

**The Department of Health and Human Services
And
The Department of Justice
Health Care Fraud and Abuse Control Program
Annual Report for Fiscal Year 2015**

FEBRUARY 2016

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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 nineteenth 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) 2015, the Federal Government won or negotiated over \$1.9 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 2015, approximately \$2.4 billion was returned to the Federal Government or paid to private persons. Of this \$2.4 billion, the Medicare Trust Funds³ received transfers of approximately \$1.6 billion during this period, and \$135.9 million in Federal Medicaid money was similarly transferred separately to the Treasury as a result of these efforts. Of the approximately \$29.4 billion returned by the HCFAC account to the Medicare Trust Funds since the inception of the Program in 1997, over \$16.2 billion has been returned between 2009 and 2015.

Enforcement Actions

In FY 2015, the Department of Justice (DOJ) opened 983 new criminal health care fraud investigations. Federal prosecutors filed criminal charges in 463 cases involving 888 defendants. A total of 613 defendants were convicted of health care fraud-related crimes during the year. Also in FY 2015, DOJ opened 808 new civil health care fraud investigations and had 1,048 civil health care fraud matters pending at the end of the fiscal year. In FY 2015, the FBI investigative efforts resulted in over 625 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 144 health care fraud criminal enterprises.

In FY 2015, HHS' Office of Inspector General (HHS-OIG) investigations resulted in 800 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid, and 667 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 4,112 individuals

¹ Hereafter, referred to as the Secretary.

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

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

and entities from participation in Medicare, Medicaid, and other federal health care programs. Among these were exclusions based on criminal convictions for crimes related to Medicare and Medicaid (1,329) or to other health care programs (424), for patient abuse or neglect (302), and as a result of licensure revocations (1,743). HHS-OIG also issued numerous audits and evaluations with recommendations that, when implemented, would correct program vulnerabilities and save program funds.

Sequestration Impact

Due to sequestration of mandatory funding in 2015, there were fewer resources for DOJ, FBI, HHS, and HHS-OIG to fight fraud and abuses against Medicare, Medicaid, and other health care programs. A total of \$22.0 million was sequestered from the HCFAC program in FY 2015, for a combined total of \$74.2 million in the past three years. Including funds sequestered from the FBI, the total equals \$101.2 million in the past three years.

STATUTORY BACKGROUND

The 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 2015 is provided as required by Section 1817(k)(5) of the Social Security Act.

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.

In FY 2015, the Secretary and the Attorney General certified \$279.7 million in mandatory funding to the Account after accounting for sequester reductions of \$22.0 million to the total appropriation. Additionally, Congress appropriated \$672.0 million in discretionary funding. A detailed breakdown of the allocation of these funds is set forth later in this report. HCFAC appropriations generally supplement the direct appropriations of HHS that are devoted to health care fraud enforcement and supported over two-thirds of DOJ’s health care fraud funding and over three-fourths of HHS-OIG’s appropriated budget in FY 2015. (Separately, the FBI, which is discussed in the appendix, received \$129.2 million from HIPAA, after accounting for \$10.2 million in mandatory sequester reductions.) Under the joint direction of the Attorney General and the Secretary, the Program’s goals are:

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.

- (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; and
- (4) to provide education and guidance regarding complying with current health care law.

The Act requires the Attorney General and the Secretary to submit a joint annual report to the Congress that 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 113-235 “Consolidated and Further Continuing Appropriations Act, 2015”) 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.”

PROGRAM RESULTS AND ACCOMPLISHMENTS

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 2015, approximately \$2.4 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. Monetary results from these transfers and deposits are provided in the table below:

| Monetary Results: Total Transfers/Deposits by Recipient FY 2015 | |
|--|------------------------|
| Department of the Treasury | |
| Deposits to the Medicare Trust Funds, as required by HIPAA | |
| Gifts and Bequests | \$10,372 |
| Amount Equal to Criminal Fines | 56,549,115 |
| Civil Monetary Penalties | 45,772,271 |
| Asset Forfeiture | 14,791,644 |
| Penalties and Multiple Damages | 512,054,108 |
| Subtotal | 629,177,509 |
| Centers for Medicare & Medicaid Services | |
| HHS-OIG Audit Disallowances — Recovered - Medicare | 132,612,502 |
| Restitution/Compensatory Damages | 793,934,739 |
| Subtotal* | 926,547,241 |
| Grand Total of Amounts Transferred to the Medicare Trust Funds | \$1,555,724,750 |
| Restitution/Compensatory Damages to Federal Agencies | |
| HHS/Other | \$31,355,848 |
| TRICARE | 14,921,254 |
| CMS | 8,253,589 |
| HHS-OIG Cost of Audits, Investigations and Compliance Monitoring | 7,766,281 |
| Other Agencies | 18,200,774 |
| Centers for Medicare and Medicaid Services | |
| Federal Share of Medicaid | 135,866,585 |
| HHS-OIG Audit Disallowances — Recovered - Medicaid | 168,955,572 |
| Subtotal | 385,319,903 |
| Relators' Payments** | 414,456,455 |
| TOTAL*** | \$2,355,501,108 |

*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 (whistleblower) 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).

Expenditures

In the nineteenth year of operation, the Secretary and the Attorney General certified \$279.7 million in mandatory funding as necessary for the Program, after accounting for mandatory sequester reductions of \$22.0 million as required by law. Additionally, Congress appropriated \$672.0 million in discretionary funding. See allocation by recipient below:

| FY 2015 ALLOCATION OF HCFAC APPROPRIATION | | | | |
|--|---|---------------------------------|--------------------------|-------------------------|
| Organization | Mandatory Allocation⁵ | Discretionary Allocation | Funds Sequestered | Total Allocation |
| Department of Health and Human Services | | | | |
| Office of Inspector General ⁶ | \$200,718,475 | \$67,200,000 | (\$14,652,449) | \$253,266,026 |
| Office of the General Counsel | 10,000,000 | 0 | 0 | 10,000,000 |
| Administration for Community Living | 8,710,136 | 0 | 0 | 8,710,136 |
| Food and Drug Administration | 3,377,220 | 0 | 0 | 3,377,220 |
| Centers for Medicare & Medicaid Services | 13,500,000 | 544,320,000 | 0 | 577,820,000 |
| Unallocated Funding | 2,802,456 | 0 | (2,802,456) | 0 |
| Subtotal | 239,108,287 | 611,520,000 | (17,454,905) | 853,173,382 |
| | | | | |
| Department of Justice | | | | |
| United States Attorneys | 31,400,000 | 20,505,542 | | 51,905,542 |
| Civil Division ⁷ | 19,538,751 | 12,093,818 | | 31,632,569 |
| Criminal Division | 4,580,184 | 10,162,659 | | 14,742,843 |
| Civil Rights Division | 2,376,000 | 5,443,276 | | 7,819,276 |
| Justice Management Division | 200,000 | 100,000 | | 300,000 |
| Department of Justice - Other | 4,574,898 | 12,174,705 | (4,574,898) | 12,174,705 |
| Subtotal | 62,669,833 | 60,480,000 | (4,574,898) | 118,574,935 |
| TOTAL⁸ | \$301,778,120 | \$672,000,000 | (\$22,029,803) | \$971,748,317 |

⁵As of FY 2007, mandatory funds are available until expended. Discretionary funds are available for two years.

⁶In addition, HHS-OIG obligated \$9.8 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).

⁷The Elder Justice Initiative, managed by the Civil Division, is included in the Civil Division figures.

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

Overall Recoveries

During this fiscal year, the Federal Government won or negotiated over \$1.9 billion in judgments and settlements, and attained additional administrative impositions in health care fraud cases and proceedings. As a result of these efforts, as well as those of preceding years, approximately \$2.4 billion was returned to the Federal Government or private persons. Of this \$2.4 billion, the Medicare Trust Funds received transfers of approximately \$1.6 billion during this period; and another \$135.9 million in Federal Medicaid money was transferred to the Treasury separately as a result of these efforts.⁹

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

The return on investment (ROI) for the HCFAC program over the last three years (2013-2015) is \$6.10 returned for every \$1.00 expended. Because the annual ROI can vary from year to year depending on the number and type 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.

Health Care Fraud Prevention and 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 perpetrators who are abusing the system and costing us all billions of dollars.
- **To reduce health care costs and improve the quality of care** by ridding the system of perpetrators who are preying on Medicare and Medicaid beneficiaries.

⁹ Note that some of the judgments, settlements, and administrative actions that occurred in FY 2015 will result in transfers in future years, just as some of the transfers in FY 2015 are attributable to actions from prior years.

- **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 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, 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.

Healthcare Fraud Prevention Partnership (HFPP)

The Healthcare Fraud Prevention Partnership (HFPP) is the groundbreaking public/private partnership between the Federal Government, State officials, law enforcement, private health insurance plans and associations, and healthcare anti-fraud associations. 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. Since its inception in 2012, the number of participants has increased to 45 public, private and state partner organizations. The Partnership has completed several studies associated with fraud, waste or abuse that have yielded successful results for participating partners. Studies have examined such subjects as “false store fronts” or “phantom providers” and top billing pharmacies. Additional studies are underway and the Partnership has established a Trusted Third Party (TTP) which conducts HFPP data exchanges, research, data consolidation and aggregation, reporting, and analysis. The TTP will not share the source of the data (i.e., which partner submitted what data) during an exchange in order to keep the identity of the data source confidential. HFPP is continuing to expand with new partners.

The Partnership 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. In FY 2015, the Partnership hosted its fifth Executive Board meeting. The meeting focused on developing a strategy to ensure the productivity of the Partnership and highlighted achievements and progress since the last meeting including data exchanges, information sharing, and partnership growth.

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 in South Florida. The Strike Force is comprised of interagency teams made up of investigators and prosecutors that focus on the worst offenders in regions with the highest known concentration of fraudulent activities. The Strike Force uses advanced data analysis techniques to identify aberrant billing levels in health care fraud “hot spots”—cities with high levels of billing fraud—and target suspicious billing patterns, as well as emerging schemes and schemes that migrate from one community to another. Based on the success of these efforts and increased appropriated funding for the HCFAC program from Congress and the Administration, DOJ and HHS expanded Strike Force operations to a total of nine areas in the United States—Miami, Florida; Los Angeles, California; Detroit, Michigan; Southern Texas; Brooklyn, New York; Southern Louisiana; Tampa, Florida; Chicago, Illinois; and Dallas, Texas.

Each Medicare Fraud Strike Force team brings the investigative and analytical resources of the FBI and HHS-OIG and the prosecutorial resources of the Criminal Division’s Fraud Section and the USAOs to analyze data obtained from CMS and bring cases in federal district court. Strike Force accomplishments in the areas noted above and USAO accomplishments in their districts during FY 2015 include¹⁰:

- 200 indictments, informations and complaints involving charges filed against 391 defendants who allegedly collectively billed the Medicare program approximately \$1.4 billion;
- 314 guilty pleas negotiated and 28 jury trials litigated, with guilty verdicts against 48 defendants; and
- Imprisonment for 263 defendants sentenced during the fiscal year, averaging more than 56 months of incarceration.

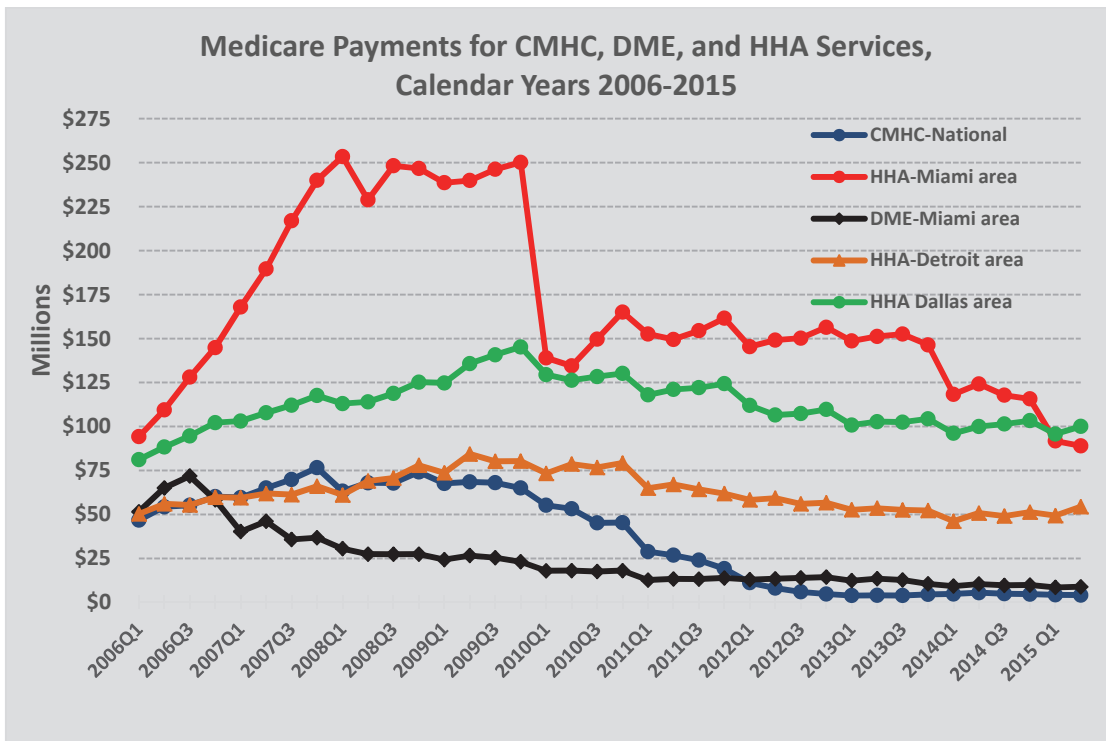
In the eight and a half years since its inception, Strike Force prosecutors filed more than 1,164 cases charging more than 2,536 defendants who collectively billed the Medicare program more than \$8 billion; 1,781 defendants pleaded guilty and 243 others were convicted in jury trials; and 1,477 defendants were sentenced to imprisonment for an average term of approximately 49 months.¹¹

Medicare payment trends demonstrate the positive impact of Strike Force enforcement and prevention efforts. For example, Medicare payments for home health care increased from 2006 until 2010. In 2009, CMS changed Medicare’s Home Health Agency (HHA) outlier coverage policy, following federal enforcement actions initiated by the HEAT Strike Force case *U.S. v. Zambrana* in Miami and HHS-OIG reports regarding home health outlier payments. As reflected

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 2015.

¹¹ These statistics are for the period of May 7, 2007 through September 30, 2015.

on the chart below, since 2010, payments for HHAs in Miami decreased by \$100 million per quarter since the peak in 2009, and continue to decline. In Dallas and Detroit, payments for HHAs are down by over \$40 million and \$25 million per quarter, respectively, since 2010. This may suggest that the home health fraud convictions not only eliminated some of the bad actors but also deterred other fraudsters from exploiting the outlier coverage policy. We have seen similar patterns of decreased Medicare payments for Durable Medical Equipment (DME) and community mental health services (CMHC) following concentrated law enforcement initiatives and administrative fraud prevention efforts.



For examples of successful Strike Force cases initiated or concluded during FY 2015, please see “Highlights of Successful Criminal and Civil Investigations” beginning on p. 12.

Highlights of Successful Criminal and Civil Investigations

Our respective Departments successfully pursued Medicare Fraud Strike Force matters, as well as other criminal and civil investigations in a wide range of areas. Cases are organized by type and presented in chronological order. **Strike Force cases are denoted by (SF) in the lead sentence.**

Ambulance and Transportation Services

In November 2014, the co-owner of Brotherly Love, a Philadelphia, Pennsylvania ambulance company, was sentenced to 5 years and 4 months of incarceration and was ordered to pay more than \$2 million in restitution after pleading guilty to health care fraud and the anti-kickback statute (AKS) charges. The investigation revealed that the co-owner and her co-conspirators transported by ambulance patients who could walk; transported patients in personally owned vehicles, but billed as if the patients were transported by ambulance; used patient information to bill as if the patients had been transported by ambulance when, in fact, the patients actually transported themselves; and paid patients to be transported by Brotherly Love.

In May 2015, five Orange County California ambulance companies in San Diego, California agreed to pay a total of more than \$11.5 million to settle civil False Claims Act (FCA) allegations that they engaged in so-called “swapping” kickback schemes by providing deeply discounted—and often below cost—ambulance services to hospitals and/or skilled nursing facilities (SNFs) in exchange for exclusive rights to the facilities’ more lucrative Medicare patient referrals in violation of the AKS. The government alleged that the arrangements resulted in false claims for Medicare Part B transports, which in essence subsidized the discounted trips. The settling defendants were Pacific Ambulance, Inc., Bowers Companies, Inc., Care Ambulance Service, Inc., Balboa Ambulance Service, Inc., and E.R. Ambulance, Inc.

(SF) In August 2015, the owner, operators, and managers of ProMed Medical Transportation, an ambulance transportation company in the greater Los Angeles area, were convicted after trial for their roles in a \$2.4 million Medicare fraud scheme. The evidence at trial demonstrated that the defendants conspired to bill Medicare for ambulance transportation services for individuals whom the defendants knew did not need such services. The defendants also instructed emergency medical technicians who worked at ProMed to conceal the true medical conditions of patients they were transporting by altering requisite paperwork and creating fraudulent documents to justify the transportation services.

(SF) In June 2015, a general manager and a dispatch supervisor of Mauran Ambulance Inc., an ambulance company in San Fernando, California, were indicted for their roles in a \$28 million Medicare fraud scheme. The defendants allegedly billed Medicare for medically unnecessary ambulance transportation services, which primarily were to and from dialysis treatments. In their respective roles at Mauran, the defendants instructed emergency medical technicians who worked at Mauran to conceal the true medical condition of patients they were transporting by altering paperwork and creating false reasons to justify Mauran’s ambulance transportation services. A former administrator of a dialysis clinic was also indicted for receiving cash kickbacks from Mauran’s general manager in exchange for patient referrals.

Clinics

In FY 2015, DaVita Healthcare Partners, Inc., the nation's largest provider of dialysis services, agreed to pay a total of \$800 million to settle allegations made in two civil FCA actions. In October 2014, DaVita agreed to pay \$350 million to settle civil FCA allegations that it paid kickbacks to induce the referral of patients to its dialysis clinics. The government alleged that DaVita offered physicians lucrative opportunities to acquire and/or sell an interest in DaVita dialysis clinics to which their patients would be referred for treatment and then prevented the physicians from referring their patients to other dialysis providers through a series of non-compete and non-disparagement agreements with the physicians. In June 2015, DaVita paid an additional \$450 million to settle civil FCA allegations pursued by two whistleblowers that it created unnecessary waste in administering the drugs Zemplar and Venofer to dialysis patients, and then billed federal health care programs for such avoidable waste.

(SF) In October 2014, two owners of several Brooklyn, NY medical clinics pled guilty to health care fraud conspiracy and falsification of records in the Eastern District of New York. The medical director of one clinic pled guilty to health care fraud conspiracy in March 2015. The defendants owned and operated a series of medical clinics that were used to submit more than \$14.3 million in Medicare claims, of which \$5.3 million was paid. The indictment alleged that the majority of the claims were fraudulent because they were for services such as vitamin infusions, physical and occupational therapy, and diagnostic tests that were medically unnecessary, not provided, or otherwise not reimbursable. The defendants also allegedly laundered the proceeds of the fraudulent scheme and falsified documents, which they then provided to Medicare auditors and the FBI in order to conceal the fraudulent scheme.

(SF) In October 2014, an occupational therapist pled guilty in the Eastern District of New York to health care fraud conspiracy for his role in a scheme that involved the payment of cash kickbacks to elderly beneficiaries who received massages and light group exercises that were billed to Medicare and Medicaid as individual one-on-one occupational therapy and other occupational therapy services. As part of the scheme, the defendant, who was a full-time therapist for the New York Board of Education, signed false and fabricated patient charts and billing records for therapy that was not actually provided. As part of the plea, the defendant agreed to restitution and forfeiture of \$1.6 million. Between February 2008 and February 2011, the defendant was the seventh-highest biller of occupational therapy in the country.

(SF) In January 2015, two physician owners of Spectrum Care P.A., a Houston community mental health clinic, were sentenced to 148 months and 120 months, respectively, for their roles in a \$97 million Medicare fraud scheme. The physician defendants were convicted, along with three co-defendants—a group home owner, a physician assistant, and an office manager—of health care fraud conspiracy and substantive counts of health care fraud following a five-week jury trial. The evidence at trial showed that the physician defendants signed admission documents and progress notes certifying that Medicare beneficiaries qualified for partial hospitalization services, when they did not. The evidence also showed that the physician defendants paid kickbacks to group home operators and patient recruiters, including their co-defendants, in exchange for the referral of beneficiaries. The group home owner was sentenced to 54 months' imprisonment, the office manager was sentenced to 60 months' imprisonment, and the physician assistant was sentenced to 68 months' imprisonment.

