedly violating the Civil Monetary Penalties Law. HHS/OIG alleged that GPM submitted false or fraudulent claims by: (1) inappropriately using certain modifiers to submit claims for payment for multiple units when only a single unit may be billed per patient encounter, and (2) inappropriately billing for certain services when less expensive services were actually provided.
- Pennsylvania – In July 2013, Bravo Health Pennsylvania, Inc. (Bravo), agreed to pay \$225,000 to resolve its liability under the CMP provisions applicable to a Medicare Advantage organization. HHS/OIG alleged that patient medical records Bravo provided to HHS/OIG were intentionally altered prior to their submission or resubmission. Specifically, Bravo allegedly added apparent diagnoses notations or signatures to the patient medical records.

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, return misspent funds and prevent future wasteful or improper payments. Among those completed in FY 2013 were:

Preventing and Detecting Medicaid Fraud

Medicaid Fraud Control Units (MFCU) are key partners in the fight against fraud, waste, and abuse in State Medicaid programs. HHS/OIG is responsible for overseeing MFCUs' activities. As part of this oversight, HHS/OIG conducts periodic reviews of all Units and prepares public reports based on these reviews.

- HHS/OIG found that from FYs 2009 to 2011, the New Hampshire Unit reported recoveries of \$14 million, filed criminal charges against 25 defendants, and obtained 15 convictions. The overall number of cases opened and closed by the Unit decreased. The Unit attributed the overall decrease primarily to staffing limitations; for all 3 years, the Unit's staffing levels were below the number of staff that the Unit requested and HHS/OIG approved. Additionally, although the Unit reported that its best source of fraud referrals was the State's Surveillance and Utilization Review Subsystem (SURS), the Unit noted that the number of referrals from SURS was low. HHS/OIG recommended that the New Hampshire Unit seek to expand staff sizes to reflect the number of staff approved in the Unit's budget, ensure that it maintains an adequate workload through referrals from SURS, ensure that case files contain documented supervisory reviews, and establish annual training plans for each professional discipline.

- HHS/OIG found that from FYs 2009 through 2011, the Louisiana Unit reported recoveries of \$95 million, obtained 192 convictions and 86 civil judgments or settlements, and received 1,043 referrals. Provider fraud referrals to the Unit increased, and the Unit received patient abuse and neglect referrals from a variety of sources. In addition, HHS/OIG found that the Unit had not updated its memorandum of understanding (MOU) with the Louisiana Department of Health and Hospitals (DHH) to reflect current law and practice. HHS/OIG recommended, among other things, that the Louisiana Unit revise its MOU with DHH to reflect current law and practice.
- HHS/OIG's analysis of collected data from FYs 2008 through 2010 shows that the South Carolina Unit's caseload increased by 65 percent and that the amount of funds the Unit recovered nearly doubled, from \$15.3 million in FY 2008 to \$30.3 million in FY 2010. In addition, HHS/OIG found that the Unit did not report program income properly in FY 2010. HHS/OIG recommended, among other things, that the Unit ensure that program income is reported properly.

Medicaid Payments to Excluded Providers

- HHS/OIG found that California made unallowable Medicaid payments of \$1.9 million (\$1.2 million Federal share) for items and services furnished, ordered, or prescribed by excluded providers. Although the amount of unallowable payments is small when compared with the \$31.5 billion in claims paid by the State agency, no Medicaid payments may be made for items or services furnished, ordered, or prescribed by excluded providers. In addition, HHS/OIG set aside for resolution by CMS \$1.1 million (\$699,000 Federal share) paid by the State for additional items or services that may have been furnished, ordered, or prescribed by providers whose exclusion status could not be verified. HHS/OIG recommended, among other things, that California refund \$1.2 million to the Federal Government for unallowable Medicaid payments and work with CMS to resolve the \$699,000 set aside.

Medicaid Data for Program Integrity

- HHS/OIG conducted a review to determine the status of national Transformed Medicaid Statistical Information System (T-MSIS) implementation. T-MSIS is designed to be a detailed national database of Medicaid and Children's Health Insurance Program information to cover a broad range of user needs, including program integrity. HHS/OIG found that overall, as of January 2013, CMS and the 12 volunteer States had made some progress in implementing T-MSIS. However, most other States had not started implementing T-MSIS, and they reported varied timeframes for when they plan to begin. Further, early T-MSIS implementation outcomes raised questions about the completeness and accuracy of T-MSIS data upon national implementation. HHS/OIG recommended that CMS establish a deadline for when national T-MSIS data will be available; ensure that States submit required T-MSIS data; and ensure that T-MSIS data are complete, accurate, and timely upon T-MSIS implementation.

Medicaid Disproportionate Share Hospital Payments

- HHS/OIG found that New Jersey claimed Disproportionate Share Hospital (DSH) payments of about \$100 million (\$50 million Federal share) for five hospitals that did not meet Federal requirements for DSH payments during our audit period. Specifically, for the five hospitals, New Jersey calculated a Medicaid Inpatient Utilization Rate (MIUR) of less than 1 percent during one or more State fiscal years but claimed DSH payments for the hospitals because it misinterpreted Federal regulations on DSH eligibility. Under the Medicaid DSH program, a State is required to make DSH payments to hospitals that serve a disproportionate share of low-income and/or uninsured patients. For a hospital to receive DSH payments, the State must classify the hospital as a DSH. A State may not define or deem a hospital as a DSH unless the hospital has a MIUR of not less than 1 percent. HHS/OIG recommended that New Jersey refund \$50 million to the Federal Government and ensure that all hospitals designated as DSHs meet Federal eligibility requirements for DSH payments.

Medicaid Inpatient Psychiatric Services

- HHS/OIG found that Indiana claimed Federal reimbursement for Medicaid inpatient psychiatric service payments made to Logansport State Hospital (Logansport) that were not in accordance with Federal requirements for inpatient psychiatric hospital services. For States to claim Federal reimbursement for such payments, the hospital's inpatient services must demonstrate compliance with the basic Medicare Conditions of Participation (CoPs) generally applicable to all hospitals and two special Medicare CoPs applicable to psychiatric hospitals. Logansport did not demonstrate compliance with the special Medicare CoPs at any time during the audit period. Therefore, none of the Federal reimbursement for Medicaid inpatient psychiatric service payments made to Logansport for claims with dates of service during the audit period was allowable. HHS/OIG recommended, among other things, that Indiana refund \$5.8 million to the Federal Government.

Medicaid Payments for Personal Care Services

- HHS/OIG's first OIG Portfolio synthesized an array of audit and evaluation work addressing improper payments for personal care services (PCS). Eligible beneficiaries can receive PCS under Medicaid State plan options or waivers. PCS must be provided at home or another approved location, must follow a specific plan of care, and are typically performed by care attendants. In the past 6 years, Medicaid costs for such services increased by 35 percent, totaling approximately \$12.7 billion in 2011. In the same period, HHS/OIG issued 23 reports on PCS and conducted numerous investigations involving related fraud. Based on this global look at the body of HHS/OIG work on PCS, HHS/OIG recommended, among other things, that CMS issue guidance to States regarding adequate prepayment controls and provide States with the data they need to identify overpayments.

Medicaid Home Health Services

- HHS/OIG found that New York claimed Federal Medicaid reimbursement for home health services claims submitted by Certified Home Health Agencies (CHHAs) in New York City that were not in accordance with Federal and State requirements. Specifically, for 17 claims, the plan of care was not reviewed every 60 days, and for 1 claim, the provider was unable to document that the service was provided. Pursuant to Federal regulations, home health services are provided to a beneficiary at the beneficiary's place of residence and on his or her physician's orders as part of a written plan of care that the physician reviews every 60 days. On the basis of our sample results, HHS/OIG estimated that the State improperly claimed \$69.1 million in Federal Medicaid reimbursement during our January 1, 2007, through December 31, 2009, audit period. HHS/OIG recommended that New York should refund \$69.1 million to the Federal Government and issue guidance to CHHAs in New York City on Federal and State requirements for physicians' orders and plans of care.

Medicaid Family-Based Treatment Rehabilitation Services

- HHS/OIG found that New York improperly claimed a Federal share of family-based treatment (FBT) rehabilitation services that did not meet Federal and State requirements. FBT rehabilitation services include training and assistance with daily living skills, medication management, socialization, counseling, family support, and health services. Of the 100 claims in our random sample, 84 did not comply and 58 contained more than 1 deficiency. These deficiencies occurred because providers did not fully comply with State regulations, authorizing physicians were not familiar with applicable State regulations and program requirements, and the State did not adequately monitor the program. HHS/OIG recommended, among other things, that New York should refund \$27.5 million to the Federal Government.

Medicaid Family Planning Services

The Federal Government pays its share of a State's medical assistance expenditures under Medicaid on the basis of the Federal medical assistance percentage, which varies depending on the State's relative per capita income. Family planning services are reimbursed at an enhanced 90-percent rate. Family planning services are those that prevent or delay pregnancy or otherwise control family size. Following are the results of family planning services reviews in Arkansas and California.

- HHS/OIG found that Arkansas claimed expenditures that did not qualify for the 90-percent rate for family planning. The expenditures exceeded limits specified in the State's infant delivery allocation methodology and resulted from errors in compiling the family planning expenditures and from errors in the computer programming used to identify infant delivery costs. HHS/OIG recommended, among other things, that Arkansas refund to the Federal Government \$1.9 million in family planning Federal share and work with CMS to determine the allowable portion of \$929,000 in family planning Federal share that it received for allocated sterilization costs.

- HHS/OIG found that California did not always comply with Federal and State requirements when claiming Federal reimbursement at the 90-percent rate for family planning services. The rate was unallowable because the primary purpose of the visits was not family planning, the visits were for follow-up properly reimbursed at the regular rate, or the supporting documentation was insufficient. HHS/OIG also found claims that contained either no procedure code or a procedure code that was not approved by CMS for reimbursement at the 90-percent rate. HHS/OIG recommended, among other things, that California refund \$5.7 million to the Federal Government.

Medicaid School-Based Services

- HHS/OIG found that New Hampshire did not always claim Federal Medicaid reimbursement for school-based transportation services submitted by schools in accordance with Federal and State requirements during calendar years 2006 through 2009. Of the 115 items in a random sample, 78 items had 1 or more transportation services that were not reimbursable. The deficiencies occurred because New Hampshire issued incorrect guidance to the school administrative units (SAUs). In addition, the State did not adequately monitor the claims for Medicaid school-based transportation services submitted by SAUs. HHS/OIG recommended, among other things, that the State refund an estimated \$2.7 million to the Federal Government.
- HHS/OIG found that Arizona did not always maintain required documentation to support the random moment time study (RMTS) methodology used to allocate school-based administrative costs to Medicaid and the RMTS methodology was not fully consistent with Federal requirements. Federal law provides for States to be reimbursed at a 50 percent matching rate for administrative activities that directly support identifying and enrolling potentially eligible children in Medicaid. HHS/OIG recommended, among other things, that the State refund to the Federal Government \$11.7 million for unallowable school-based administrative costs and work with CMS to determine the allowability of \$18.8 million that we set aside for further analysis.

