

**The Department of Health and Human Services
And
The Department of Justice
Health Care Fraud and Abuse Control Program
Annual Report for Fiscal Year 2016**

January 2017

TABLE OF CONTENTS

I.	Executive Summary	1
II.	Statutory Background	3
III.	Program Results and Accomplishments	5
	Monetary Results	5
	Expenditures	7
	Overall Recoveries	8
	Health Care Fraud Prevention and Enforcement Action Team	8
	Health Care Fraud Prevention Partnership	9
	Medicare Fraud Strike Force	10
	Highlights of Successful Criminal and Civil Investigations	12
IV.	Department of Health and Human Services	34
	Office of Inspector General	34
	Centers for Medicare & Medicaid Services	43
	Administration on Community Living	60
	Office of the General Counsel	62
	Food and Drug Administration Pharmaceutical Fraud Program	66
V.	Department of Justice	69
	United States Attorneys	69
	Civil Division	70
	Criminal Division	74
	Civil Rights Division	77
VI.	Appendix	82
	Federal Bureau of Investigation	82
	Return on Investment Calculation	85
	Total HCFAC Resources	86
VII.	Glossary of Terms	87

GENERAL NOTE

All years are fiscal years unless otherwise stated in the text.
--

EXECUTIVE SUMMARY

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a national Health Care Fraud and Abuse Control Program (HCFAC or the Program) under the joint direction of the Attorney General and the Secretary of the Department of Health and Human Services (HHS)¹, acting through the Inspector General, designed to coordinate federal, state and local law enforcement activities with respect to health care fraud and abuse. In its twentieth 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) 2016, the Federal Government won or negotiated over \$2.5 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 2016 over \$3.3 billion was returned to the Federal Government or paid to private persons. Of this \$3.3 billion, the Medicare Trust Funds³ received transfers of approximately \$1.7 billion during this period, and \$235.2 million in Federal Medicaid money was similarly transferred separately to the Treasury as a result of these efforts. Of the approximately \$31.0 billion returned by the HCFAC account to the Medicare Trust Funds since the inception of the Program in 1997, over \$17.9 billion has been returned from 2009 through 2016.

Enforcement Actions

In FY 2016, the Department of Justice (DOJ) opened 975 new criminal health care fraud investigations. Federal prosecutors filed criminal charges in 480 cases involving 802 defendants. A total of 658 defendants were convicted of health care fraud-related crimes during the year. Also in FY 2016, DOJ opened 930 new civil health care fraud investigations and had 1,422 civil health care fraud matters pending at the end of the fiscal year. In FY 2016, the FBI investigative efforts resulted in over 555 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 128 health care fraud criminal enterprises.

In FY 2016, investigations conducted by HHS' Office of Inspector General (HHS-OIG) resulted in 765 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid, and 690 civil actions, which include false claims and unjust-enrichment lawsuits filed in federal district court, civil monetary penalties (CMP) settlements, and administrative recoveries related to provider self-disclosure matters. HHS-OIG also excluded 3,635 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 The Medicare Trust Funds are 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 (1,362) or to other health care programs (262), for patient abuse or neglect (299), and as a result of licensure revocations (1,448). 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 2016, 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 \$20.6 million was sequestered from the HCFAC program in FY 2016, for a combined total of \$94.8 million in the past four years. Including funds sequestered from the FBI and the FY 2013 discretionary HCFAC sequester, the total equals \$131.3 million in the past four 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 2016 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 2016, the Secretary and the Attorney General certified \$282.1 million in mandatory funding to the Account after accounting for sequester reductions of \$20.6 million to the total appropriation. Additionally, Congress appropriated \$681.0 million in discretionary funding. A detailed breakdown of the allocation of these funds is set forth later in this report. HCFA appropriations generally supplement the direct appropriations of HHS that are devoted to health care fraud enforcement and have supported over two-thirds of DOJ’s health care fraud funding and over three-fourths of HHS-OIG’s appropriated budget in FY 2016. (Separately, the FBI, which is discussed in the appendix, received \$130.3 million from HIPAA, after accounting for \$9.5 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.
- (5) The Act requires the Attorney General and the Secretary to submit a joint annual report to the Congress that identifies both:
 - (6) The amounts appropriated to the Trust Funds for the previous fiscal year under various categories and the source of such amounts; and
 - (7) 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 114-123 “Consolidated Appropriations Act, 2016”) 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 2016, over \$3.3 billion was deposited with the Department of the Treasury and CMS, transferred to other federal agencies administering health care programs, or paid to private persons during the fiscal year. Monetary results from these transfers and deposits are provided in the table below:

Monetary Results: Total Transfers / Deposits by Recipient FY 2016	
Department of the Treasury	
Deposits to the Medicare Trust Fund, as required by HIPAA:	
Gifts and Bequests	\$7,840
Amount Equal to Criminal Fines	24,043,913
Civil Monetary Penalties	59,055,263
Asset Forfeiture	53,998,735
Penalties and Multiple Damages	788,337,475
Subtotal	925,443,226
Centers for Medicare and Medicaid Services	
HHS/OIG Audit Disallowances: Recovered–Medicare	79,251,778
Restitution/Compensatory Damages*	655,019,371
Subtotal	734,271,149
Total Transferred to the Medicare Trust Funds	\$1,659,714,375
Restitution/Compensatory Damages to Federal Agencies	
TRICARE	58,348,500
HHS/OIG	11,687,803
Office of Personnel Management	9,709,802
National Institutes of Health	7,505,000
Other Agencies	341,130,314
Subtotal	428,381,420
Centers for Medicare and Medicaid Services	
Federal Share of Medicaid	235,157,903
HHS/OIG Audit Disallowances: Recovered–Medicaid	503,844,355
Subtotal	739,002,258
Total	1,167,383,677
Relators' Payments**	526,969,605
GRAND TOTAL MONETARY RESULTS***	\$3,354,067,657

*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 twentieth year of operation, the Secretary and the Attorney General certified \$282.1 million in mandatory funding as necessary for the Program, after accounting for mandatory sequester reductions of \$20.6 million as required by law. Additionally, Congress appropriated \$681.0 million in discretionary funding. See allocation by recipient below:

FY 2016 ALLOCATION OF HCFAC APPROPRIATION				
Organization	Mandatory Allocation⁵	Discretionary Allocation	Funds Sequestered	Total Allocation
Department of Health and Human Services				
Office of Inspector General ⁶	\$201,305,390	\$67,200,000	(\$13,688,767)	\$254,816,623
Office of the General Counsel	7,550,000	0	0	7,550,000
Administration for Community Living ⁷	0	18,000,000	0	18,000,000
Food and Drug Administration	4,250,000	0	0	4,250,000
Centers for Medicare & Medicaid Services	24,083,926	535,320,000	0	559,403,926
Unallocated Funding	2,618,140	0	(2,618,140)	0
Subtotal	\$239,807,456	\$620,520,000	(\$16,306,907)	\$836,470,549
Department of Justice				
United States Attorneys	34,983,708	19,791,053	0	54,774,761
Civil Division ⁸	20,900,000	14,358,250	0	35,258,250
Criminal Division	1,183,623	16,410,697	0	17,594,320
Civil Rights Division	1,311,744	3,875,000	0	5,186,744
Justice Management Division	200,000	0	0	200,000
Federal Bureau of Investigation	0	6,045,000	0	6,045,000
Unallocated Funding	4,274,010	0	(4,274,010)	0
Subtotal	62,853,085	60,480,000	(4,274,010)	119,059,075
TOTAL⁹	\$302,660,541	\$681,000,000	(\$20,580,917)	\$963,079,624

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

⁶ In addition, HHS-OIG obligated \$12 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).

⁷ CMS’s discretionary HCFAC funds were allocated to the Administration for Community Living to support the Senior Medicare Patrol Program.

⁸ The Elder Justice Initiative, managed by the Civil Division, is included in the Civil Division figures.

⁹ Amounts only represent those that are provided by statute, and do not include other mandatory sources or discretionary appropriated sources provided through Departments’ annual appropriations.

Overall Recoveries

During this fiscal year, the Federal Government won or negotiated over \$2.5 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 \$3.3 billion was returned to the Federal Government or private persons. Of this \$3.3 billion, the Medicare Trust Funds received transfers of approximately \$1.7 billion during this period; and another \$235.2 million in Federal Medicaid money was transferred to the Treasury separately as a result of these efforts.¹⁰

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 (2014-2016) is \$5.00 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, the Attorney General and the Secretary 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.

¹⁰ Note that some of the judgments, settlements, and administrative actions that occurred in FY 2016 will result in transfers in future years, just as some of the transfers in FY 2016 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. This expanded data sharing enables the DOJ and HHS to efficiently identify and target the worst actors in the system. 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 health care 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 70 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.

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 2016, the Partnership hosted its sixth Executive Board meeting. The meeting focused on strategies to streamline, strengthen, and grow the Partnership, including a call to action to broaden the HFPP's impact.

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: Los Angeles, California; Miami and Tampa, Florida; Chicago, Illinois; Brooklyn, New York; Detroit, Michigan; Southern Louisiana; and Dallas and Southern Texas.

Each Medicare Fraud Strike Force team brings the investigative and data analytic 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 a wide variety of sources including CMS, and bring cases in federal district court. Strike Force accomplishments in the areas noted above and USAO accomplishments in their districts during FY 2016 include¹¹:

- 246 indictments, informations and complaints involving charges filed against 482 defendants who allegedly collectively billed the Medicare program approximately \$2.8 billion;
- 260 guilty pleas negotiated and 34 jury trials litigated, with guilty verdicts against 32 defendants; and
- Imprisonment for 290 defendants sentenced during the fiscal year, averaging more than 48 months of incarceration.

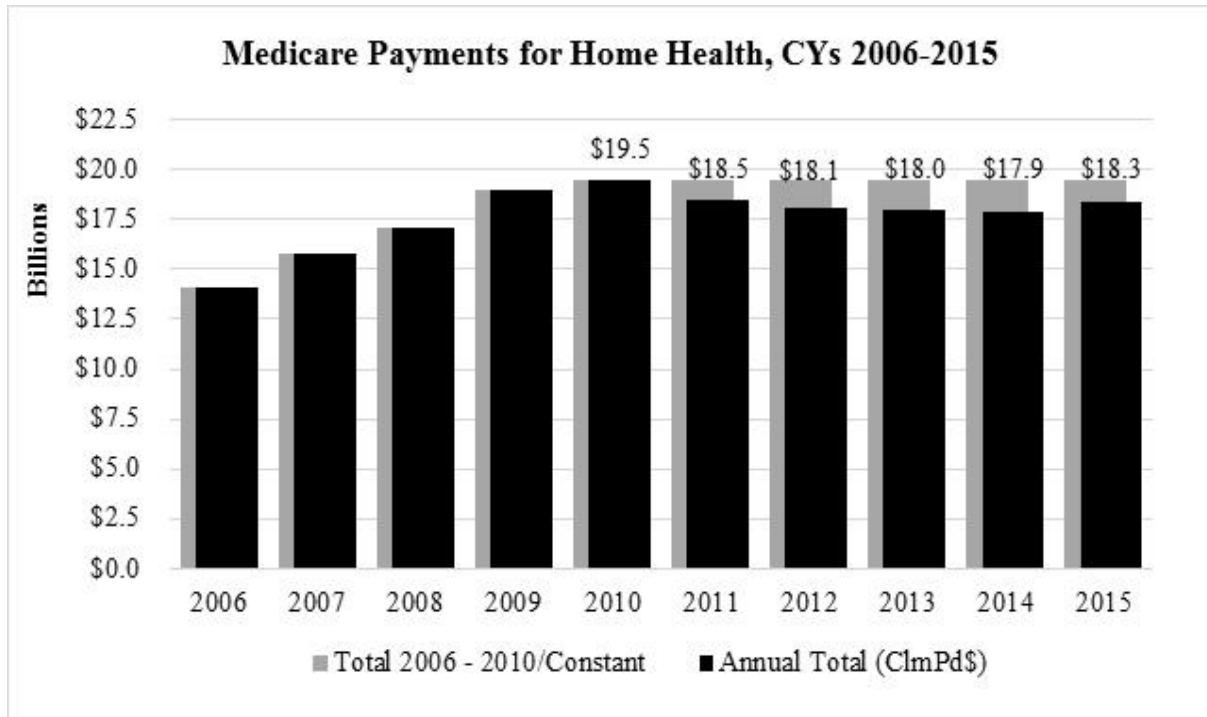
Since its inception, Strike Force prosecutors filed more than 1,410 cases charging more than 3,018 defendants who collectively billed the Medicare program more than \$10.8 billion; 2,041 defendants pleaded guilty and 275 others were convicted in jury trials; and 1,767 defendants were sentenced to imprisonment for an average term of approximately 49 months.¹² Medicare payment trends demonstrate the positive impact of Strike Force enforcement and prevention efforts.

Medicare payment trends also demonstrate the positive impact of Strike Force enforcement and prevention efforts beyond the several Strike Force locations. The HEAT Strike Force team in Miami initiated federal law enforcement actions against fraudulent home health schemes that

¹¹ The accomplishments figures presented in the bullets include all reported Strike Force cases handled by DOJ Criminal Division attorneys and AUSAs in the respective USAOs during FY 2016.

¹² These statistics are for the period of May 7, 2007 through September 30, 2016.

exploited the Home Health Agency (HHA) “outlier” payment provisions in 2009. An HHS-OIG evaluation published that same year found that Miami-Dade County accounted for more home health outlier payments than the rest of the nation combined for claims paid the previous year. Twenty-three other counties nationwide also exhibited aberrant home health payment patterns similar to that of Miami, but to a lesser extent. In 2010, CMS implemented a cap on total outlier payments not to exceed more than 10 percent of home health payments that an individual home health provider may receive annually. The following chart shows the rapid increase in annual Medicare home health payments until peaking in 2010, and the decline in home health payments by approximately one billion dollars annually since that time compared to a hypothetical constant level of HHA payments at the 2010 level.



For examples of successful Strike Force cases initiated or concluded during FY 2016, 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) before the lead sentence.**

Ambulance and Transportation Services

In November 2015, Regent Management Services L.P.—a Galveston, Texas skilled nursing facility company—paid \$2.7 million to settle civil FCA allegations that it received kickbacks from various ambulance companies in exchange for rights to Regent’s more lucrative Medicare and Medicaid transport referrals. Regent manages twelve separately owned and operated nursing facilities. The alleged remuneration included patients at Regent facilities receiving free or heavily discounted ambulance transports that Regent would otherwise have been financially responsible for at higher Medicaid rates. This settlement is the first in the nation to hold accountable the medical institution as opposed to the ambulance in this kind of “swapping” arrangement. As a part of settlement, Regent also entered into a five-year Corporate Integrity Agreement with HHS-OIG.

In November 2015, the owner of Advantage Medical Transport Inc. (Advantage) was sentenced to 2 years in prison and ordered to pay a \$300,000 fine and \$194,378 in restitution, joint and several with Advantage, for his guilty plea to false statements in health care matters. Advantage was also ordered to pay a \$250,000 fine. According to court documents, employees at Advantage submitted fraudulent claims to Medicare for the transport of beneficiaries to and from dialysis treatment centers. The owner directed Advantage’s EMTs to complete their trip sheets in a manner that concealed the fact that the patients were ambulatory and not eligible for Medicare paid ambulance transport.

In June 2016, ten North Texas companies and individuals paid \$1.1 million to resolve civil FCA allegations that Irving Holdings submitted a false affidavit to the State of Texas that CMS relied upon when paying inflated amounts for transport services. Irving Holdings, Inc. is one of the largest taxicab companies in the United States.

Clinics

In March 2016, an owner of several mental and behavioral health clinics in the Eastern District of North Carolina was sentenced to the statutory maximum of 20 years for health care fraud and money laundering for defrauding North Carolina’s Medicaid program. He was also ordered to make restitution of more than \$5.9 million to the victims of the offense, which included the North Carolina Medicaid program and a physician, whose name and identification number he used to commit the fraud. The owner had owned a company which a Medicaid audit flagged for unsupported billing. The owner closed down that company and was excluded from Medicaid. Unbeknownst to the North Carolina Medicaid program, the owner worked with a fraudulent biller to concoct numerous schemes to continue billing the Medicaid program by stealing the identities of numerous practitioners and children. The owner not only committed health care fraud, but also laundered the proceeds through his nonprofit, and then further laundered the

proceeds through another conspirator in the form of no-document loan payments. The owner later threatened to kill one of the shell company owners that he was using to bill the Medicaid program if she talked to federal agents.

In April 2016, a doctor in Maryland who specialized in interventional pain management was sentenced to 9 years and 3 months in prison, followed by three years of supervised release for one count of health care fraud, two counts of making a false statement related to a health care program, one count of obstruction of justice, four counts of wire fraud, and one count of aggravated identity theft. The doctor owned and operated Washington Pain Management Center along with his wife, who was also a licensed physician and who is now deceased. Working together, the doctors submitted claims for nerve block injections when in fact neither owned nor used imaging guidance which was necessary to administer nerve block injections. They also falsely documented patient files to indicate that imaging guidance was used when in fact it was not. Finally, when Medicare contractors visited Washington Pain Management and inquired about the imaging guidance machine, they created a false lease document reflecting the fact that they had leased the machine. As part of his sentence, the doctor was also ordered to forfeit and pay restitution of \$3.1 million.

In June 2016, the owner and operator of multiple HIV/AIDS clinics was sentenced in New York to 5 years and 3 months in prison and ordered to pay \$12.2 million in restitution, joint and several, for his guilty plea to conspiracy to commit health care fraud. According to court documents, the defendants operated health care clinics that purported to provide injection and infusion treatments to Medicare-eligible HIV/AIDS patients, but that were, in reality, health care fraud mills. As part of the scheme, he and his co-conspirators paid patients cash kickbacks for coming to the clinics, coached patients on lies to tell clinic doctors to enable fraudulent billing, and billed Medicare for medications that were never administered, administered at incorrect dosages, or were medically unnecessary. Two defendants involved in the scheme were previously sentenced to a combined 8 years and 3 months in prison and ordered to pay \$9 million in restitution, joint and several.

In July 2016, Drayer Physical Therapy Institute, LLC—with clinic locations in South Carolina and fourteen other states—paid \$7 million to the federal health care programs to settle civil FCA allegations that it was excessively billing for physical therapy services. The government alleged that Drayer would bill for services provided to multiple patients simultaneously as though the services were being provided by a physical therapist or therapist assistant to one patient at a time. As a part of settlement, Drayer also entered into a five-year Corporate Integrity Agreement with HHS-OIG.

Device Companies

In December 2015, Maryland-based splint supplier, Dynasplint Systems, Inc., and its founder and president paid approximately \$10.3 million to resolve civil FCA allegations that they improperly billed Medicare for splints provided to patients in skilled nursing facilities. Medicare pays for the health care needs of patients in skilled nursing facilities with a bundled payment intended to include splints, as well as other patient needs. The government alleged that Dynasplint and its president misrepresented that patients were in their homes or other places and

not in skilled nursing facilities to avoid this bundled payment and improperly receive separate reimbursement from the Medicare program.

In March 2016, Olympus Corporation of the Americas (OCA), the largest distributor of endoscopes and related equipment, paid \$623.2 million to resolve criminal charges and civil FCA claims relating to a scheme to pay kickbacks to doctors and hospitals in exchange for their purchase of OCA's endoscopes and other medical and surgical equipment. OCA was charged in a criminal complaint with conspiracy to violate the Anti-Kickback Statute (AKS), which prohibits payments to induce purchases paid for by federal health care programs. As a result, Olympus allegedly caused the submission of false claims to the Medicare, Medicaid, and TRICARE programs. OCA has entered into a three-year deferred prosecution agreement that will allow it to avoid conviction if it complies with the reform and compliance requirements. The \$623.2 million included a \$312.4 million criminal penalty and \$310.8 million to settle civil claims under the federal and various state False Claims Acts. This is the largest total amount paid in U.S. history for violations of the AKS by a medical device manufacturer. As a part of settlement, OCA also entered into a five-year Corporate Integrity Agreement with HHS-OIG.

In June 2016, Minneapolis-based Cardiovascular Systems, Inc. (CSI) paid \$8 million to resolve civil FCA allegations that it paid kickbacks to physicians to induce those physicians to use CSI's medical devices in violation of the Anti-Kickback Statute. The government alleged that CSI developed, distributed, and implemented certain practice development services to assist physicians in performing atherectomies in exchange for those physicians ordering or continuing to use CSI's devices for atherectomy procedures. As a part of settlement, CSI also entered into a five-year Corporate Integrity Agreement with HHS-OIG.