In January 2015, six co-conspirators in Arlington, Texas were sentenced for submitting over \$5 million in false health insurance claims to Blue Cross Blue Shield of Texas (BCBS), the Federal Employees Health Benefits Program, and other insurers for services not rendered at a chiropractic clinic. The co-conspirators included a licensed chiropractor and occupational therapist who allowed the use of their provider numbers to fraudulently bill insurers for services not provided. To further the scheme, a union representative for a Texas automotive parts manufacturer actively recruited employees to go to the co-conspirators' chiropractic clinic. The union representative and recruited employees received illegal kickback for these referrals. The sentences imposed in this case ranged from 6 months imprisonment to 156 months imprisonment, and restitution from \$1.3 to \$2.4 million.

(SF) In February 2015, the co-owners of BONB LLC, aka Bioscan, were sentenced to 57 and 37 months' imprisonment in the Middle District of Florida for their roles in a health care fraud and money laundering scheme. Bioscan was a shell company the defendants used to facilitate a multi-million dollar fraud scheme executed through several purported medical clinics. As part of their guilty pleas, the defendants admitted that their co-conspirators submitted \$12 million in fraudulent claims to Medicare, including claims resulting from illegal kickback arrangements and claims for radiology, audiology, neurology, and cardiology services that were never rendered. The defendants admitted to attempting to conceal the proceeds of the fraudulent claims by transferring funds through bank accounts for Bioscan and other entities. In addition to the prison sentences, one defendant agreed to forfeit a \$60,000 platinum and diamond ring he purchased with health care fraud proceeds.

In July 2015, the operator of a sham clinic in the Central District of California was sentenced after being convicted at trial to 15 years in federal prison for his role in a \$20 million scheme to defraud Medicare and Medicaid by fraudulently prescribing expensive anti-psychotic medications, selling these drugs on the black market, and then redistributing them to pharmacies, where the drugs would be subject to new claims made to Medicare and Medicaid as though they were new bottles of drugs. Employees of sham clinic generated thousands of prescriptions for identity theft victims—such as elderly Vietnamese beneficiaries of Medicare and Medicaid, military veterans who were recruited from drug rehab programs, and denizens of Skid Row. This case was the first in the nation involving an organized scheme to defraud government health care programs through fraudulent claims for expensive anti-psychotic medications.

Community Mental Health Centers

(SF) In December 2014, a certified nursing assistant in Miami, Florida was sentenced to 12 years and six months in prison and ordered to pay \$18.2 million in joint and several restitution after being convicted by a jury on charges of relating to health care fraud. American Therapeutic Corporation (ATC) operated several purported partial hospitalization programs (PHP) throughout Florida. Evidence at trial demonstrated that the defendant received thousands of dollars a month in cash kickbacks in exchange for referring Medicare patients to ATC. The evidence also demonstrated that the beneficiaries he sent to ATC did not need, qualify for, or receive PHP treatment. Nevertheless, ATC submitted false claims to Medicare for PHP services purportedly provided to each of these patients. To date, 30 defendants, including the owners of

ATC, have previously pleaded guilty or been convicted at trial on charges related to the ATC scheme, which resulted in more than \$200 million in fraudulent Medicare billings.

(SF) In January 2015, two physicians in Houston, Texas were sentenced to a combined 22 years and 4 months in prison and ordered to pay a combined \$8 million in restitution after being convicted by a jury on charges relating to health care fraud. The two physicians owned a community mental health center (CMHC) that purportedly provided PHP services to Medicare beneficiaries. Evidence at trial showed that the two physicians paid kickbacks to group care home operators and patient recruiters in exchange for bringing ineligible Medicare beneficiaries to their CMHC. They then signed admission documents and progress notes certifying that the beneficiaries qualified for PHP services when, in fact, they did not qualify for or need these services and/or the actual services were not performed. The CMHC billed Medicare approximately \$97 million for these fraudulent services. One of the group home owners was sentenced to 4-and-a-half years in prison and ordered to pay \$1.8 million in restitution.

(SF) In April 2015, a licensed mental health counselor in Miami, Florida was sentenced to 4 years in prison and ordered to pay \$13.6 million in joint and several restitution after pleading guilty to conspiracy to commit health care fraud. The defendant worked as a therapist for Health Care Solutions Network, Inc., in Florida (HCSN-FL). He admitted that he provided intensive therapy to mental health patients who were ineligible to receive the therapy or could not benefit from partial hospitalization program (PHP) services, including patients suffering from dementia, mental retardation, and Alzheimer's disease. He signed fabricated PHP therapy notes and other medical records, which were used to support the false claims to Medicare and Medicaid. During his employment, the defendant and his co-conspirators submitted approximately \$31 million in false claims to Medicare and Florida Medicaid programs.

Device Companies

In December 2014, OtisMed Corp. of Newark, New Jersey was ordered to pay \$34.4 million in fines and \$5.1 million in forfeiture after pleading guilty to distributing, with the intent to defraud and mislead, adulterated medical devices into interstate commerce in violation of the Food, Drug, and Cosmetic Act. OtisMed submitted a pre-market notification to the Food and Drug Administration (FDA) seeking clearance to market the OtisKnee in October 2008. In September 2009, the FDA sent OtisMed a notice that its submission was denied, stating that the company failed to demonstrate that the OtisKnee was as safe and effective as other legally marketed devices. Despite his awareness of the letter and advice from legal counsel that it would be unlawful to continue distributing the OtisKnee, the Chief Executive Officer ordered employees at OtisMed to distribute more than 200 OtisKnee devices to surgeons throughout the United States. The CEO and others also concealed the shipments from the FDA, and did not disclose that distributing OtisKnee was prohibited. The CEO pleaded guilty to introducing adulterated medical devices in interstate commerce and was sentenced on June 29, 2015 to 24 months in prison. Apart from the criminal plea, OtisMed agreed to pay a \$41.2 million settlement to resolve its civil FCA liability arising from the marketing and distribution of the OtisKnee, and to be excluded from participation in federal health care programs for 20 years.

In February 2015, medical device manufacturer ev3 Inc., formerly known as Fox Hollow Technologies Inc., agreed to pay \$1.3 million to resolve civil FCA allegations that it caused

certain hospitals to submit false claims to Medicare for unnecessary inpatient admissions for procedures involving its atherectomy device. Atherectomy is a minimally-invasive surgical procedure that uses a small cutting device to remove atherosclerosis, or hardening of the arteries, from large blood vessels within the body. The government alleged that to increase hospital purchases of its atherectomy devices, Fox Hollow advised hospitals that they should bill atherectomy procedures as more expensive inpatient claims, as opposed to less costly outpatient claims. As a result, certain hospitals allegedly claimed greater reimbursement than they were entitled to receive for procedures involving Fox Hollow's devices.

In April 2015, Medtronic plc and certain affiliated Medtronic companies agreed to pay \$4.4 million to settle civil FCA allegations that they made false statements to the U.S. Department of Veterans Affairs and the U.S. Department of Defense regarding the country of origin of certain Medtronic products sold to the United States. The Trade Agreements Act of 1979 (TAA) generally requires companies selling products to the United States to manufacture them in the United States or in another designated country. The settlement resolved allegations that Medtronic sold to the United States products manufactured in China and Malaysia; under the TAA, the Government is precluded from acquiring the products at issue from those countries. The specific Medtronic products included anchoring sleeves sold with cardiac leads and used to secure the leads to patients, certain instruments and devices used in spine surgeries, and a handheld patient assistant used with a wireless cardiac device.

In July 2015, NuVasive Inc. of San Diego, California, agreed to pay \$13.5 million to resolve allegations that the company promoted its CoRoent System for surgical uses that were not approved or cleared by the FDA and paid kickbacks to induce physicians to use its CoRoent System. The government alleged that, between 2008 and 2013, NuVasive promoted its CoRoent System for certain surgical uses, including for use in treating two complex spine deformities: severe scoliosis and severe spondylolisthesis. Because these specific uses were not approved or cleared by the FDA, the claims submitted to Medicare and Medicaid from physicians and hospitals for these spine surgeries were not eligible for reimbursement. The government also alleged that NuVasive knowingly offered and paid illegal remuneration to certain physicians to induce them to use the CoRoent System in spine fusion surgeries, in violation of the Federal anti-kickback statute. The alleged illegal remuneration consisted of promotional speaker fees, honoraria, and expenses relating to physicians' attendance at events sponsored by a group that was allegedly created, funded, and operated by NuVasive.

Drug Companies

In January 2015, Daiichi Sankyo Inc., a global pharmaceutical company, agreed to pay \$39 million to resolve civil FCA allegations that it paid kickbacks to induce physicians to prescribe Daiichi drugs, including Azor, Benicar, Tribenzor and Welchol. The alleged kickbacks took the form of honoraria payments, lavish meals, and other remuneration to physicians who participated, or supposedly participated, in speaker programs. Daiichi allegedly made payments to physicians even when physicians took turns "speaking" on duplicative topics over Daiichi-paid dinners, the recipient spoke only to members of his or her own staff in his or her own office,

or the associated dinner was so lavish that its cost exceeded Daiichi's own internal cost limitation of \$140 per person.

In February and May 2015, Medco Health Solutions, Inc., a wholly-owned subsidiary of the pharmacy benefit manager Express Scripts Holding Company, and AstraZeneca, a pharmaceutical manufacturer, agreed to pay a total of \$15.8 million to settle civil FCA allegations of a kick-back scheme involving marketing and selling pharmaceutical products. The government alleged that AstraZeneca paid kickbacks to Medco in exchange for identifying Nexium as the "sole and exclusive" proton pump inhibitor on certain of Medco's prescription drug lists known as formularies. The alleged remuneration from AstraZeneca took the form of price concessions on certain AstraZeneca drugs other than Nexium, namely on Prilosec, Toprol XL, and Plendil.

In July 2015, drug manufacturers AstraZeneca LP and Cephalon, Inc. agreed to pay a total of \$54 million to settle civil FCA allegations that they knowingly underpaid rebates owed under the Medicaid Drug Rebate Program (MDRP). Pursuant to the MDRP, drug manufacturers must pay quarterly rebates to state Medicaid programs in exchange for Medicaid's coverage of the manufacturers' drugs. The rebates are based, in part, on the Average Manufacturer Prices (AMPs) that the manufacturers report to the government for each of their covered drugs. The settlements with AstraZeneca and Cephalon resolved allegations that they underreported AMPs for a number of their drugs by improperly reducing the reported AMPs for service fees they paid to wholesalers. As a result, the government contended that AstraZeneca and Cephalon underpaid quarterly rebates owed to the states and caused the United States to be overcharged for its payments to the states for the Medicaid program.

Durable Medical Equipment (DME)

In December 2014, a medical supplies company owner was sentenced in Baton Rouge, Louisiana to 156 months imprisonment for submitting hundreds of false and fraudulent claims to Medicare for medical devices over a two year period. For instance, he submitted claims for "brace kits," regardless of whether any of the Medicare beneficiaries named in the claims needed or had prescriptions for the items, submitted claims for custom-fabricated devices which were never provided, and submitted numerous claims for expensive replacement power wheelchairs that he falsely claimed had been damaged or destroyed by a hurricane. The owner was ordered to make restitution to the Medicare program in the amount of \$1.2 million, to forfeit the proceeds of his criminal activity up to an additional \$1.2 million, and to serve a two-year term of supervised release.

(SF) In February 2015 and May 2015, two individuals pled guilty to health care fraud conspiracy for their roles in a \$13 million long-running scheme to submit false claims for durable medical equipment to a government-sponsored organization for managed care in New York. The scheme involved the defendants using information for approved, in-network equipment providers to obtain approvals that were then used to secure payments on behalf of sham companies that the defendants set up. Companies believed to have been involved in the scheme submitted fraudulent claims to the managed care organization in amounts over \$13 million since 2008. In

September 2015, one of the defendants was sentenced to 21 months in jail and ordered to pay over \$337,000 in forfeiture and the same amount in restitution.

(SF) In March 2015, an owner of Colonial Medical Supply, a durable medical equipment company in Los Angeles, was convicted after a jury trial for his role in a \$3.3 million Medicare fraud scheme. The evidence at trial established that the defendant paid cash kickbacks to medical clinics for fraudulent prescriptions for durable medical equipment, such as expensive power wheel chairs, which the patients did not need. The defendant then used these prescriptions to bill Medicare for the medically unnecessary equipment. In May 2015, the defendant was sentenced to 84 months' imprisonment.

(SF) In March 2015, an owner of Ezcor-9000, Inc., a durable medical equipment company in Valencia, California, was convicted after an eight-day jury trial for her role in a \$3.5 million Medicare fraud scheme. The evidence at trial established that the defendant paid illegal kickbacks to patient recruiters in exchange for patient referrals. The evidence also showed that the defendant paid kickbacks to physicians for fraudulent prescriptions—primarily for medically unnecessary, but expensive, power wheelchairs—that she then used to support her fraudulent bills to Medicare. In June 2015, the defendant was sentenced to 97 months in prison.

In May 2015, DME suppliers Orbit Medical Inc. and its partial successor, Rehab Medical Inc., agreed to pay \$7.5 million to settle civil FCA allegations that Orbit submitted false claims to federal health care programs for power wheelchairs and accessories. The settlement resolved allegations that Orbit sales representatives knowingly altered physician prescriptions and supporting documentation to get Orbit's power wheelchair and accessory claims paid by Medicare, the Federal Employees Health Benefits Plan and the Defense Health Agency. In particular, the government alleged that Orbit sales representatives changed or added dates to physician prescriptions and chart notes to falsely document that the prescription was sent to the supplier within 45 days of the face-to-face beneficiary exam; changed the physician prescription, chart notes, and other documentation to falsely establish medical necessity for the power wheelchair or accessory; and added facsimile stamps to supporting documentation to make it appear as though the physician's office had sent the documents to Orbit.

In May 2015, a DME supplier in Austin, Texas was sentenced to 36 months imprisonment and 3 years supervised release, and ordered to pay \$846,171 in restitution for submitting fraudulent bills through the Department of Labor for items never sent to patients. The supplier was billing primarily for electrode pads. The false claims were for DME supplies for U.S. Postal employees. The scheme ran for at least three years and involved billings to the Government of over \$1 million. The supplier paid the restitution/forfeiture up-front, and the forfeiture included cash and a 2014 BMW.

(SF) In May 2015, a registered nurse and owner of a DME company in Los Angeles, California was sentenced to 4 years in prison and ordered to pay \$4.3 million in joint and several restitution after being convicted of health care fraud and laundering of monetary instruments. According to the investigation, the nurse/owner and her co-conspirators used cash and checks to pay illegal kickbacks to recruit Medicare beneficiaries for power wheelchairs and other DME, to which the beneficiaries did not have a legitimate medical need. She and her co-conspirators also paid

illegal kickbacks to a physician in exchange for writing false prescriptions and documents for the DME, which was then used to fraudulently bill Medicare.

Electronic Health Records

In June 2015, the Chief Financial Officer (CFO) of Shelby Regional Medical Center of Center, Texas, was sentenced to 1 year and 11 months in jail and ordered to pay \$4.4 million in restitution after pleading guilty to making a false statement. As CFO he oversaw the implementation of electronic health records (EHR) for the hospital and was responsible for attesting that the hospital's EHR platform met meaningful use requirements in order to qualify for incentive payments under Medicare's EHR Incentive Program. During FY 2012, Shelby Regional did not meaningfully use the EHR platform, despite an attestation from the CFO that it did. He falsely certified to CMS that Shelby Regional met the meaningful use requirements, even though he was fully aware that Shelby Regional used the EHR system sparingly and did not meet the criteria for incentives. As a result of his conduct, Shelby Regional received a \$785,655 EHR incentive payment from CMS in FY 2012.

Health Maintenance Organization

In May 2015, an employee of several organizations in Miami, Florida, including Florida Healthcare Plus, Inc. (FHCP), was sentenced to 2 years in prison and ordered to pay \$16 million in joint and several restitution after pleading guilty to conspiracy to commit health care fraud and wire fraud. FHCP was a health maintenance organization in Florida. According to the investigation, the defendant submitted fraudulent Medicare and Medicaid enrollment applications for beneficiaries, which claimed that the beneficiaries resided in Florida, when they actually resided in Nicaragua and the Dominican Republic. In addition to the defendant, five other individuals connected to this health care fraud scheme were sentenced in June 2015 to a combined 10 years and 3 months in prison and ordered to pay \$16 million in joint and several restitution.

Home Health Providers

(SF) In October 2014, the director of two Miami-based businesses that purportedly provided home health services to Medicare beneficiaries was sentenced to 10 years and 1 month in prison and ordered to pay \$18.6 million in restitution after pleading guilty to conspiracy to commit health care fraud and payment of kickbacks in connection with a federal healthcare program. The investigation related that the director paid co-conspirators thousands of dollars in kickbacks in exchange for referring Medicare beneficiaries and also paid kickbacks to the owner of a medical clinic in exchange for home health service prescriptions.

In November 2014, CareAll Management LLC, a Nashville, Tennessee home health provider, agreed to pay \$25 million to settle civil FCA allegations that it submitted false and upcoded home health care billings to the Medicare and Medicaid programs. The settlement resolves allegations that CareAll overstated the severity of patients' conditions to increase billings and billed for services that were not medically necessary and rendered to patients who were not homebound.

(SF) In November 2014, an administrator and owner at two Miami-based Florida businesses which purportedly provided home health care and physical therapy services to Medicare beneficiaries was sentenced to 6 years and 8 months of incarceration and ordered to pay \$45 million in restitution after pleading guilty to conspiracy to commit health care fraud. The investigation revealed that administrator/owner and her co-conspirators paid kickbacks to patient recruiters for the referral of patients and for the provision of medically unnecessary or sham prescriptions, plans of care, and certifications for therapy and home health services. The businesses submitted approximately \$74 million in fraudulent claims for home health services to Medicare and were paid approximately \$45 million on those claims. Another co-conspirator was previously sentenced to 5 years in prison and ordered to pay \$27 million in restitution.

(SF) In January 2015, the owner of Nation's Best Home Health, a Miami home health care agency, was sentenced to 106 months' imprisonment for his role in a \$35 million Medicare fraud scheme. According to his plea agreement, the defendant and his co-conspirators operated Nation's Best for the purpose of billing the Medicare program for, among other things, physical therapy and other home health care services that were not medically necessary or not provided. The co-conspirators paid kickbacks to patient recruiters in exchange for patient referrals to Nation's Best, as well as prescriptions, plans of care, and certifications for medically unnecessary home health care services, all of which were used to fraudulently bill the Medicare program for unnecessary home health care services.

In January 2015, an owner and operator of Norfolk, Virginia based Community Personal Care home health care services was sentenced to 63 months in prison, followed by three years of supervised release, and his wife who was the company's office administrator and executive assistant was sentenced to 25 months in prison, followed by three years of supervised release for their operation of a massive false billing scheme. During a three week trial, the government proved that 7,800 fraudulent claims were submitted to the Virginia Medicaid program, falsely representing that personal care and respite care services had been provided to 78 Medicaid recipients by Community Personal Care. To conceal the fraudulent payments, the defendants directed employees to alter the company's office records, including home health aide time sheets. Both defendants were ordered together to pay \$1.5 million in restitution.

(SF) Between January 2015 and May 2015, five patient recruiters pled guilty for their roles in a \$4.5 million Medicare fraud scheme involving Joystar Home Health Services, LLC, a home health care company located in Richmond, Texas. According to court documents, each of the defendants agreed with Joystar's owner and director of nursing to refer Medicare beneficiaries to Joystar in exchange for kickbacks. Joystar then billed Medicare for home health care services that were medically unnecessary or not provided. The co-conspirators in the fraud also paid beneficiaries to participate in the scheme and paid physicians to authorize medically unnecessary services. Previously, the owner of Joystar was sentenced to five years' imprisonment following his guilty plea to structuring over \$1.8 million to conceal the funds he used to pay kickbacks to patient recruiters and physicians. Joystar's director of nursing, who pled guilty to health care fraud and structuring, is awaiting sentencing.

In February 2015, ResCare Iowa Inc., a home health service provider, agreed to pay \$5.6 million to settle civil FCA allegations that it submitted false home health care billings to Medicare and

Medicaid. Medicare and the state of Iowa's Medicaid program require an independent physician to certify that home health care services are medically necessary and to order the specific type and amount of health care services to be provided by the home health agency (HHA). The settlement resolves allegations that ResCare Iowa billed the government for services provided to Medicare and Medicaid patients in Iowa without documenting compliance with these requirements.