Medicaid Overpayments

- HHS/OIG found that as of December 2012, CMS reported collecting \$987.5 million of the \$1.2 billion in Medicaid overpayments that it had sustained in the 147 audit reports issued by OIG between fiscal years 2000 and 2009. However, CMS had not collected the remaining \$225.6 million. The uncollected amount related to overpayments that OIG had identified in 10 audit reports that the States had not agreed to refund. In addition, CMS could not document that \$7.2 million that it reported as collected had been collected. HHS/OIG recommended, among other things, that CMS collect the remaining \$225.6 million that is due to the Federal government.

Detecting Fraud in Medicare

- HHS/OIG found deficiencies in CMS's and its contractors' ability to identify and respond to potential fraud by home health agencies. The two CMS Medicare Administrative Contractors (MACs) in this review prevented \$275 million in HHA improper payments and referred several instances of potential fraud, but the four Zone Program Integrity Contractors (ZPICs) we reviewed did not identify any HHA-specific vulnerabilities and varied substantially in their efforts to detect and deter fraud. Two of the ZPICs recommended administrative actions and referred law enforcement cases for approximately eight times the number of HHAs as the other two. All four ZPICs served fraud-prone geographic areas. In addition, Medicare inappropriately paid five HHAs with suspended or revoked billing privileges. HHS/OIG recommended, among other things, that CMS establish additional contractor performance standards for high-risk providers in fraud-prone areas (including newly enrolled HHAs).
- One of nine MACs reviewed by HHS/OIG performed activities to detect and deter fraud by community mental health centers in 2010, and most of the activities were part of a CMS-led special project. Activities to detect and deter CMHC fraud varied substantially among ZPICs in 2010; one ZPIC performed almost all such activities, most of which were part of the same CMS-led special project. Other MACs and ZPICs performed minimal activities to detect and deter fraudulent CMHC billing, despite having jurisdiction over fraud-prone areas. Also, Medicare paid CMHCs that did not comply with its requirements after their revocations were effective and while their revocations were being approved. HHS/OIG recommended, among other things, that CMS implement additional CMHC fraud mitigation activities in all fraud-prone areas.
- CMS developed a Fraud Prevention System which uses predictive analytics to provide leads to its benefit integrity contractors for investigation. HHS/OIG found that in the first year of implementation, HHS did not fully meet the requirements for reporting actual and projected improper payments recovered and avoided in the Medicare fee-for-service program and reporting HHS's return on investment related to its use of such technologies. HHS did not report some of the amounts required by statute and had inconsistencies in its data; in addition, its methodology for calculating other reported amounts included some invalid assumptions that may have affected the accuracy of those amounts. HHS/OIG's recommendations included that HHS should require contractors to track recoveries that result from Fraud Prevention System leads and that HHS revise its methodologies to calculate projected savings and costs avoided.
- Recovery Audit Contractors (RAC) are designed to protect Medicare by identifying improper payments and referring potential fraud to CMS. HHS/OIG found that in FYs 2010 and 2011, RACs identified half of all claims they reviewed as having resulted in improper payments totaling \$1.3 billion. CMS took corrective actions to address the majority of vulnerabilities it identified in FYs 2010 and 2011; however, it did not evaluate the effectiveness of these actions. As a result, high amounts of improper payments may continue. Additionally, CMS did not take action to address the six referrals of potential fraud that it received from RACs. Finally, CMS's performance evaluations did not include metrics to evaluate RACs'

performance on all contract requirements. HHS/OIG recommended, among other things, that CMS take action, as appropriate, on vulnerabilities that are pending corrective action and evaluate the effectiveness of implemented corrective actions and ensure that RACs refer all appropriate cases of potential fraud.

Theft of Medicare Identities

- HHS/OIG's review of CMS's response to known breaches of protected health information and to medical identity theft involving Medicare identification numbers revealed opportunities for improvement. Although CMS notified Medicare beneficiaries affected by known breaches, HHS/OIG found that several requirements were not met. CMS has made progress in responding to medical identity theft by developing a compromised number database for contractors, but the database's usefulness could be improved. Further, Medicare's contractors do not consistently develop edits to stop payments on compromised numbers. HHS/OIG recommended, among other things, that CMS ensure that breach notifications meet statutory requirements, and improve the compromised number database.

Part C and Part D Program Integrity Activities

- HHS/OIG's review of the Medicare Drug Integrity Contractor (MEDIC) that has responsibility for preventing fraud, waste, and abuse in both Medicare Part C and Part D revealed that its Part C investigations and case referrals represented only a small percentage of its benefit integrity activities. HHS/OIG identified several problems hindering the MEDIC's ability to identify and investigate fraud and abuse in Part C and Part D. HHS/OIG recommendations included that CMS amend its regulations to require Part C and Part D plan sponsors to refer potential fraud and abuse incidents to the MEDIC and authorize the MEDIC to directly obtain information from entities such as pharmacies, physicians, and pharmacy benefit managers.

Payments for Individuals Ineligible for Medicare

HHS/OIG audited Medicare payments made for patients who were not lawfully present in the United States or were incarcerated. Unlawful presence occurs when a non-U.S. citizen remains in the United States longer than the time authorized by U.S. immigration agencies. Incarcerated patients are people who are under arrest, are imprisoned, reside in a halfway house, or are required to live under home detention. Medicare does not make payments for the care of unlawfully present patients and generally does not pay for incarcerated patients.

- HHS/OIG found that CMS's controls were not adequate to ensure that all improper payments for services to unlawfully present beneficiaries were detected and recouped. Also, when CMS received untimely information indicating that the unlawful presence overlapped with the dates of service on previously paid Medicare claims, CMS did not notify Medicare's contractors of this updated information. HHS/OIG recommended, among other things, that CMS ensure that Medicare contractors recoup the \$91.6 million in improper payments and that CMS implement administrative policies and procedures to detect and recoup improper payments

made for Medicare services when information relating to the unlawful presence is received on previously paid Medicare claims.

- HHS/OIG found that CMS's controls were not adequate to ensure that all improper payments for services to incarcerated beneficiaries were detected and recouped and that CMS does not always receive timely updates regarding incarceration information before Medicare contractors pay providers on behalf of incarcerated beneficiaries. In addition, when CMS's data systems did not indicate until after a claim had been processed that a beneficiary was incarcerated; CMS's controls were not adequate to identify and recoup the improper payments. HHS/OIG recommended that CMS ensure that Medicare contractors recoup the \$33.6 million in improper payments and that CMS implement administrative policies and procedures to detect and recoup improper payments when incarceration information is received on previously paid Medicare claims.

Medicare Payment for Cancelled Surgeries

- HHS/OIG estimated that, on the basis of sample results, Medicare made \$38.2 million in Part A inpatient hospital payments in calendar years 2009 and 2010 for short-stay, canceled elective surgery admissions that were not reasonable and necessary. For 80 of the 100 claims in the sample, Medicare made payments totaling \$346,000 for hospital inpatient claims involving canceled elective surgeries when a clinical condition did not exist on admission or a new condition did not emerge after admission that required inpatient care. Therefore, these inpatient claims did not satisfy Medicare's requirements that the admissions be reasonable and necessary. HHS/OIG's recommendations included that CMS adjust the 80 sampled claims representing overpayments of \$346,000 to the extent allowed under the law and strengthen guidance to better explain the Medicare rule that a clinical condition requiring inpatient care must exist for hospitals to bill for Part A prospective payments for elective surgeries that were canceled.

Medicare Medical Equipment and Supplies

- HHS/OIG found that two years after the surety bond requirement for medical equipment suppliers was implemented, CMS did not have accurate surety bond information for all suppliers. Information for thousands of bonded suppliers was missing, and surety bond amounts were not consistently maintained by supplier location. CMS can only collect \$50,000 per bonded supplier, so it is unlikely going to be able to reconcile surety bond collections with the tens of millions of dollars in overpayments owed by suppliers. HHS/OIG recommended, among other things, that CMS improve oversight of supplier data to ensure accurate and consistent information and immediately begin using the surety bond requirement to recover outstanding overpayments.

Medicare Payments for Drugs

- Herceptin (Trastuzumab) is a Medicare-covered drug used to treat breast cancer that has spread to other parts of the body. HHS/OIG conducted six reviews of Medicare contractors'

payments for Herceptin and identified improper payments. HHS/OIG found that providers reported incorrect units of service on line items with unit counts that represented full multiuse vials, did not provide supporting documentation, billed for unallowable services, and reported a combination of incorrect units of service and incorrectly coded claims. The Medicare contractors made these incorrect payments because neither the Fiscal Intermediary Standard System nor the Common Working File had sufficient edits in place during our audit period to prevent or detect the overpayments. HHS/OIG recommended that the responsible Medicare contractors recover the identified overpayments, implement or update system edits that identify for review multiuse-vial drugs that are billed with units of service equivalent to the dosage on an entire vial(s), and use the results of the audits in provider education activities.

Medicare Skilled Nursing Facilities

Skilled nursing facilities (SNFs) are nursing homes that provide skilled care to Medicare patients. SNFs are required to evaluate each patient's needs and develop a care plan specifically for that patient. Care plans identify problems and set specific treatment goals.

- HHS/OIG found that Medicare paid approximately \$5.1 billion for stays in which SNFs did not meet quality-of-care requirements. In addition, HHS/OIG found that for 37 percent of stays, SNFs did not develop care plans that met requirements or did not provide services in accordance with care plans. For 31 percent of stays, SNFs did not meet discharge planning requirements. Additionally, reviewers found examples of poor quality care related to wound care, medication management, and therapy. HHS/OIG recommended, among other things, that CMS strengthen its regulations on care planning and discharge planning.
- HHS/OIG found that SNFs misreported information to Medicare; as a result, inappropriate payments were made. In addition, SNFs billed one-quarter of claims in error in 2009; the incorrect claims resulted in about \$1.5 billion in inappropriate Medicare payments. For 47 percent of claims, SNFs misreported information on the Minimum Data Set (MDS), the system used to classify beneficiaries into resource utilization groups (RUGs) for payment. Some SNFs incorrectly reported items such as therapy and activities of daily living, thereby placing beneficiaries into higher paying RUGs. HHS/OIG recommended, among other things, that CMS change the current methodology for determining how much therapy is needed to ensure appropriate payments.

