

**The Department of Health and Human Services  
And  
The Department of Justice  
Health Care Fraud and Abuse Control Program  
Annual Report for Fiscal Year 2017**

**April 2018**



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**GENERAL NOTE**

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



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## EXECUTIVE SUMMARY

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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)<sup>1</sup>, 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 twenty-first 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) 2017, the Federal Government won or negotiated over \$2.4 billion in health care fraud judgments and settlements<sup>2</sup>, 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 2017 \$2.6 billion was returned to the Federal Government or paid to private persons. Of this \$2.6 billion, the Medicare Trust Funds<sup>3</sup> received transfers of approximately \$1.4 billion during this period, and \$406.7 million in Federal Medicaid money was similarly transferred separately to the Treasury as a result of these efforts.

### **Enforcement Actions**

In FY 2017, the Department of Justice (DOJ) opened 967 new criminal health care fraud investigations. Federal prosecutors filed criminal charges in 439 cases involving 720 defendants. A total of 639 defendants were convicted of health care fraud-related crimes during the year. Also in FY 2017, DOJ opened 948 new civil health care fraud investigations and had 1,086 civil health care fraud matters pending at the end of the fiscal year. In FY 2017, the FBI investigative efforts resulted in over 674 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 148 health care fraud criminal enterprises.

In FY 2017, investigations conducted by HHS' Office of Inspector General (HHS-OIG) resulted in 788 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid, and 818 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 3,244 individuals 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 (1,281) or to other health care programs (309), for patient abuse or neglect (266), and

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<sup>1</sup> Hereafter, referred to as the Secretary.

<sup>2</sup> 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.

<sup>3</sup> 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.

as a result of licensure revocations (973). 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 2017, 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 \$20.7 million was sequestered from the HCFAC program in FY 2017, for a combined total of \$115.5 million in the past five years. Including funds sequestered from the FBI and the FY 2013 discretionary HCFAC sequester, the total equals \$161.7 million in the past five years.

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## STATUTORY BACKGROUND

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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 2017 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.<sup>4</sup> 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 2017, the Secretary and the Attorney General certified \$279.5 million in mandatory funding to the Account after accounting for sequester reductions of \$20.7 million to the total appropriation. Additionally, Congress appropriated \$725.0 million in discretionary funding. A detailed breakdown of the allocation of these funds is set forth later in this report. HCFAC appropriations generally supplement the direct appropriations of HHS that are devoted to health care fraud enforcement and have supported over two-thirds of DOJ’s health care fraud funding and over three-fourths of HHS-OIG’s appropriated budget in FY 2017. (Separately, the FBI, which is discussed in the appendix, received \$131.3 million from HIPAA, after accounting for \$9.7 million in mandatory sequester reductions.) Under the joint direction of the Attorney General and the Secretary, the Program’s goals are:

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<sup>4</sup> 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.

Additionally, the Act requires the Attorney General and the Secretary to submit a joint annual report to the Congress that identifies both:

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

This annual report fulfills the above statutory requirements.

Additionally, this report fulfills the requirement in the annual discretionary HCFAC appropriation (Public Law 115-30“Consolidated Appropriations Act, 2017”) 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 2017, \$2.6 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:

<b>Monetary Results: Total Transfers / Deposits by Recipient FY 2017</b>	
<b>Department of the Treasury</b>	
Deposits to the Medicare Trust Fund, as required by HIPAA:	
Gifts and Bequests	\$5
Amount Equal to Criminal Fines	12,045,515
Civil Monetary Penalties	46,447,392
Asset Forfeiture	35,481,573
Penalties and Multiple Damages	446,282,175
<b>Subtotal</b>	<b>540,256,660</b>
<b>Centers for Medicare and Medicaid Services</b>	
HHS/OIG Audit Disallowances: Recovered–Medicare	365,168,853
Restitution/Compensatory Damages*	490,881,373
<b>Subtotal</b>	<b>856,050,226</b>
<b>Total Transferred to the Medicare Trust Funds</b>	<b>\$1,396,306,886</b>
<b>Restitution/Compensatory Damages to Federal Agencies</b>	
TRICARE	\$20,419,906
HHS/OIG	9,806,538
Office of Personnel Management	2,624,783
National Institutes of Health	6,620,321
Other Agencies	105,120,657
<b>Subtotal</b>	<b>144,592,205</b>
<b>Centers for Medicare and Medicaid Services</b>	
Federal Share of Medicaid	406,712,923
HHS/OIG Audit Disallowances: Recovered–Medicaid	350,147,845
<b>Subtotal</b>	<b>756,860,768</b>
<b>Total</b>	<b>\$901,452,973</b>
<b>Relators' Payments**</b>	<b>\$262,095,000</b>
<b>GRAND TOTAL MONETARY RESULTS***</b>	<b>\$2,559,854,859</b>