(SF) In April 2015, the Miami, Florida owner of a business that purportedly provided home health care and physical therapy services to Medicare beneficiaries was sentenced to 9 years and 5 months in prison and ordered to pay \$21 million in restitution after pleading guilty to conspiracy to commit health care fraud. According to the investigation, the owner and his co-conspirators paid patient recruiters to place beneficiaries at the business. The recruiters then sent the beneficiaries to doctors to obtain prescriptions for home health services that were not medically necessary and were not provided. The man and his co-conspirators caused patient documentation to be falsified in order to bill Medicare approximately \$32 million for the fraudulent services. He was indicted in May 2013 and was an HHS-OIG Most Wanted Fugitive living in Cuba until he returned to the United States in September 2014 and was arrested.

(SF) Between April and July 2015, three defendants were sentenced in the Eastern District of Michigan to a combined 20 years and 8 months in jail and ordered to pay more than \$22 million in joint and several restitution after being convicted of conspiracy to commit health care fraud and other charges. Two of the defendants jointly operated several home health agencies in Michigan, while the third, who was a daughter of one of the others, co-operated a home health agency. According to the investigation, the three defendants, along with their co-conspirators, paid kickbacks and bribes to recruiters and others for beneficiary information that would be used to falsely bill Medicare millions for home health services that were medically unnecessary and not performed. Another co-conspirator, who jointly operated several of the home health care facilities, was indicted in September 2012, but investigators believe that he fled the country.

(SF) In April 2015, the owner of AA Advanced Home Health Inc., a Miami home health care agency, was sentenced to 113 months' imprisonment for his role in a \$32 million home health care fraud scheme. As part of his guilty plea, the defendant admitted that he and his co-conspirators paid kickbacks to patient recruiters in exchange for patient referrals and billed Medicare for physical therapy and other home health care services that were medically unnecessary or not provided.

(SF) In April 2015, the owner of multiple home health care agencies in the Detroit area was sentenced to 120 months' imprisonment after being convicted in an eight-week jury trial for his role in a \$29.1 million Medicare fraud scheme. The wide-ranging scheme involved approximately 30 purported medical clinics in the Detroit area that paid kickbacks to patient recruiters and billed Medicare for home health services that were not provided. Eight co-defendants previously pled guilty and two co-defendants were convicted at trial. One of the co-defendants who owned two home health care companies involved in the scheme pled guilty and was sentenced to 80 months' imprisonment in July 2015. That defendant also received proceeds of the home health care fraud through bank accounts he controlled, withdrew substantial sums for his personal use, failed to report these proceeds on his individual federal income tax returns, and pled guilty to filing a false tax return.

(SF) In May 2015, the owner of a Miami-based business that purportedly provided home health and therapy services to Medicare beneficiaries was sentenced to 10 years in prison and ordered to pay \$13 million in joint and several restitution after pleading guilty to conspiracy to commit health care fraud. The owner admitted that he and his co-conspirators billed Medicare for, among other things, expensive physical therapy and home health care services that were not medically necessary and/or were not provided. The owner and his co-conspirators also paid kickbacks and bribes to other co-conspirators in doctors' offices and clinics in exchange for providing home health and therapy prescriptions. From approximately January 2009 to November 2014, Longcare submitted more than \$13 million in claims to Medicare for home health services that were not necessary and/or were not provided. Eight defendants who participated in the fraud scheme were previously sentenced to a combined 53 years and 7 months in jail.

In June 2015, a group of home health care companies—Friendship Home Healthcare, Inc., Friendship Home Health, Inc., Angel Private Duty and Home Health, and Friendship Home Health Agency, LLC. (collectively “Friendship”)—and their owner agreed to pay \$6.5 million to resolve civil FCA allegations that they improperly billed federal health care programs for home health services. The settlement resolves allegations that Friendship submitted false claims for private duty nursing services that were furnished or supervised by a woman who was excluded from billing federal and state health care programs and that Friendship submitted required forms containing the forged signature of Friendship’s Director of Nursing.

(SF) In July 2015, an owner and controller of multiple home health care agencies in the Detroit area and a co-owner were convicted at trial for their roles in a \$33 million home health care fraud scheme. One co-defendant, a patient recruiter, previously pled guilty for her role in the scheme. According to the evidence at trial, patient recruiters were paid kickbacks to bring Medicare beneficiaries into the scheme. In exchange for cash kickbacks and prescriptions for controlled substances, the beneficiaries signed forms and therapy visit sheets that were later falsified to indicate they received home health services that were never provided. Physicians employed by one of the defendants then purported to examine non-homebound Medicare beneficiaries for home health care services, signed false paperwork so they could be billed through four home health agencies, and provided the patients with narcotic prescriptions.

Hospice Care

In February 2015, for-profit hospice provider Good Shepherd Hospice Inc., whose main location is in Oklahoma City, and certain affiliated entities agreed to pay \$4 million to resolve civil FCA allegations that they submitted false claims for hospice patients who were not terminally ill. The Medicare hospice benefit is available for patients who elect palliative treatment for a terminal illness and have a life expectancy of six months or less if their illness runs its normal course. The settlement resolved allegations that Good Shepherd knowingly submitted false claims for hospice care for patients who were not terminally ill by pressuring staff to meet admissions and census targets, paying bonuses to staff based on the number of patients enrolled, hiring medical directors based on their ability to refer patients, and failing to properly train staff on the hospice eligibility criteria.

In June 2015, Covenant Hospice Inc., a non-profit hospice service provider, agreed to pay \$10 million to settle civil FCA allegations that it overbilled Medicare, TRICARE and Medicaid for hospice services. Hospice benefits are generally available only for patients who have a life expectancy of six months or less if their disease runs its normal course. Patients admitted to a hospice stop receiving care to cure their illnesses and instead receive medical care focused on providing them with relief from the symptoms, pain and stress of a terminal illness. The settlement resolved allegations that Covenant improperly submitted hospice claims for higher-level inpatient care that should have been billed at lower-level routine home care.

(SF) In June 2015, two physicians and three owners of hospice and home health care companies in the greater Detroit area were charged for their roles in a \$58.3 million scheme to defraud Medicare by submitting claims for home health care and hospice services that were medically unnecessary or not provided. According to court documents, the owners of the home health care and hospice companies, two of whom are also registered physical therapists, paid physicians and patient recruiters kickbacks for referring patients, then billed Medicare for services that were medically unnecessary or never provided. The companies, located in Livonia, Michigan, were A Plus Hospice and Palliative Care, At Home Hospice, and At Home Network Inc., a home health care agency. The physicians who solicited and received kickbacks also submitted claims to Medicare for medically unnecessary physician services. Court documents also allege that one of those physicians used prescriptions for controlled substances to induce beneficiaries to allow At Home Network to bill Medicare for purportedly providing services to the beneficiaries.

Hospitals and Health Systems

In October 2014, Dignity Health, the fifth largest health system in the country formerly known as Catholic Healthcare West, agreed to pay \$36.7 million to settle civil FCA allegations that 13 of its hospitals in California, Nevada, and Arizona knowingly submitted false claims to Medicare and TRICARE by admitting patients who could have been treated on a less costly, outpatient basis. Specifically, the government alleged that certain Dignity hospitals billed Medicare and TRICARE for inpatient care for certain patients who underwent elective cardiovascular procedures and elective, minimally-invasive kyphoplasty procedures and patients with certain common medical diagnoses where admission as an inpatient was medically unnecessary and appropriate care could have been provided in a less costly outpatient or observation setting.

In December 2014, the owner/operator of a hospice agency in Greenwood, Mississippi was sentenced to 5 years and 10 months in prison and ordered to pay \$7.9 million in restitution after pleading guilty to conspiracy to commit healthcare fraud. The investigation revealed that, from around March 2010 to February 2013, the owner/operator and her co-conspirators used the hospice to submit millions of dollars in fraudulent claims to Medicare, for which they were reimbursed more than \$12.5 million. These false billings included claims for patients who were not eligible for hospice benefits because they were not terminally ill and claims based on medical records containing forged signatures of the beneficiaries, the hospice Medical director, and/or the beneficiaries' attending physician. In addition, the defendant, through the hospice, submitted claims to Medicare based on patient referrals from physicians who, in actuality, never referred patients. Many of the patient names were obtained from a medical records clerk, who has been separately charged for accepting over \$240,000 in kickbacks from the defendant. The defendant

used the funds obtained from Medicare to purchase more than \$1.4 million in vehicles and property.

In December 2014, five senior hospital administrators and five hospital physicians and a podiatrist in Illinois were charged with criminal violation of conspiracy to receive kickbacks and receiving kickbacks. In December 2014, two administrators pled guilty and the remaining administrators went to trial. After a seven-week trial, on March 19, 2015, the jury found each of the defendants guilty of the charges alleged. The Court sentenced one administrator to 54 months' imprisonment and a \$770,000 fine, another administrator was sentenced to 21 months' imprisonment, and a third was sentenced to a term of imprisonment of 12 months and 1 day and to pay a fine of \$25,000 on July 30, 2015. The Court has also entered joint and several orders of forfeiture against the administrators in the amount of \$10.5 million and \$8.5 million. Three doctors pled guilty and one has been sentenced to six months imprisonment, two went to trial and one was acquitted, the third doctor is set to go trial in 2016.

In February 2015, Community Health Systems Professional Services Corporation (CHS), a nationwide hospital management company, and three of its affiliated New Mexico hospitals agreed to pay \$75 million to settle civil FCA allegations that they made illegal donations to county governments that were used to fund the state share of Medicaid payments to the hospitals. Under a program discontinued in 2014, the federal government reimbursed New Mexico for approximately 75 percent of supplemental Medicaid expenditures in rural hospitals, and required that New Mexico's 25 percent matching payments had to consist of state or county funds, and not donations from private hospitals. The government alleged that CHS knowingly made improper donations to Chaves, Luna, and San Miguel counties, which were then used by the counties, and subsequently the state, to obtain federal matching payments. The government alleged that CHS concealed the true nature of these donations, and as a result of its scheme, received supplemental Medicaid payments which were funded by the United States in the amount of three times CHS' donations.

In April 2015, The Medical Center of Central Georgia, Inc. (MCCG) agreed to pay \$20 million to resolve civil FCA allegations that it submitted false claims to Medicare for medically unnecessary inpatient admissions, including zero-day stays, one-day stays, cardiac stays with a procedure, and cardiac stays without a procedure. Specifically, these services should have been billed as outpatient or observation services due to the absence of medical necessity for inpatient services.

In April 2015, Citizens Medical Center, a county-owned hospital in Victoria, Texas, agreed to pay \$21.7 million to settle civil FCA allegations that it engaged in improper financial relationships with referring physicians. The settlement resolved allegations that the hospital provided compensation to several cardiologists that exceeded the fair market value of their services and that the hospital paid bonuses to emergency room physicians that improperly took into account the value of their cardiology referrals in violation of the Stark Law.

In June 2015, Children's Hospital in Washington, DC, Children's National Medical Center Inc., (CNMC) and its affiliated entities agreed to pay \$12.9 million to resolve civil FCA allegations that they submitted false cost reports and other applications to the components and contractors of HHS, as well as to Virginia and District of Columbia Medicaid programs. The settlement resolves allegations that CNMC misstated information regarding its available bed count and overhead costs on cost reports and applications that were used by HHS and Medicaid programs to calculate reimbursement rates to CNMC.

In June 2015, Community Health Network (CHN), an Indiana-based non-profit health system, agreed to pay over \$20 million to resolve allegations that it submitted false claims to the Medicare and Medicaid programs. CHN contracted with free-standing ambulatory surgery centers (ASCs) to provide outpatient surgical services to CHN patients. When billing Medicare and Medicaid, however, CHN allegedly represented that the surgery was performed in the outpatient department of CHN's hospitals, rather than in an ASC. Based on this prohibited practice, CHN allegedly received a higher reimbursement from the Medicare and Medicaid programs than it was entitled.

(SF) In July 2015, the former owner and chief executive officer, the chief operating officer, and the chief financial officer of Sacred Heart Hospital, a now-closed acute care facility in Chicago, were sentenced to 54 months, 21 months, and 12 months and a day in prison, respectively, for their roles in a Medicare and Medicaid kickback scheme. Following a seven-week trial, a jury convicted these defendants of conspiring to violate the AKS and of substantive AKS violations. The evidence at trial revealed that the defendants were involved in a conspiracy to pay physicians hundreds of thousands of dollars in illegal bribes and kickbacks to induce patient referrals to the hospital and to increase the patient census, which, in turn, increased hospital revenue. Five other defendants pled guilty in the case, including three physicians, a chief operating officer, and the vice president of geriatric services. Another physician defendant was found guilty of violating the AKS following a bench trial that ended in June 2015. One remaining defendant in the case, a physician, is scheduled for trial in February 2016.

(SF) In August 2015, a jury in the Southern District of Florida returned guilty verdicts against a former medical director and three therapists of Health Care Solutions Network Inc., a defunct partial hospitalization program that purported to provide intensive psychiatric treatment to Medicare and Medicaid beneficiaries. The trial evidence showed that the former medical director routinely signed what he knew to be fabricated and altered medical records without reviewing the substance of the records and, in most instances, without ever meeting with the patients. The evidence at trial also demonstrated that the three therapists fabricated medical records to support Healthcare Solution Network's false and fraudulent claims for reimbursement for intensive psychiatric services. In total, Healthcare Solutions Network submitted approximately \$63.7 million in fraudulent claims to Medicare and Medicaid, which paid \$28 million on those claims. Two co-defendants were each sentenced to six years' imprisonment in February 2015, following their convictions in a separate November 2014 trial.

In September 2015, North Broward Hospital District, a special taxing district of the state of Florida that operates hospitals and other health care facilities, agreed to pay \$69.5 million to settle civil FCA allegations that it engaged in improper financial relationships with referring physicians. The settlement resolved allegations that the hospital district provided compensation to nine employed physicians that exceeded the fair market value of their services in violation of the Stark Law.

In September 2015, Columbus Regional Healthcare System (Columbus Regional) and a physician agreed to pay more than \$25 million to settle civil FCA allegations that they submitted claims to federal health care programs that violated the Stark Law and that misrepresented the level of services they provided. The government alleged that Columbus Regional provided excessive salary and directorship payments to the physician that violated the Stark Law, submitted claims for services at higher levels than supported by the documentation, and submitted claims for radiation therapy at higher levels than the therapy that was provided. Under the settlement agreement, Columbus Regional agreed to pay \$25 million, plus additional contingent payments not to exceed \$10 million, for a maximum settlement amount of \$35 million; the physician has agreed to pay \$425,000.

In September 2015, Adventist Health Care System, a non-profit healthcare organization that operates hospitals and other healthcare facilities in 10 states, agreed to pay \$115 million to settle civil FCA allegations that they submitted false claims to Medicare and Medicaid. Adventist allegedly paid bonuses to its employed physicians based on the number of tests and procedures they ordered and billed Medicare for its employed physicians' professional services using improper coding modifiers.

Identity Theft

In June 2015, an individual in Naples, Florida was sentenced to 6 years in prison and ordered to pay \$351,358 in joint and several restitution after pleading guilty to charges relating to health care fraud, identity theft, and distribution of controlled substances. He admitted that he and his co-conspirators, including his brother, submitted claims for reimbursement from Medicare, Medicaid, and TRICARE for prescriptions that were not filled or provided to beneficiaries or recipients, including prescriptions for patients that had not been written or authorized by a licensed physician. The brother, who was a licensed pharmacist and owner of a pharmacy used to further the scheme, previously pleaded guilty to conspiracy to commit health care fraud and was sentenced to 2 years in prison in March 2014.

In June 2015, a husband and wife were sentenced to a combined 30 years and 9 months of incarceration and ordered to pay over \$1.2 million in joint and several restitution and forfeiture after being convicted of charges related to health care fraud. Evidence at trial showed that the two operated a sham clinic in Coral Gables, Florida, and employed unlicensed medical professionals to bill Medicare for HIV services that were never rendered. The clinic used billing numbers of other medical professionals without their knowledge in order to submit the fraudulent claims. The couple also paid co-conspirators to recruit Medicare beneficiaries for their Medicare identification numbers, and they instructed the beneficiaries to enroll into a targeted Medicare Part C & D plan.

Laboratories

In August 2015, in Newark, New Jersey, three physicians were sentenced after pleading guilty to charges related to a test-referral kickback scheme. According to the investigation, Biodiagnostic Laboratory Services LLC (BLS) solicited and paid bribes to physicians in exchange for referring patient blood specimens to the laboratory. As part of the kickback scheme, BLS entered into sham consulting agreements, sham rental and service agreements, and offered cash and other inducements, such as third party businesses, credit card payments, and valuable items (cars and electronics). BLS used the patient blood specimens to submit more than \$100 million in claims to Medicare and private insurers. In April and May of 2015, the physicians admitted to accepting approximately \$1,500 or more per month in return for referring patient blood specimens. The three were sentenced to a combined 7 years and 2 months in jail and ordered to pay a combined \$434,300 in restitution. BLS's owner pleaded guilty to conspiracy to commit bribery and money laundering and is awaiting sentencing.

In April 2015, two cardiovascular testing laboratories—Health Diagnostics Laboratory Inc. (HDL), of Richmond, Virginia, and Singulex Inc., of Alameda, California—agreed to resolve civil FCA allegations that they paid physicians kickbacks in exchange for patient referrals and billed federal health care programs for medically unnecessary testing. The laboratories allegedly induced physicians to refer patients for blood tests by paying them processing and handling fees of between \$10 and \$17 per referral and by routinely waiving patient co-pays and deductibles. Under the settlements, HDL will pay \$47 million and Singulex will pay \$1.5 million.

Nursing Homes and Facilities

In October 2014, Extendicare Health Services Inc., a nationwide skilled nursing facility, and its subsidiary Progressive Step Corporation (ProStep), a rehabilitation services provider, agreed to pay \$38 million to settle civil FCA allegations that they billed Medicare and Medicaid for nursing services that were so deficient that they were effectively worthless and billed Medicare for medically unreasonable and unnecessary rehabilitation therapy services. The settlement resolves allegations that Extendicare, among other things, failed to have a sufficient number of skilled nurses to adequately care for its skilled nursing residents, failed to provide adequate catheter care to some of the residents, and failed to follow the appropriate protocols to prevent pressure ulcers or falls. As a result of the inadequate care, the government alleged that patients suffered fractures, head injuries, malnutrition, dehydration, pressure ulcers, infections, and amputation of limbs. In addition, the settlement resolves allegations that Extendicare provided medically unreasonable and unnecessary rehabilitation therapy services to its Medicare Part A beneficiaries so that it could bill Medicare for those patients at the highest possible per diem rate.

In March 2015, two skilled nursing facility operators—the Catholic Health Care System, a/k/a ArchCare and Ross Manor, agreed to pay a total of \$4.7 million to resolve civil FCA allegations that they submitted false claims to Medicare for rehabilitation services delivered by their subcontractor, RehabCare Group East, Inc. (RehabCare), a part of Kindred Healthcare, Inc.. The government alleged that the nursing homes failed to prevent RehabCare from routinely providing unreasonably high levels of therapy during so-called “assessment reference periods,” and then providing less therapy to those same patients outside the assessment reference periods. As a

result of this practice by RehabCare, the nursing homes frequently billed Medicare for its patients' care at the highest therapy-based levels, even though the patients often were not receiving therapy at those levels. The settlements further resolved allegations that the nursing homes failed to prevent RehabCare from presumptively placing patients in the highest reimbursement level and planning amounts of therapy based on thresholds for billing at higher reimbursement levels rather than based on patients' clinical needs.

In June, 2015, Hebrew Homes Health Network Inc., a skilled nursing service provider in Miami-Dade County, Florida, and its former president and executive director, agreed to pay \$17 million to resolve civil FCA allegations of improperly paying doctors for referrals of Medicare patients requiring skilled nursing care. The settlement resolved allegations that Hebrew Homes hired numerous physicians ostensibly as medical directors, when in reality, most of the medical directors were required to perform few, if any, of their contracted job duties. Instead, they were allegedly paid for their patient referrals to the Hebrew Homes facilities, which increased exponentially once the medical directors were put on the payroll.

Patient Harm

In October 2014, a Westchester County, New York cardiologist was sentenced to 3 years in prison and ordered to pay \$2 million in restitution and forfeiture after pleading guilty to a charge of health care fraud. According to the investigation, the cardiologist lured new patients and maintained existing patients by offering them narcotic prescriptions in exchange for those patients undergoing unnecessary diagnostic tests and other medical procedures. He then billed Medicare, Medicaid, and private insurance carriers millions of dollars for these fraudulent claims. Investigators believe that he also performed cardiac procedures that served no legitimate medical purpose, billed for office visits that did not occur, and falsified patients' symptoms to justify costly and unnecessary diagnostic tests.