In July 2016, California-based manufacturer Acclarent, Inc., a subsidiary of Johnson & Johnson, paid \$18 million to resolve civil FCA liability for marketing and distributing its Relieva Stratus sinus spacer for unapproved uses that were not covered by federal health programs. The government alleged that Acclarent received FDA marketing clearance for the Stratus device based on misrepresentations concerning the intended use of the device. The company advised FDA that the device was intended only for use as a spacer to maintain sinus openings following surgery and that it was to be used only with saline; however, the government alleged that the company engineered and designed the product specifically for use as a drug-delivery device to elute prescription corticosteroids, the only use for which the device was marketed. The government alleged that Acclarent continued to market the Stratus for drug delivery even after a warning was added to the label concerning use of active drug substances in the device. The government filed a criminal action against Acclarent's former Chief Executive Officer and former Vice President of Sales based, in part, on the same facts, and both executives were convicted in July 2016 of ten misdemeanor counts for introducing adulterated and misbranded medical devices into interstate commerce. These individuals have filed notices of appeal.

Diagnostic Services

(SF) In December 2015, following a two-week jury trial in Tampa, Florida, a businessman and an audiologist were convicted of all charges against them in a \$12 million Medicare fraud scheme. The fraud scheme involved false and fraudulent reimbursement claims for radiology, audiology, cardiology, and neurology diagnostic services. The jury found the businessman, who

was the lead defendant, guilty on all counts, which included conspiracy to commit health care fraud and wire fraud, health care fraud, conspiracy to commit money laundering, money laundering, and aggravated identity theft. The jury found the audiologist guilty on all counts as well, which included the same charges. The businessman was sentenced to over 14 years in prison, and the audiologist was sentenced to over 7 years in prison. Three other defendants had been previously convicted in the case.

In August 2016, the owners of Bristol Laboratories LLC (Bristol) were each sentenced to 3 years in prison and ordered to pay \$1.4 million in restitution, joint and several, for their guilty plea to charges of health care fraud and conspiracy to commit health care fraud. From May 2009 to April 2012 the defendants conspired with an opioid addiction therapy doctor to bill medically unnecessary and excessive urine drug screen tests to federal and private health insurances. The doctor directed all of his patients to be tested at Bristol. The doctor died during the course of this investigation and was not charged. This was a joint investigation with the Virginia Medicaid Fraud Control Unit.

Dietary Supplements

In May 2016, a diet pill distributor was sentenced to 4 years and 2 months in federal prison for his scheme to sell illegal and mislabeled diet pills to victims throughout the United States, including Louisiana. This distributor pled guilty to engaging in a conspiracy to distribute and possess with the intent to distribute sibutramine, and introducing misbranded drugs into interstate commerce. This conduct was part of a multi-state scheme to illegally distribute diet pills containing sibutramine, a Schedule IV controlled substance, which were falsely labeled and marketed as “all natural” dietary supplements. Sibutramine was the active pharmaceutical ingredient in Meridia, a prescription weight loss drug removed from the market in 2010 following studies that showed significantly increased risk of strokes and heart attacks. Since the removal of Meridia, no drug containing sibutramine has been approved for use in humans in the United States.

Drug Companies

In October 2015, Warner Chilcott U.S. Sales LLC—a subsidiary of pharmaceutical manufacturer Warner Chilcott PLC—paid \$91.5 million to settle civil FCA allegations that it violated the AKS by paying illegal remuneration, including payments for “Medical Education Events” and speaker programs to prescribing physicians to induce prescriptions for several of the company’s drugs. The government also alleged that Warner Chilcott caused the submission of false prior authorization requests for the osteoporosis drugs Atelvia and Actonel in order to circumvent coverage restrictions implemented by certain federal health care programs. Warner Chilcott and several individuals affiliated with the company pled guilty to various criminal offenses relating to the alleged misconduct. Under the terms of the company’s plea agreement, Warner Chilcott pled guilty to a felony charge of health care fraud and paid a criminal fine of \$22.9 million.

In November 2015, Novartis Pharmaceuticals paid \$286.8 million to settle civil federal FCA allegations of a kickback scheme involving marketing and selling an iron chelation drug known as Exjade and an anti-rejection drug for kidney transplants known as Myfortic. The government alleged that Novartis paid kickbacks in the form of patient referrals and rebates to specialty

pharmacies, Bioscrip, Inc. and Accredo Health Group to induce those pharmacies to recommend Exjade refills while understating the drug's serious, potentially life-threatening side effects, and to recommend to doctors that they switch patients to Myfortic from competitor drugs. This settlement is the third recovery in this kickback scheme following settlements with Bioscrip and Accredo for \$56.7 million to resolve the same allegations. In addition to the federal recovery, Novartis paid approximately \$80 million to resolve state Medicaid liability. Novartis also made a civil forfeiture payment of \$20 million.

In April 2016, drug manufacturers Wyeth and Pfizer, Inc. paid \$413 million to settle civil federal FCA allegations that Wyeth underpaid rebates owed under the Medicaid Drug Rebate Program (MDRP) and caused the submission of false claims to the federal health care programs. 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 government alleged that Wyeth underpaid drug rebates for its proton pump inhibitor drugs, Protonix Oral and Protonix IV, by failing to disclose to the Medicaid program the best prices Wyeth had offered to thousands of hospitals under a contract that bundled the two drugs together. Wyeth offered hospitals steep discounts on both Protonix Oral and Protonix IV with the expectation that patients would continue using Protonix Oral after they were discharged from the hospitals. The United States alleged that by failing to account for these steep hospital discounts, Wyeth underestimated and underpaid the quarterly rebates it owed on those drugs to the state Medicaid programs. Pfizer acquired Wyeth approximately three years after Wyeth ended the conduct that gave rise to this settlement. In addition to the federal recovery, Wyeth paid \$371.4 million to resolve its state Medicaid liability.

In June 2016, Genentech, Inc. and OSI Pharmaceuticals, LLC paid \$62.6 million to resolve civil FCA allegations that they caused the submission of false claims to the federal health care programs when making misleading statements to market and sell the drug Tarceva. The FDA approved Tarceva to treat certain patients with non-small cell lung cancer or pancreatic cancer. The government alleged that Genentech and OSI Pharmaceuticals made misleading representations to physicians and other health care providers about the effectiveness of Tarceva to treat certain patients with non-small cell lung cancer, when there was little evidence to show that Tarceva was effective unless the patient also had never smoked or had a mutation in their epidermal growth factor receptor, a protein involved in the growth and spread of cancer cells.

In June 2016, Salix Pharmaceuticals paid a total of \$46.5 million to settle civil FCA allegations of a kickback scheme involving marketing and selling at least seven products used to treat various gastroenterology conditions. The government alleged that Salix paid kickbacks to physicians to induce them to increase their prescriptions for the products. The alleged remuneration paid to the physicians included substantial honoraria for speaker programs at high-end restaurants during which little to no time was spent discussing the products with the same physicians attending multiple dinners with their spouses who were not health care professionals.

Durable Medical Equipment (DME)

In November 2015, a supplier of durable medical equipment in North Carolina was sentenced to 3 years and 6 months in prison and ordered to pay \$2.6 million in restitution for his guilty plea to health care fraud. According to court documents, this individual submitted false claims to

Medicare for reimbursement of DME items that were allegedly provided to beneficiaries. As part of the scheme, he set up sham DME companies and purchased lists of individually identifiable health information. He used this information to submit false claims without the beneficiary's knowledge. Through this scheme, he submitted more than \$7 million in false claims for reimbursement from Medicare.

(SF) In November 2015 an owner of a durable medical equipment company in Texas was sentenced to 5 years and 3 months in prison and ordered to pay \$1.9 million in restitution after a jury found him guilty of health care fraud. He owned and operated the DME companies Hermann Medical Supplies Inc. and Hermann Medical Supplies II (collectively Hermann Medical). Through these companies, he submitted approximately \$3.4 million in fraudulent DME claims to Medicare. Specifically, the owner caused Hermann Medical to bill Medicare for components of an arthritis kit which included expensive, rigid braces and orthotics with adjustable joints that required fitting and adjustment. However, in actuality, he never purchased any of the expensive braces and instead purchased and provided to beneficiaries inexpensive, flimsy neoprene braces and equipment, to the extent that he provided any equipment at all. Medicare paid Hermann Medical \$1.9 million on these claims. This was a joint investigation with the FBI and the Texas MFCU.

In March 2016, Respiroics, Inc. paid \$34 million to resolve civil FCA allegations for paying kickbacks to DME suppliers to induce those suppliers to buy Respiroics masks that treat sleep apnea. The alleged remuneration or kickback was the provision of call-center and other related services to the DME companies to meet their patients' resupply needs at no charge as long as the DMEs promoted and sold Respiroic manufactured masks to their patients. As a part of settlement, Respiroics entered into a five-year Corporate Integrity Agreement with HHS-OIG.

In April 2016, Hollister, Inc., an Illinois-based manufacturer of disposable health care products including products for ostomy and continence care, and Byram Healthcare Centers, Inc., a supplier of medical products, paid a total of \$20.8 million to resolve civil FCA allegations that Hollister paid unlawful kickbacks to Byram with the intent to induce Byram to conduct promotional campaigns designed to refer patients to Hollister's products. The alleged illegal kickbacks included bonus commissions paid directly to Byram sales employees for successfully referring patients to Hollister's products and money for catalogs that promoted Hollister products. This settlement relates to a prior settlement with another manufacturer of these health care products, Coloplast Corp, and supplier of the products, Liberator Medical Supply, Inc., who collectively paid \$1.2 million for similar conduct.

(SF) In April 2016, the former president of a Salt Lake City durable medical equipment company was sentenced to 60 months of imprisonment followed by three years of supervised release after being convicted of three counts of conspiracy to commit health care fraud as a part of a Medicare fraud scheme. The president was also co-owner of Orbit Medical, a Utah- and Indiana-based national supplier of durable medical equipment that specialized in power wheelchairs. In order to induce Medicare into paying for their wheelchairs, Orbit sales representatives would create or alter medical charts and other documents, or forge physician signatures on prescriptions and chart notes. They would then use these forged documents to support their fraudulent Medicare claims. The former president paid \$4 million in restitution, and he also must forfeit \$776,001, the amount of his personal gain from the criminal conduct.

Electronic Health Records

In June 2016, the former owner and CEO of Nashville drug testing laboratory Prost-Data, Inc., or OURLab, OPKO Health, Inc., and OPKO Lab, LLC paid \$9.4 million to settle civil FCA allegations that they contributed to the purchase of electronic health records (EHR) systems for client physician practices in exchange for referrals to their drug testing laboratories. The contributions for the EHR systems did not conform to the Anti-Kickback Statute EHR safe harbor or the Stark EHR exception and constituted illegal kickbacks and physician remuneration. This settlement is significant because it sets the first precedent for abuse of the EHR safe harbor and Stark exception.

In September 2016, an associate of the Traveling Vice Lords (TVL) street gang pleaded guilty to witness tampering for obtaining and disclosing private health information of Traveling Vice Lords shooting victims and victims' family members to a member of the gang. The defendant admitted that from May 8, 2015 through at least January 2016, he was employed at a medical facility where he had access to a private database that contained individually identifiable health information for anyone who had been treated at a Detroit Medical Center facility. At the request of a TVL member and while employed at the medical facility, he accessed this database on at least 15 occasions to search for three TVL shooting victims. The defendant then provided information, including dates of birth, phone numbers, addresses, and information pertaining to relatives of these individuals to the TVL. He admitted that he knew the TVL member wanted this information to locate these individuals and prevent them from cooperating in the investigation and prosecution of the TVL shooting. Sentencing is scheduled for January 2017.

Health Maintenance Organization

In January 2016, CenterLight Healthcare, Inc., which administers health care plans for residents in the New York City metropolitan area, paid \$18.7 million to settle civil federal FCA allegations that it enrolled ineligible members in its Medicaid managed long-term care plan (MLTCP) who attended or were referred by social adult day care centers (SADCCs) and did not meet the criteria of the plan. The settlement resolved claims that CenterLight engaged in improper marketing practices to enroll over a thousand members through SADCCs and induced such members to use SADCCs as the members' primary source of personal care services. CenterLight continued to seek and obtain monthly capitation payments for members well after the New York State Department of Health issued guidance in early 2013 explicitly stating that an individual's attendance at SADCCs does not satisfy the MLTCP eligibility standard. In addition to the federal recovery, CenterLight paid \$28.1 million to resolve state Medicaid liability.

Home Health Providers

In October 2015, Nurses' Registry and Home Health Corporation of Lexington, Kentucky, and the estate of its former owner paid \$16 million to resolve civil FCA allegations that they fraudulently billed Medicare for medically unnecessary home health services and services tainted by kickbacks provided by the company and former owner to local physicians and others who referred patients to Nurses' Registry. The government alleged that Nurses' Registry falsified medical records and falsely certified patients to bill for medically unnecessary skilled nursing

and therapy services. The government also alleged that Nurses' Registry and its former owner provided remuneration to physicians and referral sources, such as athletic event and concert tickets and bottles of liquor, to induce referrals.

In October 2015, three office managers each pleaded guilty to health care fraud conspiracy and were ordered to pay restitution of \$5.9 million, joint and several. One was also excluded from participation in federal health care programs for 15 years, and another was sentenced to 1 year and 1 day in prison. The defendants artificially increased demand for medical services by providing beneficiaries with free goods and services and submitting false claims to Medicare for medically unnecessary services. The defendants created fake medical documents to conceal fraudulent claims submitted to Medicare that were induced by kickback, not medically necessary, and not provided.

In October 2015, Deaconess Home Health, Inc. in Wisconsin and its owner paid \$3.7 million to resolve their civil and criminal liability for submitting claims to Medicaid for personal care services that were not provided, were not provided pursuant to appropriate supervision, or were not medically necessary. The settlement also resolved allegations that Deaconess paid patient recruiters for referrals for personal care services in violation of the AKS. The investigation found that Deaconess paid patient recruiters for referrals of patients for personal care services. Both Deaconess and its owner agreed to a 15-year exclusion from federal health care programs.

(SF) In December 2015, the owner of Advance Home Health Care Services, Inc. (Advance) was sentenced to 6 years and 8 months in prison and ordered to pay \$4.5 million in restitution, joint and several, for his guilty plea to health care fraud conspiracy. The owner admitted that he billed Medicare for unnecessary home health care and therapy services, paid physicians to refer Medicare beneficiaries to Advance and sign medical documents falsely certifying that they required home health care, and paid Medicare beneficiaries cash kickbacks in exchange for signing multiple blank physical therapy records. Twelve defendants involved in the scheme were previously sentenced to a combined 37 years and 1 month in prison and ordered to pay \$17 million restitution, joint and several.

In January 2016, the lead doctor of Home Care Physicians Inc. was sentenced to 2 years' imprisonment for fraudulently certifying patients as confined to the home which allowed healthcare agencies to bill Medicare for unnecessary in-home treatment. Home Care is a Bloomingdale, Illinois company which provides home visits to patients in Illinois and which received most of its referrals from home-health nursing agencies. To get and keep patients, the doctor falsely certified patients as confined to the home and needing nursing services even when he knew that many patients did not qualify for such services. As part of his sentence the doctor was also ordered to pay \$4 million in restitution.

(SF) In March 2016, a federal jury in New Orleans convicted two defendants, a physician as well as the owner and operator of Christian Home Health Care, Inc., of conspiracy to commit health care fraud and health care fraud for their roles in a \$33 million Medicare fraud scheme. Between 2007 and 2015, the company, Christian Home Health Care, Inc., submitted over 14,000 claims to Medicare, receiving over \$28 million for these claims. In many cases, the defendants submitted claims for services that were either never provided, or not medically necessary. These same two defendants were later sentenced in October 2016 to 96 and 72 months in prison respectively.

In March 2016, the former owner, operator, and sole shareholder of Recovery Home Care, Inc. and Recovery Home Care Services, Inc. (collectively, RHC) paid \$1.8 million to resolve civil FCA allegations that he was responsible for RHC's payment of illegal kickbacks to physicians who in exchange agreed to refer Medicare patients to RHC for home health care services. The former owner orchestrated a scheme paying dozens of physicians thousands of dollars per month to serve as sham medical directors purportedly performing quality reviews of RHC patient charts when, in fact, they did little to no work for these payments.

In March 2016, the owner of Rosner Home Healthcare, an Illinois home-health nursing agency paid kickbacks to physicians and non-physicians for patient referrals was sentenced to 12 months and a day of imprisonment. The court also ordered that he pay a forfeiture judgment of \$2.26 million which represented the proceeds of the kickback conspiracy. Another doctor in the kickback conspiracy was sentenced in April 2016 to three years of probation, as well as a forfeiture judgment of \$10,800 which represented the proceeds to him from the kickbacks. Other defendants in the case pled guilty to kickback and/or health-care fraud charges, including nurses who admitted putting false information into nursing assessments.

(SF) In April 2016, the co-owner and medical director of Merfi Corp. in Florida was sentenced to 9 years in prison and ordered to pay \$30.2 million in restitution for his guilty plea to conspiracy to commit health care fraud and conspiracy to defraud the United States, namely to receive health care kickbacks and make false statements regarding health care matters. He admitted that in exchange for kickbacks and bribes, he and his co-conspirators ordered home health care and other services for Medicare beneficiaries that were not medically necessary and also falsified patient records to make it appear as if the beneficiaries qualified for these services. The co-owner of Merfi Corp. was previously sentenced to 9 years in prison and ordered to pay \$8.4 million in restitution, joint and several.

In June 2016, the owners of Global Home Health Healthcare Inc. in Washington, D.C. were sentenced to prison terms for health care fraud, money laundering, and other charges stemming from a scheme in which two owners of a home health care businesses and others defrauded the District of Columbia's Medicaid program of over \$80 million. The owners of Global Healthcare Inc. were a former nurse and her husband. According to the government's evidence, the former nurse was not entitled to take part in the Medicaid program and fraudulently got approval to become a provider. She and her owner husband led a scheme to bill Medicaid for services that were not fully provided—recruiting others, including family members, into the scam and creating fraudulent paperwork to hide the illegal activity. At trial the nurse owner was found guilty of 12 health care related charges and she was sentenced to 10 years in prison. The husband owner was also found guilty at trial of ten health care fraud related charges was sentenced to 7 years in prison. Following their prison terms, they will be placed on three years of supervised release. The defendants were ordered to pay \$80.6 million in restitution to D.C. Medicaid. They were also ordered to forfeit over \$11 million seized from 76 bank accounts; their residence, worth approximately \$1 million; \$73,000 in cash seized from their residence, and five luxury vehicles with a total purchase price of more than \$400,000. The court also imposed a forfeiture money judgment of nearly \$40 million on both defendants.

(SF) In August 2016, the owner of a HHA pleaded guilty to conspiracy to commit health care fraud for her involvement in a scheme to submit claims to Medicare for home health services that were medically unnecessary and/or induced by kickbacks. In furtherance of the scheme, the defendant recycled and reused Medicare information she had obtained via kickbacks. The defendant obtained more than \$1.9 million in proceeds from the fraud.

(SF) In August 2016, the owner and manager of three Miami-area HHAs was sentenced to 20 years in prison and ordered to pay \$36.4 million in restitution, joint and several. The owner/manager was convicted of conspiracy to commit health care fraud and wire fraud and conspiracy to defraud the United States and pay health care kickbacks for his role in a \$57 million Medicare fraud scheme. According to evidence presented at trial, from approximately 2006 to 2013, he and his co-conspirators purported to provide home health services to Medicare beneficiaries, which were not medically necessary and often were never provided. They paid kickbacks to doctors, patient recruiters and staffing groups, which, in exchange, referred beneficiaries to his home health agencies.

Hospice Care

In December 2015, the owner of Sandanna Hospice, Inc., Milestone Hospice, Inc., and Carol's Hospice & Palliative Services of Shelby, Mississippi, was sentenced to 3 years in prison and ordered to pay \$1.1 million in restitution for her guilty plea to conspiracy to commit health care fraud. The owner admitted to her involvement in a conspiracy to bill Medicare and Medicaid for hospice services for patients who were not terminally ill. She paid recruiters upwards of \$800 per patient and paid cash kickbacks to the hospice medical director for him to sign hospice orders for patients that he knew were not hospice appropriate. A billing clerk at Sandanna and Milestone was also sentenced to 1 year and 1 month of incarceration and ordered to pay more than \$1 million in restitution, joint and several, after pleading guilty to conspiracy to commit health care fraud. This case was initiated based on fraud tips provided to the HHS-OIG Hotline.

In March 2016, in the Eastern District of Pennsylvania, a nurse who authorized and supervised the admission of inappropriate and ineligible patients for hospice services at Home Care Hospice, Inc. (HCH) was sentenced to over one year in prison, three years supervised release and over \$230,000 in restitution. In April 2016, HCH also agreed to pay \$8 million to settle claims for falsely billing Medicare for hospice services. HCH billed for services their nurses and health aides provided to hospice patients who resided at nursing homes, hospitals, and private residences but who did not meet the Medicare criteria for hospice care. In addition to restitution and the settlement agreement, approximately \$11 million worth of assets belonging to the defendant were seized by the government pursuant to an injunction.