\*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 twenty-first year of operation, the Secretary and the Attorney General certified \$279.5 million in mandatory funding as necessary for the Program, after accounting for mandatory sequester reductions of \$20.7 million as required by law. Additionally, Congress appropriated \$725 million in discretionary funding. See allocation by recipient below:

<b>FY 2017 ALLOCATION OF HCFAC APPROPRIATION</b>				
<b>Organization</b>	<b>Mandatory Allocation<sup>5</sup></b>	<b>Discretionary Allocation</b>	<b>Funds Sequestered</b>	<b>Total Allocation</b>
<b>Department of Health and Human Services</b>				
Office of Inspector General <sup>6</sup>	\$205,684,560	\$82,132,000	(\$13,778,235)	\$274,038,325
Office of the General Counsel	7,000,000	0	0	7,000,000
Administration for Community Living <sup>7</sup>	0	18,000,000	0	18,000,000
Food and Drug Administration	4,371,000	0	0	4,371,000
Centers for Medicare & Medicaid Services	18,185,811	551,068,000	0	569,253,811
Unallocated Funding	2,635,252	0	(2,635,252)	0
<b>Subtotal</b>	<b>\$237,876,623</b>	<b>\$651,200,000</b>	<b>(\$16,413,487)</b>	<b>\$872,663,136</b>
<b>Department of Justice</b>				
United States Attorneys	\$39,584,043	\$31,967,412	\$0	\$71,551,455
Civil Division <sup>8</sup>	15,269,382	8,877,333	0	24,146,715
Criminal Division	1,418,888	21,046,144	0	22,465,032
Civil Rights Division	1,372,760	7,653,312	0	9,026,072
Justice Management Division	400,000	0	0	400,000
Federal Bureau of Investigation	0	4,255,799	0	4,255,799
Unallocated Funding	4,301,944	0	(4,301,944)	0
<b>Subtotal</b>	<b>\$62,347,017</b>	<b>\$73,800,000</b>	<b>(\$4,301,944)</b>	<b>\$131,845,073</b>
<b>TOTAL<sup>9</sup></b>	<b>\$300,223,640</b>	<b>\$725,000,000</b>	<b>(\$20,715,431)</b>	<b>\$1,004,508,209</b>

## Overall Recoveries

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

<sup>6</sup> In addition, HHS-OIG obligated \$9.7 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).

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

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

<sup>9</sup> 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.

During this fiscal year, the Federal Government won or negotiated over \$2.4 billion in judgments and settlements, and attained additional administrative impositions in health care fraud cases and proceedings. As a result of these efforts, as well as those of preceding years, approximately \$2.6 billion was returned to the Federal Government or private persons. Of this \$2.6 billion, the Medicare Trust Funds received transfers of approximately \$1.4 billion during this period; and another \$406.7 million in Federal Medicaid money was transferred to the Treasury separately as a result of these efforts.<sup>10</sup>

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 (2015-2017) is \$4.20 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. With the creation of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) effort, DOJ and HHS pledged a commitment to prevent and prosecute health care fraud. These teams are comprised of top level law enforcement agents, prosecutors, attorneys, auditors, evaluators, and other staff from DOJ and HHS and their operating divisions, and are 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.
- **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.

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<sup>10</sup> Note that some of the judgments, settlements, and administrative actions that occurred in FY 2017 will result in transfers in future years, just as some of the transfers in FY 2017 are attributable to actions from prior years.

Since its creation, 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 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 Health Care Fraud training program designed to teach the Strike Force concept and case model to prosecutors, law enforcement agents, and administrative support teams. In FY 2017, prescription opioid fraud and abuse training was also provided to the USAO community.

## **Healthcare Fraud Prevention Partnership (HFPP)**

The Healthcare Fraud Prevention Partnership (HFPP) is CMS's groundbreaking voluntary public/private partnership between the Federal Government, State agencies, law enforcement, private health insurance plans, employer organizations, 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 85 public, private and state partner organizations by the end of FY 2017. During FY 2017, the HFPP completed a number of studies using multiple partner data to address fraud, waste and abuse.

In FY 2017, the Partnership also hosted its Annual 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 2017 include<sup>11</sup>:

- Filed 253 indictments, informations and complaints involving charges filed against 478 defendants who allegedly billed federal health care programs more than \$2.3 billion;
- Obtained 290 guilty pleas negotiated and 33 jury trials litigated, with guilty verdicts against 40 defendants; and
- Secured imprisonment for 305 defendants sentenced, averaging more than 50 months of incarceration.