(SF) In July 2015, a Detroit area hematologist-oncologist was sentenced to 45 years' imprisonment and ordered to forfeit \$17.6 million for the health care fraud, money laundering and kickback scheme he devised and executed. The government showed at a contested sentencing that the defendant administered medically unnecessary infusions and injections to 553 individual patients, including medically unnecessary chemotherapy, cancer treatments, intravenous iron, and other infusion and injection therapies. Patients receiving these treatments suffered many serious side effects as a result. The defendant also referred patients for unnecessary cancer tests at his diagnostic facility, United Diagnostics, PLLC, in Rochester Hills, Michigan. The defendant billed Medicare, Blue Cross Blue Shield of Michigan, Health Alliance Plan, and other insurers approximately \$34 million in fraudulent claims through his cancer treatment clinic, Michigan Hematology Oncology P.C., which had multiple locations in Michigan, and through United Diagnostics. The defendant also admitted to soliciting and receiving kickbacks from Guardian Angel Hospice and Guardian Angel Home Health Care in exchange for referring his patients to those companies. Finally, he admitted that he laundered the proceeds of his infusion therapy fraud to promote his diagnostic testing fraud.

Pharmacies

In December 2014, Rite Aid Corporation, a national retail drugstore chain, agreed to pay nearly \$3 million to settle civil FCA allegations that it offered and provided improper inducements to beneficiaries of government programs to transfer their prescriptions to Rite Aid pharmacies in violation of the AKS. These inducements took the form of gift cards, gift checks, and similar promotions.

In May 2015, PharMerica Corporation, a national long-term care pharmacy provider, entered into two settlements for a total of \$31.5 million to resolve claims that it violated the FCA and the Controlled Substances Act. The government alleged that PharMerica dispensed and billed Medicare for schedule II controlled substances without a valid prescription. The prescriptions were allegedly invalid because they did not have a prescriber's signature or, in the case of emergency dispenses, were not based on an oral prescription from the prescriber followed by a written prescription with the prescriber's signature within seven days.

In July 2015, Blanding Health Mart Pharmacy, a Jacksonville, Florida-based compounding pharmacy, agreed to pay \$8.4 million to resolve civil FCA allegations that it sought reimbursement for compounding pharmaceutical prescriptions that were not medically necessary and were written by physicians that had never actually seen the patients.

In August 2015, the Chief Executive Officer of a Kentwood, Michigan pharmacy was sentenced to ten years in prison, agreed to a 50-year exclusion from federal health care programs, and is likely to pay over \$8 million in restitution in connection with a conspiracy to commit health care fraud by billing Medicare Part D plans, Medicaid, and private insurers for over \$79 million in drugs that were adulterated and misbranded in violation of the Federal Food, Drug, and Cosmetic Act. The CEO's conviction was the eighteenth criminal conviction in a case that included the felony convictions of six licensed pharmacists. This pharmacy serviced over 800 nursing and adult foster care homes between 2006 and 2010. As part of its operations they retrieved unused prescription drugs (including controlled substances) from those homes and returned those drugs to pharmacy stock in a manner that resulted in the cross-contamination of drugs, the improper labeling of drugs, the placement of different drug dosages into stock bottles, and the placement of different drugs in the same stock bottle. The pharmacy then re-dispensed and billed health care insurers for those adulterated and misbranded drugs.

Physician Practice

In October 2014, two groups of diagnostic centers agreed to pay a total of \$2.6 million to settle civil FCA allegations. The first group, doing business as One Step Diagnostic, agreed to pay \$1.2 million to settle allegations that it violated the Stark Law and the FCA by entering into sham consulting and medical director agreements with physicians who referred patients to its diagnostic centers. The second group, comprised of Complete Imaging Solutions LLC doing business as Houston Diagnostics, Deerbrook Diagnostics & Imaging Center LLC, Elite Diagnostic Inc., Galleria MRI & Diagnostic LLC, Spring Imaging Center Inc. and West Houston MRI & Diagnostics LLC, agreed to pay \$1.4 million to resolve allegations that they engaged in improper financial relationships with referring physicians and improperly billed Medicare using

the provider number of a physician who had not authorized them to do so and had not been involved in the provision of the services being billed.

(SF) In December 2014, a physician and a registered nurse were sentenced to 120 months and 48 months in prison, respectively, for their roles in a \$3 million Medicare fraud scheme following their convictions at trial in May 2014. According to the evidence at trial, the physician defendant falsely certified that beneficiaries needed home health care and, in exchange for kickbacks, referred beneficiaries to PTM Healthcare Services Inc., a defunct home health care agency in Irving, Texas, at which his co-defendant served as the director of nursing. The nurse defendant and co-conspirators then prepared falsified medical records to make it appear that beneficiaries needed home health care services and billed Medicare for services that were medically unnecessary or not provided. The owner of PTM Healthcare Services previously pled guilty in 2013 to health care fraud conspiracy.

(SF) In February 2015, a jury in Detroit convicted an unlicensed physician for his participation in a nearly \$4.7 million Medicare fraud scheme. The evidence at trial revealed that the defendant used pre-signed prescription pads from a licensed physician to prescribe drugs to Medicare patients and also referred patients for medically unnecessary home health care services in exchange for kickbacks. In January 2015, shortly before trial, the owner of Cherish Home Health Services, Inc., one of the companies to which the unlicensed physician referred patients, pled guilty and admitted to paying kickbacks to the unlicensed physician and billing Medicare for home health care services that were not provided. Two other defendants—a patient recruiter and a physician—previously pled guilty for their roles in the fraud.

(SF) In February 2015, an Illinois physician pled guilty to accepting illegal kickbacks and benefits totaling nearly \$600,000 from two pharmaceutical companies—Teva Pharmaceuticals USA Inc. and IVAX LLC—in exchange for regularly prescribing the anti-psychotic drug Clozapine to his patients. As set forth in the plea agreement, the physician agreed to switch his patients to generic Clozapine if the manufacturer agreed to pay him \$50,000 under a one-year “consulting agreement” and to provide other benefits to the physician. The physician also agreed to pay over \$3.8 million to settle a parallel civil FCA lawsuit alleging that, by prescribing Clozapine in exchange for kickbacks, he caused the submission of false claims to Medicare and Medicaid for the Clozapine he prescribed for thousands of elderly and indigent patients in at least 30 Chicago-area nursing homes and other facilities. Previously, in March 2014, Teva and IVAX paid a total of \$27.6 million to resolve allegations related to paying kickbacks to the physician defendant.

(SF) In March 2015, a New York doctor pled guilty to health care fraud conspiracy for his involvement in a scheme to fraudulently bill Medicare for \$14.2 million in claims for medically unnecessary treatments. As part of the plea, the defendant agreed to pay \$5.4 million in restitution to the Medicare program, which represents the total amount of money Medicare paid as the result of the fraudulent claims. In connection with his guilty plea, the defendant admitted that he and other medical providers at the clinic submitted approximately \$14.2 million in false and fraudulent claims to Medicare for medically unnecessary vitamin infusions, physical therapy, and occupational therapy that did not qualify for reimbursement by Medicare.

(SF) In April 2015, a physician who served as the medical director of Hollywood Pavilion, LLC, a state-licensed psychiatric hospital located in Hollywood, Florida, was sentenced to 60 months' imprisonment for his role in a \$67 million Medicare fraud scheme. Evidence at trial revealed that the defendant falsified medical records certifying that patients qualified for and received intensive outpatient services. The evidence demonstrated that the defendant signed patient files for over 400 patients, certifying that he had provided mental health services to each of them, even though he never saw or provided any treatment to the patients. Hollywood Pavilion used these falsified records to submit over 2,800 false claims to Medicare. Five other individuals previously were convicted and sentenced in this case, including Hollywood Pavilion's former chief executive officer, chief operating officer, and clinical director.

In April 2015, Family Dermatology P.C., the owner and operator of dermatology practices and a dermatopathology laboratory, agreed to pay \$3.2 million to settle civil FCA allegations that its financial relationships with certain employed physicians violated the Stark Law. Family Dermatology employs dermatologists as independent contractors and routinely required them to use Family Dermatology's in-house pathology lab, Nelson Dermatopathology, for their pathology services. The government alleged that Family Dermatology violated the Stark Law and FCA by billing Medicare for dermatopathology analyses performed by Nelson Dermatopathology on specimens that were sent to the laboratory by these employed physicians.

In April 2015, a medical doctor and sole physician at a pain clinic in Athens, Tennessee, was sentenced to 28 months and was ordered to pay \$7.5 million in restitution to Medicare for misbranding drugs with the intent to defraud. The doctor purchased 254 vials of Botox from a foreign supplier, and had used 204 vials during the course of the scheme to defraud, but had billed Medicare for 16,119 vials. A forfeiture order was also entered against the \$6.8 million seized from the defendant's bank accounts.

In May 2015, Garden State Cardiovascular Specialists P.C., a New Jersey cardiology practice that owns and operates several facilities under the name NJ MedCare/NJ Heart, agreed to pay \$3.6 million to settle civil FCA allegations that its facilities and their principals submitted claims to Medicare for various cardiology diagnostic tests and procedures, including stress tests, cardiac catheterizations, and external counterpulsation, which were not medically necessary.

(SF) In May 2015, an administrator and a biller were convicted after trial for their roles in a \$4 million Medicare fraud scheme involving Medicall Physicians Group, a home visiting physician practice in Schaumburg, Illinois. The evidence at trial revealed that Medicall billed Medicare for services that were never provided to patients, including physician oversight of patient care plans, extended patient visits, and other services purportedly provided to individuals who had already died. A third defendant, the owner and medical director of Medicall, pled guilty prior to trial. In September 2015, the lead administrator of a home visiting physician practice was sentenced to 87 months in prison and the medical biller, who submitted many of the fraudulent claims to Medicare, was sentenced to serve 45 months in prison and pay restitution of approximately \$1 million.

(SF) In August 2015, a dermatologist was sentenced to seven years' imprisonment, following a jury trial that resulted in six mail and wire fraud convictions. The defendant also was ordered to pay over \$3.7 million in restitution to Medicare, private insurers, and patients. According to the evidence at trial, the defendant misdiagnosed patients' benign skin conditions as pre-cancerous lesions and falsely billed cosmetic treatments as the destruction of large numbers of such lesions.

In August 2015, a Brooklyn doctor was sentenced to 24 months in prison for his role as the "no show" doctor in a \$13 million health care fraud conspiracy scheme. Medical services were provided by a physician's assistant who was acting without supervision by a medical doctor, but the doctor still billed Medicare and Medicaid for the services using his provider number. He also falsely certified that patient transportation by ambulance was medically necessary and billed for this unnecessary service. As part of the sentence, the court entered an order directing the doctor to pay \$6.4 million in restitution and to forfeit \$6.6 million.

Prescription Drugs

(SF) In October 2014, the operator of a Dallas family practice and weight loss management clinic based in Dallas, Texas, was sentenced to 7 years and 3 months of incarceration and ordered to forfeit his house, cars, boat, and funds from several bank accounts after pleading guilty to conspiracy to unlawfully distribute controlled substances. The investigation revealed that clinic operated as a pill mill, where "dealers" recruited and drove "patients" in groups to the clinic to obtain prescriptions for hydrocodone and Xanax. The clinic's office manager and three dealers were also sentenced during this reporting period to more than 18 years in prison, combined.

In October 2014, two individuals were sentenced to a combined 17 years and 1 month in jail and ordered to pay \$6.2 million in joint and several restitution after pleading guilty to conspiracy to commit health care fraud. The two individuals operated a Miami-based retail pharmacy. The investigation revealed that their co-conspirators recruited and paid Medicare beneficiaries to obtain prescriptions, including for expensive antipsychotic and skin treatment pharmaceutical drugs that the co-conspirators subsequently furnished back to the two men. The two then used the fraudulent prescriptions to bill the Medicare Part D program.

In November 2014, a Baltimore, Maryland individual was sentenced to 8 years and 4 months of incarceration after pleading guilty to conspiracy to distribute and possession with intent to distribute oxycodone. The investigation revealed that the individual obtained fraudulent prescriptions for oxycodone from a secretary who was stealing prescriptions from the doctor's office where she worked. The prescriptions were filled out in the names of Medicare beneficiaries and other defendants. He then either filled the prescriptions himself and billed Medicare, or he had them filled by other individuals and sold the oxycodone pills for around \$10 per pill on the streets. Eight other defendants previously pleaded guilty to charges in connection with this scheme and were sentenced to a combined 29 years and 6 months in jail.

In May 2015, the owner/operator of Astramed, a chain of purported medical clinics with multiple locations in the Bronx, New York, was convicted of conspiracy to distribute and possess with intent to distribute oxycodone and is awaiting his sentencing. The charge carries a maximum

sentence of 20 years in prison. Astramed doctors were paid cash in exchange for writing tens of thousands of medically unnecessary prescriptions for large quantities of oxycodone; these prescriptions were then filled at pharmacies by co-conspirators who, in turn, resold and distributed the drugs at vastly inflated rates. In total, Astramed issued approximately 31,500 medically unnecessary prescriptions for oxycodone, comprising nearly 5.5 million tablets with a street value of up to \$164 million. More than 20 defendants—including doctors, clinic employees, and drug traffickers—have previously pleaded guilty to their participation in the scheme.

In July 2015, the operator of an imaging center in Glendale, California, was sentenced to 15 years in prison and ordered to pay \$9.1 million in joint and several restitution after being convicted on charges relating to health care fraud, identity theft, and misbranding pharmaceutical drugs. As part of the scheme, patient recruiters brought beneficiaries to the clinic in exchange for cash or other inducements. The patients received prescriptions for anti-psychotic medications and other drugs, even though they were not evaluated by a physician or there was no medical need for the medications. The patients were then driven to a pharmacy where, under the supervision of the driver, they filled their prescriptions and then gave the drugs to the driver. The drugs were eventually sold on the black market or redistributed to pharmacies, where they could be rebilled to Medicare and Medi-Cal as “new” bottles of drugs. In addition to recruiting beneficiaries, the operator and his co-conspirators also stole the identities of beneficiaries and used their information to generate fraudulent prescriptions. Ten of his co-conspirators were previously sentenced to a combined 28 years and 3 months in prison.

Psychiatric and Psychological Testing and Services

In April 2015, Health Management Associates, Inc. (HMA) in Naples, Florida, and 14 hospitals formerly owned and operated by HMA agreed to pay \$15 million to resolve allegations that they billed Medicare for intensive outpatient psychotherapy (IOP) services that did not meet the conditions for payment, including services provided to patients whose condition did not qualify for IOP.

(SF) In June 2015, two owners were indicted for their roles in a \$25 million psychological testing scheme carried out through eight companies operating in multiple states. According to court documents, the defendants owned and operated Nursing Home Psychological Service and Psychological Care Services, each with locations in Louisiana, Mississippi, Alabama, and Florida. The indictment alleges that the defendants contracted with nursing homes in these states to allow their companies to administer psychological tests to the nursing homes’ residents. The defendants then caused the submission of claims for purported psychological testing, psychotherapy, and related services to the nursing home residents that were medically unnecessary or not provided.

Quality of Care

In May 2015, Country Villa Service Corp, d/b/a Country Villa Health Services, and the ARBA Group, Inc., CF Watsonville East, LLC and CF Watsonville West, LLC of California entered into separate settlement agreements worth a combined \$3.8 million to resolve allegations of false claims for materially substandard or worthless services. The government alleged that employees

at Country Villa Watsonville East Nursing Center and Country Villa Watsonville West Nursing Center persistently overmedicated elderly and vulnerable residents of their facilities, causing infection, sepsis, malnutrition, dehydration, falls, fractures, pressure ulcers, and for some beneficiaries, premature death. In addition to the settlements, the CF Watsonville companies entered into a 5-year CIA with HHS-OIG, under which they will retain a quality monitor chosen by HHS-OIG to perform quarterly reviews of the facilities' quality and compliance systems.

Other Medicare and Medicaid Matters

(SF) In October 2014, the owner/manager of two health centers in Baton Rouge, Louisiana was sentenced to 7 years and 6 months in prison and ordered to pay \$43.5 million in joint and several restitution after being convicted by a jury on charges of conspiracy to commit health care fraud and health care fraud. A second defendant was sentenced to 5 years in prison and ordered to pay \$3.2 million in joint and several restitution after being convicted by a jury of conspiracy to commit health care fraud and conspiracy to pay and receive health care kickbacks. The investigation revealed that owner/manager and co-conspirators recruited Medicare beneficiaries to attend medically unnecessary or sham programs at the health centers. The second defendant and others were paid cash kickbacks to recruit Medicare beneficiaries to receive partial hospitalization program services at the centers. The health centers billed Medicare more than \$258 million for these fraudulent services. In addition to these two defendants, 15 defendants have been convicted in connection with this scheme.

In January 2015, the Commonwealth of Pennsylvania agreed to pay \$48.8 million to settle civil FCA allegations that it provided benefits to ineligible aliens in violation of federal law. Under the Personal Responsibility Work Opportunity Act, only documented aliens who meet certain low-income requirements and who have been in the country for more than five years may receive non-emergency aid under Medicaid, Temporary Assistance for Needy Families (TANF) and the Supplemental Nutrition Assistance Program (SNAP), formerly known as food stamps. The United States alleged that, between 2004 and 2010, Pennsylvania provided Medicaid, TANF and SNAP benefits to ineligible aliens in violation of these restrictions.

In March 2015, heart monitoring company BioTelemetry, Inc., agreed to pay \$6.4 million to settle civil FCA allegations that its subsidiary, CardioNet, billed Medicare for Mobile Cardiac Outpatient Telemetry (MCOT) services that were not reasonable or medically necessary. An MCOT monitor is a real-time, outpatient cardiac monitoring service. The settlement resolves allegations that although CardioNet was aware that MCOT services were not eligible for Medicare reimbursement when provided to patients who had experienced only mild or moderate heart palpitations, CardioNet knowingly submitted claims to Medicare for more expensive MCOT services by using an inaccurate diagnostic code that ensured that the claims would be reimbursed by Medicare at a higher rate.

In August 2015, two workers at a wholesale drug distribution operation were sentenced for distributing counterfeit and adulterated Botox to a medical clinic in Missouri. One worker received 24 months imprisonment and another received three months imprisonment, and both were ordered to forfeit \$1 million. Eight other individuals were previously convicted in the Eastern District of Missouri's investigation, including two local doctors and a clinic owner, a

citizen of the United Kingdom, and two Turkish nationals, with sentences ranging from 30 months to probation, and over \$5 million recovered in forfeitures and fines. The USAO also reached civil settlements with three local doctors who were purchasing unapproved drugs and billing them to Medicare and Medicaid, resulting in civil program recoveries in excess of \$1.6 million.

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. In FY 2015, the Secretary and the Attorney General jointly allotted \$186.1 million to HHS-OIG after accounting for a sequester reduction of \$14.7 million. Additionally, Congress appropriated \$67 million in discretionary funding for HHS-OIG HCFAC activities.

In FY 2015, HHS-OIG investigations resulted in 800 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid; and 667 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 2015, HHS-OIG excluded a total of 4,112 individuals and entities, the details of which are below.

In FY 2015, 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, Southern 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

Investigations, audits, and evaluations frequently 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 2015, potential savings from legislative and administrative actions that were supported by HHS-OIG recommendations were estimated by third parties, such as the Congressional Budget Office or actuaries within HHS, to be \$20.5 billion—\$18.4 billion in Medicare savings and \$2.1 billion in savings to the Federal share of Medicaid.

Settlement with New York State based on HHS-OIG Audit Recommendations: Included in these savings figures is the \$1.95 billion the State of New York agreed to pay to CMS pursuant to a settlement agreement based on HHS-OIG audit work. HHS-OIG had found that New York's Medicaid daily rate for 15 selected State-operated intermediate care facilities (ICFs or development centers) for individuals with intellectual and developmental disabilities did not meet Federal requirements. The daily rate for Medicaid beneficiaries to reside in the selected

developmental centers grew by a factor of 21 between State fiscal year (SFY) 1985 and SFY 2009 because the State's rate-setting methodology significantly inflated the Medicaid daily rate for the developmental centers. On March 20, 2015, New York and CMS entered into a settlement agreement in which New York agreed to pay a total of \$1.95 billion to the Federal Government to resolve the resulting overpayment determination. In addition, CMS approved a plan amendment to New York's Medicaid program that changed the rate to better reflect the actual costs of providing care, saving approximately \$1.2 billion.