In June 2016, the owner of California Hospice Care ("CHC"), based in Covina, California was sentenced to 8 years in prison for defrauding Medicare and Medicaid. The owner of CHC and her daughter paid marketers to recruit Medicare and Medicaid beneficiaries, which CHC then falsely assessed as being terminally ill and in need of hospice services. Between March 2009 and June 2013, CHC submitted approximately \$8.8 million in fraudulent claims for those hospice services, for which Medicare and Medicaid paid nearly \$7.4 million to CHC. Two of CHC's doctors were convicted following a jury trial in May 2016 for their role in falsely certifying that the beneficiaries suffered from a terminal illness. Of the defendants who have

been sentenced one received four years for his conduct and will be required to pay more than \$1.3 million in restitution, the owner, who previously pleaded guilty, received an eight-year sentence and was ordered to pay more than \$7.4 million in restitution.

In July 2016, Evercare Hospice and Palliative Care, a Minnesota based provider, paid \$18 million to resolve civil FCA allegations that it admitted and recertified patients for hospice care who were not eligible for such care because they were not terminally ill. The government alleged that Evercare's business practices, which included discouraging physicians from recommending that ineligible patients be discharged from hospice, were designed to maximize the number of patients for whom it could bill Medicare without regard to whether the patients were eligible for and needed hospice. This is one of the largest hospice settlements to date.

Hospitals and Health Systems

In October 2015, Tuomey Healthcare System—a single-hospital system based in Sumter, South Carolina—paid \$72.4 million to resolve a civil FCA judgment entered against it for illegally billing the Medicare program for services referred by physicians with whom the hospital had improper financial relationships. During a month-long trial that concluded in May 2013, the government presented evidence that Tuomey entered into contracts with 19 specialist physicians that required the physicians to refer their outpatient procedures to Tuomey and, in exchange, paid them compensation that far exceeded fair market value and took into account part of the money Tuomey received from Medicare for the referred procedures. The jury determined that the contracts violated the Stark Law and the False Claims Act, and the trial court entered judgment for more than \$237 million in treble damages and penalties. In July 2015, the United States Court of Appeals for the Fourth Circuit affirmed the judgment. Tuomey was recently sold to Palmetto Health, a multi-hospital health care system based in Columbia, South Carolina. In September, 2016, Tuomey's former chief executive officer paid \$1 million and accepted a four-year exclusion from participation in federal health care programs to resolve civil and administrative allegations arising from his involvement in Tuomey's misconduct. As a part of settlement, Toumey also entered into a five-year Corporate Integrity Agreement with HHS-OIG.

In December 2015, 32 hospitals located in 15 states paid more than \$28 million to resolve civil FCA allegations regarding kyphoplasty procedures. Kyphoplasty is a minimally-invasive procedure used to treat spinal compression fractures, and the procedure can often be performed safely and effectively on an outpatient basis. These settlements resolve allegations that hospitals frequently billed for kyphoplasty procedures on a more costly inpatient basis to increase their Medicare billings. To date, the Department has resolved allegations of improper kyphoplasty billing with more than 140 hospitals, recovering approximately \$107 million.

In December 2015, Memorial Health, Inc., Memorial Health University Medical Center, Inc., Provident Health Services, Inc., and Memorial Health University Physicians—regional practices in Southern Georgia—paid nearly \$10 million to settle civil FCA allegations that they engaged in improper financial relationships with referring physicians that violated the Stark Law. The settlement resolved allegations that these parties executed arrangements that were not commercially reasonable or for fair market value with the intent to induce patient referrals. As a part of settlement, Memorial Health also entered into a five-year Corporate Integrity Agreement with HHS-OIG.

In February 2016, 51 hospitals located in fifteen states paid more than \$23 million to resolve civil FCA allegations regarding cardiac devices that were implanted in Medicare patients in violation of Medicare coverage requirements. The government alleged that hospitals were implanting these cardiac devices—also known as implantable cardioverter defibrillators—without regard to National Coverage Determination (NCD) that required a medically justified waiting period before implantation for patients who had recently suffered a heart attack, had heart bypass surgery, or had an angioplasty. Hospitals were implanting these cardiac devices during the periods prohibited by the NCD. These settlements represent the final stage of a nationwide investigation that has yielded settlements with more than 500 hospitals totaling more than \$280 million. As a part of settlement, two of the hospitals entered into five-year Corporate Integrity Agreements with HHS-OIG.

In July 2016, Lexington County Health Services District, Inc. d/b/a Lexington Medical Center (LMC), in South Carolina agreed to pay \$17 million to resolve its liability under the FCA. LMC operates the Lexington Medical Center hospital and associated office-based clinics. The Government alleged that LMC had compensation arrangements within the meaning of the Stark law in the form of asset purchase arrangements and employment arrangements with certain physicians that did not satisfy all the requirements of any applicable exception to Stark’s referral and billing prohibition. These problematic arrangements led LMC to submit fraudulent claims to Medicare for designated health services referred by these physicians in violation of the FCA. As a part of settlement, LMC entered into a five-year Corporate Integrity Agreement with HHS-OIG.

(SF) In September 2016, Tenet Healthcare Corporation and four of its hospitals agreed to pay approximately \$390 million to resolve criminal charges and civil federal FCA claims relating to a scheme to pay kickbacks in return for patient referrals. This amount includes approximately \$145.7 million that two of its Atlanta-area hospitals—Atlanta Medical Center, Inc. and North Fulton Medical Center, Inc.—agreed to forfeit in connection with a criminal plea. The government alleged that Tenet and its affiliated hospitals paid kickbacks to obstetric clinics serving primarily undocumented Hispanic women in return for referral of those patients for labor and delivery at Tenet hospitals. In addition to the federal recovery, Tenet paid approximately \$123.7 million to resolve state Medicaid liability. As a part of settlement, Tenet agreed to three-year Independent Compliance Monitor Agreement.

In September 2016, Vibra Healthcare LLC—a national hospital chain headquartered in Mechanicsburg, Pennsylvania—paid \$27.6 million to resolve civil FCA allegations that it billed Medicare for medically unnecessary services. Vibra operates numerous freestanding long term care hospitals (LTCHs) and inpatient rehabilitation facilities (IRFs). The government alleged that Vibra admitted and retained patients in its LTCHs and IRFs without regard to medical necessity or qualification for those services. In some instances, Vibra allegedly ignored the recommendations of its own clinicians to discharge patients. As a part of settlement, Vibra entered into a five-year Corporate Integrity Agreement with HHS-OIG.

Identity Theft

In October 2015, a registered nurse in Ohio was sentenced to nearly 8 years in prison and ordered to pay \$18.1 million in restitution for her guilty plea to health care fraud and aggravated identity theft. The nurse, whose nursing license lapsed in 2005, was excluded in April 2005 after being convicted of Medicaid fraud. During the entire time the nurse was excluded and unlicensed, she owned Heritage Home Health Agency where she provided nursing services to home-bound clients. She used the identity of another nurse with the same name to hide the fact that she was unlicensed. Heritage billed Medicaid exclusively and received more than \$20 million in reimbursement. The nurse's mother was part owner and office manager of Heritage and created false background check reports for Heritage employees who were disqualified from working as home health aides due to their felony criminal convictions. The mother was also convicted of health care fraud and sentenced to five years supervised release, 300 hours of community service, and ordered to pay \$434,747 in restitution for her guilty plea to health care fraud.

Laboratories

In October 2015, Millennium Health, LLC (Millennium)—formerly Millennium Laboratories of San Diego, California—paid \$205.6 million to resolve civil FCA allegations that it billed federal health care programs for medically unnecessary urine drug testing and genetic testing, and paid physicians kickbacks in exchange for referrals for those tests. Millennium allegedly caused physicians to order unnecessary urine drug tests (in some instances, dozens per patient) and unnecessary genetic testing without an individualized assessment of each patient's needs for those tests. To further propagate its urine drug testing scheme, Millennium allegedly provided free urine drug test cups to physicians, expressly conditioned on the physicians' agreement to return the urine specimens to Millennium for additional testing. Under a separate settlement agreement, Millennium paid \$19.2 million to CMS to resolve certain administrative actions related to Millennium's urine drug test billing practices. As a part of settlement, Millennium Health entered into a comprehensive five-year Corporate Integrity Agreement with HHS-OIG wherein Millennium agreed to make extensive changes to its business practices.

In December 2015, Pharmasan Labs, Inc., NeuroScience, Inc., and its former owners paid \$5.7 million and forfeited another \$2.9 million to resolve civil FCA allegations that they submitted false information for laboratory services billed to Medicare and billed for services referred by non-physician practitioners when such referrals are non-billable. The government alleged that Pharmasan, located in Osceola, Wisconsin, billed Medicare for food sensitivity testing that was otherwise not reimbursable but for Pharmasan creating false records about the type of test ordered. As a part of settlement, Pharmasan entered into a five-year Corporate Integrity Agreement with HHS-OIG.

In January 2016, the former owner and chief executive officer of Bostwick Laboratories—a pathology laboratory headquartered in Glen Allen, Virginia—agreed to pay approximately \$3.7 million to resolve civil FCA allegations that he knowingly caused Bostwick Laboratories to bill the federal health care programs for medically unnecessary cancer detection tests and offered incentives to physicians to induce referrals in violation of the AKS.

In August 2016, the two owners and operators of Biosound Medical Services Inc. and Heart Solutions (collectively, "Biosound"), of Parsippany, New Jersey, were sentenced to 100 and 78

months respectively in prison for health care fraud. In July 2016 they were also ordered to pay the United States \$5 million in damages and \$2.8 million in civil monetary penalties. Biosound provided mobile diagnostic testing, including ultrasounds, echocardiograms and nerve conduction studies that were used to diagnose heart defects, blood clots, abdominal aortic aneurysms and other serious medical conditions. One owner admitted to fraudulently interpreting and writing diagnostic reports produced by Biosound despite having no medical license and knowing that the reports would be used by the referring physicians to make important patient treatment decisions. The other owner admitted to assisting in forging physician signatures on the fraudulently produced reports to make them appear legitimate. Both owners admitted to falsely representing to Medicare that the neurological testing performed by Biosound was being supervised by a licensed neurologist.

In June 2016, the owner of Owings Mills, Maryland-based Alpha Diagnostics, LLC, was sentenced to 10 years imprisonment followed by 2 years of supervised release for health care fraud and wire fraud conspiracy, among other conduct, related to a scheme to defraud Medicare and Medicaid of more than \$7.5 million. Alpha Diagnostics was a portable diagnostic service provider, principally of X-rays for patients that resided in nursing homes. Based upon the evidence presented at trial, the jury found that the owner instructed his non-physician employees to interpret X-rays, ultrasounds, and cardiologic examinations and report their findings as if they were read by a licensed radiologist. In fact, no licensed radiologist ordered or interpreted the films. The jury also found that two of the reports were wrongfully interpreted by the non-physician employees resulting in the deaths of two patients.

Nursing Homes and Facilities

In January 2016, contract therapy providers RehabCare Group, Inc., RehabCare Group East, Inc., and their parent, Kindred Healthcare, Inc., paid a total of \$125 million to resolve civil FCA allegations that they caused the submission of false claims to Medicare for rehabilitation services that were not reasonable, necessary, or that never occurred. RehabCare is the largest provider of therapy in the nation, contracting with more than 1,000 skilled nursing facilities (SNFs) in 44 states to provide rehabilitation therapy to their patients. The government alleged that RehabCare's policies and practices set unrealistic financial goals and routinely scheduled unreasonably high levels of therapy irrespective of the clinical need of the patient. The government further alleged that RehabCare billed for skilled therapy that was not provided to patients because the patients were asleep or otherwise unable to undergo or benefit from the skilled therapy. This settlement relates to numerous other settlements with skilled nursing facilities that frequently billed Medicare for this unnecessary therapy and failed to prevent RehabCare's fraudulent practice. As a part of settlement, RehabCare entered into a five-year Corporate Integrity Agreement with HHS-OIG.

In June 2016, California-based Five Star Quality Care-CA, LLC d/b/a Lancaster Healthcare Center agreed to pay \$8.6 million to resolve its liability under the CMPL for conduct it disclosed to HHS-OIG. Specifically, HHS-OIG alleged that, that during the period of January 2010 through July 2014, it submitted claims for skilled nursing services without proper certifications and recertifications for services, establishment and content of therapy plans, and/or maintenance of clinical records, and that during the period of September 2014 through December 2014, it paid remuneration to a medical director for referrals.

(SF) In July 2016, three defendants were charged in a complex scheme involving the owners of nursing homes and assisted living facilities, physicians, Miami-based hospitals, and Miami-area health care providers. The lead defendant, who operated a network of skilled nursing homes and assisted living facilities, gained access to thousands of Medicare and Medicaid beneficiaries through the payment of kickbacks and bribes, and used this access to bill Medicare for medically unnecessary services. The defendants and their co-conspirators, in turn, received kickbacks from other health care providers to allow those providers to bill for medically unnecessary services for these same beneficiaries, many of whom did not need or want the services. During the course of the scheme, the defendants and their co-conspirators submitted over \$1 billion in false and fraudulent claims to the Medicare and Medicaid programs. To date, this is the Department of Justice's largest single criminal health care fraud case against individuals; trial is scheduled to commence in September 2017.

In September 2016, North American Health Care, Inc. (NAHC), its board chairman, and its senior vice president paid \$30 million to resolve civil FCA allegations that they caused the submission of false claims to the federal health care programs for medically unnecessary rehabilitation therapy services provided to residents at NAHC's skilled nursing facilities. NAHC is a private, for-profit company headquartered in Orange County, California and operates 35 SNFs, mostly in California. The government alleged that its executives helped create and reinforce the fraudulent billing scheme. As a part of settlement, NAHC entered into a five-year Corporate Integrity Agreement with HHS-OIG.

Pharmacies

In October 2015, the CEO of Kentwood Pharmacy was sentenced to 10 years in prison, ordered to pay \$8.8 million in restitution, joint and several, and banned from participation in federal health care programs for 50 years for his guilty plea to conspiracy to commit health care fraud. According to the investigation, Kentwood Pharmacy of Grand Rapids, Michigan billed Medicare and private health insurers for prescription drugs that had been dispensed to patients and subsequently inappropriately returned to pharmacy stock. During the course of the investigation, pornographic images were discovered on the computer of Kentwood Pharmacy's vice president of sales. He was convicted of child pornography as well as health care fraud and sentenced to 14 years in prison and ordered to pay \$8.8 million in restitution, joint and several. Sixteen defendants involved in the scheme were previously sentenced to a combined 22 years in prison and were excluded from participation in Federal health care programs for a combined 145 years. This case was initiated based upon fraud tips provided to the HHS OIG Hotline.

(SF) In December 2015, nine defendants were sentenced to more than 29 years in prison and ordered to pay a combined \$22.1 million in restitution for their roles in a scheme to defraud Medicare. According to court records, five of the defendants were the owners of eight pharmacies that submitted more than \$20 million in fraudulent claims to Medicare. The false claims included prescriptions for drugs that were not properly prescribed or provided to the beneficiaries. The other defendants were involved in schemes in which millions of dollars in fraudulent claims were submitted to Medicare. These conspiracies were accomplished in part by the use of patient recruiters who received kickbacks in return for referring Medicare Part D beneficiaries to the pharmacies.

In May 2016, the owner of a Florida pharmacy and a patient recruiter pled guilty to conspiracy to commit health care fraud for their part in a scheme to defraud Medicare. The two were sentenced to a total of 6 years and 6 months in prison, and ordered to pay \$5.9 million in restitution, joint and several. From November 2012 through February 2015, the owner and her husband owned and operated three pharmacies in Miami. They and others committed fraud by paying kickbacks to patients and recruiters, and for billing Medicare for medications not delivered to Medicare beneficiaries. The patient recruiter also received compensation for recruiting patients to obtain pharmaceutical drugs at the pharmacies. The patient recruiter pled guilty and is awaiting sentencing.

In June 2016, the president and owner and operator of Pharmalogical, Inc. (Pharmalogical) d/b/a Medical Device King and MDK, and Taranis Medical Corp. (Taranis), was sentenced to 5 years of imprisonment and ordered to forfeit to the government close to \$900,000 in criminal proceeds, for 64 felony counts of mail and wire fraud, and violations of the Federal Food Drug and Cosmetic Act (FFDCA). A six-week trial established the president's leadership role in a long-running scheme to sell misbranded and unapproved pharmaceutical products, including chemotherapy drugs for infusion into Stage 4 cancer patients, to medical providers across the United States. Many of the products sold did not have FDA-required warnings of potentially deadly side effects. The president would execute "bait-and-switch" transactions with doctors by advertising FDA-approved products on his website but then sending them misbranded and unapproved products. These drugs were infused into patients, including cancer patients and patients with Crohn's disease. He continued to sell these drugs well after his office was searched by FDA agents and all of his existing products were seized. To conceal the continued sales, he covertly set up a new company, Taranis, which he operated without a license and out of a storage space where he kept the drugs. As a result many of the doctors that were knowingly purchasing unapproved or misbranded drugs under this scheme are being pursued for perpetrating a fraud on government healthcare programs.

Physical Therapy

(*SF*) In October 2015, an owner of two Brooklyn-area clinics, pleaded guilty to conspiracy to commit health care fraud and conspiracy to commit money laundering in connection with a scheme to submit false claims to Medicare and Medicaid for, among other things, fraudulent physical and occupational therapy services purportedly provided. From approximately February 2008 through February 2011, the defendant and others executed a scheme in which patients were paid cash kickbacks to present themselves for treatment at the defendant's clinics. The patients received medically unnecessary services that were later falsely billed to Medicare and Medicaid as genuine physical and occupational therapy treatments. In total, fraudulent claims totaling over \$55 million were submitted to Medicare and Medicaid in connection with the scheme, and the programs paid out over \$29 million in reimbursement of those claims.

Physician and Other Practitioners

In December 2015 a Westlake, Ohio cardiologist was sentenced to 20 years in prison for overbilling Medicare and private insurers for unnecessary catheterizations, tests, stent insertions and causing unnecessary coronary artery bypass surgeries. He performed medically

unnecessary nuclear stress tests and inserted cardiac stents in patients who did not have 70 percent blockage or any blockage in their cardiac vessel. He also placed a stent in an already stenosed artery which not only failed to provide any medical benefit but also increased the risk of harm to the patient. As a result of this scheme, the cardiologist caused Medicare to be overbilled in the amount of approximately \$29 million, and Medicare and the private insurers paid him approximately \$5.7 million.

(SF) In February 2016 and April 2016, respectively, a biller and a licensed physician pled guilty for their roles in an \$11 million Medicare fraud scheme involving a home visiting physician practice. Previously, the practice's owner, a licensed physician, was sentenced to 6 years imprisonment for his role in the fraud. The practice's office manager and an unlicensed physician who worked for the practice also pled guilty and are awaiting sentencing. According to court documents, the visiting physician practice employed unlicensed individuals who held themselves out as licensed physicians and visited beneficiaries in their homes and purported to provide physicians services. The unlicensed individuals completed, but did not sign, medical forms documenting the purported services. Licensed physicians, including the practice's owner, signed the forms as if they provided the care when, in fact, they did not treat or even see the beneficiaries. The practice then fraudulently billed the services to Medicare as if they were performed by licensed physicians.

In March 2016, a general practitioner with a clinic in Quebradillas, Puerto Rico, was sentenced to 10 years imprisonment and a term of supervised release of 5 years after being found guilty by a jury of 21 conspiracies and 61 individual counts of mail fraud relating to health care fraud. The doctor was charged along with 35 patients for orchestrating a large-scale scheme where he fraudulently signed American Family Life Assurance Company (AFLAC) accidental insurance claim forms without examining the patients. The evidence presented at trial showed that the doctor caused a loss to AFLAC in excess of \$6 million. The three-week trial included the testimony of three of the doctor's employees and four patients who indicated that the doctor personally instructed them to submit the documents for his signature without examination. The evidence also showed that the scheme had grown so large and lucrative that the doctor had to hire two employees to do data entry full time in order to generate the thousands of AFLAC claim forms submitted for reimbursement under his signature. The 35 patients involved in the scheme were charged alongside and pled guilty prior to the doctor's trial. The doctor was also ordered to pay \$2.1 million in restitution to AFLAC of Columbus, Georgia.

(SF) In April 2016, a licensed physician pleaded guilty to health care fraud, admitting that he submitted false claims to Medicare for purported visits with Medicare beneficiaries, including on dates when he was out of the country, for beneficiaries who were deceased on the dates he purportedly treated them, and for services totaling more than 24 hours in one day. He agreed that he submitted approximately \$2.4 million in fraudulent claims to Medicare for which he was paid approximately \$1.2 million.