Medicare Incentive Payments for Electronic Health Records

- To qualify for Medicare incentive payments for the use of electronic health records (EHRs), professionals and hospitals must possess certified EHR technology and meaningfully use that certified EHR technology in accordance with requirements defined by CMS. Professionals and hospitals self-report data to demonstrate that they meet program requirements. HHS/OIG found that CMS does not verify the accuracy of professionals' and hospitals' self-reported information prior to payment because data necessary for verifications are not readily available. CMS also does not direct high-risk professionals and hospitals to submit supporting documentation for prepayment review. HHS/OIG recommended, among other things, that

CMS obtain and review supporting documentation from selected professionals and hospitals before payment to verify the accuracy of their self-reported information.

Medicare Part C Capitation Payments

Under the Medicare Advantage (MA) program, CMS makes monthly capitated payments to MA organizations for beneficiaries enrolled in the organizations' health care plans. These payments are adjusted on the basis of the health status of each beneficiary. CMS uses a model to calculate these risk-adjusted payments. Under this model, MA organizations collect risk adjustment data, including beneficiary diagnoses, from hospitals and other providers. CMS uses the diagnosis data to calculate a risk score for each beneficiary, which is in turn used to adjust the monthly capitated payments to MA organizations. HHS/OIG conducted two audits to determine the accuracy of MA organizations' calculation of risk scores.

- HHS/OIG found that for CY 2007 Bravo Health Pennsylvania, Inc.'s, submissions of diagnoses did not always comply with Federal requirements. The risk scores calculated using the diagnoses that Bravo submitted for 35 of the 100 beneficiaries in the sample were valid. However, the risk scores for the remaining 65 beneficiaries were invalid because the diagnoses were not supported by adequate documentation. As a result, Bravo received \$422,409 in overpayments from CMS. On the basis of these sample results, HHS/OIG estimated that Bravo was overpaid approximately \$22.1 million in CY 2007. HHS/OIG recommended, among other things, that Bravo refund to the Federal Government \$422,409 in overpayments identified for the sampled beneficiaries and that Bravo work with CMS to determine the correct contract-level adjustment for the projected \$22.1 million of projected overpayments.
- HHS/OIG found that for CY 2007 CIGNA Healthcare of Arizona, Inc.'s, submissions of diagnoses did not always comply with Federal requirements. For 60 of the 100 beneficiaries in our sample, the risk scores calculated using the diagnoses that CIGNA submitted were valid. The risk scores for the remaining 40 beneficiaries were invalid because the diagnoses were not supported by adequate documentation. As a result, CIGNA received \$151,453 in overpayments from CMS. Based on these sample results, HHS/OIG estimated that CIGNA received approximately \$28.4 million in additional overpayments for CY 2007. HHS/OIG recommended, among other things, that CIGNA refund to the Federal Government \$151,453 in overpayments identified for the sampled beneficiaries and that Bravo work with CMS to determine the correct contract-level adjustment for the projected \$28.4 million of projected overpayments.

Medicare Part D Drugs

- HHS/OIG found that over 1 million individual prescribers ordered drugs paid by Part D in 2009. Prescribing patterns varied widely by specialty. Over 700 general-care physicians had questionable prescribing patterns. Each of these physicians prescribed extremely high amounts for at least one of five measures. For example, many of these physicians prescribed extremely high numbers of prescriptions per beneficiary, which may indicate that these

prescriptions are medically unnecessary. Moreover, more than half of the 736 general-care physicians with questionable prescribing patterns ordered extremely high percentages of Schedule II or III drugs, which have potential for addiction and abuse. Although some of this prescribing may be appropriate, such questionable patterns warrant further scrutiny. HHS/OIG recommended that CMS instruct the MEDIC to expand its analysis of prescribers, provide sponsors with additional guidance on monitoring prescribing patterns, provide education and training for prescribers, and follow up on prescribers with questionable prescribing patterns.

- HHS/OIG found that nationwide, Part D inappropriately paid for drugs ordered by individuals who clearly did not have the authority to prescribe, such as massage therapists, athletic trainers, home contractors, interpreters, and transportation companies. This raises concerns about the appropriateness of Part D payments and about patient safety. In 10 States, Part D also inappropriately paid for drugs ordered by other individuals without the authority to prescribe, such as counselors, social workers, and chiropractors. Tens of thousands of these drugs were controlled substances. These drugs are of particular concern because they have potential for abuse. HHS/OIG recommended that CMS require sponsors to verify that prescribers have the authority to prescribe drugs, increase the MEDICS's monitoring of prescribers, ensure that Medicare does not pay for prescriptions from individuals without prescribing authority, and follow up on the individuals without prescribing authority who ordered prescriptions.

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. Following six live presentations in FY 2011, HHS/OIG made available online the comprehensive training materials it developed to accompany HEAT PCT, together with sixteen video modules dividing the presentation by subject area. HEAT PCT continues to reach the health care community with HHS/OIG's message of compliance and prevention via these online offerings, which in FY 2012 expanded to include a series of twelve free, downloadable video and audio podcasts that summarize a range of compliance topics.

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 2013, the HHS/OIG, in consultation with DOJ, issued 23 advisory opinions, including two modifications of advisory opinions. A total of 299 advisory opinions have been issued during the 17 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 2013, HHS/OIG was monitoring compliance with 201 such agreements.

Centers for Medicare & Medicaid Services

In FY 2013, CMS was allocated approximately \$12.5 million by HHS, and appropriated \$237.3 million in discretionary funds by Congress to support its comprehensive program integrity strategy for Medicare, Medicaid and the Children's Health Insurance Program (CHIP). With these funds, CMS is working to ensure that public funds are not diverted from their intended purpose: to make accurate payments to legitimate entities for allowable services or activities on behalf of eligible beneficiaries of federal health care programs. CMS also performs 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 and 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.

Our approach is guided by four major principles that support the strategic goal of improving program integrity:

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

1. Prevention

Moratoria

Building on strong anti-fraud efforts already underway in the home health provider and ambulance supplier arenas, CMS in July 2013 announced the first use of its temporary moratoria authority granted by the Affordable Care Act. The moratoria stops the enrollment of new home health and ambulance enrollments in Medicare, Medicaid and the Children's Health Insurance Program (CHIP) in three fraud "hot spot" areas of the country with demonstrated oversupply of certain types of providers. The temporary enrollment moratoria apply to newly-enrolling home health agencies in the Miami and Chicago metropolitan areas; and newly-enrolling ground ambulance companies in the Houston metropolitan area.

The goal of the temporary moratoria is to fight fraud and safeguard taxpayer dollars, while ensuring patient access to care. Under the moratoria, existing providers and suppliers can continue to deliver and bill for services, but no new provider and supplier applications will be approved in these areas, allowing CMS and its law enforcement partners to remove bad actors from the program while blocking provider entry or re-entry into these already over-supplied markets. CMS is required to re-evaluate the need for such moratoria every six months.

One Program Integrity

In FY 2013, CMS continued making improvements and changes to 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 improves CMS' ability to detect fraud, waste, and abuse with consistent, reliable, and timely analytics.

One PI users have access to the CMS Integrated Data Repository (IDR) to perform data analytics. The IDR contains a comprehensive and accurate set of Medicare provider, beneficiary and claims data from Medicare Parts A, B, and D back to January 2006. The IDR includes claims data at three distinct points in the claim life-cycle: at the time the claims are enumerated, the time claims are adjudicated, and at the time the claims have payment data posted. This access allows users to perform pre-payment analytics on historical data and develop models that can be applied in CMS' predictive analytics system, the Fraud Prevention System. With claims available from 2006, ZPICs will also be able to improve their analytics for post-payment detection of fraud, waste, and abuse.

In order to streamline access for our law enforcement partners, CMS is transitioning STARS, a healthcare fraud, waste, and abuse analytics tool to the One PI suite tools in 2013. The One PI team is also replacing on-site instructor led training with virtual instructor led training to reduce training costs and provide better access to training for law enforcement

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 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 conducted several 3-day training sessions in FY 2013. CMS trained 100 individuals in FY 2013.

Compromised Number Checklist

Since January 2010, CMS has maintained a national database of compromised Medicare beneficiary and provider ID numbers called the Compromised Number Checklist (CNC). This database is populated by monthly submissions from CMS program integrity contractors. The purpose of the CNC is to share compromised ID numbers and any associated corrective actions that have been taken among CMS staff and contractors. CMS uses this national CNC database to enhance efforts to detect and prevent fraud and abuse in Medicare.

The compromised numbers list is updated on an ongoing, real-time basis by the PSCs/ZPICs and MEDIC.

The Command Center

CMS opened its state-of-the-art Command Center on July 31, 2012 to facilitate improvements in 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 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 is using the Command Center to collaborate in unprecedented ways with the private sector, law enforcement, and our State partners. The Command Center's advanced technologies and collaborative environment allow multi-disciplinary teams 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. These collaborative activities enable CMS to take administrative actions, such as revocations of Medicare billing privileges and payment suspensions, more quickly and efficiently.

In FY 2013, the Command Center conducted 93 missions that included participants from CMS and our partners, including the OIG and FBI, that are designed to 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 870 experts met since the opening of the Command Center representing policy analysts, investigators, lab modelers, FBI, OIG, ZPICS, field office staff, clinicians, Contracting Officer Representatives (CORs), and other CMS staff. CMS is also

working with other Federal agencies in the Command Center to pool resources to tackle cross-cutting issues surrounding fraud prevention.

DME Initiatives

DME suppliers pose a high risk of fraud to the Medicare Program and CMS has undertaken an aggressive strategy to address this risk. Through the DME Stop Gap Project, initiated in 2009, ZPICs/PSCs have increased site visits and interviews of DME suppliers, providers, and beneficiaries receiving DME products in high billing areas for DME supplies and products. In FY 2013, these additional funds supported DME investigations which included site visits to, and interviews of, suppliers, doctors and patients that were identified as potentially suspicious or high risk.

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. Implementation of the Transformed-Medicaid Statistical Information System (T-MSIS) by states will be on a rolling basis with a goal of all states submitting data by July 1, 2014. T-MSIS is an expansion of the existing CMS Medicaid Statistical Information System (MSIS) extract process. The new T-MSIS extract format is expected to further CMS and State’s goals for improved timeliness, reliability, and more robust data analysis process through monthly updates and an increase in the amount of data provided.

The accomplishments for FY 2013 include:

- MACBIS – Implement change control process for the MACBIS program, of which MACPro and T-MSIS are the two main projects within. The change control process coordinates and manages change across both projects which provide efficiencies and eliminates duplication.
- T-MSIS – Awarded the Baltimore Data Center and Virtual Data Center Contract which will provide the infrastructure to accept, validate and house T-MSIS data from states from a short term and long term perspective. Awarded the Development and Testing contracts that will develop and test the receipt and control of the submitted T-MSIS files, validation routines for ensuring data quality and storage capacity for the T-MSIS data. In addition, provided project management and technical assistance to states during the on-boarding process for migrating from MSIS to T-MSIS.
- MACPro – While MACPro is being designed and developed, we implemented an interim technology solution to support the data collection of Medicaid and CHIP and Alternative

Benefit Plan State Plan Amendments for meeting the October 1, 2013 Affordable Care Act mandates.