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 2015, HHS-OIG excluded a total of 4,112 individuals and entities. Among these were exclusions based on criminal convictions for crimes related to Medicare and Medicaid (1,329) or to other health care programs (424); for patient abuse or neglect (302); or as a result of licensure revocations (1743). 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 2015. In addition to those mentioned in the Program Accomplishments section above, exclusion actions by HHS-OIG included:

- Michigan—In July 2015 a pharmacist was excluded for a minimum period of 18 years based on his conviction for, among other charges, conspiracy to distribute and possess with intent to distribute controlled substances. The pharmacist owned and operated a pharmacy in Detroit, Michigan. He conspired with other individuals to bring him fraudulent prescriptions, to which he dispensed controlled substances with no legitimate medical purpose. The pharmacist then received cash payments for illegally dispensing the controlled substances. He was sentenced in February 2015 to 6 years of incarceration.
- Indiana—In June 2015 an employee of a group home was excluded for a minimum period of 20 years based on his conviction for criminal deviate conduct. While working in a group home, he instructed a mentally retarded patient to perform sex acts on him in the living room of the group home. As a result of his conviction, he was sentenced in October 2014 to 10 years of incarceration.
- Florida—In May 2015 an employee of a chiropractic clinic was excluded for a minimum period of 15 years based on his conviction for conspiracy to commit mail fraud. The employee helped recruit individuals to participate in staged automobile accidents, instruct those recruited on how to participate in the accident and how to collect police reports, told them what clinics they should go to for treatment, and prepared fraudulent documentation to support medically unnecessary treatment. As a result of his conviction, Sacerio was sentenced in July 2015 to 4 years in prison and ordered to pay approximately \$1.1 million in restitution.

- New York—In January 2015 a physician was excluded for a minimum period of 50 years on the basis of his conviction health care fraud, conspiracy to defraud the United States Railroad Retirement Board (RRB), and other related charges. From approximately 1998 through 2008, the physician assisted employees from the Long Island Railroad (LIRR) in applying for disability benefits from the RRB, even though he knew they were not disabled. The LIRR employees generally paid the physician \$800 to \$1200, often in cash, to prepare medical assessments and/or illness narratives for submission to the RRB. He prescribed and billed patients’ insurers for unnecessary medical tests and he ordered physical therapy and medical treatments in an effort to pad their medical files. The physician fabricated and fraudulent assessments enabled 242 LIRR employees to supplement their pensions with a collective \$70 million in RRB disability benefit payments to which they were not entitled. He was sentenced to 8 years in prison and ordered to pay \$70.6 million in restitution. The New York State Board for Professional Medical Conduct revoked his medical license, and the New York State Office of the Medicaid Inspector General excluded him from participation in the Medicaid program.
- Texas—In December 2014 a pharmacist was excluded for a minimum period of 10 years on the basis of her conviction for conspiracy to unlawfully distribute controlled substances. The pharmacist owned and operated Urban Independent Pharmacy (UIP). The investigation revealed that she participated in a scheme whereby “dealers” recruited “patients” to obtain unlawful prescriptions for controlled substances and drove the patients to UIP, where she filled their prescriptions. After the pharmacist filled the prescriptions, the patients provided the pills to the dealers, who then sold them on the street for a profit. She was sentenced to 5 years in prison.
- Iowa—In November 2014 a pediatrician was excluded for a minimum of 30 years on the basis of his conviction of possession of child pornography. The investigation revealed that the pediatrician used a hidden camera to take pictures and videos of his minor patients without the advice or knowledge of the patients, their parents, or guardians. The images and videos were taken during what were purported to be necessary medical exams. Investigators searched his computers and found files that included child pornography along with videos and images of the minor patients. Jones was sentenced to 10 years and 1 month in prison. The Iowa Board of Medicine also accepted the surrender of his license to practice as a medical doctor.

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

- New Jersey—In March 2015 Sandoz, Inc. agreed to pay \$12,640,000 to settle allegations that it misrepresented drug pricing data to the Medicare program. Sandoz, a division of Novartis

Pharmaceuticals and one of the world's largest generic manufacturers, markets hundreds of generic medications in the United States. Under federal law, drug makers must report both accurate and timely Average Sales Price (ASP) information to CMS, which CMS uses to set payment amounts for most drugs covered under Medicare Part B. OIG alleged that Sandoz failed to submit accurate ASP data to CMS for each quarter from January 2010 through March 2012. OIG previously pursued CMPs against Sandoz for late reporting of drug pricing information to CMS. That case was settled in December 2011 with Sandoz agreeing to a \$230,000 settlement. The 2015 Sandoz settlement is the largest ever under OIG's drug price reporting CMP authority.

- Texas—In October 2014 three Houston-area physicians collectively agreed to pay \$200,266 for allegedly violating the Civil Monetary Penalties Law (CMPL) provisions applicable to kickbacks. OIG alleged that a family practitioner and two orthopedic surgeons received illegal remuneration from another physician and his practice. This improper remuneration took the form of the physician paying the salary of one of the family practitioner's employees to serve as a "referral coordinator" and hiring the two surgeons as medical directors. OIG alleged that these arrangements took into account the volume or value of referrals made to the physician's practice. To date, 11 physicians have agreed to pay a collective total of \$1,415,137 to resolve their CMPL liability for allegedly receiving kickbacks from the physician's practice. Yet another physician agreed to be excluded from participation in federal health care programs for 3 years.
- New York—In December 2014 a physician and his medical clinic entered into a \$694,887 settlement agreement with OIG. The settlement resolved allegations that, from May 2008 to December 2013, the physician and the clinic knowingly submitted, or caused to be submitted, fraudulent claims to Medicare for physical therapy services. Specifically, OIG alleged that these claims were fraudulent for one or more of the following reasons: (1) physical therapy services were not provided or supervised by the rendering provider, (2) group services were billed as one-on-one provider-patient physical therapy services, (3) services were performed by unqualified individuals, and (4) claims for time-based physical therapy services did not accurately reflect the actual time spent performing the services.
- California—In February 2015, Hyundai Drugs and its owner agreed to pay \$1,342,295 to resolve allegations under the CMPL. From January 1, 2009 through April 12, 2014, Hyundai allegedly submitted claims to Medicare Part D for prescription drugs that it knew or should have known were not provided as claimed and were false or fraudulent. The case was investigated as part of Operation Pharm Fury, a joint effort between OIG's Office of Investigations, Office of Evaluation and Inspections, and Office of Counsel to the Inspector General. Operation Pharm Fury has exposed pharmacies across the country that have shown a pattern of questionably high billing practices when submitting claims to Medicare for prescription drugs.
- Kansas—In March 2015 Newton Healthcare Corporation d/b/a Newton Medical Center (NMC) agreed to pay \$45,000 to resolve its liability under EMTALA. OIG alleged that NMC failed to provide an adequate medical screening examination for a patient who arrived at its emergency department 38 weeks pregnant and complaining of abdominal and lower back pain. OIG contended that NMC did not record the patient's medical history, take any

vitals, conduct fetal monitoring, test for fetal movement, or perform any exam on the patient. Instead, OIG alleged that NMC instructed the patient to leave and see her personal physician. The patient left NMC by private vehicle and arrived at the emergency department of another hospital, where she was admitted and delivered a stillborn baby.

Audits and Evaluations

The focus of HHS-OIG's audits and evaluations is determined through a dynamic process and adjustments are made to HHS-OIG's work plan throughout the year to meet priorities and to anticipate and respond to emerging issues with the resources available. HHS-OIG assesses relative risks in Medicare and Medicaid (as well as the many other programs for which HHS-OIG has oversight authority) to identify the areas most in need of attention and, accordingly, to set priorities for the sequence and proportion of resources to be allocated. In assessing this relative risk, HHS-OIG considers a number of factors, including:

- Mandatory requirements for OIG reviews, as set forth in laws, regulations, or other directives;
- Requests made or concerns raised by Congress, HHS management, or the Office of Management and Budget (OMB);
- Top management and performance challenges facing HHS;
- Work to be performed in collaboration with partner organizations;
- Management's actions to implement our recommendations from previous reviews; and
- Timeliness.

As a consequence of this work planning process, HHS-OIG identified questionable or improper conduct in Medicare and Medicaid, and recommended corrective actions that, when implemented, will return misspent funds and prevent future wasteful or improper payments. Among HHS-OIG's audit and evaluation findings in FY 2015 were the following:

Medicaid Orthodontic Services

Texas did not ensure that requests for prior authorization of Medicaid orthodontic services were approved in accordance with State Medicaid guidelines. HHS-OIG estimated that Texas paid at least \$133.4 million for unallowable orthodontic services. Of 106 sampled orthodontic prior-authorization requests, 89 were improperly approved: 78 did not qualify for orthodontic services, and 11 did not have sufficient documentation to determine whether they qualified.

Medicaid Pediatric Dental Services

HHS-OIG identified 329 general dentists and 6 orthodontists in California with questionable billing. Medicaid paid these providers \$117.5 million for pediatric dental services in 2012. These 335 dental providers—representing 8 percent of the California general dentists and orthodontists whom we reviewed—provided either a large number of services or provided certain services to an extremely large number of children, among other practices. Half of the dental providers with questionable billing worked for dental chains.

Medicaid Drug Rebates

Missouri did not always comply with Federal Medicaid requirements for billing drug

manufacturers for rebates for physician-administered drugs. Missouri did not collect the national drug codes (NDCs) that were required for it to invoice manufacturers for rebates associated with about \$34.8 million in physician-administered drugs. In addition, Missouri did not capture the utilization and coding data necessary to collect rebates for all physician-administered drugs. Without the NDCs, HHS-OIG was unable to determine whether Missouri improperly claimed federal reimbursement for an additional \$13.2 million for other physician-administered drug claims.

Medicaid Home Health Services

CMS could not rely on New York's or New Jersey's qualification requirements to ensure quality of care was provided to Medicaid beneficiaries receiving home health services. Some New York and New Jersey home health agencies (HHAs) did not meet certain Federal and State requirements for employee health screenings and training, among other issues. HHS-OIG estimated that \$31.9 million in Federal Medicaid reimbursement was associated with HHA workers who did not meet Federal and State requirements (\$27.9 million in New York and \$4 million in New Jersey).

Terminated Medicaid Providers

The Affordable Care Act (ACA) requires States to terminate providers who were already terminated for cause in another State, yet States face challenges complying with this mandate. HHS-OIG found continued participation from providers terminated in one State in other States' Medicaid program, and about one-third received payments for services provided to Medicaid beneficiaries after the providers' terminations for cause. Continued participation of providers after their terminations for cause presents a vulnerability to Medicaid and raises concern that these providers could continue to treat Medicaid beneficiaries.

Developmental Disabilities Waiver Program

New York improperly claimed an estimated \$76.8 million in Federal Medicaid reimbursement for some Office for People With Developmental Disabilities (OPWDD) waiver program services during CYs 2006 through 2008. The OPWDD waiver program is intended to enable adults and children with developmental disabilities to live in the community as an alternative to intermediate care facilities for individuals with intellectual disabilities.

Access to Medicaid Managed Care Services

Slightly more than half of providers reviewed could not offer appointments to enrollees. Notably, 35 percent could not be found at the location listed by the plan, and another 8 percent were at the location but were not participating in the plan. Among the providers who offered appointments, the median wait time was two weeks. However, over a quarter had wait times of more than one month. Finally, primary care providers were less likely to offer an appointment than specialists; however, specialists tended to have longer wait times.

Non-Emergency Medical Transportation Services

During FY 2011, Texas claimed at least \$30.4 million for unallowable Medicaid payments for nonemergency medical transportation (NEMT) services. Federal regulations require each State to ensure that Medicaid beneficiaries have necessary transportation to and from medical providers. Prior OIG reviews have found that States' claims for NEMT services were not always in accordance with Federal and State requirements.

Targeted Case Management Services

Missouri claimed \$11.5 million of unallowable Medicaid payments for Targeted Case Management (TCM) services provided to individuals with developmental disabilities during State FYs 2011 through 2013. Missouri did not address OIG's recommendations to, among other things, refund \$11.5 million to the Federal Government.

Anti-Psychotic Drugs Prescribed to Children

In the five States reviewed, medical reviewers identified quality-of-care concerns in the medical records associated with 67 percent of claims for second-generation antipsychotic (SGA) drugs prescribed to children. Quality-of-care concerns identified through medical record reviews corresponded to the following issues: dosage, duration, indications for use, monitoring, polypharmacy (too many drugs), patient age, and side effects. The high percentage of claims for which our reviewers identified quality-of-care concerns indicates that more needs to be done to ensure the quality of care provided to children receiving SGAs paid for by Medicaid.

Payments to Delinquent Providers

CMS made \$10.7 million in Medicare and Medicaid payments associated with 23 of 82 individual physicians with delinquent debts after CMS had referred their Medicare debts to the U.S. Department of the Treasury (Treasury) for collection. In addition, 13 of the 23 individual physicians had ownership interest in and/or managing control of 15 Medicare Part B entities that received Medicare reimbursement from CMS after CMS referred the individual physicians' debts to Treasury. CMS is required to seek recovery of all identified overpayments and can recoup or offset overpayments against a provider's future Medicare and/or Federal share of Medicaid payments.

Medicare Outpatient Drugs

Medicare contractors in 13 jurisdictions overpaid providers \$35.8 million for selected outpatient drugs from July 1, 2009, through June 30, 2012. For 88 percent of the overpayments, providers billed either incorrect units of service or, otherwise, a combination of incorrect units of service and incorrect Healthcare Common Procedure Coding System codes. The Medicare claims processing systems did not have sufficient prepayment edits in place to prevent all overpayments.

Financial Incentives to Provide Hospice Care

Medicare payments for hospice care provided in assisted living facilities (ALFs) more than doubled in 5 years, totaling \$2.1 billion in 2012. Hospices provided care much longer and received much higher Medicare payments for beneficiaries in ALFs than for beneficiaries in other settings. Beneficiaries in ALFs often had diagnoses that usually require less complex care. This report raises concerns about hospices' targeting beneficiaries in ALFs because they may offer the hospices the greatest financial gain.

Potential Fraud in Medicare Part D

Spending for Part D drugs, especially commonly abused opioids, has grown substantially. HHS-OIG identified questionable billing by 1,400 pharmacies that may indicate fraudulent activity. Each of these pharmacies billed for extremely high amounts for one or more of our billing

measures. HHS-OIG also identified geographic hotspots for certain drugs that point to possible fraud and abuse.

Medicare Part D Program Integrity

This portfolio presents an overview of HHS-OIG investigations, audits, evaluations, and legal guidance related to Part D. It synthesizes numerous HHS-OIG reports that have identified weaknesses in Part D program integrity, and provides updates on Departmental efforts to address these weaknesses. In particular, HHS-OIG has identified weaknesses in the use of data to identify vulnerabilities, as well as in the oversight by all parties responsible for protecting Part D: CMS, Part D plan sponsors, and the Medicare Drug Integrity Contractor. OIG has made recommendations to strengthen Part D program integrity, and progress has been made. However, Part D remains vulnerable to fraud, as evidenced by ongoing investigations.

Swing-Bed Services at Critical Access Hospitals

Medicare spending for swing-bed services in critical access hospitals (CAHs) steadily increased to, on average, almost four times the costs of similar services at alternative facilities from calendar years 2005 through 2010. Medicare reimburses CAHs at 101 percent of their reasonable costs for providing services to beneficiaries rather than at rates set by Medicare's prospective payment system or Medicare's fee schedules. Medicare could have saved \$4.1 billion over a 6-year period at CAHs if swing-bed services were reimbursed using the skilled nursing facility prospective payment system rate.

Skilled Nursing Facilities

The findings of this and prior HHS-OIG reports demonstrate the need for CMS to reevaluate the skilled nursing facility (SNF) payment system. Medicare payments for therapy greatly exceeded SNFs' costs for therapy. Combined with the current method of paying for therapy, this large difference between therapy payments and costs creates a strong financial incentive for SNFs to bill for higher levels of therapy than necessary. Increases in SNF billing—particularly for the highest level of therapy—resulted in \$1.1 billion in Medicare payments in FYs 2012 and 2013.

Hospital Outlier Payments

Medicare contractors did not always refer Medicare cost reports whose outlier payments qualified for reconciliation to CMS. In addition, the 13 contractors did not always reconcile the outlier payments associated with cost reports whose outlier payments qualified for reconciliation. The financial impact to Medicare of the unreconciled outlier payments and cost reports for all the contractors was approximately \$428.3 million. Medicare supplements basic prospective payments for inpatient hospital services by making outlier payments for unusually high-cost cases.

Deceased Beneficiaries

Medicare paid for HIV drugs for over 150 deceased beneficiaries in 2012. CMS has edits (i.e., systems processes) in place that reject prescription drug event records for drugs with dates of service more than 32 days after death. This practice allows payment for drugs for deceased beneficiaries for dates of service within 32 days of death. A change in the edits would affect all Part D drugs, not just HIV drugs.

Ambulance Transports

Medicare paid \$24 million in the first half of 2012 for ambulance transports that did not meet certain program requirements justifying payments, and that about one in five ambulance suppliers had questionable billing. These findings indicate that inappropriate and questionable billing for ambulance transports pose vulnerabilities to Medicare program integrity.

Other OIG Fraud and Abuse Prevention Activities

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 2015, the HHS-OIG, in consultation with DOJ, issued 15 advisory opinions. A total of 329 advisory opinions have been issued during the 19 years of the HCFAC program.

Corporate Integrity Agreements

Many health care providers elect to settle their cases before litigation. As part of the settlements, providers often agree to enter into Corporate Integrity Agreements (CIA) with OIG to avoid exclusions from Medicare, Medicaid, and other federal health care programs. Under a CIA, a provider commits to establishing a program and taking other specified steps to ensure future compliance with Medicare and Medicaid rules. The compliance programs are designed, in part, to prevent future fraud. OIG monitors providers' compliance with these agreements. OIG may impose penalties on entities that fail to comply with the requirements of their CIAs, as shown in the example below:

- Illinois—In March 2015, LifeWatch Services, Inc., a durable medical equipment supplier, agreed to pay \$737,572 to settle allegations that it knowingly submitted false claims to Medicare from February 21, 2013 through June 30, 2014 for cardiac monitoring services. Specifically, OIG alleged that LifeWatch submitted claims to Medicare for Ambulatory Cardiac Telemetry (ACT) services for which the medical record documentation did not support that the physician had ordered ACT services. The settlement resolves a reportable event submitted by LifeWatch as required under its CIA. LifeWatch entered into the CIA in March 2012 as part of an \$18.5 million civil settlement with the United States, resolving allegations that, among other things, it submitted claims to Medicare for cardiac monitoring

services that were not medically necessary and encouraged the use of more expensive cardiac monitoring devices when a less expensive device was sufficient to meet the patient's needs.

Centers for Medicare & Medicaid Services

In FY 2015, CMS was allocated \$13.5 million by HHS, and appropriated \$544.3 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 and Medicaid improper payment rate measurement and activities, the Fraud Prevention System, Recovery Audit Program activities, and prior authorization initiatives are discussed in separate reports, and CMS will submit a combined Medicare and Medicaid Integrity Program report to Congress later this year.

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 in certain counties in Florida, Illinois, and Texas. The moratoria stops the enrollment of new home health and ambulance enrollments in Medicare, Medicaid, and CHIP in fraud "hot spot" areas of the country with demonstrated oversupply of certain types of providers. In January 2014, CMS extended the original enrollment moratoria for these locations and expanded the enrollment moratoria to include HHAs in Broward county Florida; the Michigan counties of Wayne, Macomb, Monroe, Oakland, and Washtenaw; and the Texas counties of Dallas, Collin, Denton, Ellis, Kaufman, Rockwall, Tarrant, Harris, Brazoria, Chambers, Fort Bend, Galveston, Liberty, Montgomery, and Waller. CMS also expanded the moratorium on ground ambulance suppliers in the Philadelphia area, including several New Jersey counties, at the same time. All of these moratoria actions continue to be extended an additional six months with the latest notice effective January 2016. The focus of these efforts is to prevent and deter fraud, waste, and abuse in problematic services and areas across the country while ensuring beneficiary 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. After reviewing the number of providers in the moratoria areas and recent Medicare Payment Advisory Commission (MedPAC) reports, CMS determined that the moratoria do not adversely impact beneficiary access to care. CMS is required to re-evaluate the need for such moratoria every six months.

One Program Integrity

In FY 2015, 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 continues 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, C, 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, at the time claims are adjudicated, and at the time the claims have payment data posted. This access allows users to perform prepayment 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, Zone Program Integrity Contractors (ZPICs) are also able to improve their analytics for post-payment detection of fraud, waste, and abuse.

In order to streamline access for our law enforcement partners, in 2015, CMS released a re-engineered version of the Services Tracking Analysis and Reporting System (STARS) that improves system access, enhances the end-user experience, and improves overall performance. STARS, a health care fraud, waste, and abuse analytics tool, is part of the One PI suite of tools. The One PI team enhanced the overall training process by including virtualized training in combination with on-site instructor led training to reduce training costs and provide better access for law enforcement. Additionally, STARS initiated a monthly end users group to increase collaboration.