Since its inception, Strike Force prosecutors filed more than 1,660 cases charging more than 3,490 defendants who collectively billed the Medicare program approximately \$13 billion; 2,331 defendants pleaded guilty and 315 others were convicted in jury trials; and 2,117 defendants were sentenced to imprisonment for an average term of approximately 50 months.<sup>12</sup> Medicare payment trends demonstrate the positive impact of Strike Force enforcement and prevention efforts.

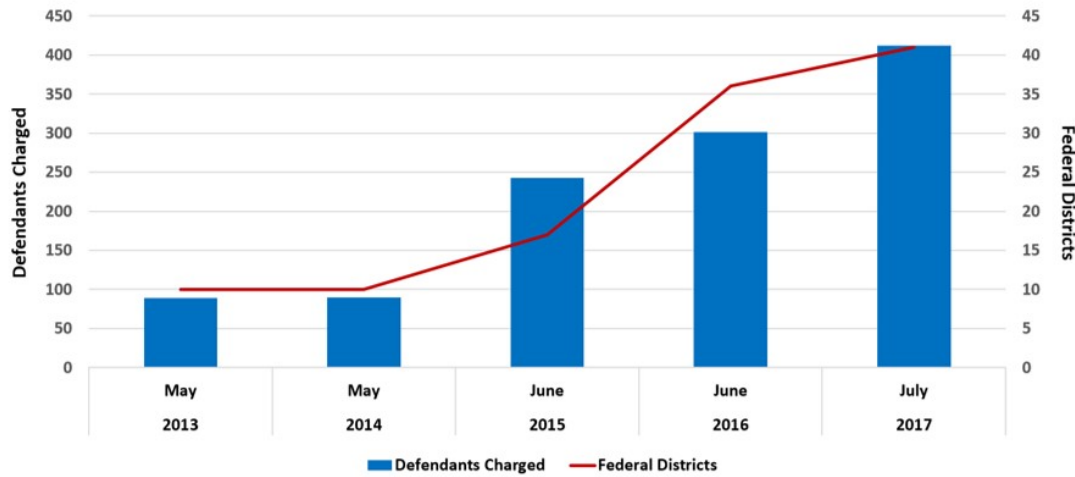
Increased USAO outreach by the Strike Force partners is another positive measure that reflects the overall impact of the HCFAC program. This year, the Criminal Division's Fraud Section hosted its largest ever National Health Care Fraud Training Conference, which was attended by over 310 prosecutors and law enforcement agents, including 130 AUSAs representing almost 60 USAOs. The Fraud Section's Health Care Fraud Data Analytics Team and HHS-OIG's Consolidated Data Analysis Center have supported investigations, led trainings, and conducted analyses in over 35 districts, including the 12 districts selected for the Attorney General's Opioid Fraud and Abuse Detection Unit initiative. In addition, the 2017 National Health Care Fraud Takedown involved 412 charged defendants across 41 federal districts with an estimated loss to federal health care programs of \$1.3 billion, including 115 doctors, nurses, and other licensed medical professionals. The following chart shows the national health care fraud takedown trends from FY 2013 to FY 2017.

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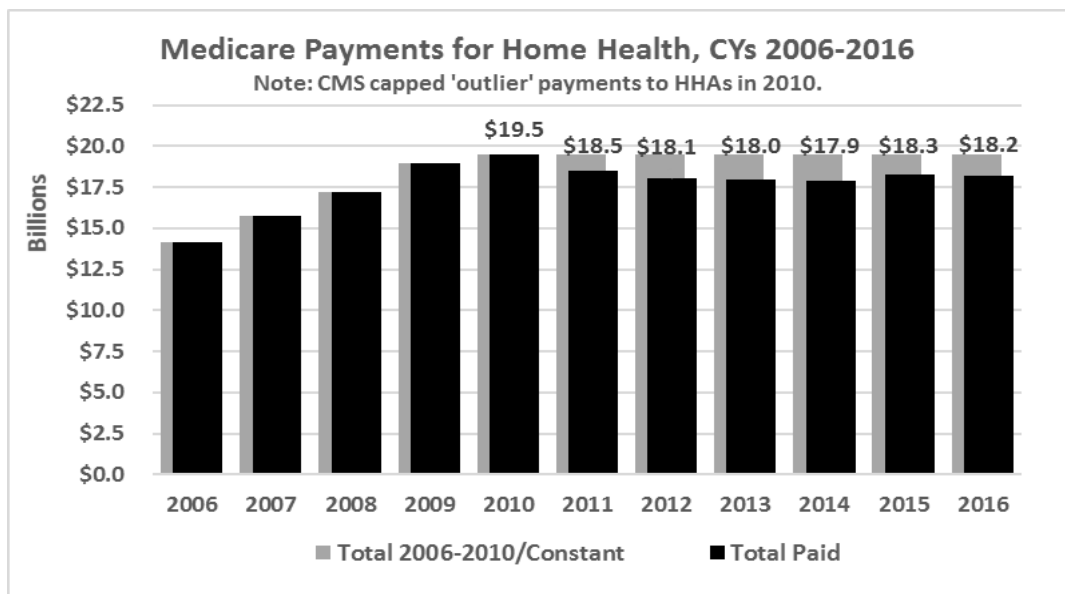
<sup>11</sup> The accomplishments figures presented in the bullets include all reported Strike Force cases handled by DOJ Criminal Division attorneys and AUSAs in the respective USAOs during FY 2017.