- Information Technology Support – Integrated MACBIS processes into CMS’s enterprise shared services efforts including, master data management, identity management, and portal development.

Outreach & Education Campaign

In FY 2013, CMS developed and implemented a multimedia outreach and education campaign. The campaign included national television, radio, print and outreach to specific ethnic communities where Medicare fraud is more prevalent. The advertising campaign ran from May 27 - August 11, 2013, resulted in-increased awareness of how to detect and report Medicare fraud.

2. Detection

Strengthened Program Integrity Activities in Medicare Advantage and Medicare Part D

In FY 2013, CMS enhanced its data analysis and improved coordination with law enforcement to get a more comprehensive view of activities in the Medicare Advantage (MA) and Prescription Drug (Part D) programs. All MA and Part D plan sponsors are required to have a comprehensive plan to detect, correct and prevent fraud, waste and abuse. This plan consists of written policies, procedures, and standards that articulate the organization’s commitment to comply with all applicable federal and state standards related to fraud and abuse. Sponsors must have a properly trained, effective compliance officer, and provisions for internal monitoring and auditing, as well as other requirements. These requirements help ensure that sponsors track and identify potential beneficiary or provider abuse. CMS issued Compliance Program Guidelines in Chapter 9 of the “Prescription Drug Benefit Manual” (PDBM) and Chapter 21 of the “Medicare Managed Care Manual” Both Chapters are identical, and apply equally to Medicare Advantage Plans and Prescription Drug Plans.

To combat fraud, waste and abuse more effectively, CMS evaluates sponsors operations to ensure that they are compliant with the regulations and guidance. CMS also contracts with a private organization, called the Medicare Drug Integrity Contractor (MEDIC), to assist CMS in managing audit, oversight and anti-fraud efforts. The MEDIC’s main functions include identifying and investigating potential fraud, and abuse, developing cases for referral to law enforcement agencies, acting as a liaison to law enforcement and collaborating with sponsors on the identification of potentially fraudulent schemes.

In FY 2013, CMS continued to invest HCFAC discretionary funds to strengthen Medicare Advantage (Part C) and Part D oversight, 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 beneficiaries and enforce Medicare's rules;
- Providing basic tips for beneficiaries 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 June 2013, the national benefit integrity MEDIC received on average approximately 532 actionable complaints per month; processed 35 requests for information from law enforcement per month; and referred an average of 34 cases to law enforcement per month. CMS also hosted quarterly workgroup meetings to promote information sharing on the latest fraud schemes. Representatives from sponsoring organizations, Pharmacy Benefit Managers, CMS, law enforcement, and CMS Program Integrity Contractors gather to share information and discuss current fraud trends and anti-fraud efforts.

In FY 2011, CMS established a contract for Medicare Part C and Part D outreach and education. This contractor is responsible for providing support in designing, developing and implementing compliance training, education and outreach for internal and external stakeholders, including plan sponsors. In addition, this contractor supports the development of tools, models and program best practices to share and communicate goals and expectations in order to reinforce CMS' approach to compliance and enforcement. CMS continued efforts to do this by successfully broadcasting the 2013 Medicare Advantage & Prescription Drug Plan Spring Conference using webcast technology. This conference provided guidance and real time information on significant topics such as benefits and formulary updates for 2014; Part C and Part D monitoring, as well as marketing, surveillance and compliance updates.

Since 2011, CMS has been taking steps to ensure that valid prescriber identifiers accompany Part D claims, and that the MEDIC and plan sponsors are monitoring pharmacy billing patterns. In 2011, to enhance then existing practice and in collaboration with the Drug Enforcement Administration (DEA), we directed Part D sponsors to ensure that the prescriber identifier submitted on a Prescription Drug Event (PDE) record was active and valid starting in the 2012 coverage year, whether it was a National Provider Identifier (NPI), DEA number, unique physician identifier number, or state license number. Additionally, we began validating the format of all prescriber identifiers on PDEs that were coded as an NPI and excluded from payment reconciliation PDEs with invalid NPIs. We began assessing each sponsor's performance regarding NPI use and validity and notified them of their performance. We also directed Part D sponsors to check that all prescriptions for controlled substances under Part D were associated with DEA numbers that indicated there was appropriate authority to prescribe the controlled substance.

Through rulemaking finalized in 2012, CMS required Part D sponsors to submit PDEs with active and valid individual prescriber NPIs, beginning January 1, 2013. CMS, through the annual Medicare "Dear Doctor" letter, explained the NPI requirement to prescribers. CMS began to deny any PDE without an active and valid NPI beginning on May 6, 2013. We have continued to assess each sponsor's performance regarding NPI use and validity of submitted NPIs and notified

sponsors of their performance in preparation for this deadline. Based on this assessment, we found that 99.6 percent of the 2013 PDEs received during the first quarter of the coverage year reported the prescriber's NPI; all but 0.002 percent of the reported NPIs were valid and currently active, or active within a year of the date of service. We also examined the taxonomy codes, which are self-reported by the providers to identify their specialty. We found 0.5 percent of these codes would be unreasonable for a prescriber. Based on a review of the PDEs reporting these unreasonable taxonomy codes, CMS determined that about 10.6 percent were for controlled substances. We further determined that all but 16.5 percent of these PDEs for controlled substance the prescriber in fact did have a valid DEA number.

These actions ensure improved sponsor compliance with PDE reporting requirements, enhance CMS's ability to review claims data to identify possible fraud and abuse, and help determine whether prescribers of controlled substances are writing prescriptions in accordance with their DEA registration.

Additionally, CMS is working to improve the data available for MA oversight. In January 2012, CMS required MA plan sponsors to begin submitting Part C data to its new Encounter Data System. This new requirement will enable the MEDIC to undertake future Part C projects once the Part C data is located in a central repository.

In addition to the work of the MEDICs, CMS enhanced other Part C and Part D oversight functions in FY 2013 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 2013, CMS conducted 30 program audits of sponsoring organizations and tested plan policies and procedures for compliance with program requirements in the following areas: Part D formulary and benefit administration, Part C and D organizational/coverage determinations, appeals, and grievances; outbound enrollment verification, special needs plans' models of care, and compliance program effectiveness. The organizations audited provide MA and Part D services to 21 percent of the beneficiaries enrolled in MA and Part D as of April 2013.

Marketing Surveillance Activities

CMS also strengthened program integrity in MA and Part D through marketing surveillance activities and compliance actions based on surveillance activities. In FY 2013, CMS conducted 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 and lessened incidents of agent/broker misconduct.

Secret Shopping

Secret shopping provides undercover surveillance of formal MA, MA-PD, and PDP marketing events. Plan sponsors report formal sales/marketing events to CMS from which contractors and CMS identify a sampling of events to secret shop. Shoppers use a CMS developed tool to facilitate and electronically record their evaluations of marketing events' compliance with CMS requirements. The tool is designed to capture various compliance aspects of the representatives' or agents' presentations, actions and provided materials. Additionally, it collects general

information about the event, such as the number of people in attendance, the type of venue where the event was held, and the language in which the agent presented the event.

For the 2013 Annual Enrollment Period (AEP), CMS conducted 1,781 secret shopping events. Of the events shopped, 1,176 (65.7%) had no validated deficiencies and were considered entirely compliant with Medicare regulations.

Of the 114 parent organizations shopped, 23 (or 20.2%) had no validated deficiencies noted. These 23 parent organizations represented 605 shops or approximately 33% of the total completed shops. Forty-five (2.4%) of the completed shops were presented in a language other than English, including:

- 24 events presented in Spanish;
- 15 events presented in Cantonese or Mandarin;
- 2 events presented in Armenian;
- 1 events presented in Korean;
- 1 event presented in Russian; and,
- 1 event presented in Vietnamese.

Compliance Actions Based on Surveillance Activities

CMS issues the following types of letters to sponsors who have had deficiencies related to our surveillance:

- Technical Assistance Letters (TAL) (not formal compliance notices);
- Notices of Non Compliance (NONC);
- Warning Letters with a Request for Business Plan; and,
- Ad-hoc Corrective Action Plans (CAPs).

To determine the appropriate action for deficiencies identified by secret shopping, CMS developed an objective, data-driven, and performance-based model. This model not only automated the review process, but also accounted for the seriousness of each deficiency to develop proper compliance action for identified deficiencies. Within this model, CMS categorized each deficiency and assigned a weighted value: administrative errors (1 point), errors of omission (2 points), undue beneficiary influence or harm (4 points), and marketing misrepresentations (6 points). To determine a plan sponsor's overall performance score (OPS), CMS added the total number of points for all shops for each plan sponsor and divided by the total number of shops conducted for that plan sponsor.

The following three tables provide additional information on our process and findings. The first table shows how the OPS score is determined, while the second table is CMS' tool to determine what type of compliance action should be issued based on the OPS score. Finally, the Compliance Action table provides a break out, by risk, of the types of compliance actions taken and how many of each action were taken.

$\frac{\text{Total \# of deficiency points for all shops}}{\text{Total number of shops conducted}} = \text{OPS}$
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OPS Ranges and Corresponding Compliance Actions

Overall Shopping Performance Score Range	Compliance Action Taken
0.01 – 1.49	Technical Assistance Letter
1.50 – 3.49	Notice of Non-Compliance
3.50 – 6.99	Warning Letter with Business Plan
7.00+	Ad-hoc CAP

Compliance Actions Taken by Risk Level for Secret Shopping

Action ^b	High	Medium	Low	Total
Technical Assistance Letter	105	72	13	183
Notice of Non-Compliance	2	1	1	4
Warning Letter	2	0	0	2
Total Letters Issued	109	73	14	189

The unreported marketing events initiative is an attempt to determine if plan sponsors appropriately reports and represented their sales events activity to CMS. Daily and weekly print publications in U.S. domestic markets nationwide, including advertisements in several non-English languages are reviewed. CMS conducted reviews of 4,846 Medicare advertisements representing 8,699 total advertised events. These advertisements represented events hosted by 36 plan sponsors.

Of those advertisements reviewed, CMS identified 406 marketing events that were unreported, indicating a deficiency for each plan sponsor that had failed to submit a marketing event. Based on the results, CMS issued 18 TALs and 4 NONCs to plan sponsors related to unreported marketing events. NONCs were issued to plan sponsors that incurred deficiency rates of 5% or higher.