In April 2016, a Roseville, California podiatrist was sentenced to three years in prison and ordered to pay a \$10,000 fine for one count of health care fraud and he was also ordered to pay restitution in the amount of \$1.2 million. Between 2009 and 2014, this podiatrist submitted over \$2.8 million in fraudulent claims for reimbursement to Medicare, Medicaid, TRICARE and private insurers. He falsely claimed that he performed more expensive procedures than he

actually performed or that the routine foot care was justified because of illnesses or symptoms that were not present. To satisfy the restitution order, \$1.2 million from the podiatrist's retirement account was forfeited.

In May 2016, in the Western District of Kentucky, a doctor was sentenced to 8 years and 4 months for conspiracy to unlawfully distribute controlled substances, among other conduct. The doctor operated pain management clinics in both Louisville, Kentucky and Jeffersonville, Indiana where he unlawfully distributed Schedule III controlled substances. He saw more than 100 patients on various dates, by himself, spending approximately three minutes or less with each patient but falsely and fraudulently billed various health care benefit programs by submitting claims for office visits at a higher code than the service provided. The doctor also illegally billed group sessions as individual counseling, and upcoded for numerous services. As part of his sentence the doctor was also ordered to pay \$827,000 in restitution to various health care benefit programs, pay \$20,000 to DEA for investigative costs, ordered to forfeit his medical license and a building.

In June 2016, the University of Missouri-Columbia paid the United States \$2.2 million to settle allegations that it violated the civil FCA by submitting claims for radiology services to federal health care programs. The United States alleged that certain attending physicians certified that they had reviewed the images associated with interpretative reports prepared by resident physicians when, in fact, they had not reviewed those images. As a part of settlement, the University of Missouri-Columbia entered into a five-year Corporate Integrity Agreement with HHS-OIG.

(SF) In July 2016, following a three-week trial in the Eastern District of New York, a physician was convicted of one count of health care fraud, three counts of making false statements in connection with health care matters, and two counts of money laundering. The evidence at trial showed that the defendant, a general surgeon, billed the Medicare program for thousands of wound-debridement and incision-and-drainage surgical procedures that he did not in fact perform. The defendant billed Medicare over \$7 million and was paid well over \$3 million in reimbursement by Medicare in the three year period 2011 through 2013 for claims that were shown at trial to be fraudulent.

In August 2016, a pediatric dentist who operates two dental practices in Connecticut was alleged to have violated the FCA. The allegations arise out of the taking of pediatric dental x-rays. Under Connecticut law, a licensed dentist may delegate to dental assistants the taking of dental x-rays if the dental assistant can demonstrate successful completion of the dental radiography portion of an examination prescribed by the Dental Assisting National Board (DANB). The certification provided by the DANB examination is important to ensure dental assistants are appropriately trained in the use of x-ray procedures and to ensure the x-rays are performed safely. The Government's investigation found that the majority of x-rays taken at the dental clinics were taken by dental assistants who were not DANB certified. X-rays taken by uncertified dental assistants are not payable by the Medicaid program. To resolve the allegations under the federal and state False Claims Acts, the dentist and his clinics paid \$1.4 million. As a part of settlement, the dentist and his two dental practices entered into a three-year Integrity Agreement with HHS-OIG.

Prescription Drugs / Medicare Part D

In January 2016, in the first case of its kind in the nation, in the Central District of California a total of 16 defendants at Manor Medical Clinic were convicted in a \$20-million scheme to defraud Medicare and Medicaid by filing fraudulent claims for expensive anti-psychotic medications. As a part of the scheme, a doctor pre-signed thousands of prescriptions for those anti-psychotic medications. Other employees at Manor Medical in Glendale, California, then used the prescriptions to submit claims for medications by using the names of victims of identity theft. These victims were often elderly Vietnamese beneficiaries, military veterans recruited from drug rehab programs, and homeless individuals living on Los Angeles' Skid Row. Once the prescriptions were filled, the drugs were often sold on the black market and redistributed to pharmacies, where they were subject to new claims to Medicare and Medicaid. The doctor received a 9-year sentence. The owners of Manor Medical were also sentenced and, one owner received a 15-year sentence. Fifteen defendants involved in the scheme were previously sentenced to a combined 46 years and 3 months in prison. Those convicted were ordered to pay \$9 million in restitution to Medicare and Medicaid.

(SF) In March 2016, five defendants—including the owners of several Detroit-area home health and hospice companies and two physicians—pleaded guilty to conspiracy to commit health care fraud and wire fraud charged in a June 2015 Indictment. As part of the fraudulent scheme, defendants paid numerous physicians for beneficiary referrals to their home health companies, the largest of which was At Home Network. These kickbacks took multiple forms, including cash payments, checks for purported medical director services, and checks for purported rent. In the case of a co-defendant, the kickbacks also included free labor and the purchase of a Mercedes Benz. A co-defendant physician would receive illegal kickbacks, and in exchange, bribe his patients to accept services from At Home Network by providing them with medically unnecessary controlled substance prescriptions, which were billed to Medicare Part D. The associated companies were paid over \$33 million by Medicare for purported home health and hospice services many of which were induced by kickbacks, medically unnecessary and/or not provided.

(SF) In August 2016, mother-and-son co-owners of Miami-area pharmacies each pleaded guilty to charges of conspiracy to commit health care fraud in connection with an approximately \$14 million scheme that exploited Part D of the Medicare Program. The defendants' pharmacies engaged in massive overbilling fraud by submitting claims for millions of dollars' worth of medications that they never ordered.

Psychiatric and Psychological Testing and Services

In November 2015, the owner, director, and administrator of Greater Miami Behavioral Healthcare Center (GMBC), was sentenced to 16 years in prison and ordered to pay more than \$15.2 million in restitution after pleading guilty to conspiracy to commit health care and wire fraud. The owner and another defendant devised a scheme to pay kickbacks and bribes to patient brokers in return for referring Medicare beneficiaries and falsifying medical records to support claims for services that were never provided. GMBC's director of finance was sentenced to 8 years and 1 month in prison after pleading guilty to conspiracy to commit money laundering. The director of finance and other defendants devised a scheme to conduct financial transactions

in order to conceal the payment of kickbacks to patient brokers. Two other defendants involved in the scheme were previously sentenced to a combined 6 years and 4 months in prison and ordered to pay \$848,106 in restitution.

(SF) In January 2016, a jury in the Southern District of Florida convicted the president of a transportation company for his role in a scheme to defraud Medicare effectuated through several Miami-area mental health centers. The evidence showed that the defendant and his co-conspirators used the transportation company to coordinate the payment of illegal health care kickbacks to recruiters, who in return referred Medicare beneficiaries to three now-defunct mental health clinics, which purported to provide mental health services to these beneficiaries, though the beneficiaries did not qualify or receive the services, and were themselves receiving kickbacks. Between January 2008 and December 2010, the centers submitted approximately \$70 million in false and fraudulent claims to Medicare and were paid approximately \$28 million on those claims. In March 2016, the defendant was sentenced to a 5 year prison term.

In April 2016, a psychiatrist at Riverside General Hospital (Riverside) in Texas was sentenced to 12 years in prison and ordered to pay \$6.3 million in restitution. A jury convicted the psychiatrist of conspiracy to commit health care fraud, health care fraud, and making false statements relating to health care matters. According to evidence presented at trial, from 2006 until 2012 the psychiatrist and others engaged in a scheme to defraud Medicare by submitting through Riverside approximately \$158 million in false claims for partial hospitalization program (PHP) services, an intensive outpatient treatment for severe mental illness. Beneficiaries for whom Riverside billed Medicare did not receive PHP services; in fact, beneficiaries rarely saw a psychiatrist and did not receive intensive psychiatric treatment at all. Six defendants involved in the scheme were previously sentenced to a combined 120 years in prison and ordered to pay \$46.7 million in restitution, joint and several. Six additional defendants pled guilty or were found guilty and are awaiting sentencing.

(SF) In September 2016, two clinical psychologists pled guilty in the Eastern District of Louisiana to conspiracy to commit health care fraud, and conspiracy to submit false statements. The defendants and their co-conspirators carried out the scheme by contracting with nursing homes to give their company's psychologists access to nursing home residents, some of whom were incapacitated. The psychologists then billed for services that were not needed and were not provided, often billing for the work of unlicensed assistants as if it were rendered by licensed clinical psychologists. In over a little more than five years, the defendants billed Medicare for more than \$26.2 million in psychological testing and related services, the vast majority of which were fraudulent.

Quality of Care

In March 2016, 21st Century Oncology, Inc., the largest physician led integrated cancer care provider in the country, paid \$34.7 million to resolve civil FCA allegations that it billed Medicare and TRICARE for performing a procedure known as Gamma function in situations that were medically unnecessary, where the medical personnel performing the procedure and interpreting the results were untrained, and where the results were reported too late to be of use or not reported at all due to technical failures with the imaging equipment. Previously, in December 2015, a wholly owned subsidiary of 21st Century Oncology, Inc. (21st Century

Oncology, LLC) paid \$19.75 million to settle civil FCA claims that it performed medically unnecessary laboratory tests used to detect genetic abnormalities associated with bladder cancer (also known as fluorescence in situ-hybridization cytology or FISH tests), and that it encouraged its physicians to order the unnecessary tests by offering bonuses based in part on the number of tests referred to the company. As part of this settlement, two individual physicians paid \$1.5 million and \$250,000, respectively. Pursuant to both settlements, 21st Century Oncology is under a five-year Corporate Integrity Agreement with HHS-OIG.

In May 2016, the owner and operator of Advanced Pain Management in Kentucky was sentenced to 8 years and 4 months in prison and ordered to pay \$827,000 in restitution for his guilty plea to conspiracy to unlawfully distribute and dispense Schedule II and III controlled substances, health care fraud, and money laundering. According to court records, from November 2009 through May 2014, the owner/operator distributed and dispensed narcotics to patients without a legitimate medical purpose and beyond the bounds of professional practice, leading to a patient's death. In addition, he falsely billed the health care benefit programs by submitting claims for office visits at a higher code than the services provided.

Other Medicare and Medicaid Matters

In November 2015, a licensed insurance agent in Florida was sentenced to 1 year and 6 months in prison and ordered to pay \$2.4 million in restitution, joint and several, for her role in a Medicare Part C and Medicaid fraud scheme. Evidence showed that, from June 2013 to April 2014, the agent was employed by a Medicare Advantage Organization (an HMO) to market and sell their plans. Under the scheme, the agent recruited Medicare beneficiaries living in Nicaragua to enroll in a Medicare Advantage plan. She submitted fraudulent enrollment requests to Medicare, falsely representing that the beneficiaries actually resided in Florida. This was a joint investigation with the FBI and the Florida MFCU.

In June 2016, Planned Parenthood Health Systems, Inc. (Planned Parenthood) agreed to pay \$1.5 million to resolve its liability under the CMPL for conduct it disclosed to HHS-OIG. Specifically, HHS-OIG alleged that, between November 2004 and February 2015, Planned Parenthood submitted claims to Medicaid in North Carolina, South Carolina, Virginia, and West Virginia for services using a provider number different than the medical professional who provided the services and billed for the services of non-physician practitioners who were not properly enrolled in their state Medicaid program.

In July 2016, MD2U Holding Company, its related companies, and individually named owners, paid \$21.5 million to resolve civil FCA allegations that they billed for medically unnecessary services and altered records to support those false claims. MD2U was a regional provider of home-based care in Louisville, Kentucky. The government alleged that MD2U and affiliated companies and owners submitted false claims for patients who were neither homebound nor home-limited and for services that were medically unnecessary, upcoded, or not properly rendered. As a part of settlement, MD2U entered into a five-year Corporate Integrity Agreement with HHS-OIG.

In August 2016, a registered nurse owned and operated Mt. Zion Home Health Agency in Denton, Texas. From April 2008 to October 2013, a nurse carried out a scheme to defraud

Medicare through the submission of false and fraudulent claims for skilled nursing services which were not provided and which were not authorized by the patients' physicians. At times, the nurse submitted claims for services which she allegedly provided when she was out of state. At other times, the nurse submitted claims for services which she allegedly provided to patients who testified that they did not know her and had never heard of her company. She was found guilty by a jury of nine counts of health care fraud following a four-day trial. She was sentenced to 97 months in federal prison and ordered to pay restitution in the amount of \$775,099 to Medicare, and to pay a forfeiture judgment in the amount of \$491,488.

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 2016, the Secretary and the Attorney General jointly allotted \$187.6 million to HHS-OIG after accounting for a sequester reduction of \$13.7 million. Additionally, Congress appropriated \$67.2 million in discretionary funding for HHS-OIG HCFAC activities.

In FY 2016, HHS-OIG investigations resulted in 765 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid; and 690 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 2016, HHS-OIG excluded a total of 3,635 individuals and entities, the details of which are below.

In FY 2016, 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 2016, 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 \$22.1 billion—\$21.0 billion in Medicare savings and \$1.1 billion in savings to the federal share of Medicaid.

Additional information about savings achieved through such policy and procedural changes may be found in the HHS-OIG 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 2016, HHS-OIG excluded a total of 3,635 individuals and entities. Among these were exclusions based on criminal convictions for crimes related to Medicare and Medicaid (1,326) or to other health care programs (262); for patient abuse or neglect (299); or as a result of licensure revocations (1,448). 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 2016. In addition to those mentioned in the Program Accomplishments section above, exclusion actions by HHS-OIG included:

Iowa—In October 2015, a provider of personal care services was ordered to pay restitution of \$8,327 for her guilty plea to tampering with records. The provider was also excluded from participation in Federal health care programs. According to the investigation, she billed Medicaid for personal care services that she did not actually perform. In most instances, it was determined that she was working for her outside, full-time employer while also billing for personal care services that she did not provide.

Colorado—In December 2015, a certified nurse assistant was excluded for a minimum period of 25 years based on his convictions for sexual assault. The nurse assistant performed sexual acts on a person who had a traumatic brain injury that rendered her unable to give consent to the acts. He was sentenced to 15 years of incarceration. In addition, his license to practice as a certified nurse assistant was revoked by the Colorado State Board of Nursing.

Texas—In January 2016, a doctor of osteopathy was excluded for a minimum period of 25 years based on his conviction of conspiracy to commit health care fraud, among other charges. Beginning around April 2009 and continuing to about February 2010, the doctor conspired with others to defraud the Medicare program. As part of the conspiracy, he billed Medicare for procedures and services that were never performed. As a result of this activity, the court sentenced the doctor to pay \$1.2 million in restitution and serve 10 years in prison. The Texas State Board of Medicine revoked his license to practice and the Virginia State Board of Medicine suspended his license.

California—In May 2016, a doctor of osteopathy was excluded for a minimum period of 50 years based on her conviction of 2nd degree murder, unlawful controlled substance prescription, and obtaining a controlled substance by fraud. According to court documents, the doctor prescribed massive quantities of controlled substances to patients with no legitimate need. She was sentenced to 30 years in prison. In addition, her license to practice as a doctor was suspended by the Osteopathic Medical Board of California.

Florida—In June 2016, the owner and registered representative of Comprehensive Care Clinic (CCC) was excluded for a minimum period of 55 years based on his conviction of conspiracy to commit health care fraud and wire fraud. The owner conspired with CCC employees to pay kickbacks to Medicare beneficiaries for allowing them to utilize their Medicare information for

fraudulent purposes and was sentenced to 4 years and 3 months in prison and ordered to pay \$20 million in restitution.

Civil Monetary Penalties

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

New Jersey—In October 2015, Ascend Laboratories, LLC (Ascend) agreed to pay \$1.3 million to settle allegations that it failed to submit drug pricing data to CMS. The Medicaid Drug Rebate Program requires pharmaceutical companies to enter into and have in effect a national rebate agreement with the Secretary of HHS in order for Medicaid payments to be available for the pharmaceutical company's covered drugs. Companies with such rebate agreements are required to submit certain drug pricing information to CMS, including quarterly and monthly average manufacturer's price (AMP) data. HHS-OIG can seek penalties against manufacturers that misrepresent, or fail to timely report, drug pricing information. HHS-OIG alleged that Ascend failed to submit timely monthly and quarterly AMP data for certain months and quarters in 2013 and 2014.

Texas—In December 2015, two physicians and a podiatrist agreed to pay \$208,000, \$75,000, and \$65,000, respectively, to settle allegations that they received improper remuneration in exchange for the referral of patients to an independent diagnostic testing center, OneStep Diagnostic, Inc. (OneStep), in the Houston area. Specifically, HHS-OIG alleged that from January 1, 2008, through June 30, 2012, the three practitioners each received improper remuneration from OneStep in the form of compensation from a Medical Directorship agreement and that took into account the value and volume of referrals made to OneStep. In October 2014, OneStep agreed to pay \$1.2 million and adhere to a 5-year CIA to resolve their related liability.

Ohio—In December 2015, the Kroger Company agreed to pay \$21.5 million to resolve its liability under the CMPL for conduct disclosed to HHS-OIG. Kroger is an Ohio for-profit corporation that operates more than 2,109 pharmacies and 2,640 supermarkets and multi-department stores in 34 states. HHS-OIG alleged that Kroger employed 14 individuals who were excluded from participation in Federal health care programs. Kroger also filled prescriptions, for which payment was made under a federal health care program, that were written by 84 excluded prescribers.

Alabama—In October 2015, Community Health United Home Care, LLC (CHUHC) agreed to pay \$9.8 million to resolve its liability under the CMPL for conduct it disclosed to HHS-OIG. Specifically, HHS-OIG alleged that, from January 1, 2008, through February 29, 2012, CHUHC submitted claims for hospice services at Center Home Care Corporation and Fallbrook Home Care Services without certifications of terminal illness, face-to-face encounters, and/or physician narratives, as required by hospice regulations.

Georgia—In May 2016, Grady Memorial Hospital Corporation d/b/a/ Grady Health System (Grady) agreed to pay a penalty of \$40,000 to resolve its potential liability under EMTALA. HHS-OIG alleged that Grady failed to provide an adequate medical screening examination and stabilizing treatment to a patient, specifically that a patient was extracted from his apartment by a SWAT team and brought to Grady’s emergency department (ED) by a police officer due to complaints of suicidal and homicidal ideations. While at Grady, two Licensed Professional Counselors (LPCs) evaluated the patient and determined that the patient should be held involuntarily for further evaluation and treatment. Approximately five hours after the patient’s arrival in the ED, the ED physician discharged the patient without consulting the LPCs or the on-call psychiatrist.

California—In June 2016, Enloe Medical Center (Enloe) agreed to pay \$570,912 to settle allegations that Enloe submitted claims for emergency ambulance transportation to destinations such as skilled nursing facilities and patient residences that should have been billed at the lower non-emergency rate.

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.

Through this work planning process, HHS-OIG focuses its efforts on four important outcomes:

- Fraud Prevention through Effective Provider Enrollment Safeguards and Oversight;
- Analyzing Payment Trends, Questionable Billing, and Potential Fraud;
- Preventing and Reducing Improper Payments; and
- Protecting Beneficiaries.