<sup>12</sup> These statistics are for the period of May 7, 2007 through September 30, 2017.

### National Health Care Fraud Takedown Trends FY 2013 - FY2017



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 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.



## **Opioid Fraud and Abuse Detection Unit**

In August FY 2017, the Attorney General announced the formation of the Opioid Fraud and Abuse Detection Unit, a new Department of Justice pilot program that utilizes data to help combat the devastating opioid crisis that is ravaging families and communities across America. This unit will focus specifically on opioid-related health care fraud using data to identify and prosecute individuals that are contributing to this prescription opioid epidemic.

As part of the program, the Department is committed to funding 12 experienced AUSAs for a three-year term who will work with dedicated HHS-OIG, FBI, and DEA investigators to focus solely on investigating and prosecuting health care fraud related to prescription opioids, including pill mill schemes and pharmacies that unlawfully divert or dispense prescription opioids for illegitimate purposes. The following districts have been identified for participation in the program: Middle District of Florida, Eastern District of Michigan, Northern District of Alabama, Eastern District of Tennessee, District of Nevada, Eastern District of Kentucky, District of Maryland, Western District of Pennsylvania, Southern District of Ohio, Eastern District of California, Middle District of North Carolina, and Southern District of West Virginia.



## Highlights of Significant 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 January 2017, a previously excluded provider, was sentenced in New Jersey to 18 years in prison for, among other things, his illegal operation of an ambulance company that billed Medicare and Medicaid. In 2004, the defendant was excluded from participating in Medicare or Medicaid for a minimum of 11 years as a result of a state conviction for Medicaid fraud. From at least 2005-2014 and in violation of the exclusion, the defendant operated K&S Invalid Coach in his brother's name. During this time, Medicare and Medicaid paid over \$9 million in claims to K&S. The defendant also engaged in tax evasion, paying numerous employees' salaries and all employees overtime "off the books." In response to a Department of Labor audit in 2014, the defendant instructed all of the company's employees to lie to the Department of Labor about the number of hours they worked and instructed certain employees to falsify timekeeping records to match false reports that had been made to the company's payroll accountant. Following a bench trial, during which the defendant attempted to influence a government witness, he was convicted of all 17 counts of the indictment charging him with health care fraud, obstructing a federal audit, tax evasion, and money laundering. The defendant was also ordered to pay \$8.8 million in restitution.

In January 2017, Medstar Ambulance, Inc. and its two owners agreed to pay \$12.7 million to resolve allegations in the District of Massachusetts that from January 2011 through October 2014, Medstar submitted false claims to Medicare for ambulance transport services. Specifically, the United States alleged that Medstar routinely billed for services that did not qualify for reimbursement because the transports were not medically reasonable and necessary, billed for higher levels of services than were required by patients' conditions, and billed for higher levels of services than were actually provided. As part of the settlement agreement, Medstar agreed to enter into a 5-year Corporate Integrity Agreement (CIA) with HHS-OIG.

In April 2017, the owners of an ambulance company were sentenced to 5 years and 3 months and 4 years and 9 months in prison, respectively, and ordered to pay more than \$2.3 million in restitution in the Southern District of Texas. The defendants owned and operated KMD Healthcare Services Inc. (KMD) from their home in a gated townhouse community in Houston. As part of their guilty pleas, the pair admitted they submitted approximately \$6 million in false and fraudulent claims to Medicare, Medicaid and Tricare (another government health program) for ambulance services that were not provided. The defendants admitted they transported Medicare beneficiaries with only one of the two required emergency medical technicians and in vans instead of ambulances. They also admitted they paid a Houston physician \$500 for certificates of medical necessity and paid some of the Medicare beneficiaries to ride in the vans.