Medicare Advantage Encounter Data Processing System Contract

The Medicare Advantage (MA) Encounter Data Processing System (EDPS) is currently being maintained and modified 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 15 million beneficiaries. Previously, CMS had not collected encounter data, which 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 500 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, in January 2012 agency launched an initiative to collect encounter data from Medicare Advantage organizations. The encounter data detail each item and service provided to enrollees of Medicare Advantage organizations. 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 use encounter data to determine the risk adjustment factors used to adjust payments, as required under CMS regulations at 42 CFR §422.304, to update risk adjustment models, to calculate Medicare Disproportionate Share Hospital percentages, for Medicare coverage purpose and to conduct quality review and improvement activities. The collection of MA encounter data is expected to provide CMS with a more complete picture of MA member utilization.

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 2013 through the continued efforts of these specialists, CMS removed an estimated \$2.7 billion (with approximately \$375 million recovered and \$2.4 billion resolved) of approximately \$9.7 billion identified in questionable Medicaid costs.

Furthermore, an estimated \$188 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 refers to CMS. OIG receives complaints through its TIPS Hotline and uploads certain complaints to the OIG Hotline database for review by CMS. 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 from 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 September, 2014.

3. Transparency and Accountability

Healthcare Fraud Prevention Partnership

One of the Secretary's key health care fraud prevention initiatives is to establish an ongoing partnership with the private sector to fight fraud across the health care system. Data collected and shared across payers can assist payers in evaluating trends, recognizing patterns consistent with potential fraud, and potentially uncover schemes or bad actors they could not otherwise identify using only their own information. Such collaboration is the purpose of the Healthcare Fraud Prevention Partnership (HFPP) which brings together both public and private, federal and state-level individuals and organizations combatting health care fraud across all payers.

The legal authority for the Partnership is 42 U.S.C. § 1320a-7c. The delegated authority allows for the Partnership to consult with, and arrange for the collection of data from, and sharing of data with representatives of health plans under the HCFAC program.

Several key milestones occurred in FY2013FY 2013 including the signing of the official Healthcare Fraud Prevention Partnership Charter by Secretary Sebelius and US Attorney General Holder and the second Executive Board meeting of the Healthcare Fraud Prevention Partnership which took place on April 1, 2013. The Board Meeting was followed immediately by two days of working sessions with committees at the CMS Program Integrity Command Center. Over 60 participants representing over 20 partnership organizations attended the two days of working sessions. In total, over a dozen meetings were held within the partnership including four in-person meetings which proved highly effective in distilling the critical spirit of collaboration and partnership.

The HFPP has successfully completed a significant pilot information exchange, in which 11 entities, including CMS, contributed fraud related data for aggregation and analysis, realizing in immediate cost savings and additional administrative actions for many of the participants. Future data exchanges, both non-identifiable and identifiable, will significantly expand in complexity and require substantial technologies and infrastructure including relevant contactors and a data exchange partner to serve as a Trusted Third Party. To plan for this function, CMS has invested in a strategic contractor with the objective of defining the requirements for a Trusted Third Party contract, to be procured in FY 2014.

CMS added additional partners to the HFPP and is targeting further expansion of the partnership to include additional willing public and private payers once the technical and legal components of the program are in place. The increase in members providing data will increase the resources necessary for the trusted third party contractor to process and store the increased number of claims data from the new members.

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), amended by the Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA) 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 improper payments. To comply with the IPIA, IPERA and IPERIA, CMS established the Payment Error Rate Measurement program (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 measures 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, the PERM error rate was published for the first time in FY 2008.

In FY 2013, after consultation with OMB, CMS made two improper payment rate calculation methodology enhancements to improve the accuracy of the Medicaid improper payment rate estimate. These two enhancements include: (1) replacing the three-year weighted average national Medicaid improper payment rate with a single-year rolling national Medicaid improper payment rate, and (2) incorporating prior year state-level improper payment rate recalculations.

In past AFRs, CMS reported a three-year weighted average national Medicaid improper payment rate representing the percentage of expenditures improperly paid over the past three years. The three-year rate was calculated by utilizing a weighted average of the PERM cycle error rates from the three most recent years. This methodology was implemented to ensure Medicaid improper payment rate reporting included findings from all states.

In response to an OIG report (OIG Report A-06-08-00078, "Oversight and Evaluation of the FY 2007 PERM Measurement Program"), CMS is now reporting a single-year rolling national Medicaid improper payment rate, a more precise estimate that represents the percentage of expenditures improperly paid during one fiscal year. The single-year rolling rate is calculated by multiplying each state's most recently observed error rate by that state's expenditures from the fiscal year being reported and dividing by the expenditures for that fiscal year. The single-year rolling rate treats the three most recent PERM cycles as a contiguous sample (as if all states were observed in the fiscal year being reported) which allows CMS to report on findings from all states with improved precision.

Additionally, past AFRs did not incorporate State-level error rate recalculations that occur after the cycle cut-off date. For the most recent cycle of States measured, these recalculations occur after AFR publication. In response to a Government Accountability Office report (GAO-13-229, Enhancements Needed for Improper Payments Reporting and Related Corrective Action Monitoring), State-level error rate recalculations for the previous two cycles measured are now incorporated into the national Medicaid improper payment rate, and will be incorporated in future calculations.

CMS is reporting in the FY 2013 Agency Financial Report the national Medicaid error rate that is based on measurements that were conducted in fiscal years 2011, 2012, and 2013. The national Medicaid error rate is 5.8 percent or \$14.4 billion in estimated improper payments and has decreased from FY 2012 (7.1 percent or \$19.2 billion). The national component error rates are as follows: Medicaid FFS – 3.6 percent, Medicaid managed care – 0.3 percent, and Medicaid eligibility – 3.3 percent. The major cause of error 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. HHS commenced CHIP error rate reporting in FY 2012 and, therefore, only two CHIP cycles of states have been measured for reporting in the FY 2013 Agency Financial Report.

The two Medicaid improper payment rate calculation methodology enhancements described above also apply to the CHIP improper payment rate estimate with one difference since only two cycles of states have been measured. For FY 2013, the 34 measured states will be treated as a contiguous sample and projected to the 17 states that have not yet been measured.

CMS is reporting in the FY 2013 Agency Financial Report the national CHIP error rate that is based on measurements that were conducted in fiscal years 2012 and 2013. The FY 2013 national CHIP error rate is 7.1 percent or \$0.6 billion in estimated improper payments. The national component error rates are as follows: CHIP FFS – 5.7 percent, CHIP managed care – 0.2 percent, and CHIP eligibility – 5.1 percent. The main source of error is beneficiaries found to be ineligible for CHIP. Other errors are due to policy violations, payments made for non-covered services, and insufficient documentation.

CMS is currently measuring cycles that will be reported in 2014 and 2015. 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 Executive Order 13520—Reducing Improper Payments and Eliminating Waste in

Federal Programs, the PERM program also reports error rate information on the Treasury improper payment dashboard at PaymentAccuracy.gov, and annually reports 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 IPERA, CMS has implemented a systematic plan regarding improper payments for Part C and 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 2013 (based on calendar year CY 2011) is 9.5 percent, or \$11.8 billion. The Part C payment error estimate has decreased from the FY 2012 estimate of 11.4 percent or \$13.1 billion. 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 Part C payment 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 three specific actions described below: contract level audits, Medicare Advantage Organization guidance, and physician outreach.

- **Contract-level audits:** The contract-specific Risk Adjustment Data Validation (RADV) audits are designed to recover overpayments to Part C plans. CMS will conduct payment recovery based on extrapolated estimated beginning with audits based on calendar year 2011 payments. CMS expects to audit about 30 MA contracts a year. Additionally, the CY 2007 contract-level RADV audits are in the final stages. In FY 2013, CMS recovered a total of \$5.0 million from contracts involved in the CY 2007 RADV Targeted audits. CMS plans to conduct further recovery on the CY 2007 audits in FY 2014.
- **Medicare Advantage Organization Guidance:** CMS has also implemented a process to assist MA plans while they are submitting medical record documentation for review under the Part C error estimate.
- **Physician Outreach:** CMS has begun a program that enhances physician understanding of the way HHS pays MA organizations and the payment methodology impact on physicians. The focus of this effort is to improve medical record documentation prepared by physicians to support risk adjustment diagnoses.

The Part D payment error estimate reported for FY 2013 (based on CY 201) is 3.7 percent, or \$2.1 billion. The FY 2013 Part D error estimate represents the combined impact on Part D payments of four sources of error: Payment error related to low income subsidy status; payment error related to Medicaid status; payment error related to prescription drug event data validation; and payment error related to direct and indirect remuneration.

Probable Fraud Measurement Pilot

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 better evaluate the success of ongoing fraud prevention activities. In collaboration with the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), 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. CMS received OMB approval in May 2013.

This project will estimate probable fraud in the Home Health benefit 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 involves establishing intent – a determination that is made through the judicial system. 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 Medicare. CMS will begin collecting data on probable fraud and have an estimate of probable fraud within HHAs in 2015.

4. Recovery

Suspension

CMS in FY 2013 continued its use of the new Affordable Care Act authority to suspend payments to providers during an investigation of a credible allegation of fraud. CMS also has authority to suspend payment if reliable information of an overpayment is brought to light. As of September 2013, CMS had 297 providers under active payment suspension, with 105 of those suspensions having been approved in FY 2013.

Field Offices

CMS has designated program integrity field offices located in or near the HEAT cities of Miami, Los Angeles, and Brooklyn that provide a CMS presence in high risk fraud areas of the country. 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. The field offices also work with CMS central office and the ZPICs to 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.

The field office staff performs outreach and education to partners in their areas, including law enforcement, Senior Medicare Patrol and state Medicaid agencies. The field offices train US Attorneys, OIG and FBI agents, analysts and forensic accountants on Medicare policy and coding clarification, as well as provide data and billing analysis for specific cases. These staff also provides significant support during the prosecution of health care fraud cases through testimony, depositions and victim impact statements.

The field offices develop solutions to the most challenging program integrity issues in their region. In Miami, for example, the field office has boots on the ground working to root out fraud in home health by performing provider and beneficiary interviews. The Los Angeles staff is working with county Emergency Medical Service licensing authorities, CMS contractors and local law enforcement to address emerging schemes in ambulance providers. These efforts have resulted in nearly 100 revocations of Medicare billing privileges in FY 2013. Additionally, the trial support provided by the Brooklyn field office has helped result in three convictions in FY 2013.

In FY 2013, the field offices also expanded their collaboration with Medicaid program integrity staff, including the CMS Medicaid Integrity Contractor (MIC) and the state Medicaid agency. The Los Angeles field office began two projects around the hospice benefit which is anticipated to result in administrative actions against providers.

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 June 30, 2013, First Coast Service Operations, Inc. (FCSO), the MAC conducted 5,492 site verifications to verify providers and suppliers’ operational status, deactivated 77 practice locations, and revoked or denied 486 providers. FCSO saved \$10,834,126 from prepayment review. Safeguard Services, Services (SGS), the ZPIC conducted over 296 on-site investigations resulting in 102 requests for provider revocation or deactivation. SGS placed 48 providers on prepayment review saving \$3,766,349.36 and requested \$133,232,024 in overpayments.