Compromised Number Checklist

In January 2010, CMS created the repository of compromised Medicare beneficiary and provider ID numbers called the Compromised Number Checklist (CNC). In March 2013, CMS deployed a Web-based application that allows direct update and real-time access of CNC information by CNC users. This database is populated by 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, program integrity contractors, and law enforcement such as the FBI. CMS uses the national CNC database to enhance efforts to detect and prevent fraud and abuse in Medicare.

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. 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 2015, the Command Center conducted 41 missions that included participants from CMS and our partners, including the HHS-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. CMS is also working with the FBI, HHS-OIG, and 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/Program Safeguard Contractors (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 2015, 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.

National Correct Coding Initiative (NCCI)

CMS developed the National Correct Coding Initiative (NCCI) to promote national correct coding methodologies and to control improper coding leading to inappropriate payment in Medicare claims. The use of the NCCI edits saved the Medicare program \$681.9 million in FY 2014.¹² In FY 2015, CMS also continues to work with states to fully and correctly implement the NCCI methodologies in their Medicaid programs, to add new Medicare and Medicaid NCCI edits to the quarterly Medicaid NCCI edit files that are compatible with claims filed with Medicaid, and to update the technical guidance document for states.

Medicaid Enterprise System

Today's modern design of IT systems encompasses the use of current technologies that span across the entire Medicaid Enterprise. These systems work in concert with one another and must adhere to certain regulations and guidance, including the Medicaid Information Technology Architecture (MITA) framework and the Seven Standards and Conditions. Adhering to these mandates will promote the consistency of business and technical processes and IT platforms, as well as standards across the Medicaid Enterprise.

The project includes independent technical assistance for IT and policy requirements, including monitoring and oversight, in working with state-specific system requirements, IT system builds, and associated interfaces for all states and the territories. All fifty states and the territories received technical assistance with moving through the Enterprise Life Cycle (ELC) Gate Review Process, including any associated consults. States received assistance with project management, implementation, and operations. Technical artifacts required by statute were analyzed and tracked to assess state progress. Gap analyses were done on a regular basis and risk registers were studied to identify opportunities for improvement.

¹² NCCI savings are from Medicare Part B Medically Unlikely Edits (MUEs) and Part B Procedure-to-Procedure (PTP) Edits.

2. Detection

Strengthened Program Integrity Activities in Medicare Advantage and Medicare Part D Medicare Drug Integrity Contractors (MEDICS)

National Benefit Integrity

In FY 2015, the National Benefit Integrity (NBI) MEDIC received on average approximately 762 actionable complaints per month, processed an average of 54 requests for information from law enforcement per month, and referred an average of 48 cases to law enforcement per month through July. NBI MEDIC referrals have resulted in sentences ordering restitution of \$41.4 million, forfeitures of \$13.6 million, and civil settlements of \$12.2 million according to FY 2015 notifications from law enforcement. The NBI MEDIC was responsible for assisting the OIG and the Department of Justice (DOJ), through data analysis and investigative case development, in achieving 68 convictions, 35 arrests, and 45 indictments from FY 2015 notifications. In one case, the NBI MEDIC investigated complaints concerning out-of-country beneficiary enrollments in Nicaragua and the Dominican Republic alleging that a Medicare plan was advertising improper inducements for Medicare-eligible beneficiaries to sign up for the plan. Ten subjects involved were charged with multiple counts of health care fraud and have pled guilty. As of July 2015, 6 of the 10 have been sentenced for their involvement in a transnational health care fraud scheme and ordered to pay restitution of \$14.5 million.

Outreach and Education

In FY 2015, the Outreach and Education (O&E) MEDIC facilitated the CMS Parts C & D Fraud Waste and Abuse (FWA) training sessions that offered Medicare Advantage organizations and Prescription Drug plans an opportunity to collaborate and discuss techniques on how to prevent and detect fraud, waste, and abuse in the Medicare Advantage and Part D programs. These FWA training sessions are designed to educate Medicare Advantage organization and Prescription Drug plan staff through enhanced collaboration, information sharing, data analytics and communication. FWA training session stakeholders include plan sponsors, Pharmacy Benefit Managers (PBMs), representatives from law enforcement agencies—including HHS-OIG, U.S. DOJ, and other state and local law enforcement entities. These FWA training sessions provide a forum for stakeholders to learn about the most recent fraud schemes and fraud prevention best practices to assist in developing effective fraud prevention programs.

The O&E MEDIC is also responsible for other outreach activities and has developed many courses and resources to train Medicare Advantage organizations and Prescription Drug plans on best practices to detect and investigate Medicare Advantage and Prescription Drug fraud, waste, and abuse. In order to help Parts C and D Plan sponsors better educate their enrollees on fraud waste and abuse, the O&E MEDIC developed a video on Open Enrollment Fraud, as well as several fraud alerts on identity theft, prescription drug abuse, telemarketing, and phishing schemes. The O&E MEDIC also created a video tutorial for providers to explain how to enroll in PECOS and comply with the CMS-4159-F requirements. In FY 2015, the O&E MEDIC also updated its most comprehensive fraud fighting tool, the “Medicare Advantage and Part D Fraud Handbook: Practical Techniques and Approaches on Detecting and Preventing Fraud,” and an Online Training Module for Medicare Advantage organizations (MAOs) and Part D sponsors. The handbook is a modular online reference providing MAOs and Part D sponsors with industry best practices regarding processes, methods, and resources to support fraud prevention,

detection, corrective action, preliminary investigation, and referral activities. The training is an online presentation covering each chapter of the Fraud Handbook in an on-demand webcast format.

Medicare Advantage (MA) Benefits Review Activities

Each year, MA organizations are required to submit bids detailing how their MA plans will provide coverage to beneficiaries for the following year. These 3,600 MA plans cover more than 17 million beneficiaries. Bid submissions are reviewed to ensure they do not discriminate against beneficiaries and comply with all CMS regulations. Plan requirements are established and communicated annually and the following reviews are performed:

- **Low Enrollment Plans**—Each year, CMS evaluates existing MA plans that have low total enrollment to make sure these plans are sustainable over time and protect beneficiaries from selecting a potentially unsustainable plan.
- **Total Beneficiary Cost (TBC)**—Evaluate increases in beneficiary cost sharing or decreases in plan benefits from one year to the next. This evaluation ensures beneficiaries receive value in their benefit package selection and do not experience large increases in out of pocket costs.
- **Maximum Out of Pocket Costs (MOOP)**—This review examines the maximum out-of-pocket costs that face beneficiaries who enroll in MA. These reviews protect beneficiaries from very high out of pocket medical costs.
- **Meaningful Difference**—This review helps to reduce potential confusion for beneficiaries when they are choosing between multiple plan options. By conducting this review, CMS helps to protect meaningfully different choices between plans and prevent MA organizations from offering similar plans in the same geographic area.
- **Service Category Cost-Sharing Standards**—Each year, CMS evaluates the cost-sharing standards plans include in their bids to make sure the plans do not exceed established limits. There are currently 26 cost-sharing health care service categories that have established limits and this review enables CMS to protect beneficiaries from discriminatory cost sharing levels.
- **Actuarial Equivalence**—CMS also reviews bids to make certain the actuarially estimated cost sharing presented in the bid does not exceed the cost-sharing levels in Original Medicare. CMS currently examines four categories for actuarial equivalence and this examination helps guard against plans imposing discriminatory cost-sharing on beneficiaries.
- **Supplemental Benefits**—There are several reviews conducted in this area, including a review of supplemental benefits that help make sure that any optional supplemental benefits offered are of reasonable value, as well as a review to make certain the benefits are offered in a non-discriminatory fashion.

All of these reviews are conducted in careful coordination with the Office of the Actuary and the Medicare Drug Benefit Group to make certain that plans make all necessary changes to their bids. These reviews occur between early June and August and involve communications with MA organizations to correct issues and resubmit their bids. Following bid approval, MA organizations must complete the contracting process with CMS and may market to beneficiaries beginning October 1. MA benefits requirements and review processes are intended to protect beneficiaries from discrimination and to make sure that MA plans provide value to enrollees.

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. To date, CMS has collected over 1.7 billion encounter data (ED) records.

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. The encounter data collected by EDPS will allow CMS to recalibrate the risk adjustment payment model, so that MA payments more accurately reflect the patterns of care and the predicted costs of diseases for MA enrollees. Recalibrating the model on MA diagnoses and expenditures, rather than using the FFS experience, will result in payments that are more accurate to MA organizations. CMS is also able to use the information to evaluate service utilization, assess quality of care, and assess the performance of MA plans.

Beginning with payment year 2015, CMS began to use encounter data as an additional source of diagnoses to risk adjust payments to Medicare Advantage Organizations. For payment year 2016, CMS continued that transition and will ultimately use encounter data as the sole source of plan-submitted diagnosis information.

Medicaid/CHIP Financial Management Project

Under this project, funding specialists, including accountants and financial analysts, worked to improve CMS' financial oversight of the Medicaid Program and CHIP. In FY 2015 through the continued efforts of these specialists, CMS removed an estimated \$2.5 billion (with approximately \$1 billion recovered and \$1.5 billion resolved) of approximately \$9.4 billion identified in questionable Medicaid costs.

Furthermore, an estimated \$1.028 billion 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

OIG Hotline Operations accepts tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement in HHS' programs. The CMS-OIG HOTLINE database is used by CMS and its contractors to investigate and resolve those complaints that are sent from the HHS OIG.

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

CMS added additional partners to the HFPP and is targeting further expansion of the HFPP 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.

The HFPP has completed eight studies to date, listed below:

- Study 1, Iterations 1 & 2 (counted as two studies): Misused Codes and Fraud Schemes—To share information on misused codes and potential fraud schemes to improve overall awareness of fraud patterns and trends.
- Study 2, Iterations 1 & 2 (counted as two studies): Non-Operational Providers—To create an aggregate list of non-operational provider entities for use in investigations.
- Study 3: Terminated/Revoked Providers—To create an aggregate list of terminated/revoked provider entities for potential investigations.
- Study 4: Top Billing Pharmacies—To identify outlier pharmacies that are dispensing a high amount of controlled prescription drugs.
- Study 5: Urine Drug Screens—To study how providers bill for qualitative and quantitative urine drug screens.

- In-Person Study: High Risk Procedures—To view summary data live and examine potential trends in high-risk procedures.

The HFPP also has received input from partners about which study topics would have the highest potential value and identified 15 study topics of common interest in addition to the eight studies previously mentioned.

After using the first study's findings for analyses and corrective action determinations, CMS reported \$187.7 million in savings to the Medicare Trust Funds from system edits, revocations, and payment suspensions related to the first two studies listed above. This estimate is based on CMS' latest savings calculation methodologies, but the estimate is subject to change due to improvements in the methodological approach and data accuracy. However, CMS does not expect any changes to be significant.

Participating HFPP partners received results for studies 1-5. Partners have been assessing and continue to assess the results and independently determine appropriate corrective actions. Partner outcomes, savings, and cost avoidance data will be available in the future.

Improper Payment Rate Measurement and Increased Accountability in Medicaid and CHIP Programs

The Improper Payments Information Act (IPIA) of 2002, as 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. CMS estimates improper payment rates in Medicaid and CHIP established through the Payment Error Rate Measurement (PERM) Program. The improper payment 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 improper payment rates using a 17-state rotation so that each state is reviewed once every three years.

In light of changes to the way states adjudicate eligibility for Medicaid and CHIP under the Affordable Care Act, CMS is currently updating the PERM eligibility component measurement methodology and related program regulations to reflect the required changes. During this time, CMS will not conduct the eligibility measurement component of PERM and the national Medicaid eligibility improper payment rate will be held constant at the FY 2014 reported rate as a proxy in the overall improper payment rate calculation. In place of PERM eligibility, all states are required to conduct eligibility review pilots through FY 2018. The eligibility review pilots provide more targeted, detailed information on the accuracy of eligibility determinations and provide states and CMS with critical feedback during initial implementation.

CMS reported in the FY 2015 Agency Financial Report the national Medicaid improper payment rate that is based on measurements that were conducted in FYs 2013, 2014, and 2015. The FY 2015 national Medicaid improper payment rate is 9.8 percent, representing \$29.1 billion in

estimated improper payments compared to the FY 2014 improper payment rate of 6.7 percent or \$17.5 billion in improper payments. The national component improper payment rates are as follows: Medicaid FFS—10.59 percent, Medicaid managed care—0.12 percent, and Medicaid eligibility—3.11 percent. The Medicaid eligibility component improper payment rate is held constant at the FY 2014 reported rate of 3.1 percent. The major cause of error was state difficulties achieving compliance with new system requirements that were put in place to strengthen program integrity. The Affordable Care Act requires all referring/ordering providers to be enrolled in Medicaid and requires claims to contain the referring/ordering provider National Provider Identifier (NPI). The Affordable Care Act also requires states to screen providers under a risk-based screening process prior to enrollment. Additionally, a new Health Insurance Portability and Accountability Act of 1996 (HIPAA) standard requires the attending provider's NPI be on all electronically-filed institutional claims. While these requirements will ultimately strengthen the integrity of the program, it takes time for states to make the necessary compliant systems changes.

CMS reported in the FY 2015 Agency Financial Report the national CHIP improper payment rate that is based on measurements that were conducted in FYs 2013, 2014, and 2015. The FY 2015 national CHIP improper payment rate is 6.8 percent, representing \$0.6 billion in estimated improper payments compared to the FY 2014 improper payment rate of 6.5 percent or \$0.6 billion in improper payments. The national component improper payment rates are as follows: CHIP FFS—7.33 percent and CHIP managed care—0.37 percent. The CHIP eligibility component improper payment rate is held constant at the FY 2014 reported rate of 4.2 percent. The major cause of error in CHIP is the same cause described in Medicaid above. CMS is currently measuring cycles that will be reported in FYs 2016 and 2017.

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

In compliance with IPIA, as amended by IPERA and IPERIA, CMS has implemented a systematic plan regarding improper payments for Part C and D programs.

The Part C payment error estimate reported for FY 2015 (based on calendar year CY 2013) is 9.5 percent. 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 improper payment rate, CMS has implemented two key specific corrective actions described below: contract level audits and new regulatory provisions.

- **Contract-Level Audits:** CMS conducts Risk Adjustment Data Validation (RADV) contract-level audits to recover overpayments. RADV verifies, through medical record review, the accuracy of enrollee diagnoses submitted by MA organizations for risk adjusted payment. RADV audits are HHS's primary corrective action to recoup overpayments from MA organizations. CMS expects that payment recovery will have a sentinel effect on the quality of risk adjustment data submitted by plans for payment. RADV audits of payment year 2011, which began in FY 2014, will be the first CMS reviews to recoup funds based on extrapolated estimates.

- New Regulatory Provisions: In CMS-4159-F, “Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program” (79 FR 100), HHS codified the Affordable Care Act requirement that MA organizations must report and return overpayments that they identify. In CMS-1613-FC, “CMS-Identified Overpayments Associated with Submitted Payment Data” (79 FR 66769), HHS also established a payment recovery and appeal mechanism to be applied when HHS identifies erroneous payment data submitted by an MA organization.

The Part D payment error estimate reported for FY 2015 (based on CY 2012) is 3.6 percent. The FY 2015 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.

In an effort to improve the Part D error rate, CMS has implemented two key specific corrective actions described below: outreach to plan sponsors and new regulatory provisions.

- Outreach: Formal outreach to plan sponsors will continue for invalid/incomplete documentation.
- New Regulatory Provisions: HHS codified the ACA requirement that Part D sponsors must report and return overpayments that they identify. CMS also proposed a payment recovery and appeal mechanism to be applied when CMS identifies erroneous payment data submitted by a Part D sponsor.

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 FFS 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. CMS awarded a contract in September 2015 to conduct the pilot.

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 began collecting data on probable fraud to establish an estimate of probable fraud within HHAs in 2015.

4. Recovery

Suspension

CMS in FY 2015 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 exists. During FY 2015, there were 420 payment suspensions that were active at some point during the fiscal year (data reflected as of September 10, 2015). Of the 420 payment suspensions, 105 new payment suspensions were imposed during FY 2015.

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.

CMS program integrity field offices develop solutions to the most challenging fraud issues in their regions. For example, the Miami field office has implemented a comprehensive, multi-agency approach to address Medicare and Medicaid aspects of health care fraud in South Florida and has served as a testing ground for efforts that have been expanded to a national level. To address emerging fraud schemes by ambulance providers, the Los Angeles staff is working with county Emergency Medical Service licensing authorities and related health care providers; CMS contractors; and local, state, and federal law enforcement.

Enrollment Special Study

This is a project designed to utilize and expand the existing programmatic infrastructures to take administrative actions under existing CMS authorities by conducting site verifications of potentially high risk providers and suppliers. The information obtained during site verifications is used to determine if provider enrollment requirements are met and to calculate a fraud level indicator.

Since inception in July 2009, this project has produced significant results; including an increased number of revocations, deactivations, and prepayment edit savings. The project has also provided valuable information that CMS has used to identify and implement programmatic changes that have proven successful to deter and prevent Medicare fraud.

As of June 30, 2015, the Medicare Administrative Contractor covering Florida (First Coast Service Operations), had conducted 6,838 site verifications to verify providers' and suppliers' operational status, deactivated 117 practice locations, and revoked or denied 773 providers. CMS saved \$8,919,228 from prepayment medical record review.

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 2015, the Administration for Community Living (ACL) was allocated \$3.4 million in HCFAC funding by HHS to support infrastructure, technical assistance, and other SMP program support. In addition to this funding, ACL was allocated \$5.3 million for capacity-building activities designed to enhance the effectiveness of state-wide SMP programs. During FY 2010 and FY 2011, CMS had provided this capacity funding to ACL for the SMP projects. Since FY 2012 HCFAC funding has been allocated 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, U.S. Virgin Islands and the District of Columbia) 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 August 2015, a total of 5,249 active volunteers served SMP projects during 2014. These volunteers performed an essential function of this program, contributing 117,300 hours and conducting over 202,862 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 2014, SMP projects held 12,417 community outreach education events reaching more than 1,118,982 people, and were responsible for over 110,615 media airings to increase beneficiary awareness about issues related to Medicare fraud. In addition, over 452,714 beneficiaries were educated through 14,692 group educational sessions conducted by SMP programs in local communities. SMP projects nationwide received 94,368 inquiries for information or assistance in 2014 from or on behalf of beneficiaries. This included receipt of 1,614 complex issues, i.e., beneficiary complaints requiring further research, assistance, case development, and/or referral. SMP projects reported that 1,369 complex issues were resolved for beneficiaries during 2014, while 660 complex issues with an estimated dollar value of over \$994,603, 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 \$200,598 in health care expenditures were avoided and nearly \$741,562 in Medicare, Medicaid and other savings resulted from actions taken by the SMP program.

Since the program's inception, the program has educated over 6.6 million beneficiaries in group or one-on-one counseling sessions and has reached more than 30 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 specific 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 extremely difficult to quantify in dollars and cents. As HHS-OIG indicated in the August 2015 report:

We continue to emphasize the projects may not be receiving full credit for savings attributable to their work. 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. 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 assessed the national design and implementation of the SMP program, the adequacy of current SMP performance measures, and sought to determine the most appropriate measures of SMP program value (benefits, results and impact). The contract concluded in December 2013 and ACL is reviewing the evaluation recommendations for implementation in FY 2015. In addition, in FY 2013, the SMP program issued a three-year 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 grant is intended to 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, HHS-OIG has documented in the annual performance report over \$122 million in savings attributable to the program as a result of beneficiary complaints since its inception in 1997.

SMP Infrastructure and Program Support

SMP Resource Center

In FY 2014, the SMP Resource Center's grant was up for competition and a new three-year grant was awarded. The SMP Resource 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 health care integrity outreach and education. The Center has been instrumental in supporting ACL efforts to forge national visibility for the SMP program.

SMP Data System

The SMP program issued a contract in FY 2014 for the development of a new data system designed to support the evolving needs of the SMP program. The previous system, SMART FACTS, has been in operation for seven years and is at the end of its functionality. The new system will be operational in late FY 2015 and is expected to last at least 10 years.

Integration Project Grants

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 that initiated seventeen-month projects seeking to increase awareness, empowerment, and actions to prevent health care fraud amongst these generally underserved populations. The goal of these grants is 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. This work ended in FY 2015.

Prevention Research Grant

As mentioned above in FY 2013, the SMP program 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. This work continued in FY 2014.