In September 2017, the owner of Triumph Ambulance Inc. pled guilty to 12 counts of health care

fraud and was sentenced to 3 years confinement and ordered to pay \$690,390 in restitution. The owner had engaged in a scheme to defraud Medicare. Specifically, Triumph Ambulance employees, at the direction of the owner, transported Medicare beneficiaries by ambulance or in personally-owned vehicles to regularly-scheduled dialysis treatments. These patients were not medically eligible for ambulance transportation reimbursed by Medicare. The owner submitted false claims to Medicare for reimbursement and also provided kickbacks to Medicare beneficiaries.

## **Clinics**

*(SF)* In January and February 2017, 4 defendants pled guilty to various charges, including 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. From 2008 through 2011, the defendants and others executed a scheme in which patients were paid cash kickbacks to present themselves for treatment at various Brooklyn-area clinics. The patients received medically unnecessary services that were later falsely billed to Medicare and Medicaid as genuine physical and occupational therapy treatments. 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 on those claims. Together with these defendants, over 20 individuals have pleaded guilty to various charges in this case for their participation in the schemes perpetrated through these and other clinics.

In February 2017, an Alabama physician was sentenced to 15 years in prison for illegally prescribing controlled substances and conducting health care fraud involving \$9.5 million in unneeded and unused urine tests. The defendant was a pain management doctor who operated a pill mill, Chronic Pain Care Services. In 2012, about 80 to 145 patients a day visited his clinic, with him seeing the majority of patients and writing all prescriptions. According to court documents, initial patient visits typically lasted five minutes or less, and follow-ups two minutes or less.

*(SF)* In March 2017, an owner of several physical and occupational therapy clinics in the Central District of California was sentenced to 5 years and 3 months in prison after pleading guilty to health care fraud conspiracy. He was also ordered to pay more than \$2.4 million in restitution to Medicare. At the clinic at the center of the case, the defendant hid his ownership in the name of a co-conspirator and instructed therapists and others to bill Medicare for physical and occupational therapy services that were medically unnecessary and not provided. The defendant also directed his co-conspirators to fabricate patient files to make it appear as if the services billed to Medicare had been rendered and were medically necessary. In January 2016, the same defendant was sentenced to 10 years and 1 month in prison and ordered to pay \$3 million in restitution for his trial conviction on 19 counts related to other clinics where the defendant directed billing to Medicare for physical therapy services that were medically unnecessary and never provided.

In May 2017, two doctors were sentenced to 20 years and 21 years, respectively, for running a massive pill mill in Mobile, Alabama. The two doctors had jointly owned and operated two pain management clinics under the name Physicians Pain Specialists of Alabama (“PPSA”) as well as

C&R Pharmacy. Of particular importance in the trial were two brand name instant-release fentanyl drugs — Subsys and Abstral. Both doctors almost exclusively prescribed these drugs off-label, and the jury found that the doctors received illegal kickbacks from Insys Therapeutics, the manufacturer of Subsys, in exchange for the defendants prescribing massive quantities of this drug. The doctors also purchased approximately \$1.6 million worth of stock in Galena Biopharma, the manufacturer of Abstral, and sought to manipulate the stock price by driving up Abstral sales.

*(SF)* In June 2017, the owner and medical director of 4 Orlando-area clinics were sentenced to 7 years and 6 months and 5 years and 4 months in prison, respectively, and ordered to pay \$9.8 million in restitution after pleading guilty to conspiracy to commit health care fraud. The owner admitted to billing Medicare more than \$13 million for services that were never provided. Among other fraudulent billings, the owner billed Medicare over \$7 million in claims for Sandostatin, an expensive medication used to treat side effects of intestinal tumors, and over \$4.5 million in claims for Intravenous Immune Globulin, a solution made from human plasma that contains antibodies and is used to help individuals with immune deficiencies combat infection. In reality, the clinics never administered either drug. The medical director admitted to accepting money in exchange for signing medical records authorizing administration of the drugs even though they were not medically necessary and were never provided. He further admitted to signing medical records authorizing patients to receive physical therapy at the clinics, even though the clinics had no trained physical therapists on staff. The government obtained through forfeiture real property that was purchased with the fraud proceeds and valued at more than \$1 million.