Among HHS-OIG’s audit and evaluation findings in FY 2016 were the following, organized by outcome:

Fraud Prevention through Effective Provider Enrollment Safeguards and Oversight

Screening of Medicare Providers: After CMS implemented risk screening and site visit enhancements to strengthen the provider enrollment process, HHS-OIG found that providers submitted fewer enrollment applications to CMS in the post implementation period. There was also an increase in the rate of applications that CMS returned to providers and a higher rate of approvals (lower rate of denials) among CMS's enrollment determinations. CMS's additional efforts to revalidate all existing enrollments yielded substantial revocations and deactivations of existing providers' billing privileges. HHS-OIG also found gaps in contractors' verification of key information on enrollment applications that could leave Medicare vulnerable to illegitimate providers. In addition, contractors were inconsistent in applying site visit procedures and using site visit results for enrollment decisions. Finally, CMS's enrollment data system does not contain the information needed for effective oversight and evaluation of the enhancements to the enrollment screening process. (OEI-03-13-00050)

Screening of Medicaid Providers: HHS-OIG found that State implementation of risk-based screening is incomplete. Most states reported not having fingerprint-based criminal background checks while waiting for the requirement to take effect. Although CMS did not initially require States to conduct these checks, pending additional guidance, CMS did issue this guidance in June 2015. In addition, 11 states reported that they have not implemented site visits. Meanwhile, most states reported challenges and concerns regarding substitution of screening results from Medicare or other states for their own. These included difficulties accessing external screening data and ensuring the quality of other state and/or Medicare screening efforts. Some states that did not have all screening activities in place still enrolled and revalidated thousands of providers categorized as posing a high or moderate risk to Medicaid. (OEI-05-13-00520)

Medicare Provider Enrollment: HHS-OIG found that over three-quarters of Medicare providers in our review had owner names on record with CMS that did not match those that providers submitted to HHS-OIG. Further, nearly all providers in this review had owner names on record with CMS that did not match those on record with state Medicaid programs. Additionally, two of the 11 CMS contractors did not check all required exclusions databases, which could allow providers with excluded owners to enroll in the Medicare program. Taken together, these findings reveal vulnerabilities that could allow potentially fraudulent providers to enroll in the Medicare program and limit CMS's ability to provide adequate oversight. (OEI-04-11-00591)

Medicaid Provider Enrollment: HHS-OIG found that few state Medicaid programs requested that providers disclose all federally required ownership information. In addition, 14 state Medicaid programs reported that they did not verify the completeness or accuracy of provider ownership information. HHS-OIG also found that 14 state Medicaid programs reported that they did not check all required exclusions databases. Further, most providers in our review had names on record with state Medicaid programs that did not match those on record with CMS or with HHS-OIG. The prevalence of nonmatching owner names raises concern about the completeness and accuracy of information about Medicaid providers' ownership. It also demonstrates that providers may not be complying with the requirement to report ownership changes to state Medicaid programs. (OEI-04-11-00590)

Analyzing Payment Trends, Questionable Billing, and Potential Fraud

Medicaid Drug Prices: HHS-OIG found that generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 22 percent of the quarterly average manufacturer prices we reviewed. If the provision for brand-name drugs were extended to generic drugs, Medicaid would receive additional rebates. Medicaid would have received \$1.4 billion in additional rebates for the top 200 generic drugs, ranked by Medicaid reimbursement, from 2005 through 2014. (A-06-15-00030)

Provider-preventable conditions (PPCs): PPCs are certain reasonably preventable conditions caused by medical accidents or errors in a health care setting. Federal regulations effective July 1, 2011 prohibit Medicaid payments for services related to PPCs. HHS-OIG conducted this review to determine whether Washington was in compliance with the new regulations for inpatient hospital services. HHS-OIG found that Washington State claimed Federal Medicaid reimbursement for inpatient hospital services related to treating certain PPCs. Washington did not determine the unallowable portion of \$18.3 million (\$10.8 million federal share) that was for services related to treating PPCs and should not have been claimed for Federal Medicaid reimbursement. HHS-OIG set aside this amount for resolution by CMS and Washington. (A-09-14-02012)

Home Health Fraud: HHS-OIG analyzed Medicare claims data from calendar years 2014 and 2015 to assess the national prevalence and distribution of selected characteristics commonly found in HHS-OIG-investigated home health fraud cases. Our analysis identified a substantial number of providers—over 500 HHAs and over 4,500 physicians—that were outliers in comparison to their peers nationally with respect to multiple characteristics commonly found in HHS-OIG-investigated cases of home health fraud. It is important to note that our analysis does not demonstrate that these providers were engaged in fraudulent activity. Our analysis also identified 27 geographic hotspots in 12 states, i.e., areas where characteristics commonly found in HHS-OIG home health fraud cases are prevalent. (This data brief was released in tandem with an HHS-OIG Alert which focused on improper arrangements and conduct by HHAs and physicians). (OEI-05-16-00031)

Power Mobility Devices: HHS-OIG's objective was to determine whether Hoveround Corporation, which received the second largest Medicare reimbursement for power mobility devices (PMDs) in 2010, claimed federal reimbursement for PMDs in accordance with Medicare requirements. For this review, HHS-OIG found that for 154 of the 200 sampled beneficiaries reviewed, Hoveround received payments for claims that did not comply with Medicare requirements. For 144 sampled beneficiaries, Hoveround did not support the medical necessity of PMDs, and for 10 sampled beneficiaries, Hoveround provided incomplete documentation to support the PMD claims. HHS-OIG estimated that Medicare paid Hoveround at least \$27 million for PMDs that did not meet Medicare requirements during 2010. (A-05-12-00057)

Medicaid Durable Medical Equipment and Supplies: During recent Medicaid audits, HHS-OIG determined that selected durable medical equipment and supplies (DME) are available to CMS at a cost well below what is available to state Medicaid agencies. In audits of four state Medicaid agencies, HHS-OIG found that the states could have saved \$18.1 million on the purchase of selected DME items if they obtained pricing comparable to pricing under Round 1 of Medicare's

Competitive Bidding Program. Since issuing those audit reports, HHS-OIG identified \$12 million in additional savings for the selected DME items if the four states had used pricing comparable to Medicare's Round 2 Competitive Bidding and National Mail-Order Programs. Medicaid provider reimbursement rates for selected DME items varied significantly among those States. Opportunities exist for these states to lower provider reimbursement rates, resulting in \$30.1 million in potential savings for the states and the Federal Government. (A-05-15-00025)

Opioids and Compounding Drugs: In 2015, HHS-OIG found that total Part D spending reached \$137 billion, marking the third consecutive year that spending increases surpassed \$10 billion. Notably, spending for commonly abused opioids exceeded \$4 billion, raising concerns about misuse. The growth in Part D spending for compounded drugs is also striking-particularly spending for compounded topical drugs, which has increased more than 3,400 percent since 2006. (OEI-02-16-00290)

Preventing and Reducing Improper Payments

Improper Payments to Hospices: HHS-OIG's review found that hospices billed one-third of general inpatient care (GIP) stays inappropriately, costing Medicare \$268 million in 2012. HHS-OIG also found that hospices often did not meet all care planning requirements and sometimes provided poor-quality care. Recent HHS-OIG investigations have shown instances in which hospices inappropriately billed Medicare for GIP, including care being billed but not provided and beneficiaries receiving care they did not need. (OEI-02-10-00491)

Bone Marrow and Stem Cell Transplant Procedures: HHS-OIG's objective was to determine whether Medicare paid selected inpatient claims for stem cell transplants in accordance with Medicare requirements. Recent HHS-OIG reviews identified Medicare overpayments to two hospitals that did not always comply with Medicare billing requirements for inpatient claims for stem cell transplants, resulting in overpayments of approximately \$4 million. For this review, HHS-OIG found that 133 of the 143 selected Medicare inpatient claims we reviewed for bone marrow and stem cell transplant procedures did not comply with Medicare requirements. As a result, Medicare overpaid the hospitals by \$6.3 million. (A-09-14-02037)

Mechanical Ventilation: A previous HHS-OIG review found that hospitals did not fully comply with Medicare requirements for billing inpatient claims with certain Medicare Severity Diagnosis-Related Groups (MS-DRGs) that required beneficiaries to have received 96 or more consecutive hours of mechanical ventilation. A subsequent HHS-OIG review found that claims with longer lengths of stay were also at risk for billing errors. The objective was to determine whether Medicare payments to hospitals for inpatient claims with certain MS-DRGs that required 96 or more consecutive hours of mechanical ventilation complied with Medicare requirements. HHS-OIG found that, for 63 of the 200 claims we reviewed, Medicare payments to hospitals were assigned incorrectly to MS-DRGs 207 and 870, resulting in \$1.5 million of overpayments. Based on this sample, HHS-OIG estimated that the hospitals received (1) overpayments of \$3.7 million for claims with a potential procedure length of 4 days or fewer; and (2) overpayments of \$15.9 million for claims with a potential procedure length of 5 days. (A-09-14-02041)

Incorrect Coding: HHS-OIG found that states' inconsistent implementation and use of National Correct Coding Initiative (NCCI) edits may reduce their ability to promote correct coding by providers and prevent improper Medicaid payments. Additionally, states' lack of reporting of cost savings estimates, and the limitations of the estimates that were reported, inhibit CMS's ability to meaningfully estimate national NCCI cost savings. (OEI-09-14-00440)

Withdrawal of Federal Medicaid Funds by States: CMS has not issued guidance instructing states on the appropriate handling of Medicaid withdrawals. All three states that HHS-OIG audited withdrew more funds than necessary to meet immediate cash needs: Alabama and Maryland had overdrawn more than \$130 million in Medicaid funds that they had not refunded to the Federal Government. Although Illinois refunded overdrawn Medicaid funds, its withdrawals exceeded its expenditures by an average of \$60 million a quarter. (A-06-14-00068)

Federal Matching Without State Contributions: During its audit of the Alabama's hospital certified public expenditures (CPEs) program for FY 2010, HHS-OIG noticed that Alabama had claimed, for FYs 2010 and 2011, more than \$5 million in Federal funds related to CPEs for three hospitals that appeared to be private hospitals. The three hospitals were owned but not operated by State or local governments. Alabama's definition of a public hospital indicates that a facility only has to be owned by a public entity, regardless of whether the facility is operated by a public entity or whether State or local government funds are used in its operation. As a result, Alabama received more than \$5 million in federal funding by claiming CPEs from the three hospitals, even though no state or local government funding was used to operate the hospitals. (A-06-16-08005)

Protecting Beneficiaries

Adverse Events: HHS-OIG found that an estimated 29 percent of Medicare beneficiaries experienced adverse or temporary harm events during their rehab hospital stays, resulting in temporary harm; prolonged stays or transfers to other hospitals; permanent harm; life-sustaining intervention; or death. This harm rate is in line with what HHS-OIG found in prior work in hospitals (27 percent) and in SNFs (33 percent). Physician reviewers determined that 46 percent of these adverse and temporary harm events were clearly or likely preventable. Physicians attributed much of the preventable harm to substandard treatment, inadequate patient monitoring, and failure to provide needed treatment. Nearly one-quarter of the patients who experienced adverse or temporary harm events were transferred to an acute-care hospital for treatment, with an estimated cost to Medicare of at least \$7.7 million in one month, or at least \$92 million in one year, assuming a constant rate of hospitalization throughout the year. (OEI-06-14-00110)

Medicaid Data Integrity: HHS-OIG summarized the high-risk security vulnerabilities that we identified in our previous reviews of information system general controls at three California Medicaid managed care organizations (MCOs). HHS-OIG identified 74 high-risk security vulnerabilities, most of which were significant and pervasive, in the information system general controls at the three Medicaid MCOs. These consolidated findings from the individual reports raise concerns about the integrity of the systems used to process Medicaid managed-care claims. (A-09-15-03004)

Inadequate Dental Care: HHS-OIG found that three out of four Medicaid children in California, Indiana, Louisiana, and Maryland did not receive all required dental services, with one in four children failing to see a dentist at all. While these States reported that they employ a variety of strategies to address this problem and CMS has taken some positive steps in this area, HHS-OIG continues to have concerns that children are not receiving required dental services. (OEI-02-14-00490)

Background Checks for Long Term Care Employees: The ACA provides grants to states to implement background check programs for prospective long-term-care employees. HHS-OIG found that, four years into the National Background Check Program, the 25 states that are receiving program grants reported having achieved varying levels of program implementation. For example, only six of the 25 states submitted to CMS data sufficient to calculate the percentage of prospective employees who were disqualified. This raises concerns about whether CMS can determine program outcomes and conduct effective oversight of the National Background Check Program. (OEI-07-10-00420)

Medicaid Critical-Incident Reporting: HHS-OIG found that Connecticut and Massachusetts did not comply with federal waiver and state requirements for critical incidents involving developmentally disabled Medicaid beneficiaries living in group homes. Connecticut did not adequately safeguard 137 of 245 developmentally disabled Medicaid beneficiaries living in group homes that we reviewed, and Massachusetts did not adequately safeguard 146 out of 334. Neither State ensured that (1) group homes reported all critical incidents to the appropriate agencies; (2) data on all critical incidents were obtained, analyzed, or reported; and (3) all reasonable suspicions of abuse or neglect were reported. Connecticut also did not ensure that group homes always reported incidents at the correct severity level. (A-01-14-00002 and A-01-14-00008)

Potentially Avoidable Hospitalizations: HHS-OIG conducted a review of West Carroll Care Center (the Nursing Home). About 75 percent of its resident hospitalizations during the audit period occurred because of conditions a CMS-sponsored study found to be associated with potentially avoidable hospitalizations. A urinary tract infection was the most frequent reason for the hospitalizations. HHS-OIG found that the Nursing Home did not always provide services to its residents in accordance with their care plans, as required by Federal regulations, before they were hospitalized with UTIs. Specifically, the Nursing Home staff did not monitor and document residents' hydration status, monitor and document residents' conditions, or document residents' urine appearances as their care plans required. (A-06-14-00073)

Other OIG Fraud and Abuse Prevention Activities

HCFA 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. HHS-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 HHS-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 2016, the HHS-OIG, in consultation with DOJ, issued 14 advisory opinions, modified 10 advisory opinions, and terminated three advisory opinions. A total of 343 advisory opinions and 20 modifications to advisory opinions have been issued, and four opinions terminated, during the 20 years of the HCFAC program.

Corporate Integrity Agreements (CIA)

Many health care providers elect to settle their cases before litigation. As part of the settlements, providers often agree to enter into CIAs with HHS-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. HHS-OIG monitors providers' compliance with these agreements. HHS-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 2016, CMS was allocated \$24.1 million by HHS, and appropriated \$553.3 million in discretionary funds by Congress to support its comprehensive program integrity strategy for Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). In FY 2016, Congress required HHS to fully fund the Administration for Community Living's (ACL) Senior Medicare Patrol's activity. Therefore, \$18.0 million of CMS's \$553.3 million in discretionary funding was allocated to ACL to support the program. 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.

Address the Full Spectrum of Fraud, Waste, and Abuse

CMS uses a multi-faceted approach to target all causes of fraud, waste, and abuse (FWA) that result in improper payments, with an emphasis towards prevention activities. This includes a focus on initiatives that are foundational to addressing program integrity across the continuum of FWA and improving payment accuracy.

During FY 2016, CMS continued to integrate Medicare and Medicaid efforts, and provide technical guidance to states, providers, and other stakeholders on program integrity activities. CMS continued to conduct Medicare and Medicaid fraud investigations and provider audits, as well as state program integrity reviews.

This section describes the wide range of program integrity activities that CMS utilizes to comprehensively address FWA. These activities include many different approaches to program integrity, such as data analysis, investigations and audits, and recovery actions.

Fraud Prevention System

The Fraud Prevention System (FPS) is the predictive analytics technology required under the Small Business Jobs Act of 2010¹³ (SBJA). Since June 30, 2011, the FPS has run predictive algorithms and other sophisticated analytics nationwide against all Medicare FFS claims on a continuous basis prior to payment in order to identify, prevent, and stop potentially fraudulent claims. The FPS helps CMS target fraudulent providers and suppliers, reduce the administrative and compliance burden on legitimate providers and suppliers, and prevent fraud so that funds are not diverted from providing beneficiaries with access to quality health care.

The FPS helped identify or prevent \$604.7 million in inappropriate payments during FY 2015 through actions taken due to the FPS or through investigations expedited, augmented, or corroborated by the FPS. This resulted in an \$11 to \$1 return on investment. Since CMS implemented the technology in June 2011, the FPS has identified or prevented more than \$1.4 billion in inappropriate payments by identifications of new leads or contribution to existing investigations. During FY 2015, the FPS models generated 718 leads that were included in the ZPIC workload. The leads resulted in 492 new investigations and augmented information for 226 existing investigations (FY 2016 numbers were not available at the time of this report).

¹³ Public Law 111-240.

National Correct Coding Initiative

Medicare

Due to the volume of claims processed by Medicare each day and the significant cost associated with conducting medical review of an individual claim, CMS heavily relies on automated edits to identify inappropriate claims. The National Correct Coding Initiative (NCCI) program consists of edits designed to reduce the Medicare Parts A and B, Medicare DME, and Medicaid improper payments. This program was originally implemented in the Medicare program in January 1996 with procedure-to-procedure edits to ensure accurate coding and reporting of services by physicians. In addition to procedure-to-procedure edits, CMS established the Medically Unlikely Edit (MUE) program to reduce the paid claims error rate for Medicare Part B claims as part of the NCCI program. The first MUE edits were implemented January 1, 2007, and MUE edits have since been extended to cover Part A and DME.

Since October 2008, all procedure-to-procedure edits and the majority of MUEs have been made public and posted on the CMS website. Certain edits are not published to protect against use or manipulation by fraudulent or abusive individuals and entities. The use of procedure-to-procedure edits developed through the NCCI saved the Medicare program \$393.9 million in FY 2016. In addition, MUE edits within Medicare Part B outpatient and DME saved the Medicare program \$222.1 million during the first nine months of FY 2016. (Savings for Part A are not yet available).

Medicaid

Section 6507 of the Affordable Care Act requires CMS to notify states which NCCI methodologies are compatible with claims filed with Medicaid and requires states to use these methodologies to process applicable Medicaid claims filed on or after October 1, 2010.¹⁴ CMS has worked closely with state Medicaid agencies to implement the NCCI methodologies in their Medicaid programs. Fully and correctly implementing the NCCI methodologies in state Medicaid programs will be a long-term undertaking by both CMS and the states. However, use of the Medicaid NCCI methodologies in adjudicating Medicaid claims is producing significant savings in federal and state Medicaid program expenditures due to reductions in improper payments for Medicaid claims with improper coding, as has occurred in the Medicare program.

In FY 2013, CMS created a major, new technical guidance document for states that compiles, organizes, and integrates CMS requirements for state implementation for the Medicaid NCCI methodologies. This document is continually updated as new implementation issues are decided. In addition, many new Medicaid NCCI edits were added to the quarterly Medicaid NCCI edit files and even more Medicaid-only NCCI edits were developed. CMS is currently working on technical guidance for the states related to calculating savings from Medicaid NCCI savings.

¹⁴ CMS reported on the implementation of this requirement in a March 2011 report to Congress, accessible at: <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Data-and-Systems/Downloads/ReporttoCongresspdf.pdf>.

One Program Integrity (One PI) Portal

CMS continues to augment the data available in the Integrated Data Repository (IDR) to provide a comprehensive view of Medicare and Medicaid data including claims, beneficiary data, and drug information. CMS is using the IDR to provide broader and easier access to data and enhanced data integration while strengthening and supporting CMS's analytical capabilities.

CMS continues to integrate new data sources into the IDR, including recent additions like Shared Systems and submitter data. CMS is also working to incorporate state Medicaid data into the IDR while also working with states to improve the quality and consistency of the data from each state, described more fully below.

CMS uses the One Program Integrity (One PI) web-based portal with the IDR to provide access to robust business intelligence analytical tools (including Business Object, SAS, and STARS) and to facilitate data sharing with program integrity contractors and law enforcement. The portal provides a single access point to the data within the IDR, as well as the analytic tools to review the data.

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 2016, the Command Center conducted 15 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. ZPICs/Program Safeguard Contractors (PSCs) have continued to conduct site visits and interviews of DME suppliers, providers, and beneficiaries receiving DME products in high billing areas for DME supplies and products. In FY 2016, 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.

Probable Fraud Measurement Pilot

The Probable Fraud Measurement (PFM) Pilot was designed to test the methodologies, protocols, and instruments used to estimate probable fraud that were developed for possible use in a nationwide program. The PFM Pilot was conducted from December 2015 to March 2016 in the Miami-Dade County, Florida home health service area. The PFM Pilot consisted of extracting claims data; performing field interviews of beneficiaries, HHAs and attending providers (APs); collecting medical documentation; evaluating the methodologies; revising and re-testing methodologies (when necessary); providing recommendations for improvement; and identifying best practices.

In the context of the PFM Pilot, a review panel of experienced health care analysts, clinicians, policy experts, and fraud investigators reviewed collected data to determine whether there was sufficient evidence to refer any of the cases to ZPICs for further investigation. At the conclusion of the pilot, twenty cases were identified for possible referrals to ZPICs. Although the PFM Pilot was not designed to generate actual referrals, the findings warranted that additional analysis be conducted to determine whether these cases should, in fact, be referred to the ZPICs for further investigation. This analysis is ongoing.

CMS will assess the value of expanding the pilot to a larger geographic area (e.g., national) and expanding the measurement to other areas of Medicare.

Proactively Manage Provider Screening and Enrollment

Provider enrollment is the gateway to the Medicare and Medicaid programs and is the key to preventing ineligible providers and suppliers from entering either program. CMS is committed to maintaining operational excellence in its provider enrollment screening process. Through provider screening and enrollment, CMS continues to prevent and reduce fraud, waste, and abuse in the Medicare and Medicaid program and ensure that only eligible providers are caring for beneficiaries and receiving payment.

Medicare Provider Screening and Site Visits

CMS implemented the Affordable Care Act's additional screening provisions through a final rule¹⁵ published by the Federal Register on February 2, 2011. There are three levels of provider and supplier enrollment risk-based screening: "limited," "moderate," and "high," and each provider and supplier specialty category is assigned to one of these three screening levels.

The Advanced Provider Screening system (APS)¹⁶ automatically screens all current and prospective providers against a number of data sources, including provider licensing and criminal records. APS identifies and highlights potential program integrity issues that are investigated proactively by CMS.

CMS's provider screening and enrollment initiatives in Medicare have had a significant impact on removing ineligible providers from the program. Site visits, revalidation and other initiatives have contributed to the deactivation¹⁷ and revocation¹⁸ of more than 652,000 enrollment records since CMS started implementing the requirements of the Affordable Care Act.