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, 2013, the hotline has received more than 107,938 calls leading to 1,057 new fraud investigations. In addition, the ZPIC has placed 223 providers on prepayment review saving over \$16 million, revoked or deactivated 192 provider numbers, referred 52 cases to law enforcement, and sent 160 Immediate Advisements to the HHS-OIG. Additionally, law enforcement has seized \$3 million in provider bank accounts.

Administration for Community Living

The mission of the Senior Medicare Patrol (SMP) program is to empower and assist Medicare beneficiaries, their families, and caregivers to prevent, detect, and report health care fraud, errors, and abuse through outreach, counseling, and education. In FY 2013, the Administration for Community Living (ACL) was allocated \$3.378 million in HCFAC funding by HHS to support infrastructure, technical assistance, and other SMP program support. In addition to this funding, ACL was initially allocated \$7.331 million for capacity-building activities designed to enhance the effectiveness of state-wide SMP programs. This funding was reduced to \$7.170 million later due to the funds requested by the SMP grantees. During FY 2010 and FY 2011, CMS had provided this capacity funding to ACL for the SMP projects. In FY 2012 and FY 2013 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, US Virgin Islands and D.C.) with funds authorized in the Older American Act and the HCFAC Wedge. In addition to the projects' base grants, funded from the Older American Act, the SMP program offers HCFAC funds to each grantee so that they can expand their program. Prior to FY 2013, the additional funding was based largely on the known fraud prevalence within each state. However, in FY 2013, the program moved to a formula-driven allocation taking into account the number of Medicare beneficiaries living in each state and the ruralness of the state. The new formula is intended to provide a more equitable allocation of funds and reflects the reality that the prevalence of fraud is much broader than a few selected states.

According to the most recent annual performance report from HHS-OIG's Deputy Inspector General for Evaluation and Inspections, issued July 2013, 5,137 active volunteers served SMP projects during 2012. These volunteers performed an essential function of this program, contributing 120,953 hours and conducting over 113,000 one-on-one counseling sessions in efforts to educate beneficiaries about how to prevent and detect Medicare fraud within local communities.

Outreach to Medicare beneficiaries is a key element of the SMP program. During 2012, SMP projects held 10,032 community outreach education events reaching more than 996,000 people, and were responsible for over 188,199 media airings to increase beneficiary awareness about issues related to Medicare fraud. In addition, over 449,500 beneficiaries were educated through 14,748 group educational sessions conducted by SMP programs in local communities.

SMP projects nationwide received 86,331 inquiries for information or assistance in 2012 from or on behalf of beneficiaries. This included receipt of 2,270 complex issues—i.e., beneficiary complaints requiring further research, assistance, case development, and/or referral. SMP projects reported that 1,748 complex issues were resolved for beneficiaries during 2012, while 908 complex issues with an estimated dollar value of over \$27.5 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 \$133,971 in health care expenditures were avoided and nearly \$6.2 million in Medicare, Medicaid and other savings resulted from actions taken by the SMP program.

Since the program's inception, the program has educated over 5.2 million beneficiaries in group or one-on-one counseling sessions and has reached nearly 28 million people through community education outreach events. While SMPs make numerous referrals of potential fraud to investigators, 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 July 2013 report:

“We continue to emphasize that it is not always possible to track referrals to Medicare contractors or law enforcement from beneficiaries who have learned to detect fraud, waste, and abuse from the projects. Therefore, the projects may not be receiving full credit for savings attributable to their work. In addition, the projects are unable to track the substantial savings derived from a sentinel effect whereby fraud and errors are reduced by 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 will conclude in December 2013. In addition, in FY 2013, the SMP program issued a research grant designed to

measure the value of prevention activities. As the SMP program is focused on education and prevention, the true value of the program comes from beneficiaries avoiding fraud in the first place. This new grant is intended help the program identify a way to measure that effect.

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 over \$112 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.

Integration Project Grant

The goal of the SMP program is to provide education to all Medicare beneficiaries. However, there are specific populations that are historically hard-to-reach. Three of these populations: Medicare beneficiaries under age 65; Lesbian, Gay, Bisexual and Transgender (LGBT) Medicare beneficiaries; and American Indian/Alaska Native (AI/AN) Medicare beneficiaries, were specifically identified as target populations. In FY 2013, ACL awarded five grants to organizations who have initiated 17 month projects which seek to increase awareness, empowerment, and actions to prevent healthcare fraud amongst these generally underserved populations. The goal of these grants will be to develop new, efficient, and sustainable approaches for ensuring high quality and culturally competent service delivery and help educate consumers to prevent health care fraud.

Prevention Research Grant

As mentioned above, in FY 2013, the SMP program has issued a three-year research grant to identify a way to measure the overall impact of the SMP program. Specifically, the grantee will develop and test an evaluation method to determine how to best measure the effects of the SMP program's community education techniques on health care fraud prevention.

Office of the General Counsel

In FY 2013, the Office of the General Counsel (OGC) was allocated approximately \$8.88 million in HCFAC funding by HHS to supplement OGC's efforts to support program integrity activities. OGC's efforts in FY 2013 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 its active litigation role in order to assist in the recovery of program funds. During FY 2013, OGC was involved in a wide range of HCFAC efforts that resulted in Government recoveries of over \$1.57 billion in judgments, settlements, or other types of recoveries, savings, or receivables as 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 2013, as new ACA programs were implemented, OGC spent significant time and resources working with the relevant agencies to ensure that program integrity issues were reviewed and resolved, and assisted the agencies in addressing program integrity and compliance problems as they occurred.

HEAT

During FY 2013, 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 2013, OGC participated in FCA and related matters that recovered over \$1 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 2013, 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 2013, 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 2013, OGC continued to provide extensive advice to CMS on a variety of Part D and Medicare Advantage (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 2013, 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.

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 2013, OGC petitioned these agencies to recover funds in both criminal and civil litigation matters in which Medicare was a victim of fraud.

Regulatory Review and Programmatic Advice

In FY 2013, OGC advised CMS on a variety of regulatory and program issues, all to assist CMS in strengthening its programs and activities against fraud and to prevent the wrongful disbursement of program funds in the first instance. Some highlights of OGC efforts include its work to develop and implement the Physician Payment Sunshine Rule, the Durable Medical Equipment (DME) Face-to-Face Rule, and the Provider Enrollment and Incentive Reward Program Proposed Rule. Further, OGC provided extensive counsel regarding the CMS final rule on new survey procedures and alternative sanctions available for Home Health Agencies (HHAs) that are not meeting program participation requirements.

Medicaid Integrity

Continuing recent trends, OGC saw continued increasing involvement in FY 2013 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 2013, OGC reviewed and offered extensive comments on participation agreements or amendments to such agreements governing various initiatives of the Center for Medicare & Medicaid Innovation, including the Pioneer Accountable Care Organization Model, Bundled Payment for Care Improvement ("BPCI") Models 2-4, and the Comprehensive ESRD Care Initiative. In addition, OGC worked closely with OIG and CMS in devising new waivers of the fraud and abuse laws for the BPCI models. OGC also advised CMS regarding matters disclosed under the new Stark self-disclosure protocol, now numbering over 200.

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 2013, OGC has been successful in establishing the right to recover over \$7.7 million for Medicare under the MSP program. Recent statutory changes implementing mandatory insurance 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 protects Medicare funds from waste in bankruptcy cases by asserting CMS's recoupment rights to collect overpayments, arguing to continue suspension or termination actions against debtors, seeking adequate assurances from the bankruptcy court that CMS interests in the debtor's estate will be protected, arguing for the assumption of the Medicare provider agreement as an executory contract, and petitioning for administrative costs where appropriate. In FY 2013, 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, collecting or establishing the right to collect over \$2.4 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 2013, 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 2013, FDA was allocated \$3.37 million in HCFAC funding by HHS for the FDA Pharmaceutical Fraud Program (PFP). The PFP was instituted to enhance 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 Federal Food, Drug, and Cosmetic Act (FFDCA), 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 concerning biologics, drugs, and medical devices. The goal of the program is the early detection and prosecution of such fraudulent conduct and furthers FDA's public health mission by helping to reduce health care costs, in most cases before they are incurred, 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 sixty-four criminal investigations. In FY 2013, FDA's third full fiscal year of HCFAC Program activity, OCI, through its PFP, opened twenty-three criminal investigations, described below:

- One investigation involving misbranding allegations, including minimization of risk and marketing two drugs by a single manufacturer for unapproved uses. The investigation involves marketing of the drugs for conditions not indicated in the approved labeling and for deceptive marketing practices regarding the safety of the drug products.
- Three investigations involving allegations of misbranding by medical device manufacturers for selling and/or distributing devices for conditions which are not FDA cleared and/or for making misleading representations about the device benefits and efficacy.
- Seven investigations involving allegations of flagrant manufacturing practices concerning both drugs and devices causing those products to be misbranded and/or adulterated and resulting in a safety risk to the public.
- Twelve investigations involving allegations of clinical trial and/or application fraud. These investigations consist in part of individuals suspected of improperly commencing and conducting clinical trials, falsifying clinical trial data, forging signatures of clinical investigators, and enrolling ineligible or non-existent subjects in clinical trials, as well as falsifying approval and/or clearance applications made to the FDA.

In regards to judicial action, the types of criminal investigations conducted through the PFP tend to be complex in nature requiring extensive document review and coordination with the affected FDA Center. It is not unusual for these complex fraud investigations to last five years or more from initiation to conclusion. Nevertheless in March 2013, an application fraud investigation, opened in FY 2011, obtained an individual guilty plea for submitting a report to the FDA which was materially false or misleading during the device approval process. The individual has agreed to assist in the prosecution of additional subjects related to this investigation and will be sentenced after this cooperation obligation is completed. Additionally in August 2013, an indictment was secured against the main target in a clinical trial fraud case, also opened in FY 2011, charging false statements in a matter within the jurisdiction of the FDA.

Furthermore, FDA believes that various investigations already initiated under the PFP show promise of future judicial action that may include criminal prosecution and monetary recoveries. These cases include an investigation of a large drug manufacturer for serious and pervasive manufacturing violations, as well as several investigations of clinical trial principal investigators who have allegedly fabricated study subjects, omitted exclusion/inclusion criteria and provided false data to drug and device sponsors representing these investigational products as safe and effective when, in fact, they are not.

In addition to these investigative activities, FDA conducted a three day training session in late June 2013 for criminal investigators and supervisors covering PFP related topics. The instruction consisted of legal training provided by OGC on the FFDCIA in areas relevant to PFP cases, investigative scenario training on clinical trial fraud investigations and case presentations on successful prosecutions involving misbranding and other fraud schemes encompassing both drugs and medical devices. The training also provided background on FDA'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 2013, the United States Attorney's Offices (USAOs) were allocated approximately \$42.0 million in FY 2013 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: \$1.5 billion from Abbott Laboratories and \$500 million from Ranbaxy Laboratories Limited and its subsidiary, Ranbaxy USA, Inc.. 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 Strike Forces 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 Strike Forces 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.