*(SF)* In July 2017, a grand jury sitting in the Eastern District of New York returned a 2-count indictment against 5 high-billing medical professionals who worked at a network of Brooklyn-area clinics where patients were paid illegal kickbacks in return for subjecting themselves to purported physical and occupational therapy, diagnostic testing, and other medical services. The defendants—a medical doctor, a physical therapist, a chiropractor, and 2 occupational therapists—paid recruiters and others in return for the referral of patients to their clinics, which submitted fraudulent claims to Medicare for approximately \$100 million.

In July 2017, 8 defendants were charged in the Eastern District of Tennessee with drug trafficking, money laundering, and anti-kickback violations in connection with the operation of pain clinics and/or prescription of vast quantities of opioids outside the scope of professional practice without legitimate medical purposes. The clinics generated revenues in excess of \$21 million and were responsible for prescriptions totaling approximately 12 million opioid pills and other narcotics. Two defendants were also charged with operating kickback schemes with national reference laboratories, which resulted in approximately \$13.6 million billed to Medicare for medically unnecessary services.

## **Dental**

In December, 2016, Texas-based MB2 Dental Solutions and 21 pediatric dental practices affiliated with MB2, along with their owners and marketing chief, agreed to pay \$4.2 million to

settle federal civil FCA allegations that they submitted or caused the submission of false claims for pediatric dental services that were not rendered, were tainted by kickbacks, or falsely identified the person who performed the service. In addition to the federal recovery, MB2 and the associated practices and owners paid \$4.2 million to resolve state Medicaid liability for the same alleged conduct. As part of the settlement agreement, MB2 Dental Solutions agreed to enter into a 5-year CIA with HHS-OIG.

In June, 2017, a Fruitland, Idaho woman was sentenced to 5 years in prison to be followed by 3 years of supervised released for health care fraud and aggravated identity theft. Evidence at trial demonstrated that between January 2010 and December 2013, the defendant executed a scheme to defraud health care benefit programs, including Medicaid. Even though the defendant was only a dental hygienist, she performed and billed for dental treatments that may only be performed by a dentist. These treatments included fillings, extractions, and dentures. The defendant also billed for dental hygiene services performed without the supervision and direction of a dentist, contrary to state law and licensing requirements. The defendant received payment for those treatments from health care benefit programs while fraudulently misrepresenting that the treatments had been performed, and supervised, by a dentist, and while using the name and provider number of a particular dentist who was not in the office and who was unable to practice at the time due to disability.

### **Device Companies**

In November 2016, Pennsylvania-based Biocompatibles Inc. pleaded guilty to misbranding its embolic device LC Bead in violation of the Federal Food, Drug and Cosmetic Act. As part of the criminal resolution, Biocompatibles agreed to pay a total of \$11 million in criminal fines and forfeiture. LC Bead was cleared by the FDA as an embolization device that can be placed in blood vessels to block or reduce blood flow to certain types of tumors and arteriovenous malformations. The government alleged that Biocompatibles marketed LC Bead for drug delivery despite the fact that it has been never been cleared or approved by the FDA for use as a combination product or drug-delivery device. Biocompatibles also paid \$23.6 million to resolve federal civil FCA allegations that the company caused false claims to be submitted to government health care programs for procedures in which LC Bead was loaded with chemotherapy drugs and used as a drug-delivery device. In addition to the federal recovery, Biocompatibles paid approximately \$1.4 million to resolve state Medicaid liability.

In January 2017, Shire Pharmaceuticals LLC and other subsidiaries of Shire, which is headquartered in Ireland with operational headquarters in Lexington, Massachusetts, agreed to pay approximately \$343.9 million to settle federal civil FCA allegations that Shire and the company it acquired in 2011, Advanced BioHealing (ABH), employed kickbacks and other unlawful methods to induce clinics and physicians to use or overuse its Dermagraft product, which is a bioengineered human skin substitute approved by the FDA for the treatment of diabetic foot ulcers. The government alleged that Dermagraft salespersons unlawfully induced clinics and physicians with lavish dinners, drinks, entertainment and travel; medical equipment and supplies; unwarranted payments for purported speaking engagements and bogus case studies; and cash, credits and rebates, to induce the use of Dermagraft in violation of the Anti-Kickback Statute, the Anti-Bribery Statute, and the Federal Acquisition Regulations. In addition to the kickback allegations, the government further alleged that Shire and its predecessor ABH

unlawfully marketed Dermagraft for uses not approved by the FDA, made false statements to inflate the price of Dermagraft, and caused improper coding, verification, or certification of Dermagraft claims and related services. The settlement is the largest FCA recovery in a kickback case involving a medical device. In addition to the federal recovery, Shire paid \$6.1 million to resolve state Medicaid liability. The related criminal investigation resulted in guilty pleas of three ABH executives and two physicians in the Middle District of Florida.