Suspensions

CMS in FY 2016 continued its use of the Affordable Care Act authority to suspend Medicare payments to providers during an investigation of a credible allegation of fraud. CMS also has authority to suspend Medicare payment; if reliable information of an overpayment exists. During FY 2016, there were 508 payment suspensions that were active at some point during the fiscal year (data reflected as of October 31, 2016). Of the 508 payment suspensions, 291 new payment suspensions were imposed during FY 2016.

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.

From July 1, 2015 through September 30, 2016, the Medicare Administrative Contractor covering Florida (First Coast Service Operations) had conducted 9,891 site visits to verify

¹⁵ 76 FR 5862 (Feb. 2, 2011).

¹⁶ Previously referred to as the Automated Provider Screening system.

¹⁷ Deactivation means the provider's or supplier's billing privileges were stopped, but can be restored upon the submission of updated information. See 42 CFR 424.540.

¹⁸ Revocation means the provider's or supplier's billing privileges are terminated. See 42 CFR 424.535.

providers' and suppliers' operational status, deactivated 422 practice locations, and revoked or denied 1,157 providers. CMS saved \$12.9 million from prepayment medical record review.

Medicaid Screening and Enrollment

During FY 2016, CMS significantly expanded its efforts to assist states with meeting Medicaid screening and enrollment requirements. These efforts include enhanced sharing of Medicare enrollment and screening data with states, providing a new data compare service to help states identify providers for which the state is able to rely on Medicare's screening, providing technical assistance to states through site visits, and publishing additional guidance in the Medicaid Provider Enrollment Compendium (MPEC).

CMS shares Medicare enrollment and screening data to assist states with meeting Medicaid screening and enrollment requirements. Specifically, CMS shares the Medicare provider enrollment record via the Provider Enrollment, Chain and Ownership System (PECOS) administrative interface and in bulk data extracts from PECOS. CMS also shares OIG exclusion data with states. In May 2016, CMS began to offer a data compare service that allows a state to rely on Medicare's screening, in lieu of conducting state screening. Using the data compare service, a state provides an extract of Medicaid provider enrollment data to CMS and then CMS returns information to the state indicating for which providers the state is able to rely on Medicare's screening.

CMS continually provides ongoing guidance, education, and outreach (site visits and technical assistance) to states on federal requirements for Medicaid enrollment and screening. In addition, CMS published the MPEC in March 2016, which is sub-regulatory guidance designed to assist states in applying certain regulatory requirements.

CMS also offers training, technical assistance, and support to state Medicaid program integrity officials through the Medicaid Integrity Institute. The FY 2016 course schedule included seminars in May and September 2016 that focused exclusively on provider screening and enrollment compliance provisions of the Affordable Care Act. More information on the Medicaid Integrity Institute can be found at: <https://www.justice.gov/mii>.

Medicaid Provider Enrollment Oversight

As part of its oversight role in Medicaid, CMS works closely with state Medicaid agencies to provide regulatory guidance, technical assistance, and other support with respect to provider enrollment. State Medicaid agencies may rely on the screening completed by CMS for dually-enrolling providers to assist them in complying with their Medicaid screening requirements, and states may use Medicare screening data including site visits, payment of application fees, and fingerprint-based criminal background checks.

State Medicaid programs must terminate any provider that has been terminated by Medicare or another state Medicaid program or CHIP “for cause.”¹⁹ Additionally, CMS has the discretionary authority to revoke Medicare billing privileges where a state has terminated a provider’s or supplier’s Medicaid billing privileges for cause. CMS has established a voluntary process and system for states to report and share information about Medicaid terminations.

Provider Enrollment Moratoria

CMS has used the authority provided to the Secretary in the Affordable Care Act to temporarily prevent the enrollment of new Medicare, Medicaid, and CHIP providers and suppliers where the Secretary has determined such moratoria are necessary to combat fraud, waste, or abuse. In each moratorium area, CMS prohibits the new enrollment of certain provider and supplier types while we take administrative actions, such as payment suspensions and revocations, as well as working with law enforcement to support investigations and prosecutions. Capitalizing on the effectiveness of this fraud and abuse preventive tool, in FY 2016, CMS expanded the enrollment moratoria statewide for HHA providers in Texas, Florida, Illinois, and Michigan and for Non-emergent ambulance providers in Texas, New Jersey, and Pennsylvania.

Continue to Build States’ Capacity to Protect Medicaid

CMS assists states in building their internal capacity to conduct program integrity activities for Medicaid. CMS continues to use HCFAC program discretionary funds to develop and implement enterprise systems that support Medicaid, in particular the Medicaid and CHIP Business Information Solution (MACBIS) initiative, which will improve the ability of CMS and the states to gather and analyze data that will support program integrity activities. HCFAC funding also supports the preparation and dissemination of educational toolkits for states to use to enhance awareness of Medicaid fraud, waste, and abuse among providers, beneficiaries, managed care organizations, and others. Through reviews of state processes and procedures, CMS also identifies areas of improvement and works with the states to make sure their integrity programs are robust.

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 50 states and the territories

¹⁹ Medicare denial of enrollment is covered at 42 CFR 424.530. Medicare revocation of enrollment is covered at 42 CFR 424.535. Medicaid denial or revocation of enrollment is covered at 42 CFR 455.416.

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. In addition, numerous tasks as part of this effort are geared towards achieving reduction in fraud, waste, and abuse and reduction of cost of these Medicaid Management Information Systems. One such effort includes the development of an open source provider enrollment and screening module that will be able to be reused and shared by any state and integrated into its MMIS. This could potentially save CMS at least 75 percent of the average cost to procure a provider enrollment and screening module per state, across all states that will utilize this module.

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 Act of 2010 (IPERA) and the Improper Payments Elimination and Recovery Improvement Act of 2012 (IPERIA), requires each agency to periodically review programs it administers and identify programs that may be susceptible to significant improper payments. For those programs determined to be susceptible, the agency is required to 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, during FY 2016, CMS continued to update the PERM eligibility component measurement methodology and related program regulations to reflect the required changes. During this time, CMS did not conduct the eligibility measurement component of PERM and the national Medicaid eligibility improper payment rate was 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 2016 Agency Financial Report (AFR) the national Medicaid improper payment rate that is based on measurements that were conducted in FYs 2014, 2015, and 2016. The FY 2016 national Medicaid improper payment rate is 10.48 percent, representing \$36.3 billion in gross improper payments. The FY 2016 national component improper payment rates are as follows: Medicaid FFS—12.42 percent, and Medicaid managed care—0.25 percent. The Medicaid eligibility component improper payment rate is held constant at the FY

2014 reported rate of 3.11 percent. The Medicaid improper payment rate increased from 9.78 percent in FY 2015 to 10.48 percent in FY 2016. The increase was due to state difficulties coming into compliance with new requirements for: (1) all referring or ordering providers to be enrolled in Medicaid and the inclusion of the referring or ordering National Provider Identifier (NPI) on claims; (2) states to screen providers under a risk-based screening process prior to enrollment; and (3) the inclusion of the attending provider NPI on all electronically filed institutional claims. While these requirements will ultimately strengthen Medicaid's integrity, it is not unusual to see increases in improper payment rates following the implementation and initial measurement of new requirements because it takes time for states to make changes required for compliance.

CMS also reported in the FY 2016 AFR the national CHIP improper payment rate that is based on measurements that were conducted in FYs 2014, 2015, and 2016. The FY 2016 national CHIP improper payment rate is 7.99 percent, representing \$0.7 billion in gross improper payments. The national component improper payment rates are as follows: CHIP FFS—10.15 percent and CHIP managed care—1.01 percent. The CHIP eligibility component improper payment rate is held constant at the FY 2014 reported rate of 4.22 percent. The CHIP improper payment rate increased from 6.80 percent in FY 2015 to 7.99 percent in FY 2016. The increase was due to state difficulties coming into compliance with the new requirements described in Medicaid above.

Medicaid 1115 Financial Oversight

The Medicaid Section 1115 demonstration is an increasingly important vehicle for state innovation in Medicaid and CHIP program development, expansion and financing. Three quarters of states operate at least one 1115 demonstration, and there are nearly 60 active demonstrations for which federal outlays totaled \$89 billion in FY2014. The Medicaid portfolio of Section 1115 demonstrations is growing in number, federal outlays, and policy importance and complexity. CMS has committed additional staff and reorganized Section 1115 demonstration work to develop and implement a more robust approach to monitoring and oversight of these demonstrations.

Staff activities in 2016 included developing a new budget neutrality calculation policy under which projected expenditures that are compared to estimated demonstration costs will be based on more current and realistic expenditure growth assumptions, a new uncompensated care (UC) pools policy that resizes the pools to the extent the pool has been substituting for payment that could be provided by Medicaid through payment of appropriate rates or expansion of coverage, and participating on a new taskforce to develop a phased approach to building standard operating procedures and reporting tools to strengthen Section 1115 fiscal and program monitoring. The staff are working closely with technical assistance contractors to build core performance measurement sets for high priority demonstrations. They also work with states to include these measures in the demonstration design and reporting requirements, and then monitor demonstration progress against them. The same staff supports a CMS IT contractor in developing business requirements for an information management system that will strengthen federal monitoring and analysis of performance trends across states and over time. The second version of this system was recently released and staff are being trained on it.

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 2016 through the continued efforts of these specialists, CMS removed an estimated \$608 million (with approximately \$230 million recovered and \$378 million resolved) of approximately \$8.0 billion identified in questionable Medicaid costs.

Furthermore, an estimated \$666 million in questionable reimbursement was actually averted due to the funding specialists' preventive work with states to promote proper state Medicaid financing. The funding specialists' activities included reviews of proposed Medicaid state plan amendments that related to reimbursement; development of financial management reviews; research regarding state Medicaid financing policy and practices; collaboration with states to resolve the Medicaid and CHIP portions of the A-133 "Single State" audits; and identification of sources of the non-Federal share of Medicaid program payments to ensure proper financing of Medicaid program costs.

Extend Work in Medicare Parts C and D

CMS is committed to expanding program integrity activities in capitated, managed care programs in Medicare. For example, CMS has strengthened oversight of Medicare Part C and Part D plan sponsors by conducting audits that detect whether plans are delivering the appropriate health care services and medications for which they are being paid.

Medicare Drug Integrity Contractor (MEDIC)

There are two MEDIC contractors, each with distinct responsibilities related to Part C and Part D benefits.

- The National Benefit Integrity MEDIC is responsible for processing and tracking all Part C and Part D complaints, requests for information, and referrals to law enforcement, and conducting proactive data analysis and investigations.
- The Outreach and Education MEDIC is responsible for conducting outreach and education activities for Part C and Part D stakeholders.

National Benefit Integrity (NBI) MEDIC

In the first nine months of FY 2016, NBI MEDIC referrals have resulted in sentences ordering restitution of \$72.5 million, and \$0.9 million in civil settlements according to FY 2016 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 arrests, indictments, and convictions, from FY 2016 notifications. As a result of the NBI MEDIC's data analysis projects, HHS recovered \$78.5 million in the first nine months of FY 2016 from Part D sponsors.

Outreach and Education (O&E) MEDIC

The Outreach and Education MEDIC provides Part C and Part D plans with training tools through online content, webinars, and facilitation of quarterly fraud work groups. CMS hosts Medicare Parts C and D Fraud Waste and Abuse (FWA) Trainings, as in-person events and virtual training webinars. Program integrity professionals from plan sponsors, pharmacy benefit managers (PBMs), law enforcement, CMS, and CMS's contractors from across the nation attended these events. These trainings provide valuable information about Part C and Prescription Drug fraud schemes and anti-FWA activities and initiatives. Additionally, during in-person trainings, attendees share data and leads on suspected potential fraud that they take back to their organizations for further investigation. CMS also provides outreach and educational materials to program integrity stakeholders through the CMS O&E MEDIC website, which had more than 3,000 vetted members at the close of FY 2016.

Medicare Parts C and D Marketing Oversight

CMS takes compliance action against Part C, Part D Prescription Drug Plans (PDPs), Section 1876 Cost Plans, and Medicare-Medicaid Plans (MMPs) that fail to send timely and accurate Annual Notice of Change (ANOC)/Evidence of Coverage (EOC) documents to Medicare enrollees. Both documents provide Medicare enrollees with vital information that can impact their ability to make informed choices concerning their Medicare health care and prescription drug options.

Program Audit

CMS conducts program audits of Part C and Part D plan sponsors to evaluate their delivery of health care services and medications to beneficiaries. In order to conduct a comprehensive audit of a sponsor's operation and maximize Agency resources, program audits in 2016, as well as in prior years, occur at the parent organization level.

Sponsors have all program areas audited when possible, unless a protocol was not applicable to their operation. Sponsors who have deficiencies cited in their audit report are required to correct all deficiencies and undergo validation to ensure issues have been corrected before the program audit can be closed.

In general, program audits give CMS reasonable assurance that sponsors deliver benefits in accordance with the terms of their contract and plan benefit package. However, we also have authority to take enforcement actions, up to and including termination, if warranted, for findings that involve direct beneficiary harm or the potential to result in such harm.

We have greatly increased the level of transparency with respect to our audit materials, the performance of our audits, and the results of those audits, including any enforcement actions that may result. We believe that program audits and consequences of possible enforcement actions are continuing to drive improvements in the industry and are increasing sponsor's compliance with core program functions in the Part C and Part D program.

Compliance and Enforcement

CMS has the authority to take enforcement or contract actions when CMS determines that a Part C or Part D plan sponsor either:

- Substantially fails to comply with program and/or contract requirements,
- Is carrying out its contract with CMS in a manner that is inconsistent with the efficient and effective administration of the Medicare Part C and Part D program requirements, or
- No longer substantially meets the applicable conditions of the Medicare Part C and D program.

Enforcement and contract actions include:

- Civil monetary penalties (CMP)
- Intermediate sanctions (i.e., suspension of marketing, enrollment, payment), and
- Terminations.

Part C Benefits Review Activities

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

- Low Enrollment Plans—Each year, CMS evaluates existing Part C 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 makes sure beneficiaries receive value in their benefit package selection and protects them from 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 Part C and protects 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 Part C organizations from offering similar plans in the same geographic area.
- Service Category Cost-Sharing Standards—Each year, CMS evaluates the cost-sharing plans include in their bids and plan benefit packages to make sure the plans do not exceed established limits and are not discriminatory.

- Actuarial Equivalence—CMS also reviews bids to make certain the estimated cost sharing presented in the bid is actuarially equivalent to the cost-sharing levels in Original Medicare. CMS currently examines four categories for actuarial equivalence and this review 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 and plan benefit packages. These reviews occur between early June and August and involve communications with Part C organizations to correct issues and resubmit their bids and plan benefit packages as necessary. Following bid and plan benefit approval, Part C organizations must complete the contracting process with CMS and may market to beneficiaries beginning October 1. Part C benefits requirements and review processes are intended to protect beneficiaries from discrimination and to make sure that Part C plans provide value to enrollees.

Part C Encounter Data Processing System Contract

The Part C 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 Part C organizations to submit encounter data for each item and service provided to Part C plan enrollees. Consistent with this authority, CMS is requiring Part C organizations to submit encounter data for dates of service January 3, 2012 and later. Part C plans are required to submit data for all institutional, professional, and DME services provided to Part C Medicare Advantage 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 Part C 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 Part C payments more accurately reflect the patterns of care and the predicted costs of diseases for Part C enrollees. Recalibrating the model on Part C diagnoses and expenditures, rather than using the FFS experience, will result in payments that are more accurate to Part C organizations. CMS is also able to use the information to evaluate service utilization, assess quality of care, and assess the performance of Part C plans.

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

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 gross improper payment estimate reported for FY 2016 (based on calendar year 2014) is 9.99 percent or \$16.2 billion. The Part C payment error is driven by errors in risk adjustment data (clinical diagnosis data) submitted by Part C plans to CMS for payment purposes. Specifically, the Part C payment error estimate reflects the extent to which diagnoses that plans report to CMS are not supported by medical record documentation.

In an effort to improve the Part C improper payment rate, CMS has implemented four key specific corrective actions described below:

- **Contract-Level Audits:** CMS is proceeding with the RADV contract-level audits to recover overpayments. RADV verifies, through medical record review, the accuracy of enrollee diagnoses submitted by Part C organizations for risk adjusted payment. RADV audits are CMS's primary corrective action to recoup improper payments. CMS expects that payment recovery will have a sentinel effect on the quality of risk adjustment data submitted by plans for payment. Payment recovery for the pilot audits has been completed and totaled \$13.7 million (\$5.4 million was recovered in FY 2014, \$5.0 million in FY 2013, and \$3.4 million in FY 2012). RADV audits of payment year 2011, which began in FY 2014, will be the first HHS reviews to recoup funds based on extrapolated estimates. In addition, during FY 2016, payment year 2012 audits continued and payment year 2013 audits were initiated.
- **Overpayment Recoveries Related to Regulatory Provisions:** In CMS-4159-F, "Policy and Technical Changes to the Part C and the Medicare Prescription Drug Benefit Programs" (79 FR 29843, May 23, 2014), CMS codified the Affordable Care Act requirement that Part C organizations must report and return overpayments that they identify. In CMS-1613-F, "The Calendar Year 2015 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Rule" (79 FR 66769, November 10, 2014), CMS also established a payment recovery and appeal mechanism to be applied when CMS identifies erroneous payment data submitted by a Part C organization. In FY 2016, Part C organizations reported and returned approximately \$317 million in self-reported overpayments.
- **Recovery Audit Contractor:** As part of the procurement process to secure a Medicare Part C RAC, CMS posted a Request for Quote in June 2014; however, no responses were received from that solicitation. More recently, a Request for Information was posted in December 2015 to solicit additional feedback from industry regarding this program. CMS received several submissions in response to the announcement. CMS continues its implementation efforts and anticipates awarding contract in 2017.

- Training: CMS continued its national fraud, waste, and abuse in-person and webinar training sessions for Part C plans.

The Part D gross improper payment estimate reported for FY 2016 (based on CY 2014) is 3.41 percent or \$2.4 billion. The methodology for calculating the FY 2016 Part D error estimate has been revised from prior years, when CMS reported a Part D composite rate consisting of four components: Payment Error Related to Low Income Subsidy Status (PELS); Payment Error Related to Medicaid Status (PEMS); Payment Error Related to Prescription Drug Event Data Validation (PEPV); and Payment Error Related to Direct and Indirect Remuneration (PEDIR).

With OMB's approval, for FY 2016 and subsequent years, the Part D error estimate measures only one component, the PEPV, which is the area where the majority of error for the program exists. The three other previously measured components—PELS, PEMS, and PEDIR—pose very little risk of payment error to the government. Over the years of measurement, the error estimates for these components significantly decreased, such that the effort and resources required to measure them were no longer cost effective.

In an effort to improve the Part D error rate, CMS has implemented three key specific corrective actions described below:

- Training: CMS continued its national training sessions for Part D sponsors on payment and data submission. CMS also continued its national fraud, waste, and abuse in-person and webinar training sessions for Part D sponsors.
- Outreach: CMS continued formal outreach to plan sponsors for invalid/incomplete documentation. CMS distributed Plan Sponsor Summary Reports to all plans participating in the national payment error estimate. This report provided feedback on their submission and validation results against an aggregate of all participating plan sponsors.
- Overpayment Recoveries Related to Regulatory Provisions: CMS codified the Affordable Care Act requirement that Part D sponsors must report and return overpayments that they identify. CMS also established a payment recovery and appeal mechanism to be applied when CMS identifies erroneous payment data submitted by a Part D sponsor. In FY 2016, Part D sponsors reported and returned approximately \$9.5 million in self-reported overpayments.

Provide Greater Transparency into Program Integrity Issues within Medicare and Medicaid

CMS is dedicated to providing greater transparency into program integrity issues through education, outreach, partnership, strategic communications, and data releases. CMS is well positioned to work with its partners and stakeholders to share best practices and lessons learned in program integrity. Increased transparency and accountability ensure program efficiency and effectiveness.

Provider Outreach and Education

One of the goals of provider education and outreach is to reduce the Medicare and Medicaid improper payment rates by giving Medicare and Medicaid providers the timely and accurate information they need to bill correctly the first time. The Medicare FFS claims processing contractors, known as Medicare Administrative Contractors (MACs), educate Medicare providers and their staff about Medicare policies and procedures, including local coverage policies, significant changes to the Medicare program, and issues identified through review of provider inquiries, claim submission errors, medical review data, and Comprehensive Error Rate Testing program data. Medicare contractors use a variety of strategies and communication channels to offer Medicare providers and suppliers a broad spectrum of information about the Medicare program, including CMS-developed materials and contractor-developed materials.