Office of the General Counsel

In FY 2015, the Office of the General Counsel (OGC) was allocated approximately \$10 million in HCFAC funding by HHS to supplement OGC's efforts to support program integrity activities. Many of OGC's efforts in FY 2015 were 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 2015, OGC was involved in a wide range of HCFAC efforts that resulted in Government recoveries of over \$2.4 billion in judgments, settlements, or other types of recoveries, savings, or receivables as described elsewhere in this report.

The Affordable Care Act

The Affordable Care Act (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, strengthening overpayment provisions to specifically invoke the False Claims Act (FCA), and creating a statutory disclosure protocol for violations of the physician self-referral prohibition known as the "Stark law." During FY 2015, as new ACA programs continued to be implemented, OGC spent significant time and

resources working with the relevant CMS client components to ensure that program integrity issues were reviewed and resolved, and assisted the client in addressing program integrity and compliance problems as they occurred.

HEAT

During FY 2015, OGC was involved in Health Care Fraud Prevention and Enforcement Action Team (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 assisted 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 supported DOJ in assessing qui tam actions filed under the FCA by interpreting complex Medicare and Medicaid rules and policies to assist DOJ in discerning which allegations were program violations and should be pursued, and to help DOJ focus government resources 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 often extensive requests for documents and information. OGC also expended considerable resources in responding to requests for information and witness testimony in declined qui tams that were litigated by relators. In FY 2015, OGC participated in FCA and related matters that recovered over \$452 million for the Government. The types of FCA cases that OGC worked collaboratively with DOJ on included: drug pricing manipulation, illegal marketing activity by pharmaceutical manufacturers that resulted in Medicare and Medicaid paying for drugs for indications not covered, physician self-referral violations, and provider upcoding 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 through the appeal process. In FY 2015, OGC attorneys were involved in a myriad of suspension and recoupment actions, which involved suspected fraudulent billings by many different segments of the health care industry, including DME suppliers, ambulance companies, physicians, infusion clinics, therapists, home health agencies, and diagnostic testing facilities. OGC also represented CMS when a provider or supplier appealed a denial of enrollment or revocation. In FY 2015, OGC represented CMS in appeals before the HHS Departmental Appeals Board (DAB) and worked to resolve these cases without formal hearings. Further, OGC 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 2015, 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, Civil Monetary Penalty (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 2015, 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, U.S. Attorney's Offices, 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 2015, 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 2015, OGC advised CMS on a vast 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: providing counsel to the CMS "Innovation Center" regarding new payment and delivery models to improve the quality of care and reduce costs to the Medicare and Medicaid programs, working with CMS to implement the agency's second notice related to provider and supplier enrollment moratoria, and providing counsel on the program integrity issues to CMS to assist in the development of the Notice of Proposed Rulemaking for the Medicare Shared Savings Program published on December 8, 2014. Further, OGC worked on a final rule amending CMS's enrollment regulations to establish new authority for CMS to deny or revoke billing privileges from individuals and entities that pose a program integrity risk to the Medicare program. Among many other things, the regulation provides new authority to deny enrollment to individual or entity affiliated with entities that have an existing Medicare debt and new authority to revoke enrollment from providers and suppliers that have a pattern or practice of billing for services that do not meet Medicare requirements. In addition, OGC routinely works with CMS to review legislative proposals regarding program integrity matters.

Medicaid Program Integrity

Continuing recent trends, OGC saw continued increasing involvement in FY 2015 in Medicaid program integrity issues as CMS devoted more resources to financial reviews and oversight and as states continued to present innovative proposals to reconfigure their Medicaid programs. For example, in *Detroit-Wayne Mental Health Authority*, OGC obtained a fully favorable decision from the DAB, sustaining the Division of Cost Allocation's denial of the Authority's request to use unspent Medicaid funds to reduce its pension obligations, and resulting in an affirmative

recovery of \$4.8 million as the State of Michigan recently refunded the unspent funds to CMS. Further, OGC assisted CMS with the Indiana Medicaid Program's pilot project to recover Medicare overpayments through the offset of the FFP portion of Medicaid payments. To date, this pilot project has recovered nearly \$1 million. OGC anticipates providing similar support to CMS with a recently launched initiative with the State of Ohio Medicaid Program that has so far recovered over \$100,000.

Physician Self-Referral

OGC provided guidance to CMS and DOJ in navigating the complexities of the Stark physician self-referral law. This consultation helps to build stronger cases and focus investigatory efforts, leading to successful results for the Government. In FY 2015, OGC provided extensive counsel to CMS in its ongoing implementation of the Medicare Physician Self-Referral Disclosure Protocol (SRDP)—created under the ACA to enable Medicare providers to self-disclose technical violations of the Stark law's physician self-referral prohibition. OGC advised CMS regarding numerous matters disclosed under this protocol, now numbering over 350.

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 HCFA statutory goal of facilitating the enforcement of all applicable legal remedies for program fraud and abuse. During FY 2015, OGC has been successful in establishing the right to recover over \$4.8 million for Medicare under the MSP program. Further, 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 the authority for CMS to impose substantial CMPs for failure to report.

Bankruptcy Litigation

OGC protects Medicare funds from waste in bankruptcy cases by asserting CMS recoupment rights to collect overpayments, arguing to continue suspension or termination actions against debtors, seeking adequate assurances from the bankruptcy court that CMS interests in the debtor's estate will be protected, arguing for the assumption of the Medicare provider agreement as an executory contract, and petitioning for administrative costs where appropriate. In FY 2015, 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 \$16 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 2015, 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.

In summary, OGC's FY 2015 work in support of CMS advances the specific goals of the HCFAC program, including program integrity, fraud prevention, and fraud response. Most CMS operations have a fraud/abuse component, and OGC's work supporting all CMS substantive program areas directly supports the HCFAC program's goals of fraud and abuse prevention in those operational program areas.

Food and Drug Administration Pharmaceutical Fraud Program

In FY 2015, \$3.4 million in HCFAC funding was made available 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 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. By initiating investigations of pharmaceutical fraud schemes earlier in their lifecycle, FDA is able to preclude potential public harm by barring medical products, which have not followed the legal FDA approval processes and do not meet FDA standards, from making it to market, thus saving valuable health care dollars from being spent.

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 one hundred twenty criminal investigations. In FY 2015, FDA's fifth full fiscal year of HCFAC Program activity, OCI, through its PFP, opened twenty-nine criminal investigations, described below:

- Two investigations involving allegations of questionable manufacturing practices of foreign-based drug firms. The investigations are focused on violations related to application fraud, data integrity, data manipulation, and adulteration.
- Two investigations involving allegations of questionable manufacturing practices of an injectable drug by a domestic firm causing the finished product to be sub-potent. The investigation is focused on misbranding and/or adulteration.
- Three investigations involving allegations of questionable manufacturing practices of medical devices ultimately causing public safety risks. The investigations are focused on misbranding and/or adulteration.
- Five investigations involving marketing schemes by medical device and drug manufacturers. These investigations involve alleged misbranding of devices and drugs

by offering them for sale to address conditions for which they are not FDA cleared or approved.

- Seventeen investigations involving allegations of clinical trial or application fraud. These investigations are focused in part on individuals or companies 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 or clearance applications made to the FDA.

In regard 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. For example, in February 2015, one of our PFP investigations opened in FY 2011 concluded with a clinical trial coordinator being sentenced to 36 months in prison, 36 months of probation, and ordered to pay approximately \$200,000 for making false statements in a matter within the jurisdiction of the FDA. Specifically, an FDA investigator found evidence to show a number of study subjects that had been reported as being enrolled in a clinical study of an HIV drug did not actually participate in the study and that all the data regarding their participation had been fabricated.

Additionally, in March 2015, the first investigation opened at the inception of our PFP program in mid-FY 2010, concluded with a large prescription and over-the-counter drug manufacturer located in the Philadelphia area pleading guilty for introducing adulterated infant's and children's liquid medications into interstate commerce. The investigation netted a \$25,000,000 recovery.

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 promising cases include several large foreign generic drug manufacturers under investigation for data integrity and other manufacturing violations which would deem their products adulterated and could possibly pose a risk to the public's health and safety. Sixty percent of generic drugs in the United States come from foreign manufacturers.

In addition to these investigative activities, FDA conducted a one day training session in early March 2015 for criminal investigators covering PFP related topics. 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. Due to this training, FDA has seen a measurable increase in HCFAC Program awareness, interest, and level of skill in conducting the investigations.

DEPARTMENT OF JUSTICE

United States Attorneys

In FY 2015, the United States Attorneys' Offices (USAOs) were allocated approximately \$51.9 million in HCFAC funding to support civil and criminal health care fraud and abuse litigation, as exemplified in the Program Accomplishments section. The USAOs dedicated substantial district resources to combating health care fraud and abuse in 2015, 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. USAOs work with CMS by reviewing and conferring with CMS about their imposing any potential civil monetary penalties against a provider. Additionally, the Attorney General Advisory Committee's (AGAC) Health Care Fraud Working Group has supported and is working on efforts to reduce the number of home health care fraud cases. The effort to reduce this type of fraud is in working on proposals to change the home health care documentation, and providing extended education to providers about their responsibilities to correctly certify service for these programs and the risks they face for not submitting correct information.

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 Fraud 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, and 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. Most notably, health care giant Johnson & Johnson agreed to pay \$2.2 billion to resolve criminal and civil liability arising from allegations relating to the prescription drugs Risperdal, Invega and Natrecor, including misbranding related to the promotion for intended uses not approved as safe and effective by the Food and Drug Administration (FDA) and payment of kickbacks to physicians and to the nation's largest long-term care pharmacy provider.

Other major pharmaceutical cases included: Endo Health Solutions Inc., which agreed to pay to

pay \$192.7 million to resolve criminal and civil liability arising from Endo's marketing of the prescription drug Lidoderm for intended uses not approved as safe and effective by the FDA, which rendered the drug misbranded; and Teva Pharmaceuticals USA Inc., which agreed to pay the Government and the State of Illinois \$27.6 million for allegedly violating the FCA by making payments to induce prescriptions of an anti-psychotic drug for Medicare and Medicaid beneficiaries. Most of the major civil 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, distribution of drugs for uses not approved by FDA, and kickbacks.

The USAOs also partner with the Criminal Division in the Medicare Fraud Strike Forces currently operating in nine areas across the country. Each USAO has dedicated several AUSAs and support personnel to work with Criminal Division attorneys in this important initiative. Additionally, USAOs in Strike Force and non-Strike Force cities work on other substantial cases which result in high monetary recovery or have a substantial impact on the law and the community. Examples of successful cases that were not initiated or concluded in districts as part of a Strike Force team during FY 2015 are detailed earlier in this report.

In addition to the positions funded by HCFAC, the Executive Office for United States Attorneys' Office of Legal Education (OLE) uses HCFAC funds to train AUSAs and other DOJ attorneys, as well as paralegals, investigators, and auditors in the investigation and prosecution of health care fraud. In April 2015, OLE offered a Health Care Fraud Seminar which was attended by over 85 AUSAs and DOJ trial attorneys. In November 2015, OLE offered training for USAO auditors, investigators, and paralegals which included a focus on health care fraud investigations. Many USAO attorneys, investigators, auditors, and paralegals served as faculty at these OLE trainings, and also participate in other federal, state, and private health care fraud seminars.

Criminal Prosecutions¹³

In FY 2015, the United States Attorney's Offices (USAO) opened 983 new criminal health care fraud investigations. Assistant United States Attorneys (AUSA) filed criminal charges in 463 cases involving 888 defendants. A total of 613 defendants were convicted of health care fraud-related crimes during the year.

Civil Matters and Cases¹⁴

In FY 2015, USAOs opened 808 new civil health care fraud investigations and had 1,048 civil health care fraud matters pending at the end of the fiscal year.

¹³ FY 2015 numbers are actual data through the end of September 2015. This data includes records classified either with the primary or tertiary 03G — Health Care Fraud program code.

¹⁴ FY 2015 numbers are actual data through the end of September 2015. This data includes those records classified under with the FRHC — Health Care Fraud civil code.

Civil Division

In FY 2015, the Civil Division received approximately \$31.6 million in FY 2015 HCFA 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 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 United States Attorneys' Offices and often team with the Consumer Protection Branch, HHS-OIG, state Medicaid Fraud Control Units and other law enforcement agencies to pursue allegations of healthcare fraud. 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 \$1.9 billion in FY 2015 alone.

The Fraud Section investigates and resolves matters against a wide array of health care providers and suppliers. In FY 2015, some of the most significant matters pursued by the Fraud Section involved hospitals and physicians. In some of these cases, the hospitals allegedly improperly admitted patients who could have been treated on a less costly outpatient basis (such as the Dignity Health, MCCG, and CHS matters discussed above). Other cases against hospitals and physicians involved alleged violations of the Stark Law, which prohibits physicians from referring their patients to other entities for services payable by Medicare when the physician or an immediate family member of the physician has a direct or indirect financial relationship with the entity (such as the North Broward Hospital District, Robinson Health System, Citizen's Medical Center, Columbus Regional, and Adventist Health Care System matters discussed above). The Fraud Section continues to look closely at these types of arrangements to make sure that Medicare and Medicaid, as well as the beneficiaries of these programs, are protected from the distorted medical decision-making that these improper financial deals can cause.

The Fraud Section has been called upon to litigate an increasing number of FCA cases that in the past may have been settled. For example, while it has settled allegations against for profit hospice providers relating to the admission of beneficiaries not eligible for the hospice benefit (such as the Good Shepherd Hospice and Covenant Hospice matters discussed above), the Section has filed complaints and committed significant resources to litigating claims against a number of other hospice providers, including Vitas Hospice Services, AseraCare Hospice, Creekside Hospice, and Evercare Hospice and Palliative Care (now known as Optum Palliative Care and Hospice). Similarly, while the Section has settled allegations against nursing homes and healthcare providers relating to medically unnecessary and inappropriate levels of rehabilitation therapy administered to elderly residents (such as the Extencare Health Services and RehabCare matters discussed above), it has filed complaints against other providers, including Life Care Centers of America, Inc. and HCR Manorcare.

Matters involving pharmaceutical and device manufacturers were historically some of the most complex and resource intensive cases handled by the Fraud Section, and the Section's historic recoveries in these areas have had a significant deterrent effect on industry. The Section continues to investigate allegations that drug and device manufacturers caused the submission of false claims to federal healthcare programs by promoting drugs for uses not approved by the FDA and not covered by federal health care programs (as alleged in the Inspire Pharmaceuticals matter discussed above), by distributing unapproved and non-reimbursable medical devices (as alleged in the OtisMed and NuVasive matters discussed above), and by paying kickbacks to healthcare providers to recommend or prescribe particular products (as alleged in the Daiichi Sankyo and Medco Health/AstraZeneca matters discussed above).

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 handles some of the most complex matters and 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 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, subpoena 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. Elder Justice Initiative members represent the Justice Department on Interagency Working Groups such as the Elder Justice Coordinating Council's Working Group. The Civil Division maintains the Elder Justice Website (www.justice.gov/elderjustice), a valuable resource for elder abuse victims and their families, state and local prosecutors, elder abuse researchers, as well as practitioners.

The Consumer Protection Branch

The Consumer Protection Branch (CPB) litigates consumer fraud actions to end dangerous practices that harm America's most vulnerable populations, like the sick and elderly. Among its top priorities are pursuing cases against those who market unsafe or fraudulent products and services that endanger the health and safety of patients. CPB works closely with United States

Attorney's Offices, the Commercial Litigation Branch's Fraud Section, the Food and Drug Administration (FDA), and other law enforcement partners on a wide range of health care fraud cases, including those involving the promotion and distribution of unapproved and adulterated drugs and medical devices. CPB has made significant headway in fighting fraud schemes that endanger the public health, having successfully prosecuted dozens of cases resulting in significant jail terms, fines, and forfeitures. This litigation serves to deter companies and individuals from marketing and selling unsafe pharmaceuticals and medical products to the American public.

In partnership with key agencies, in FY 2015, CPB prosecuted medical device maker OtisMed Corporation and its former president and CEO for distributing an unapproved medical device used in knee replacement surgery. OtisMed marketed the OtisKnee cutting guide as a tool to assist surgeons in making accurate bone cuts during knee replacement surgery. After FDA notified OtisMed and its CEO that the OtisKnee had failed to demonstrate that it was as safe and effective as other legally marketed devices and therefore that distribution of the device was prohibited, the CEO ordered the shipment of approximately 218 devices to surgeons nationwide. The corporation pled guilty to violating the Federal Food, Drug, and Cosmetic Act and paid a criminal fine and forfeiture totaling \$39.6 million. It also entered into a civil settlement with the federal government and the states of more than \$40 million. The CEO was sentenced to 24 months in prison followed by one year of supervised release, and ordered to pay a \$75,000 fine.

In another medical device matter, CPB, in collaboration with the U.S. Attorney's Office for the Middle District of Florida, entered into a deferred prosecution agreement with Genzyme Corporation, a wholly-owned biotechnology subsidiary of French pharmaceutical company Sanofi, to resolve criminal charges that it violated the Federal Food, Drug, and Cosmetic Act with regard to Seprafilm, a surgical device it markets and promotes. A two-count criminal information charged that, between 2005 and 2010, Genzyme caused Seprafilm to become adulterated and misbranded while held for sale. For instance, some Genzyme sales representatives taught surgeons how to mix Seprafilm sheets into a slurry that could be squirted through the narrow tubes used during laparoscopic surgery, even though Seprafilm was never FDA-approved for use in such procedures. In addition, during the course of the government's investigation, Genzyme voluntarily disclosed that it had distributed promotional material that implied that Seprafilm had been proven safe and effective for use in gynecologic cancer surgeries, even though Seprafilm's FDA-approved label cautioned against such use. Genzyme paid a monetary penalty of more than \$32 million and agreed to undertake several measures to enhance its internal compliance program. In 2013, the government entered into a separate \$22.3 million civil agreement to resolve allegations under the False Claims Act related to Seprafilm.

CPB has also increased its attention to dietary supplement manufacturers that sell misbranded and adulterated products, which pose a danger to the public and scam consumers out of money for misrepresented products. For example, last fiscal year, CPB along with the FDA, and the U.S. Attorney's Office in New Jersey, teamed together to prosecute the owner and president of the dietary supplement company, Raw Deal Inc. The president instructed employees to add fillers like maltodextrin, rice flour, and cocoa replacer to dietary ingredients in supplements sold

to customers. The company president was sentenced to prison and ordered to forfeit \$1 million in profits from his fraudulent scheme.

CPB brought actions in FY 2015 to ensure the safety and integrity of the nation's drug supply. McNeil-PPC, Inc., a wholly-owned subsidiary of Johnson & Johnson, pled guilty in U.S. District Court for the Eastern District of Pennsylvania to delivering for introduction into interstate commerce adulterated infants' and children's over-the-counter (OTC) liquid medicines from in or around May 2009 to in or around April 2010. The drugs were adulterated because McNeil did not manufacture them in compliance with current Good Manufacturing Practices (cGMP), which is required under the Federal Food, Drug, and Cosmetic Act. Among other things, McNeil received a consumer complaint regarding "black specks" in its Children's Tylenol (later identified as nickel/chromium-rich inclusions, which were not intended ingredients in the OTC liquid drug). In addition to this consumer complaint, McNeil discovered other OTC batches with particulates. However, McNeil did not initiate or complete a Corrective Action Preventive Action plan as required by its standard operating procedures. Consequently, McNeil was not in compliance with cGMP regarding the manufacturing of certain OTC liquid drugs. As part of the plea, McNeil agreed to pay a \$20 million fine and forfeit \$5 million in substitute assets.

CPB also made inroads in the area of drug diversion, successfully prosecuting multiple individuals engaged in a massive drug diversion scheme involving more than \$390 million worth of prescription drugs. In FY 2015, these individuals were charged with conspiracy and related offenses as part of this scheme relating to sale of prescription drugs from illegal, unlicensed sources to wholesalers and pharmacies throughout the United States. To hide the true, illegal sources of their prescription drugs, the defendants falsified pedigree documents required by law that show the source of drugs. In FY 2015, five defendants pled guilty to crimes relating to their part in the scheme.

Criminal Division

In FY 2015, the Criminal Division was allocated \$14.7 million in FY 2015 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.

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 regions. In FY 2015, 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 regions. The Fraud Section's key litigation accomplishments in FY 2015 can be summarized as follows:

- Filed 200 indictments, informations and complaints involving charges filed against 391 defendants who allegedly collectively billed the Medicare program approximately \$1.4 billion;
- Obtained 314 guilty pleas and litigated 28 jury trials, with guilty verdicts against 48 defendants; and
- Secured imprisonment for 263 defendants sentenced during the fiscal year, averaging more than 56 months of incarceration.

The 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, Southern Texas, Brooklyn, Southern Louisiana, Tampa, Dallas, and Chicago.