In March 2017, two salesmen who admitted they bought expired and nearly expired weight loss gastric bands, which doctors later surgically implanted into patients in southern Florida, were sentenced to 1 year and 6 months and 7 months in prison, respectively. Between June 2014 and October 2015, the defendants, both senior account executives for Apollo Endosurgery, Inc., engaged in a scheme to unlawfully enrich themselves by misbranding LAP-BAND Adjustable Gastric Banding Systems, changing the serial number and expiration date in order to sell expired medical devices for profit. The defendants purchased expired and nearly expired LAP-BANDS through the internet and created false labels with fraudulent serial numbers and expiration dates to hide the true expiration date of the LAP-BANDS. They then sold the misbranded LAP-BANDS to local physicians. At least seven of these misbranded LAP-BANDS were subsequently implanted into patients.

### **Diagnostic Services**

In November 2016, New York-based Zwanger & Pesiri Radiology Group, LLP, Zwanger Radiology, P.C., and one provider (collectively, “defendants”) entered into a settlement agreement to resolve allegations that between July 2009 and February 2014 they billed Medicare and Medicaid for radiology testing performed or supervised by physicians who were not properly credentialed with Medicare and Medicaid programs, or which were performed at an unauthorized practice location. The defendants agreed to pay \$8.1 million to resolve their federal and state civil FCA liability. Contemporaneously with the civil settlement, Zwanger-Pesiri pleaded guilty to two counts of health care fraud for illegally performing and billing for procedures that had not been ordered by treating physicians and agreed to forfeit an additional \$2.4 million. As part of the settlement agreement, defendants agreed to enter into a 5-year CIA with HHS-OIG.

In January 2017, seven individuals were sentenced to varying prison terms in the Southern District of Texas in connection with a scheme involving fraudulent billing for diagnostic testing done at three different clinics from September 2008 to May 2010. Patients were paid to come to the clinics and the clinics then billed for tests that were either not performed or not medically necessary. Patients were brought to the clinics by recruiters/marketers who were paid for each patient they delivered.

In April 2017, Valley Tumor Medical Group (Valley Tumor) in California paid \$3 million to resolve federal FCA allegations that from January 2006 through November 2015, it billed Medicare, Medi-Cal (California’s Medicaid program), and TRICARE for radiation treatments at the Ridgecrest location without the requisite physician supervision. Specifically, radiation therapists employed by Valley Tumor allegedly regularly administered radiation treatments when no doctor was present on-site and, thus, physically available to supervise such treatments.

In May 2017, Poplar Healthcare PLLC and Poplar Healthcare Management LLC of Memphis, TN, agreed to pay nearly \$900,000 to resolve civil FCA allegations that Poplar, directly and through a subsidiary known as GI Pathology, promoted and billed the government for diagnostic tests that the government contends were not medically necessary. The HHS-OIG and the United States Attorney's Office for the District of Rhode Island investigated Poplar's promotion of these tests, known as immunohistochemical mast cell tryptase stains, and alleged that Poplar conducted an extensive, multi-year promotional campaign designed to promote the use of the stain with the claim that Poplar could use the test to definitively diagnose a condition known as "mast cell enterocolitis." The United States further alleged that Poplar's promotion of the test was not consistent with FDA approval requirements and not supported by adequate scientific evidence.

In June 2017, AMI Monitoring Inc., also known as Spectocor, Spectocor's owner, Medi-Lynx Cardiac Monitoring LLC, and Medicalgorithmics SA agreed to pay approximately \$13.5 million to resolve civil FCA allegations that they billed Medicare for higher and more expensive levels of cardiac monitoring services than requested by the ordering physicians. The government alleged that Spectocor and its owner, and later Medi-Lynx, marketed the Pocket ECG as capable of performing three separate types of cardiac monitoring services. When a physician sought to enroll a patient for Pocket ECG, however, the enrollment process allegedly only allowed the physician to enroll in Pocket ECG for the service, which provided the highest rate of reimbursement provided by a patient's insurance, thus steering the ordering physician to a more costly level of service. As part of the settlement, the owner of AMI and Spectocor agreed individually to pay \$1 million.