Beneficiary Education

CMS and HHS launched the Fraud Prevention Campaign in January 2010 to increase public awareness about Medicare's fight against fraud. Each year, CMS informs Medicare beneficiaries on an ongoing basis about the importance of guarding their personal information against identity theft and how they can protect against and report suspected fraud. In FY 2015, this effort included the *Medicare & You* handbook and other beneficiary education materials, 1-800-MEDICARE, and www.medicare.gov. Similar messages are disseminated through a wide range of beneficiary touch points, including the Medicare Summary Notice (MSN), the myMedicare.gov Message Center, and response letters to beneficiary inquiries.

Healthcare Fraud Prevention Partnership (HFPP)

In July 2012, the Secretary of HHS and the U.S. Attorney General announced a ground-breaking partnership to fight fraud, waste, and abuse across the health care system. The HFPP is a voluntary, public-private partnership consisting of the Federal Government, state agencies, law enforcement, private health insurance plans, and health care anti-fraud associations. The purpose of the HFPP is to improve the detection and prevention of health care fraud, waste, and abuse by:

- Exchanging data and information between the public and private sectors;
- Leveraging various analytic tools against data sets provided by HFPP Partners;
- Providing a forum for public and private leaders and subject matter experts to share successful practices and effective methodologies for detecting and preventing health care fraud, waste, and abuse.

In FY 2016, the HFPP reached a membership level of 70 partner organizations, representing over 65 percent of covered lives within the United States, and an increase of 30 percent since FY 2015. The amount of data collected in support of studies has increased by 300 percent in FY 2016, leading to the performance of new studies, the replication of prior studies with new data, and the attainment of actionable leads.

Open Payments

Open Payments is a national program that promotes transparency by publishing data on the financial relationships between the health care industry (applicable manufacturers and group purchasing organizations, or GPOs) and health care providers (physicians and teaching hospitals).

The Affordable Care Act requires the Secretary of the Department of Health and Human Services (HHS) to collect and display information on payments and other transfers of value and ownership/investment interest annually. CMS publishes information for each reporting year on its public website, and updates the website annually with an additional full year of data. The public can search, download, and evaluate the reported data. The data displayed on the Open Payments website are self-reported by applicable manufacturers and GPOs.

In Fiscal Year 2016, CMS published \$7.5 billion in payments and ownership and investment interests that were made from applicable manufactures and GPOs to physicians and teaching hospitals. This amount is comprised of 11.9 million total records attributable to 618,931 physicians and 1,116 teaching hospitals. Payments in the three major reporting categories included:

- \$2.6 billion in general (i.e., non-research related) payments
- \$3.9 billion in research payments
- \$1.0 billion of ownership or investment interests held by physicians or their immediate family members

Over the course of the Open Payments program since 2014, CMS has published \$28.2 million records, accounting for \$16.8 billion in payments and ownership and investment interests.

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 2016, HHS allocated \$18 million in HCFAC funding to the Administration for Community Living (ACL) to support SMP program infrastructure and provide grants to SMPs in 53 states and territories.

Until FY 2016, ACL received funding from a separate Congressional appropriation (the Older Americans Act) to support SMP base grants. However, the Consolidated Appropriations Act of 2016 required the SMP program to be fully funded by HCFAC in FY 2016. As such, ACL was allocated \$18 million from CMS's Medicare Integrity Program portion of the discretionary HCFAC appropriation to support the SMP program.

SMP Project Activities and Outcomes

ACL uses the majority of its HCFAC allocation to fund SMP projects in each state, Guam, Puerto Rico, and the District of Columbia. In FY 2016, ACL awarded \$14.7 million in grant funding to SMPs nationwide. Each SMP grantee receives a standard, base amount of funding to

support the operation of their project, as well as an additional, variable amount of funding based on the number of Medicare beneficiaries residing in the state and the ruralness of the state.

Each year, the HHS Office of the Inspector General (HHS-OIG) completes an annual performance report on the SMP projects. For 2015, ACL requested that the OIG complete only an abbreviated version of the report that is typically produced due to transitions in the SMP program last year, including a mid-year transition to a new data reporting system and the rollout of updated performance measures. As such, the 2015 OIG report included only data for those SMP performance measures that remained the same, including documented cost avoidance (\$21,533), expected recoveries to Medicare and Medicaid (\$2.5 million), and savings to beneficiaries and others (\$35,059) that resulted from the SMP projects. Annual HHS-OIG performance reports on the SMP program will resume as usual beginning for CY 2016.

Since SMP'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 outreach events. The primary focus of these sessions is on education, prevention, and teaching beneficiaries how to protect themselves and avoid fraud in the first place. This is the true value of the SMP program. However, the impact of these education and prevention activities is extremely difficult to quantify in dollars and cents. As HHS-OIG indicated in their June 2016 report on the SMP program:

We continue to emphasize the projects may not be receiving full credit for recoveries, savings, and cost avoidance 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 Medicare beneficiaries' scrutiny of their bills reduce fraud and errors.

ACL recognizes the importance of measuring the value of the SMP program impact to the fullest degree possible. Toward that end, in FY 2013, ACL awarded a three-year research grant to Tufts University to measure the value of SMP prevention activities. Tufts has designed a research methodology, collaborated with SMPs to pilot the methodology, and collected data about the health care fraud knowledge, attitudes, and behaviors of beneficiaries both before and (three to six months) after attending SMP education sessions. Preliminary results appear to show it is possible to quantify and demonstrate the incredible value of SMP prevention efforts. Final research results are expected in early FY 2017.

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 over \$124.6 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 2016, the National SMP Resource Center will be awarded year three of their three year grant. The SMP Resource Center has provided technical assistance, support, and training to the

SMP projects since 2003. The goal of the Center is to provide professional expertise and technical support, serve as an accessible and responsive central source of information, maximize the effectiveness of the SMP projects in health care fraud outreach and education, and ensure a fully consolidated national approach to reaching Medicare beneficiaries. The Center has also been instrumental in supporting ACL efforts to forge national visibility for the SMP program.

SMP Information and Reporting System (SIRS)

In FY 2016, ACL implemented a new SMP data reporting system (SIRS) to support the evolving needs to the SMP program. The previous SMP reporting system, SMART FACTS, had been in operation for seven years and was at the end of its functionality. SIRS is expected to last at least 10 years and provides SMPs with advanced reporting features and data analytics to help them better manage their programs.

Target Population 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. In FY 2015, ACL awarded four grants to organizations that initiated seventeen-month projects to increase awareness, empowerment, and actions to prevent health care fraud amongst several generally underserved populations, including Medicare beneficiaries under age 65, Lesbian, Gay, Bisexual and Transgender (LGBT) beneficiaries, Hispanic and Latino beneficiaries, and Asian American and Pacific Islander beneficiaries. The goal of these grants is to develop new, efficient, and sustainable approaches for ensuring high-quality, culturally competent service delivery to help educate consumers to prevent health care fraud. This work continued in FY 2016 and will conclude in FY 2017.

SMP Customer Satisfaction Survey

In late FY 2015, ACL issued a contract to develop a customer satisfaction survey for the SMP program. This will be the first national survey to ascertain the quality and effectiveness of the services provided by SMP and to determine if beneficiaries are receiving accurate, relevant and timely information. While the SMP program currently tracks output and outcome measures such as number of SMP team members, group outreach and education events, individual interactions, and savings, customer satisfaction is not one of them. As a result, there is no current understanding of the link between the quality of the information received and the likelihood to avoid health care fraud, errors, and abuse.

The survey will be conducted over a three-year period beginning in early 2017. The intent is to have each SMP project surveyed during one of the three years. The results from the survey will be used to measure satisfaction among individuals who attend SMP group education sessions, as well, as how the program can be improved to provide better service to its target population.

Office of the General Counsel

In FY 2016, the Office of the General Counsel (OGC) was allocated approximately \$7.5 million in HCFAC funding by HHS to supplement OGC's efforts to support program integrity activities. Many of OGC's efforts 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 2016, OGC was involved in a wide range of HCFAC efforts that resulted in Government recoveries of over \$2 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 2016, as 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 CMS in addressing program integrity and compliance problems as they occurred.

HEAT

During FY 2016, 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 Federal 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 Federal 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 significant litigation support, including assisting DOJ in evaluating the merits of the allegations, 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 2016, OGC participated in FCA and related matters that recovered over \$1.8 billion for the Federal Government. The types of FCA cases that OGC worked collaboratively with DOJ on included: drug pricing manipulation, marketing activity by pharmaceutical manufacturers that resulted in Medicare and Medicaid paying for drugs for non-covered indications, fraudulent billing by laboratories, hospice fraud, physician self-referral violations, “incident to” violations, provider upcoding, and Medicare Advantage matters, especially relating to various risk adjustment issues.

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 2016, 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 2016, 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) and Part C Compliance

During FY 2016, OGC continued to provide extensive advice to CMS on a variety of Part D and Part C-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 Part C 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 2016, 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. In addition, OGC provided extensive legal advice and guidance to CMS as well as the Department on the implementation and interpretation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act, Pub. L. 114-74) which adjusts for inflation all applicable penalty amounts under the Social Security Act.

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 2016, 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 2016, 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 additional notice related to provider and supplier enrollment moratoria, and providing counsel on the program integrity issues to CMS to assist in the ongoing implementation of existing models.

Further, OGC worked on a rule amending CMS's enrollment regulations to strengthen program integrity. Using existing authority from the Social Security Act, including authority added by the Affordable Care Act, these proposals would, among other things: (1) require providers and suppliers to disclose any affiliation with a provider or supplier that has certain characteristics indicating elevated risk (and would allow CMS to deny or revoke billing privileges based on this affiliation); (2) require those who order, refer, or prescribe a Medicare Part A or B item or service to be enrolled in Medicare or to have formally opted out of the Medicare program; (3) establish several new bases for CMS to revoke Medicare billing privileges; (4) expand the re-enrollment bar following revocation; and (5) amend the regulations governing moratoria on enrollment. OGC also worked closely with CMS on an extremely complex final regulation that clarifies providers' and suppliers' obligations to report and return self-identified overpayments. OGC also provided counsel to CMS in developing a proposed rule to refine the Medicaid error rate measure, or PERM, program and counseled CMS regarding the release of more granular payment error rate data. In addition, OGC routinely worked with CMS to review legislative proposals regarding program integrity matters.

Medicaid Program Integrity

Continuing recent trends, OGC saw continued increasing involvement in FY 2016 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. OGC provided advice on Medicaid payment suspensions as well as advised on regulatory efforts to coordinate Medicaid provider and supplier enrollment. 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 2016, 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 580.

Medicare Secondary Payer (MSP) Workload

OGC's efforts to recover conditional payments by Medicare that are the primary responsibility of other payers directly supports the HCFAC statutory goal of facilitating the enforcement of all applicable legal remedies for program fraud and abuse. During FY 2016, OGC has been successful in establishing the right to recover over \$10.5 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 2016, 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 \$14.5 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 2016, 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 2016 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 2016, \$4.25 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 Food and Drug Division (OGC-FDD). OCI, with the support of OGC-FDD, 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 medical product 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 151 criminal HCFAC investigations. In FY 2016, FDA's sixth full fiscal year of HCFAC Program activity, OCI, through its PFP, opened 31 criminal investigations, described below:

- Two investigations involving allegations of questionable manufacturing practices of foreign-based drug firms. These investigations are focused on violations related to application fraud, data integrity, data manipulation, and product adulteration.
- Two investigations involving allegations of questionable manufacturing practices of an injectable drug by a domestic firm causing the finished product to be super-potent. These investigations focused on of misbranding and/or adulteration violations of misbranding and/or adulteration.
- Three investigations involving allegations of questionable manufacturing practices of drug and medical devices ultimately causing public safety risks. These investigations focused on misbranding and/or adulteration violations.
- One investigation involving marketing schemes by medical device and drug manufacturers. The investigation focused on device and drug misbranding violations related to intended uses, which are not FDA cleared or approved.
- Twenty investigations involving allegations of clinical trial fraud. These investigations focused in part on individuals suspected of falsifying/manipulating clinical trial data or conducting clinical trials without FDA oversight.
- Three investigations involving allegations of application fraud. These investigations are focused on individuals or companies who either submitted false/fraudulent information to FDA in order to obtain approval/clearance for an article did not submit the required information to legally market drugs, devices or biologics.
- Of these investigations, four involve foreign-based companies.

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. Nevertheless, in April 2016, one of our PFP investigations opened in FY2014 resulted with a clinical trial coordinator being arrested and charged for falsifying documents within multiple clinical trials he was controlling. The investigator was forging the primary investigator's signature and "back dating" the forms he submitted to drug sponsors in order to receive payments. It is estimated that the investigator profited nearly \$500,000 from his actions.

Additionally, in July 2016, the majority owner of a compounding pharmacy that infected 750 people with mold and resulted in 64 deaths and her husband pled guilty. The remaining defendants are scheduled for trial in early 2017.

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 health and safety. Sixty percent of generic drugs in the United States are manufactured in foreign facilities.

In addition to these investigative activities, in May 2016, FDA conducted a one-day training session for newly hired criminal investigators covering PFP-related topics. In July 2016, FDA conducted a three day training session for current FDA criminal investigators. The attendees were provided background on FDA's PFP and resources available to assist in investigations conducted under the PFP. Information also included legal training by OGC-FDD on the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF JUSTICE

United States Attorneys

In FY 2016, the United States Attorneys' Offices (USAOs) were allocated \$54.8 million in HCFAC funding for civil and criminal health care fraud enforcement efforts. These funds supported attorneys, paralegals, auditors, and investigators, as well as litigation expenses for health care fraud investigations and cases. The 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 through fraud, waste, and abuse. The USAOs litigate a wide variety of health care fraud matters, including false billings by physicians and other providers of medical services, overcharges by hospitals, Medicaid fraud, kickbacks to induce referrals of Medicare or Medicaid patients, fraud by pharmaceutical and medical device companies, home health and hospice fraud, and failure of care allegations against nursing home owners. The USAOs also coordinate with CMS regarding the imposition of potential civil monetary penalties against a provider.

To ensure a focused and coordinated approach to health care fraud enforcement, each USAO has designated criminal and civil health care fraud coordinators. These coordinators work closely with outside investigative agencies and with trial attorneys in the Department's Civil and Criminal Divisions on health care fraud matters. While the USAOs receive many health care fraud referrals directly from investigative agencies, they also receive referrals from the Civil Division's Commercial Litigation Branch (Civil Fraud Section) and through the filing of qui tam (or whistleblower) complaints. Qui tam cases either are handled jointly with trial attorneys in the Civil Fraud Section or are delegated to the USAO to handle independently. The USAOs also handle most criminal and civil litigation at the federal appellate level.

The USAOs also partner with the Department's Criminal Division on Medicare Fraud Strike Forces Teams which currently operate in nine areas across the country. Each Strike Force team consists of dedicated AUSAs and support personnel from the USAO, as well as from the Criminal Division. Examples of successful Strike Force cases are noted earlier in this report.

To ensure that USAO personnel are knowledgeable and up-to-date on the law and tools for combatting health care fraud, HCFAC funding is used to train AUSAs and trial attorneys, as well as paralegals, investigators, and auditors on a wide variety of health care fraud enforcement matters. In FY 2016, the Office of Legal Education (OLE) offered multiple trainings for auditors, investigators, and paralegals which included health care fraud topics. OLE also offered an attorney's health care fraud course in May 2016, which was attended by more than 70 AUSAs and 30 Department trial Attorneys. In August 2016, OLE hosted a white collar crime seminar that included a breakout session on health care fraud investigations. Moreover, the Executive Office for United States Attorneys (EOUSA) presented approximately one webinar per month during FY 2016 on health care fraud issues. Many AUSAs, investigators, auditors, and paralegals served as faculty for these OLE trainings, and also participated in other federal, state, and private health care fraud seminars.

Criminal Prosecutions²⁰

In FY 2016, the USAOs opened 975 new criminal health care fraud investigations and filed criminal charges in 480 cases involving 802 defendants. During that same time period, 658 defendants were convicted of health care fraud-related crimes during the year.

Civil Matters and Cases²¹

In FY 2016, the USAOs opened 930 new civil health care fraud investigations and had 1,422 civil health care fraud matters pending at the end of the fiscal year.

Civil Division

In FY 2016, the Civil Division received approximately \$35.3 million in FY 2016 HCFAC funding to support the health care fraud activities of the Commercial Litigation Branch's Fraud Section and the Consumer Protection Branch. This amount also included funding to support the Department of Justice's Elder Justice 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 False Claims Act (FCA) to recover money on behalf of defrauded federal health care programs including Medicare, Medicaid, TRICARE, the Department of Veterans Affairs (VA), and the Federal Employee Health Benefits Program (FEHBP). The Fraud Section works closely with the United States Attorneys' Offices and often teams with the Consumer Protection Branch, HHS-OIG, state Medicaid Fraud Control Units and other law enforcement agencies to pursue allegations of health care fraud. As a result of these efforts, the Fraud Section has obtained settlements and judgments in health care cases of over \$2 billion almost every year since FY 2010 and over \$2.4 billion in FY 2016 alone.

The Fraud Section investigates and resolves matters involving a wide array of health care providers and suppliers. Matters involving pharmaceutical and device manufacturers and hospitals continued to constitute some of the most significant matters pursued by the Fraud Section this past year. Some cases involved allegations of hospitals and drug and device manufacturers paying kickbacks to health care providers, including physician practices, pharmacies, and hospitals, for referrals of patients, drugs, or devices (such as the Tenet, Novartis, Olympus, Millennium, Salix, Respironics, and Hollister matters discussed in the Highlights section) in violation of the Anti-Kickback Statute (AKS). Other cases involved allegations of drug manufacturers underpaying drug rebates to the Medicaid program (the Wyeth/Pfizer matter discussed earlier in this report) and marketing and selling products based on misleading or false information (the Genentech and Qualitest matters discussed earlier).

²⁰ FY 2016 numbers are actual data through the end of September 2016. This data includes records classified either with the primary or tertiary 03G – Health Care Fraud program code.

²¹ FY 2016 numbers are actual data through the end of September 2016. This data includes those records classified under with the FRHC – Health Care Fraud civil code.

The Fraud Section also pursued several significant matters involving alleged violations of the Stark Law. The Stark Law prohibits overutilization of services by physicians, practice groups, and hospitals that stand to profit from referring patients to other health care providers in which they have a financial interest. The AKS prohibits the willful solicitation or payment of remuneration to induce the purchase of a good or service for which payment may be made under a federal health care program. The Fraud Section's recoveries on AKS claims were particularly significant this year. The Department recovered the largest total amount paid to date for violations of the AKS by a medical device manufacturer from Olympus Corporation. The Department also recovered hundreds of millions of dollars from hospitals (the Tenet matter) and a laboratory (the Millennium matter) for allegations of business schemes that caused the submission of thousands of claims to the federal health care programs due to unlawful remuneration paid to clinics and physician practice groups. Likewise, the Fraud Section reached FCA settlements resolving Stark law allegations with other hospitals and laboratories, including Tuomey Healthcare System, Memorial Health, and OUR Lab discussed earlier.

The Fraud Section also has successfully pursued individuals responsible for illegal conduct. To illustrate, in the past year, the Department has pursued a range of civil cases against individuals, including a hospital CEO allegedly responsible for improper financial relationships with physicians in violation of the Stark law (the Tuomey matter discussed earlier), the CEO of a durable medical equipment supplier that allegedly improperly charged Medicare for splints provided to residents in skilled nursing facilities (the Dynasplint matter discussed earlier), and the owner of a laboratory that allegedly billed federal health care programs for unnecessary cancer detection tests (the Bostwick matter discussed earlier).

The Fraud Section is litigating an increasing number of FCA cases in order to obtain an appropriate resolution. The Section has filed complaints and committed significant resources to litigating claims against a number of hospice providers, including Vitas Hospice Services, AseraCare Hospice, and Creekside Hospice. In the AseraCare matter, a jury found that AseraCare—a for-profit nationwide hospice provider—submitted false claims for a majority of sampled patients who were not terminally ill. Notwithstanding the findings of the jury, the district judge set aside the jury verdict, and on August 31, 2016, the United States appealed that ruling to the United States Court of Appeals for the Eleventh Circuit where it is pending. Similarly, the Department continues to litigate claims against nursing homes and health care providers relating to medically unnecessary rehabilitation therapy administered to elderly residents, including suits filed against HCR Manorcare, Lifecare, and Sava SeniorCare. The Department also filed suit against Prime Healthcare Services, Inc., its owner, Prem Reddy, MD, and 14 of its hospitals in California, alleging that the hospital chain billed for excessive and unnecessary inpatient hospital services instead of less costly outpatient or observation services.