In FY 2015, the Criminal Division organized the largest national health care fraud takedown in history, both in terms of individuals charged and the loss amount. On June 18, 2015, Attorney General Loretta E. Lynch and Department of Health and Human Services (HHS) Secretary Sylvia Mathews Burwell announced a nationwide sweep led by the Medicare Fraud Strike Force in 17 U.S. Attorneys' Offices, resulting in charges against 243 individuals, including 46 doctors, nurses and other licensed medical professionals, for their alleged participation in Medicare fraud schemes involving approximately \$712 million in false billings. In addition, the Centers for Medicare & Medicaid Services (CMS) also suspended a number of providers using its suspension authority as provided in the Affordable Care Act.

In addition to Medicare Fraud Strike Force cases, the Fraud Section handles corporate criminal health care fraud investigations. Often, such cases are handled in a parallel manner by the Fraud Section's prosecutors along with DOJ Civil Division attorneys and/or AUSAs from USAOs across the country. In FY 2015, the Criminal Division opened several new corporate health care fraud matters and had over a dozen active investigations into large, nationwide medical providers.

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 FY 2015, the Fraud Section's 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. Finally, the Fraud Section

also held a National Health Care Fraud Training Conference in September 2015 that was attended by 280 criminal and civil prosecutors (representing over 50 U.S. Attorneys' Offices) and law enforcement personnel.

The Organized Crime and Gang Section (OCGS)

The Criminal Division's Organized Crime and Gang Section (OCGS) supports and conducts investigations and prosecutions of fraud and abuse targeting private sector health plans as well as health care fraud and abuse perpetrated by domestic and international organized crime groups. With respect to private sector health care fraud, OCGS supports and conducts enforcement efforts combatting fraud and abuse directed at the 2.5 million private sector health plans sponsored by employers and/or labor organizations which cover some 137 million Americans. OCGS also works 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 2015, six OCGS attorneys were assigned to health care fraud prosecutions and investigations. Two OCGS attorneys worked with the Organized Crime Strike Force in the Philadelphia United States Attorney's Office on prosecutions involving Medicare fraud in the operation of a hospice. A third OCGS attorney conducted the prosecution of an employer in the District of Maryland who created false documents to conceal the company's underpayment of required contributions for employee benefits. Additional OCGS attorneys were engaged in health care fraud investigations involving fraudulent billings by an ambulance service provider, embezzlement and fraud targeting large collectively bargained health plans, fraud in the operation of a pharmacy, and theft of personally protected health care information from a health clinic.

The Philadelphia case involved the prosecution of a registered nurse in connection with a scheme to defraud Medicare in the operation of a hospice. The nurse, who served as the Director of Professional Services and supervised the nursing staff at the hospice, is alleged to have authorized the submission of more than \$9.5 million in fraudulent medical claims for hospice services provided to patients who did not receive services or were ineligible for the benefits claimed. The hospice founder, a co-owner, the medical director, and four staff nurses have previously been convicted and sentenced in connection with this false billing scheme. The massive fraud was alleged to be successful due to participation by nurses and other staff in the altering of patient records to make patients appear eligible for hospice services when, in reality, they were not. Trial for the remaining defendant is scheduled for FY 2016.

The District of Maryland prosecution involved the victimization of a union health care plan by an employer who underpaid contributions to the plan which were required by a collective bargaining agreement and concealed the underpayment in plan records and reports for three years. In October 2014, the company owner was sentenced to probation and ordered to make restitution for making false statements in documents required by the Employee Retirement Income Security Act.

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). Litigation support is provided as requested at any stage of the prosecution from indictment through trial and on appeal. 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 and prosecutions 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 training and guidance 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 is also responsible for drafting and reviewing criminal legislative proposals affecting employee health benefit plans. Finally, 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 and Medicaid frauds as well as private sector health care frauds.

Civil Rights Division

In FY 2015 the Civil Rights Division was allocated approximately \$7.8 million in FY 2015 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 and nonresidential health care facilities and service systems, as well as 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 program includes review of conditions in facilities for persons who have mental illness, facilities for persons with developmental disabilities, and nursing homes.

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. In addition to violating the civil rights of individuals with disabilities, such unnecessary institutionalization often results in unnecessarily increased Medicaid costs inconsistent with the Medicaid requirements for home and community-based services. Both the Special Litigation Section and the Disability Rights Section have undertaken initiatives to combat the use of Medicaid funding for the unjustified institutionalization of persons with disabilities.

The Educational Opportunities Section of the Civil Rights Division also participates in the HCFAC Program to address the use of Medicaid funding for unnecessary institutionalization of youth with disabilities in segregated education placements in violation of the ADA.

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

Fiscal Year 2015 Accomplishments

Key litigation and enforcement accomplishments in FY 2015 by the Civil Rights Division can be summarized as follows:

- Number of matters in active enforcement: 19;
- Cumulative estimate of individuals with disabilities affected: 33,322; and
- Number of institutional facilities affected: 2,172.

Special Litigation Section

In Fiscal Year 2015, the Special Litigation Section resolved two major systemic reform cases after the jurisdictions complied with settlement agreements; issued findings that a state unnecessarily institutionalizes children with mental illness; opened one statewide investigation regarding the unnecessary institutionalization of people with mental health disabilities in nursing facilities; monitored compliance of 10 statewide settlement agreements and four facility-focused agreements impacting thousands of people; monitored an agreement with an urban police department requiring them to connect individuals with mental illness to community-based services instead of costly institutional services and to avoid unnecessary criminal justice involvement; and filed one statement of interest in litigation regarding a Protection and Advocacy organization's ability to access investigatory records needed to ensure individuals at a health care facility were not subjected to abuse and neglect. In FY 2015, the Section's work—including its formal investigations, monitoring of remedial agreements, and active litigation—affected more than 1,700 health care facilities in 17 states as well as the District of Columbia. The large number of health care facilities reflects the Section's expanded focus on whether states are ensuring that nursing facilities and other institutional settings do not inappropriately admit persons who should be served in more integrated settings.

An important aspect of the Division's work is the active enforcement of its agreements (i.e., ongoing monitoring to ensure agreements are successfully implemented and pursuit of remedial measures where expected compliance is not occurring). Because of these agreements' scope and

complexity, this work typically spans several years. In FY 2015, the Special Litigation Section brought to a successful close two such agreements after years-long enforcement efforts. In Nebraska, the Section concluded a seven-year enforcement effort to improve conditions at the State's largest institution for people with intellectual and developmental disabilities, the Beatrice State Developmental Center, and enact system reforms to improve community services throughout the state. The court-ordered agreement required the State to remedy health, safety, and welfare issues at the institution, and more importantly, required the State to significantly expand and enhance community capacity and to establish robust quality assurance mechanisms in the community. It impacted the lives of hundreds of people who have received services at the institution and thousands of people who benefited from the system-wide reforms called for by the settlement. In Connecticut, the Section concluded a six-year enforcement effort to improve conditions at the Connecticut Valley Hospital. The agreement there required the State to remedy health, safety, and welfare issues for people with mental health disabilities at the institution, improve treatment and planning, and more appropriately consider community-based services for people residing at the facility.

The Section continued monitoring implementation of large-scale, systemic reform agreements in numerous jurisdictions across the country. These ongoing enforcement efforts include:

- A statewide agreement in *Amanda D. v. Hassan / United States v. New Hampshire* (D.N.H. 2012) requiring the creation of robust community alternatives—including high-intensity services for at least 1,500 people, integrated housing for hundreds of people, and employment supports for hundreds of people—that will reduce the risk that people needing only community-based services will be psychiatrically hospitalized unnecessarily;
- An agreement with the City of Portland in *United States v. City of Portland* (D. Or. 2012) requiring the Portland Police Department to train officers in mental health crisis intervention and connect individuals with mental illness to community-based mental health services to avoid unnecessary criminal justice involvement and institutionalization;
- A statewide settlement agreement in *United States v. Virginia* (E.D. Va. 2012) requiring the development of approximately 4,200 home and community-based waivers for people with intellectual and developmental disabilities who are on waitlists for community services and individuals transitioning from four State-run institutions;
- A statewide agreement in *United States v. Delaware* (D. Del. 2011) requiring the development of comprehensive community mental health supports—including high-intensity services for more than 1,000 people, integrated housing for 650 people, and employment supports for 1,100 people—for people with mental health disabilities in, or at risk of being placed in, the Delaware Psychiatric Center; and
- A statewide agreement in *United States v. Georgia* (N.D. Ga. 2010) requiring the development of community resources to serve thousands of people with serious mental illness or intellectual disabilities who reside in Georgia's State Hospitals or are at risk of being institutionalized there.

In FY 2015, the Section also issued findings in its investigation into West Virginia's children's mental health system. The United States concluded that West Virginia fails to serve children with mental health conditions in the most integrated setting appropriate to their needs in violation of the Americans with Disabilities Act (ADA) and *Olmstead v. L.C.* More than 1,000 children in the state reside in segregated, expensive residential facilities, often for long periods unrelated to their disability, because of a lack of less expensive, community-based service options. Negotiations began this fiscal year to resolve these issues in a comprehensive agreement.

Also in FY 2015, the Section opened an investigation into Louisiana's use of nursing facilities to serve people with mental illness and continued its investigation into South Dakota's use of nursing facilities to serve older adults and people with disabilities.

The Section filed one statement of interest in Idaho regarding a Protection and Advocacy organization's ability to access investigatory records needed to ensure individuals at a health care facility were not subjected to abuse and neglect.

Disability Rights Section

In FY 2015, the Disability Rights Section resolved one major, statewide litigation; continued to actively litigate another systemic, statewide case; monitored compliance of three statewide settlement agreements, under which more than 15,700 people collectively will obtain relief; and filed two statements of interest in litigation raising issues of needless segregation.

The Section entered into a proposed statewide settlement agreement with the State of Oregon in *Lane v. Brown* (D. Or.), a class action in which the United States intervened and which addresses the unnecessary segregation of individuals with disabilities in sheltered workshop and facility-based day programs in violation of Title II of the ADA. Under the agreement, the State has pledged a sustained commitment to transform its service system, impacting approximately 7,000 people. The State will provide supported employment services so that 1,115 working-age individuals will obtain competitive, integrated employment. The State will also reduce the number of individuals receiving services in segregated settings, and will ensure that at least 4,900 youth ages 14 to 24 are provided the employment services necessary for them to prepare for, choose, and maintain integrated employment.

The Section continued to litigate *United States v. Florida* (S.D. Fla. 2013), a case in which the United States alleges, among other things, that the State of Florida administers its Medicaid service system for children with significant medical needs in violation of the ADA and *Olmstead* by unnecessarily segregating them in nursing facilities, when they could, and want to, be served at home or in other community-based settings.

The Section also continued to monitor the implementation of its eight-year settlement agreement with the State of North Carolina, pursuant to which the State is providing opportunities to individuals with mental illness in adult care homes to transition to less costly, integrated service settings. To date, more than 400 individuals have moved from institutions to community-based settings, and more than 4,000 people receive community-based mental health services.

It also continued to monitor its settlement agreements with the State of Rhode Island and the City of Providence, addressing the unnecessary segregation of individuals with disabilities in sheltered workshop and facility-based day programs. Under the agreements, the State will provide supported employment placements to roughly 2,000 individuals with intellectual and developmental disabilities.

The Section also monitored its 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 benefits at least 2,500 people and 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 filed two statements of interest in litigation raising issues of needless segregation in Florida and Indiana. These briefs have addressed issues relating to the unnecessary institutionalization of individuals in state-run and private institutions.

Educational Opportunities Section

The Educational Opportunities Section (EOS) has participated in the HCFAC Program for the past two years. The Section has carefully analyzed the legal issues related to unnecessary segregation in the context of K-12 schools.

In FY 2015, the Section completed its investigation of the Georgia Network of Educational and Therapeutic Services (GNETS) program, which provides segregated educational services for approximately 5,000 Georgia students with emotional and behavioral disabilities. On July 15, 2015, the Division issued a letter of findings to the State identifying the ways in which the State unnecessarily segregates children with disabilities in its operation and administration of the program. GNETS is funded and operated by the State and provides services to most of the students in the program in segregated GNETS Centers throughout the State rather than providing community-based behavioral health services for these children.

The Section filed five statements of interest or *amicus* briefs in litigation raising issues of needless segregation of children in Pennsylvania, Mississippi, and the U.S. Court of Appeals for the Third and Eleventh Circuits. These briefs have addressed issues relating to the unnecessary institutionalization of children in state-run and private, state-funded institutions.

APPENDIX

Federal Bureau of Investigation

In FY 2015, the FBI was allocated \$129.2 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 797 positions (476 Agent, 321 Support).

In FY 2015, the FBI initiated 642 new Health Care Fraud (HCF) investigations and had 2,744 pending investigations. Investigative efforts produced 718 criminal HCF convictions and 1,038 indictments and informations. In addition, investigative efforts resulted in over 625 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 144 HCF criminal enterprises.

The FBI is the primary investigative agency involved in the fight against HCF that has jurisdiction over both federal and private insurance programs. HCF investigations are considered a high priority within the FBI's Complex Financial Crime Program. Each of the 56 FBI field offices had personnel assigned specifically to investigate HCF matters.

The FBI seeks to approach the HCF crime problem in a threat-based and intelligence-driven manner. The approach employs the prioritization of enforcement efforts, at both the national and field office levels, to ensure limited resources are focused on the most significant entities committing health care fraud and abuse. As part of the process, the FBI gathers relevant data and information to understand the impact of the crime problem and to identify intelligence "gaps," or areas which require additional research and analysis. The need and availability of resources to support mitigation efforts, including enforcement and intelligence related activities, are also factored into the analysis. The process is constantly on-going and requires collaboration not only between FBI components, but also with our public and private partners.

As part of our collaboration efforts, the FBI maintains investigative and intelligence sharing partnerships with government agencies such as other DOJ components, HHS-OIG, state Medicaid Fraud Control Units, and other enforcement and regulatory agencies. On the private side, the FBI conducts significant information sharing and coordination efforts with private insurance partners, such as the National Health Care Anti-Fraud Association, the National Insurance Crime Bureau, and private insurance investigative units. The FBI is also 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 HCF.

As a result of the collaboration and review process, the FBI has designated criminal enterprises and other crime groups, corporate-level fraud and abuse, and public safety issues as the priority HCF threat areas of focus. Each field office conducts a similar analysis to determine their areas of focus and the actions they will take to mitigate the associated threat.

FBI field offices throughout the U.S. proactively address the HCF threat through joint investigative efforts; intelligence collection, sharing, and analysis; and the utilization of advanced and sophisticated investigative techniques. Each FBI field office is involved in a HCF

Task Force and/or working group. Members of the groups include US Attorney's Office and HHS-OIG personnel, and in many cases also include other federal, state, local, and private insurance personnel. Based on information sharing and coordination, additional cases are vetted and identified for investigation. These activities seek to identify and pursue investigations against the most egregious offenders involved in health care fraud and abuse.

The FBI's Health Care Fraud Unit (HCFU) oversees program efforts, including providing guidance to field offices, to ensure the threat is mitigated in an effective and efficient manner. In support of joint agency activities and general threat mitigation efforts the HCFU has promulgated three initiatives, including the Health Care Fraud Prevention and Enforcement Action Team (HEAT), Large Scale Conspiracies, and Major Provider Fraud Initiatives.

HEAT is DOJ's and HHS' Cabinet-level commitment to prevent and prosecute HCF. 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 (Strike Force) teams are a key component of HEAT. As part of the HEAT Initiative, the FBI coordinates with the DOJ and HHS-OIG on all HEAT aspects including funding, resource allocation, Strike Force expansion, target identification, training, and operations. The FBI has 62 agents assigned to the nine Strike Forces in Miami, New York City, Southern Texas, Tampa, Detroit, Los Angeles, Southern Louisiana, Dallas, and Chicago. In addition to funding agent resources, the FBI funded undercover operation expenses, financial and investigative analysis support, offsite and evidence storage locations, and other investigative costs. The 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 health care programs. The continued support of Medicare Strike Force operations is a top priority for the FBI. In addition, the FBI completes coordination and intelligence sharing with HHS and DOJ components on other prevention and enforcement activities, including efforts associated with the Large Scale Conspiracies and Major Provider Fraud Initiatives.

The Large Scale Conspiracies Initiative seeks to identify and target criminal enterprises and other groups whose schemes result in significant losses to health care benefit programs. Intelligence efforts for this initiative include information sharing and analysis of billing data with HCF enforcement partners. As the FBI continued to focus efforts on these groups, statistical accomplishments associated with the operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of criminal enterprises have consistently increased, with an over fifty percent increase from FY 2012 to FY 2015. 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 conviction of the former medical director of, and three therapists employed by, a now-defunct mental health provider for conspiracy to commit HCF and related charges for their roles in a scheme to fraudulently bill Medicare and Florida Medicaid more than \$63 million. According to the evidence presented at trial, from approximately 2004 through 2011, the provider billed Medicare and Medicaid for mental health services that were not medically necessary or never provided, and paid kickbacks to assisted living facility owners and operators

who in exchange referred beneficiaries to provider. The FBI is committed to addressing this type of crime problem through the disruption, dismantlement and prosecution of those involved in criminal enterprises and other organized criminal activities.

The Major Provider Fraud Initiative seeks to identify and target corporate-level groups involved in fraud and abuse schemes with significant billing to health care 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. These investigations frequently involve pharmaceutical manufacturers, hospital corporations, and regional or national medical provider agencies. 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 cases nationwide. An example of these types of cases would include the investigation of Health Diagnostics Laboratory Inc. (HDL), of Richmond, Virginia, which resulted in HDL agreeing to pay \$47 million to resolve allegations they violated the False Claims Act. The FBI coordinates efforts in these types of cases with our law enforcement partners, such as DOJ components, HHS-OIG, and other federal agencies.

The FBI actively provides training and guidance on HCF matters. The FBI has teamed with the DOJ, HHS, and private insurance organizations to provide training in the priority threat areas of HCF. Funded training has included innovative methods of employing advanced investigative techniques; basic HCF training for FBI special agent and professional staff newly assigned to investigate HCF; and sessions on new and current HCF trends and issues. FBI personnel training opportunities included sessions offered by the FBI, other government agencies and the private sector. In FY 2015, more than 223 FBI HCF investigators and analysts received training. FBI personnel also conducted a wide range of training for external audiences, including private insurance and regulatory personnel.

Funding received by the FBI is used to pay direct and indirect personnel-related costs associated with the 797 funded positions. Funds not used directly for personnel matters, are used to provide operational support for HCF 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 81).
- 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 the HCFAC 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. However, FBI spending and monetary results are not required to be reported per the statute. Therefore, even though the FBI mandatory HIPAA funding is included in the HCFAC ROI calculation, it is not reflected in the table on page 7 of this report.
- Only certain portions of discretionary HCFAC Account funding are included in the ROI calculation. 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 calculates the impact of the prevention activities supported by the MIP mandatory and discretionary funds is calculated separately from the HCFAC ROI and is reported outside of the HCFAC report. Impacts for both the CMS Medicaid and Medicare program integrity funding are included 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 2015, 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 Resources¹ | Fiscal Year 2015 |
|---|-------------------------|
| Office of Inspector General | \$186,066,026 |
| Health and Human Services Wedge ² | 35,587,356 |
| Medicare Integrity Program ³ | 863,773,251 |
| <i>MIP/Medicare (non-add)</i> | <i>797,329,155</i> |
| <i>Medi-Medi (non-add)</i> | <i>66,444,096</i> |
| Department of Justice Wedge ² | 58,094,935 |
| Federal Bureau of Investigation ⁴ | 129,216,580 |
| Subtotal, Mandatory HCFAC | \$1,272,738,148 |
| Discretionary Resources | |
| Office of Inspector General | \$67,200,000 |
| CMS Program Integrity | 544,320,000 |
| <i>Medicare Program Integrity (Non-Add)</i> | <i>477,120,000</i> |
| <i>Medicaid Program Integrity (Non-Add)⁵</i> | <i>67,200,000</i> |
| Department of Justice | 60,480,000 |
| Subtotal, Discretionary HCFAC | 672,000,000 |
| Grand Total, HCFAC | \$1,944,738,148 |

¹ All mandatory resources are post-sequester.

² 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.

³ 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 regarding MIP activities.

⁴ 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.

⁵ This does not include 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

AKS— Anti-Kickback Statute

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

CMPL—Civil Monetary Penalties Law

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

CNC—Compromised Number Contractors

CPI—Center for Program Integrity

CRIPA—Civil Rights of Institutionalized Persons Act

CY—Calendar Year

D.XX or X.D.Xx—Federal judicial district of a state, which may include north, south, east, west

DME—Durable Medical Equipment

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

HFPP—Health care Fraud Prevention Partnership

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