Criminal Prosecutions

In FY 2013, the USAOs received 1,013 new criminal matters involving 1,910 defendants, and had 2,041 health care fraud criminal matters pending,¹⁷ involving 3,535 defendants. The USAOs filed criminal charges in 480 cases involving 843 defendants, and obtained 718 Federal health care fraud related convictions.

Civil Matters and Cases

In FY 2012, the USAOs had opened 1,083 new civil health care fraud investigations. At the end of FY 2012, the USAOs had 1,079 civil health care fraud investigations pending.¹⁸

¹⁷ 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.

¹⁸ The accomplishments figures presented in this paragraph include all reported Strike Force cases handled by DOJ Criminal Division attorneys and AUSAs in the respective USAOs during FY 2013.

Civil Division

In FY 2013, the Civil Division received approximately \$28.0 million in FY 2013 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 complex health care fraud allegations and files suit 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, United States Attorneys' Offices, 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 in health care cases of over \$1 billion almost every year since 2000 and over \$2.3 billion in FY 2013 alone.

The Fraud Section investigates and resolves matters against a wide array of health care providers and suppliers. Matters involving pharmaceutical and device manufacturers continue to constitute some of 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 Abbott, Amgen, AstraZeneca and Wyeth matters discussed above-- involved allegations that the pharmaceutical manufacturer improperly promoted its drug for uses not approved by the FDA. Other cases, like the Ranbaxy matter, involved allegations relating to the manufacture and distribution of adulterated drugs. Lastly, many pharmaceutical fraud cases involve allegations that the drug or device manufacturer paid kickbacks to physicians to prescribe its products. These cases are significant not only because of the significant dollars involved, but because they protect Medicare and Medicaid beneficiaries by preserving the integrity of the FDA's approval process as well as the doctor-patient relationship.

In addition to pharmaceutical fraud, the Fraud Section also investigated and resolved several matters involving hospitals and physicians. For example, 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. Likewise, the Fraud Section successfully resolved its investigation against a Florida doctor for violating the Anti-Kickback Statute by accepting free pathology services and billing Medicare as if he had personally performed those services. As a result of its investigation, the government recovered over \$26 million, and the doctor agreed to be voluntarily excluded for five years from participating in any federal health care program.

Because the Fraud Section receives every FCA complaint filed across the country by whistleblowers (otherwise known as "relators"), it has a unique vantage point over health care fraud trends and developments nationwide and therefore regularly takes the lead on coordinating national investigations with its law enforcement partners. Likewise, given the diversity of health

care fraud cases pursued by the Fraud Section, it frequently 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 Food, Drug, and Cosmetic Act (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; since 2009, these fines, penalties, and forfeitures have totaled more than \$6 billion.

In the area of pharmaceutical and medical 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. These cases, such as the Amgen, Ranbaxy, and Wyeth cases mentioned above, which involve allegations of misbranding or adulteration of pharmaceuticals, often require in-depth analyses of pharmaceutical and medical device manufacturers' clinical studies, manufacturing practices, or commercial activities. Typically, they involve the review of hundreds of thousands or even millions of company and third party documents, as well as dozens of witness interviews or testimony. These cases are significant not only because of the monetary fines and non-monetary remedies that are imposed for criminal violations of the FDCA, but because of the public health and safety issues that they implicate. In the Abbott case discussed above, for instance, not only did the company misbrand Depakote through its unlawful promotion and targeting of vulnerable elderly dementia patients, but it downplayed safety risks apparent from its own clinical studies and encouraged nursing homes to use Depakote to avoid reporting

requirements designed to prevent the use of unnecessary drugs.

In addition to prosecuting major pharmaceutical and medical device companies for health care offenses, CPB prosecutes smaller-scale, yet equally dangerous schemes involving online sale of pharmaceuticals and drug diversion. For example, in FY 2013, together with the U.S. Attorney's Office in the Southern District of Florida, CPB prosecuted a Canadian citizen, Andrew J. Strempler, for his role in a scheme to defraud consumers purchasing pharmaceuticals online. Strempler pled guilty to conspiracy to commit mail fraud in connection with his role as owner and president of Mediplan Health Consulting Inc., a Canadian company that also operated under the name RxNorth.com. RxNorth was an Internet, mail, and telephone order pharmacy, through which Strempler and others marketed and sold prescription drugs to residents of the United States. Strempler and his co-conspirators falsely represented that RxNorth was selling safe prescription drugs in compliance with regulations in Canada, the United Kingdom and the United States, when in fact, Strempler obtained the prescription drugs from various other source countries without properly ensuring the safety or authenticity of the drugs. In fact, some of the drugs sold by Strempler included counterfeit drugs. In January 2013, Strempler was sentenced to 48 months in prison, and was ordered to pay a fine of \$25,000 and restitution in the amount of \$300,000.

In yet another example, in FY 2013, CPB prosecuted Lina Ada Mendoza, a/k/a Nicole Rodriguez and Michael Jackson in the Southern District of Florida for their role in a conspiracy involving the operation of an Internet pharmacy business that illegally shipped over \$1.5 million of pharmaceuticals to U.S. and overseas purchasers. Rodriguez owned an Internet-pharmacy business used to advertise, sell and distribute a wide variety of controlled substances and prescription drugs in the United States and abroad. Rodriguez and Jackson conspired to sell the prescription drug known as Adderall, which contains amphetamine, a Schedule II controlled substance. Rodriguez was sentenced to 72 months' imprisonment, and ordered to forfeit \$36,112. Jackson was also sentenced to 72 months' imprisonment and ordered to forfeit \$18,862.

Criminal Division

In FY 2013, the Criminal Division was allocated \$8.1 million in FY 2013 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 2013, 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 2013 follows:

- Filed 60 new health care fraud cases involving charges against 159 defendants who collectively billed the Medicare and Medicaid programs more than \$1 billion;
- Obtained 93 guilty pleas and litigated 18 jury trials, winning guilty verdicts against 29 defendants;¹⁹⁶
- Secured prison sentences in health care fraud cases averaging more than 62 months; and
- Secured court-ordered restitution, forfeiture and fines exceeding \$1.1 billion.

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, South Louisiana, Tampa, Dallas, and Chicago.

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

On May 14, 2013, Fraud Section and USAO Strike Force prosecutors in eight cities executed a nationwide operation that resulted in charges against 89 individuals, including doctors, nurses, and other medical professionals, for their alleged participation in Medicare fraud schemes involving approximately \$223 million in false billing. Earlier in the fiscal year, on October 4, 2012, Fraud Section and USAO Strike Force prosecutors in seven cities executed a nationwide operation that resulted in charges against 91 individuals, including doctors, nurses, and other medical professionals, for their alleged participation in Medicare fraud schemes involving approximately \$492.2 million in false billing.

Of particular note during the FY2013, the Fraud Section charged a Michigan oncologist/hematologist in August 2013 with health care fraud in wide-ranging and dangerous fraudulent billing scheme. According to the original complaint and subsequent indictment, the doctor allegedly provided chemotherapy and other medical treatments to patients who did not need the treatments, including patients who were in remission and did not need chemotherapy; the defendant also supposedly directed his staff to falsify medical documents to justify the treatments. The allegations against the defendant raised serious health concerns, particularly given the physical effect of chemotherapy and some of the other treatments administered to patients. At the time of arrest, the defendant was treating 1200 patients. The Fraud Section, working with the U.S. Attorney's Office for the Eastern District of Michigan, undertook a massive and aggressive effort to make insure that victim witnesses received all necessary support in finding new medical care. Between August 2010 and August 2013, the defendant's business, Michigan Hematology Oncology, Inc. (MHO), billed Medicare \$150 million and was paid \$62 million. In addition,

¹⁹ Fraud Section attorneys were responsible for many of the cases summarized in the "Medicare Fraud Strike Force" section of this report.

private insurer Blue Cross/Blue Shield also paid the doctor \$78 million on claims submitted by MHO.

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. Throughout FY2013, Fraud Section prosecutors met with federal prosecutors and agents across the United States to provide training, investigative leads based on data analysis, and related support. 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 2013, four OCGS attorneys and one paralegal were assigned to health care fraud prosecutions, although the section has remained under severe budget restrictions. Three OCGS attorneys worked with AUSAs in the Organized Crime Strike Force in Philadelphia on prosecutions involving Medicare fraud in the operation of hospice facilities and ambulance companies. A fourth OCGS attorney worked on an investigation of health care fraud involving a private sector employment based health care plan.

In Philadelphia, an OCGS attorney partnered with an AUSA in the prosecution of four cases involving seven defendants for criminal charges in connection with the operation of a hospice facility. In June 2013, a doctor who served as the medical director of the hospice was convicted after trial of receiving more than \$300,000 in illegal payments for regularly referring Medicare and Medicaid patients to the hospice. Sentencing was pending at the end of the fiscal year. The conviction will result in the doctor's mandatory exclusion from participation in any federal health

care program and the possible loss of his medical license. A second doctor remains under indictment for receiving illegal referral payments from the hospice. In September 2013, the trial of a hospice co-owner commenced on charges of 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 for the benefits claimed. His trial was ongoing at the close of the fiscal year. Four nurses who worked at the hospice are scheduled for trial in late 2013 and early 2014 on charges that they fabricated and falsified documents in support of hospice care for patients who were not eligible for hospice care, or for a higher, more costly level of care than was actually provided to the patients. The nurse defendants are alleged to have submitted approximately \$9,328,000 in fraudulent claims to Medicare and created fraudulent nursing notes for approximately 150 patients indicating that services were being provided, when, in reality, they were not.

Two additional OCGS attorneys worked with Philadelphia AUSAs on prosecutions of the 5 defendants involved in the operation of three different ambulance service companies. In May 2013, the operator of one ambulance company was sentenced to 92 months' imprisonment for defrauding Medicare of approximately \$5.4 million by billing for ambulance services which were not medically necessary. The operator, who was an émigré from Ukraine, recruited a straw owner, with the payment of \$60,000, to apply for a license to operate after he was denied a license under his own name due to a prior criminal conviction. Once licensed, the operator recruited patients who were capable of walking and submitted claim forms to Medicare falsely claiming that patients were unable to transport themselves. The straw purchaser and wife of the ambulance company operator have pleaded guilty to charges in connection with the operation of this ambulance company and await sentencing. Owners of two additional ambulance companies were indicted in May 2013 for health care fraud and conspiracy to pay kickbacks to patients in an alleged scheme to recruit ambulatory dialysis patients for whom they billed Medicare for medically unnecessary ambulance services.