Because the Fraud Section receives every FCA complaint filed by whistleblowers (otherwise known as “relators”) across the country, 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 on the FCA and health care fraud issues to AUSAs and agents. The Section works closely with HHS Office of the Inspector General (HHS-OIG) and the Office of Counsel to the Inspector General (OCIG) 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 helps 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 Department on Interagency Working Groups such as the Elder Justice Coordinating Council. The Civil Division maintains the Elder Justice Website (www.elderjustice.gov), a valuable resource for elder abuse victims and their families, state and local prosecutors, elder abuse researchers, as well as practitioners. On March 30, 2016, the Department of Justice announced the launch of ten regional Elder Justice Task Forces. These teams bring together federal, state and local prosecutors, law enforcement, and agencies that provide services to the elderly, to coordinate and enhance efforts to pursue nursing homes that provide grossly substandard care to their residents. The Elder Justice Task Forces are led by representatives from the U.S. Attorneys' Offices, state Medicaid Fraud Control Units, state and local prosecutors' offices, the Department of Health and Human Services (HHS), state Adult Protective Services agencies, Long-Term Care Ombudsman programs, and law enforcement. The ten districts are the Northern District of California, Northern District of Georgia, District of Kansas, Western District of Kentucky, Northern District of Iowa, District of Maryland, Southern District of Ohio, Eastern District of Pennsylvania, Middle District of Tennessee, and the Western District of Washington.

The Consumer Protection Branch

The Consumer Protection Branch (CPB) enforces consumer protection laws 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 the Commercial Litigation Branch's Fraud Section, U.S. Attorney's Offices, the Food and Drug Administration, 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. Under a new provision to the U.S. Attorney's Manual, U.S. Attorney's Offices must consult with CPB about investigations under the Federal Food, Drug, and Cosmetic Act (USAM 4-8.200). This requirement enables CPB to provide sample pleadings and tools necessary to prosecute these cases and to provide guidance on the appropriate exercise of prosecutorial

discretion and enforcement authority. During FY 2016, CPB made significant headway in fighting harmful practices that endanger the public health, employing innovative strategies to deter companies and individuals from selling unsafe pharmaceuticals and medical products to the American public.

In partnership with the United States Attorney's Office for the Eastern District of North Carolina, CPB investigated and resolved criminal liabilities with B. Braun Medical Inc. (B. Braun), in connection with its sale of contaminated pre-filled saline flush syringes. On May 18, 2016, B. Braun entered into a non-prosecution agreement requiring the company to implement compliance measures designed to increase oversight of its product suppliers. B. Braun also agreed to pay \$4.8 million in penalties and forfeiture and up to \$3 million in restitution as part of the settlement. The agreement represents an important enforcement step in that it holds a health care company responsible for its role in failing to properly oversee one of its third-party suppliers.

The conduct at issue in the case related to B. Braun's sale of sterile saline syringes it purchased from AM2PAT, Inc. (AM2PAT), despite knowing of AM2PAT's manufacturing problems. In 2007, AM2PAT notified B. Braun of its intentions to move to a new manufacturing facility and to change its sterilization process. B. Braun began selling AM2PAT's saline syringes before B. Braun's quality department approved either of these changes. B. Braun later approved AM2PAT's changes, even though B. Braun had received complaints about syringes changing color and it knew that AM2PAT was making changes to its sterilization process to avoid "overcooking" the syringes. Less than two months later, B. Braun recalled all of the syringes it had bought from AM2PAT because the sterilization process caused dangerous white particles to develop inside the syringes. Nonetheless, B. Braun eventually resumed buying saline syringes from AM2PAT; less than a month afterwards, AM2PAT manufactured saline syringes contaminated with *Serratia Marcescens* bacteria. These contaminated syringes infected patients in California, Texas, New York, and Nebraska.

The non-prosecution agreement with B. Braun includes ground-breaking terms requiring the company to increase oversight of its product suppliers by conducting on-site audits of companies that design and make finished products that bear the B. Braun name. B. Braun agreed to test such products periodically for sterility, identity, and purity. B. Braun will also be monitored by an independent compliance auditor who will assess B. Braun's implementation and maintenance of the enhanced compliance measures through on-site audits of B. Braun. B. Braun's CEO and board of directors will review and certify B. Braun's compliance efforts on an annual basis.

The Consumer Protection Branch further extended its efforts to protect consumers from unsafe products through a nationwide sweep of dietary supplements in November 2015. Conservative estimates put the market for dietary supplements in the United States at over \$20 billion. Regulation of that market is less than robust, and has led to the rampant sale of unlawful products. CPB and its federal partners pursued civil and criminal cases against more than 100 makers and marketers of dietary supplements. The sweep included federal court cases in 18 states against 117 individuals and entities. Of those, 89 were the subject of cases filed since November 2014. As part of the sweep, CPB partnered with the Uniformed Services University of the Health Sciences' Consortium for Health and Military Performance and with the U.S.

Anti-Doping Agency (USADA), who developed educational resources for service members to protect them from risky dietary supplements. Through this partnership, the organizations jointly launched an online interactive educational module and two mobile applications: a high risk supplement list for service members and a mobile application for athletes, both of which are publicly accessible. These resources help service members, athletes, and general consumers recognize and reduce the risks associated with using supplement products. Finally, in March 2016, the Department sought to capitalize on the successful sweep through a public education campaign featuring Attorney General Lynch in a video about supplements filmed as part of National Consumer Education week.

Criminal Division

In FY 2016, the Criminal Division was allocated \$17.6 million in FY 2016 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 employs 56 criminal prosecutors focused solely on initiating and coordinating complex health care fraud prosecutions and supports the USAOs with legal and expert investigative guidance, including the use of data analytics and training, as well as 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 2016, the Fraud Section continued to provide attorney staffing, litigation support, and leadership and management oversight for numerous Strike Force prosecutions in all of the nine regions. The Fraud Section's key litigation accomplishments in FY 2016 can be summarized as follows:

- Filed 146 indictments, informations and complaints involving charges filed against 230 defendants who allegedly collectively billed the Medicare program approximately \$2.1 billion;
- Obtained 131 guilty pleas and litigated 13 jury trials, with guilty verdicts against 18 defendants; and
- Secured imprisonment for 125 defendants sentenced during the fiscal year, averaging more than 53 months of incarceration.

The Fraud Section attorneys staffed and led the Division's health care fraud litigation through the existing Medicare Fraud Strike Force teams in Los Angeles, California; Miami and Tampa, Florida; Chicago, Illinois; Southern Louisiana; Detroit Michigan; Brooklyn, New York; and Dallas and Southern Texas.

In FY 2016, 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 22, 2016, 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 with the cooperation of 36 U.S. Attorneys' Offices and the largest number ever of participating Medicaid Fraud Control Units (MFCUs). This effort resulted in charges against 301 individuals, including 60 doctors, nurses and other licensed medical professionals, for their alleged participation in Medicare and Medicaid fraud schemes involving approximately \$900 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 2016, the Criminal Division formally established a Corporate Health Care Fraud Strike Force based in Washington, D.C. This new Corporate Strike Force has opened several new corporate health care fraud matters, undertaken over a dozen active investigations, and is in active negotiations for corporate resolutions. In addition, this Strike Force is proceeding to build cases to charge responsible individuals within organizations found culpable of health care fraud. The Corporate Strike Force secured its first significant resolution in September 2016. Tenet Healthcare Corporation agreed to a global resolution of criminal and civil liability relating to a kickback scheme at four hospitals in Georgia and South Carolina and will pay a total of \$513 million. Two of the Tenet hospitals pled guilty to conspiring to violate the Anti-Kickback Statute, and a Tenet subsidiary entered into a Non-Prosecution agreement with the Department requiring cooperation with the Department's ongoing investigation and an independent compliance monitor.

In addition to health care fraud litigation, the Fraud Section 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 2016, 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 2016 that was attended by 290 criminal and civil prosecutors (representing over 59 U.S. Attorneys' Offices) and law enforcement personnel. In addition, as part of its efforts to lead and coordinate a national approach to combating health care fraud, in November 2015 the Fraud Section launched the Health Care Fraud Intranet. Through the launch of the HCF Intranet, the

Fraud Section's Health Care Fraud Unit seeks to assist prosecutors in effectively and efficiently identifying and prosecuting individuals and entities, and to learn about emerging trends in the field. As with the National Health Care Fraud Training Conference and national health care fraud takedowns, the HCF Intranet will continue to strengthen the Fraud Section's partnerships with USAOs across the country in combating health care fraud. These combined efforts will better enable USAOs and the Fraud Section to investigate and prosecute fraudulent conduct across district lines, including through corporate health care fraud prosecutions and coordinated multi-district prosecutions.

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 2.3 million private sector health plans sponsored by employers and/or labor organizations which cover some 143 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 2016, six OCGS attorneys were assigned to health care fraud prosecutions and investigations.

In Philadelphia, an OCGS attorney worked with the Organized Crime Strike Force in the United States Attorney's Office to obtain the trial conviction and sentencing of a registered nurse, who served as director of a for-profit hospice service business, for her participation in a scheme to defraud Medicare of more than \$9 million through the submission of false claims for hospice services. The trial evidence showed that the defendant authorized and supervised the admission of inappropriate and ineligible patients for hospice nursing services allegedly provided for patients at nursing homes, hospitals and private residences. This case is summarized above in the Hospice Care section of the Highlights of Successful Criminal and Civil Investigations.

A second OCGS attorney worked with the United States Attorney's Office in Detroit to obtain the conviction of a medical facility employee who obtained and disclosed individually identifiable health information from the facility's private database at the direction of a member of the Traveling Vice Lords (TVL) gang. The employee, an associate of the Vice Lords street gang, pleaded guilty to witness tampering for obtaining private health information of Vice Lords shooting victims and victims' family members and disclosing the information to a member of the TVL gang knowing that this information was wanted to locate these individuals and prevent them from cooperating in the investigation and prosecution of a TVL shooting. This case is summarized above in the Electronic Records section of the Highlights of Successful Criminal and Civil Investigations.

Additional OCGS attorneys were engaged in investigations of health care fraud and abuse including fraud and kickbacks by a service provider in connection with a large employee health benefit plan.

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 2016 the Civil Rights Division was allocated approximately \$5.2 million in FY 2016 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 through the work of several sections. 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 2016 Accomplishments

Key litigation and enforcement accomplishments in FY 2016 by the Civil Rights Division can be summarized as follows:

- Number of matters in active enforcement: 17;
- Cumulative estimate of individuals with disabilities affected: 37,017; and
- Number of institutional facilities affected: 2,251

Special Litigation Section

In Fiscal Year 2016, the Special Litigation Section resolved a Civil Rights of Institutionalized Persons Act case involving a nursing facility; suspended an investigation into a state's mental health system under Title II of the Americans with Disabilities Act when the state issued a plan in which it memorialized the steps it will take over the next three years to help individuals with serious and persistent mental health illness live successfully in community settings; issued findings that a state unnecessarily institutionalizes older adults and adults with disabilities in nursing facilities; monitored compliance of 10 statewide settlement agreements and two facility-focused agreements benefiting thousands of people; monitored an agreement with an urban police department requiring it 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 addressing the risk of unnecessary institutionalization caused by a state's imposition of cost-reimbursement caps on community-based services below the costs of institutional services. During this time, the Section's work – including its formal investigations, monitoring of remedial agreements, and active litigation – affected more than 1,700 health care facilities in 18 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 2016, the Special Litigation Section brought to a successful close one such agreement after years-long enforcement efforts. In Missouri, the Section concluded a three year enforcement effort to ensure that individuals at risk of institutionalization at Maple Lawn Nursing Home and individuals living at Maple Lawn are served in the most integrated setting appropriate to their needs and that those individuals living at Maple Lawn receive necessary care, protections, supports, and services. The parties agreed and stipulated that Maple Lawn had achieved substantial compliance on January 15, 2014 and had remained in substantial compliance at all times to and through January 15, 2016, and therefore the matter was dismissed on April 18, 2016.

The Section continued monitoring implementation of large-scale, systemic reform agreements in numerous jurisdictions across the country. These ongoing enforcement efforts are helping individuals with intellectual, developmental, and mental health disabilities avoid unnecessary institutionalization in New Hampshire, Virginia, Georgia, and Delaware.

In FY 2016, the Section began monitoring Oregon's implementation of a Performance Plan for Mental Health Services for Adults with Serious and Persistent Mental Illness ("Plan"). Oregon developed the Plan in response to the Division's investigation of the state's mental health system under Title II of the Americans with Disabilities Act, which had been pending since 2010. The Plan memorializes steps the State will take over the next three years to help individuals with serious and persistent mental illness live successfully in community settings. An Independent Consultant will assess and issue semi-annual reports on the State's compliance with the Plan. If the State successfully implements the Plan, the Section will close its investigation.

The Section entered a court-enforceable addendum (called an "Extension Settlement Agreement") to its existing 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. The Extension Settlement Agreement memorializes additional commitments the State will undertake to ensure the health and safety of people with intellectual and developmental disabilities in community settings.

In FY 2016, negotiations continued with the State of West Virginia to resolve the Section's findings that West Virginia fails to serve children with mental health conditions in the most integrated setting appropriate to their needs.

Also in FY 2016, the Section continued an investigation into Louisiana's use of nursing facilities to serve people with mental illness opened in FY 2015.

In FY 2016, the Section issued findings in its investigation into South Dakota's use of nursing facilities to serve older adults and people with disabilities. The United States concluded that South Dakota fails to serve older adults and people with disabilities 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 6,300 individuals reside in South Dakota's nursing facilities at any given time, often for long periods unrelated to their age or disability, because of a lack of community-based service options. Negotiations began this fiscal to resolve these issues in a comprehensive agreement.

The Section filed one statement of interest in California regarding whether Plaintiffs are at risk of unnecessarily entering an institution by virtue of Defendants' ad hoc practice regarding cost limitation exceptions.

Disability Rights Section

In FY 2016, the Disability Rights Section received court approval for the settlement of one major, statewide litigation; continued to actively litigate another systemic, statewide case; monitored compliance of four 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 seven-year statewide settlement agreement with the State of Oregon in *Lane v. Brown* (D. Or.), and the United States District Court for the District of Oregon approved the settlement agreement on December 29, 2015. The court then entered a Final Judgment, which incorporated the settlement agreement as an order of the court, on January 27, 2016. The settlement resolves 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, provide employment services to at least 4,900 youth ages 14 to 24, and provide an Individual Plan for Employment to at least half of those youth. The Section is monitoring the State's progress toward the agreement's goals.

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 850 individuals have moved from institutions to community-based settings, while 650 of those individuals continue to live and receive services in the community. The agreement obligates the State to serve 3,000 individuals in community-based settings by July 1, 2020. Over 5,000 people are receiving Assertive Community Treatment services, and over 700 are receiving Supported Employment 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 by 2024, and roughly 3,400 individuals will benefit from systemic changes to the State's employment and day service systems.

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. To date, more than 330 people have moved into the community. Another 1,500 people have expressed interest in and are working toward living and receiving services in the community.

The Section filed two statements of interest in litigation raising issues of needless segregation in Florida and Ohio. 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 three years. The Section has carefully analyzed the legal issues related to unnecessary segregation in the context of K-12 schools.

After completing the first-ever statewide investigation of a State education system for violation of Title II of the ADA based upon unnecessary segregation, the Section issued a Letter of Findings (LOF) on July 15, 2015 against the Georgia Network of Educational and Therapeutic Services (GNETS) program. GNETS provides segregated educational services for approximately 5,000 Georgia students with emotional and behavioral disabilities. During FY 2016, the Department unsuccessfully sought to resolve the LOF with the State during months-long settlement discussions. On August 29, 2016, DOJ filed suit against the State for unnecessarily segregating students with disabilities in isolated GNETS programs at GNETS Centers throughout the State rather than providing community-based behavioral health services for these children.

The Section also coordinated with advocates around the country to review complaints of similar segregation on the basis of disability and, in particular, has developed an investigation plan for pursuing unnecessary segregation in State foster care systems. As part of that investigation, the Section is investigating the role of childhood trauma in segregated placements and the harms to children with disabilities, in particular, from trauma related treatment before and during segregation in school.

The Section also filed a successful statement of interest in litigation raising issues related to segregation of children with disabilities by a school district in New York State, which the court referenced in a favorable ruling issued in spring 2016. EOS also coordinated with other agencies on a similar argument in a Sixth Circuit amicus brief supporting strong enforcement of the Protection and Advocacy for Individuals with Mental Illness Act, the Developmental Disabilities Assistance and Bill of Rights Act, and the Protection of Individual Rights Act (the "P&A Acts"). These briefs addressed issues relating to the unnecessary institutionalization of children in state-run and private, state-funded institutions.

APPENDIX

Federal Bureau of Investigation

In FY 2016, the FBI was allocated \$130.3 million in funding from HIPAA and \$6.0 million from DOJ's HCFAC funds to support the facilitation, coordination and accomplishment of the goals of the HCFAC Program. This yearly appropriation was used to support 814 positions (486 Agent, 328 Support).

In FY 2016, the FBI initiated 624 new Health Care Fraud (HCF) investigations and had 2,822 pending investigations. Investigative efforts produced 637 criminal HCF convictions and 892 indictments and informations. In addition, investigative efforts resulted in over 555 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 128 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 four initiatives, including the Health Care Fraud Prevention and Enforcement Action Team (HEAT), Large Scale Conspiracies, Major Provider Fraud, and Prescription Drug 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 had approximately 101 Agents supporting the nine Strike Forces located in Miami, Detroit, Houston (also includes McAllen, Texas), New York City (Brooklyn), Tampa, Los Angeles, Chicago, Dallas, and Southern Louisiana (Baton Rouge and New Orleans). In addition to funding agent resources, the FBI funded undercover operation expenses, financial and investigative analysis support, offsite and evidence storage locations, operational travel, 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 FBI participated in the June 2016 DOJ National Health Care Fraud Takedown resulting in the charging of 301 subjects, including 61 doctors, nurses and other licensed medical professionals, for their alleged participation in health care fraud schemes involving approximately \$900 million in false billings. 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, Major Provider Fraud, and Prescription Drug 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. 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. Examples of these types of cases were the convictions, following a six-week trial, of a physician and three owners of home health agencies in Texas. Between 2006 through 2011, the doctor approved and certified in excess of 11,000 Medicare beneficiaries, who were not home bound, for home health care services. The conspiracy resulted in the

submission of nearly \$375 million in fraudulent claims. In Houston, a psychiatrist was sentenced to 144 months in prison for her role in a \$158 million Medicare fraud scheme involving false claims for mental health treatment. In Miami, a physician was sentenced to 108 months in prison for his role in a \$30 million health fraud scheme involving home health care and other services that were either not medically necessary or never provided. 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 includes the investigation of Novartis Pharmaceuticals Corporation, which resulted in a \$390 million civil settlement 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 Prescription Drug Initiative seeks to identify and target criminal enterprises and other groups or individuals engaged in prescription drug schemes, and where appropriate prosecute improper prescribing and dispensing practices of controlled substances. These schemes are a significant crime problem and impact public health and safety. Examples of these types of cases are a Philadelphia doctor convicted at trial of running a pill mill and causing a death through illegal distribution of controlled substances, including oxycodone, methadone, and amphetamines. And a Kentucky Anesthesiologist was sentenced to 100 months in prison for his role in the unlawful distribution of controlled substances, health care fraud, conspiracy and money laundering.

The FBI actively provides training and guidance on HCF matters and 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 Agents 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 2016, more than 229 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 814 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 86).
- 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 2016, 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 2016
Office of Inspector General	\$187,616,623
Health and Human Services Wedge ²	35,883,926
Medicare Integrity Program ³	866,475,419
<i>MIP/Medicare (non-add)</i>	799,823,463
<i>Medi-Medi (non-add)</i>	66,651,955
Department of Justice Wedge ²	58,579,074
Federal Bureau of Investigation ⁴	130,303,282
Subtotal, Mandatory HCFAC	\$1,278,858,324
Discretionary Resources	
Office of Inspector General	\$67,200,000
CMS Program Integrity	553,320,000
<i>Medicare Program Integrity (Non-Add)</i>	468,120,000
<i>Medicaid Program Integrity (Non-Add)⁵</i>	67,200,000
<i>Senior Medicare Patrols (ACL Non-Add)⁶</i>	18,000,000
Department of Justice	60,480,000
Subtotal, Discretionary HCFAC	\$681,000,000
Grand Total, HCFAC	\$1,959,858,324

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 are not part of this report to Congress. A separate report to Congress addresses 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.

⁶ The Consolidated Appropriations Act of 2016 requires that the full cost of the Senior Medicare Patrol funding be supported by discretionary HCFAC funds.

Glossary of Terms

The Account—The Health Care Fraud and Abuse Control Account

ACA — Affordable Care Act

AKS— Anti-Kickback Statute

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

FFDCA—Federal Food, Drug, and Cosmetic Act

FWA—Fraud, Waste, and Abuse

FY—Fiscal Year

HCFA—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—Payment 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