In addition to conducting health care fraud investigations and prosecutions, OCGS attorneys routinely provide litigation support and advice to AUSAs and criminal investigative agencies in the investigation and prosecution of corruption and abuse of private employment-based group health plans covered by the Employee Retirement Income Security Act (ERISA). Such 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 also provide support to investigations of fraud schemes by corrupt entities that sell unlicensed health insurance products as well as fraud schemes by corrupt employers that cheat workers out of health benefits required by the prevailing wage laws and regulations.

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 covers prosecutions involving abuse of private sector employee health plans subject to ERISA and health plans sponsored by labor organizations as well as fraud and abuse committed in connection with the operation of multiple employer welfare arrangements. OCGS also drafts and reviews criminal legislative proposals affecting employee health benefit plans. In addition, OCGS 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 and private sector health care frauds.

Civil Rights Division

In FY 2013, the Civil Rights Division was allocated approximately \$4.1 million in FY 2013 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*, 527 U.S. 581. 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 2013 Accomplishments

Special Litigation Section staff conducted preliminary reviews of conditions and services at 16 health care facilities in 13 states during Fiscal Year 2013. 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 2013, the Section opened or continued formal investigations, entered remedial agreements, or monitored existing remedial agreements regarding 64 health care facilities in 15 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 2013, the Section entered into a letter agreement to resolve its investigation of Oregon State Hospital and the State of Oregon's state-wide system for serving individuals with mental illness. The Agreement will be effective for four years. Pursuant to the Agreement, Oregon will collect and furnish state-wide system data to the Section. Throughout the Agreement period, Oregon and the Section will continue discussions on identifying gaps in the community service system, development of outcome measures, and whether positive outcomes are being achieved in the process.

The Section entered into a settlement agreement to resolve its investigation of Maple Lawn Nursing Home in Palmyra, Missouri. Pursuant to the Agreement, the facility will implement pre-admission measures to ensure that individuals who are inappropriate for admission to this facility are not housed there. The Agreement also requires discharge and transition planning, provision of adequate care and protections from harm for individuals, and quality outcome measures.

The Section filed a memorandum in support of class certification in Amanda D. v. Hassan, (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 is scheduled to go to trial in 2014.

The Section entered into an interim settlement agreement in Steward v. Perry, (W.D. TX.), to resolve a suit against the State of Texas for its failure to provide adequate community-based services to persons with intellectual disabilities residing in nursing homes. Negotiations are continuing to resolve all issues pursuant to a comprehensive agreement.

The Section filed four statements of interest in ongoing litigation: ILADD v. Quinn, (N.D. Ill.); Hunter v. Cooke, (N.D. Ga.); J.B. v. Bryant, (S.D. Miss.); and Sciarrillo v. Christie, (D.N.J.). The Section filed the statements of interest to clarify and articulate the views of the United States pertaining to the Title II of the ADA and Olmstead and remedies therein, in matters where the

United States is not a formal party.

The Section continued its investigations of 12 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; Utah State Hospital, in Provo, Utah; 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 22 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; Central Virginia Training Center, in Lynchburg, Virginia; Northern Virginia Training Center, in Fairfax, Virginia; Southeastern Virginia Training Center, in Chesapeake, Virginia; Southside Virginia Training Center, in Portsmouth, Virginia; Southwestern Virginia Training Center, in Hillsville, Virginia. 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.

The Section also monitored the implementation of remedial agreements regarding 13 state-operated residential facilities for persons with mental illness: Napa State Hospital, in Napa, California; Metropolitan State Hospital, in Norwalk, 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 Oregon State Hospital, in Portland, Oregon. These remedial agreements include the provision of adequate support and services to enable individuals to live successfully in the community.

In addition, the Section monitored remedial agreements at two nursing facilities: William F. Green State Veterans' Nursing Home, in Bay Minette, Alabama; and Maple Lawn Nursing Home, in Palmyra, Missouri.

In Fiscal Year 2013, the Disability Rights Section monitored the implementation of its 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, costly institutional settings known as adult care homes. Under the agreement, North Carolina is providing opportunities to individuals with mental illness in adult care homes to transition to less costly, supported housing settings – integrated housing that promotes inclusion and independence and enables individuals with mental illness to participate fully in community life.

The Section intervened in Lane v. Kitzhaber (D. OR.), a class action brought on behalf of persons with intellectual and developmental disabilities alleging that Oregon is in violation of 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. The litigation is ongoing.

The Section also filed suit against the State of Florida, in United States v. Florida, (S.D. Fla. 2013) alleging that it administers its service system for children with significant medical needs in violation of the ADA and Olmstead by unnecessarily segregating children in nursing facilities, when they could, and want to, be served at home or in other community-based settings. The Section's complaint further alleges that the State violates the ADA by administering its system of care in a manner that places many other children with complex medical conditions at risk of unnecessary institutionalization in nursing facilities.

The Section entered into an interim settlement agreement with the State of Rhode Island and the City of Providence, in United States v. Rhode Island and City of Providence, (D.R.I. 2013), resolving the Section's findings that the State and City unnecessarily segregated persons with intellectual and developmental disabilities (I/DD) in a sheltered workshop and segregated day activity service program, and placed public school students with I/DD at risk of unnecessary segregation in that same program. Under the agreement, the State and City will provide supported employment services to individuals with intellectual and developmental disabilities and provide integrated day services to enable such individuals to participate in integrated activities when they are not working.

The Section also entered into a settlement agreement with the State of New York and private plaintiffs regarding New York's mental health service system, in United States v. New York (E.D.N.Y. 2013). The agreement remedies discrimination by the State in the administration of its mental health service system and ensures that individuals with mental illness who reside in 23 large adult homes in New York City receive services in the most integrated setting appropriate to their needs consistent with the ADA and Olmstead. Under the agreement, such individuals will have the opportunity to live and receive services in the community such that they are able to live, work, and participate fully in community life. 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 six statements of interest or *amicus* briefs in litigation raising issues of needless segregation in Illinois, the District of Columbia, Florida, Mississippi, Georgia, and New Jersey. 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 2013, the FBI was allocated \$128.1 million in funding from HIPAA to support the facilitation, coordination and accomplishment of the goals of the HCFAC Program. This yearly appropriation was used to support 801 positions (480 Agent, 321 Support). In FY 2013, the FBI initiated 674 new health care fraud investigations and had 2,868 pending investigations. Investigative efforts produced 794 criminal health care fraud convictions and 1,023 indictments and informations. In addition, investigative efforts resulted in over 425 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 115 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 \$2.9 trillion dollars in FY 2013, 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-OIG, the Internal Revenue Service-CI, state Medicaid Fraud Control Units, and other state and local agencies. On the private side, the FBI is actively involved in the Healthcare 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 seek to identify and pursue investigations against the most egregious offenders involved in health care fraud and abuse, including criminal enterprises and other crime groups; corporations; companies; and providers whose schemes affect public safety.

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 responsibility, the FBI provides oversight and guidance to field offices. The guidance has included three initiatives to combat the crime problem, including the Health Care Fraud Prevention & Enforcement Action Team (HEAT), Large Scale Conspiracies, and Major Provider Fraud.

A description of, and examples of results obtained by, the HEAT Initiative are contained in the

body of this report. Contained within the HEAT section of the report is a description of, and examples of results obtained by, the Medicare Fraud Strike Forces (MFSFs), a key component of HEAT. The FBI coordinates with the DOJ and HHS-OIG on all HEAT aspects including funding, resource allocation, MFSF expansion, target identification, training, and operations. The FBI has 62 agents assigned to the nine Strike Forces in Miami, New York City, Houston, Tampa, Detroit, Los Angeles, South Louisiana, 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.

The Large Scale Conspiracies Initiative seeks to identify and target criminal enterprises and other groups whose schemes result in significant losses, or potential losses, to health care benefit programs. Large Scale Conspiracies include criminal enterprises and other crime groups collaborating in fraud schemes. Intelligence efforts for this initiative include information sharing and analysis of billing data with DOJ components, CMS, and HHS-OIG. Additional review of suspect/abnormal providers is conducted by the FBI's HCF Fusion Cell. Investigative assistance provided to field offices as part of the initiative can include support for undercover operations, source identification and support, and funding of investigative costs. An example of these types of cases was the Biscayne Milieu Health Center, Inc., investigation involving the submission of over \$50 million in false or fraudulent claims for partial hospitalization program services. Instead of providing these services, the clinic owners paid recruiters kickbacks to obtain Medicare beneficiary information and billed Medicare for services which were not rendered or necessary. Over 35 defendants have been charged and over 30 have either pled guilty or have been convicted at trial as part of the investigation.

The Major Provider Fraud Initiative seeks to identify and target corporations, companies, and other groups involved in fraud schemes with significant billing to government and private healthcare benefit programs. The related schemes are frequently complex, challenging to identify, and can involve conduct that is nationwide in scope. Extensive resources and coordination are frequently required due to the complexity and scope of the schemes. Qui Tams are a significant intelligence source for these types of cases. In addition to the work completed at the field office level, and in response to this substantial threat, the FBI has established a centralized support team to provide investigative assistance on these types of cases nationwide. Examples of significant major provider investigations have included Amgen Inc. and Wyeth Pharmaceuticals which agreed to pay \$762 million and \$491 million respectively, to resolve criminal and civil liability. The FBI coordinates efforts against the crime problem with our law enforcement partners, such as DOJ components, HHS/OIG, and FDA.

In addition to the FBI's involvement in the above initiatives, each field office is involved in a HCF Task Force and/or working group. The groups include US Attorney Office and HHS-OIG personnel, and in many cases also include state, local, and private insurance personnel. Based on information sharing, including billing analysis by the group partners, additional cases are vetted and identified for investigation.

The FBI actively provides training and guidance on health care matters. The FBI has teamed with the DOJ, 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 2013, more than 160 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 801 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 103).
- 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 2013, including sequester reductions. 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 2013
Office of Inspector General	\$187,097,926
Health and Human Services Wedge ¹	\$34,819,122
Medicare Integrity Program ²	\$851,509,634
<i>MIP/Medicare (non-add)</i>	<i>\$797,581,005</i>
<i>Medi-Medi (non-add)</i>	<i>\$53,928,629</i>
Department of Justice Wedge ¹	\$58,164,042
Federal Bureau of Investigation ³	\$128,149,615
Subtotal, Mandatory HCFAC	\$1,259,740,339
Discretionary Resources	
Office of Inspector General	\$28,121,691
CMS Program Integrity	\$237,343,109
<i>Medicare Program Integrity (Non-Add)</i>	<i>\$207,984,175</i>
<i>Medicaid Program Integrity (Non-Add)</i> ⁴	<i>\$29,358,934</i>
Department of Justice	\$28,121,691
Subtotal, Discretionary HCFAC	\$293,586,491
Grand Total, HCFAC	\$1,553,326,830

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 - 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