## **Drug Companies**

In December 2016, Forest Laboratories LLC, located in New York and Forest Pharmaceuticals Inc. agreed to pay \$35.5 million to settle federal civil FCA allegations that Forest paid kickbacks in violation of the Anti-Kickback Statute to induce prescriptions of the drugs Bystolic, Savella, and Nameda. The government alleged that Forest employed speaker program payments and meals as improper inducements; Forest allegedly provided these benefits even when the speaker programs were cancelled, no licensed health care professionals attended the programs, the same attendees had attended multiple programs over a short period of time, or the meals associated with the programs exceeded Forest's internal cost limitations. In addition to the federal recovery, Forest paid \$2.5 million to resolve state Medicaid liability.

In July 2017, drug manufacturer Celgene Corp. agreed to pay approximately \$259.3 million to settle federal civil FCA allegations that it caused the submission of false claims to federal health care programs for non-covered uses for two drugs manufactured by Celgene. The settlement resolved claims that Celgene promoted two cancer treatment drugs, Thalomid and Revlimid, for uses that were not approved by the FDA and not covered by federal health care programs. The settlement also resolved claims that Celgene used false and misleading statements in promoting the drugs and that Celgene paid kickbacks in violation of the Anti-Kickback Statute to induce physicians to prescribe the drugs. In addition to the federal recovery, Celgene paid approximately \$20.7 million to resolve state Medicaid liability.

Also in July 2017, Novo Nordisk Inc., headquartered in Plainsboro, New Jersey, paid a

disbursement of approximately \$12.2 million to settle allegations under the Federal Food, Drug, and Cosmetic Act that it failed to comply with the FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) for its Type II diabetes drug Victoza. At the time of Victoza's approval, the FDA required a REMS to mitigate the potential risk in humans of a rare form of cancer called Medullary Thyroid Carcinoma associated with the drug. The REMS required Novo Nordisk to provide information to physicians regarding Victoza's potential risk. A manufacturer that fails to comply with the requirements of the REMS, including requirements to communicate accurate risk information, renders the drug misbranded under the law. The government alleged that some Novo Nordisk sales representatives gave information to physicians that created the false or misleading impression that the Victoza REMS-required message was erroneous, irrelevant, or unimportant. Novo Nordisk also paid approximately \$43.1 million to settle federal civil FCA allegations that Novo Nordisk promoted Victoza with false and misleading messages regarding the importance of the REMS-required information and promoted the use of Victoza for uses not covered by federal health care programs. In addition to the federal recovery, Novo Nordisk paid approximately \$3.3 million to resolve state Medicaid liability.

In August 2017, drug manufacturers Mylan Inc. and Mylan Specialty L.P., headquartered in Canonsburg, Pennsylvania, agreed to pay approximately \$231.7 million to settle federal civil FCA allegations that Mylan underpaid rebates owed under the Medicaid Drug Rebate Program (MDRP) and caused the submission of false claims to Medicaid. The government alleged that Mylan erroneously classified its patented, brand name drug EpiPen, which has no therapeutic equivalents or generic competition, as a generic drug to Medicaid while significantly increasing its price, thereby avoiding its obligation to pay higher rebates for EpiPen and its price increase. Between 2010 and 2016, Mylan allegedly increased the price of EpiPen by approximately 400 percent yet paid only a fixed 13 percent rebate to Medicaid during the same period. The government further alleged that while Mylan claimed generic treatment for Medicaid purposes, it advocated the drug as a unique brand product elsewhere – including before the FDA. In addition to the federal recovery, Mylan also paid \$213.9 million to resolve state Medicaid liability. As part of the settlement agreement, Mylan agreed to enter into a 5-year CIA with HHS-OIG.

### **Durable Medical Equipment (DME)**

In March 2017, Braden Partners, L.P., doing business as Pacific Pulmonary Services, agreed to pay \$11.4 million to resolve allegations against it and its general partner, Teijin Pharma USA LLC, that they violated the civil FCA. California-based Pacific Pulmonary Services furnishes stationary and portable oxygen tanks and related supplies, and sleep therapy equipment, such as continuous positive airway pressure and bi-level positive airway pressure masks and related supplies, to patients' homes in California and other states. The United States alleged that beginning in about 2004, Pacific Pulmonary Services began submitting claims for home oxygen and oxygen equipment without obtaining a physician evaluation and authorization, as required by program rules. Further, beginning in 2006, certain of the company's patient care coordinators also allegedly agreed to make patient referrals to sleep testing clinics in exchange for those clinics' agreement to refer patients to Pacific Pulmonary Services for sleep therapy equipment in violation of the Anti-Kickback Statute. As part of the settlement agreement, Pacific Pulmonary Services agreed to enter into a 5-year CIA with HHS-OIG.

In May 2017, three individuals were sentenced in South Carolina for conspiracy to commit mail fraud. In 2010, when Moore merged with Providence Hospital, the director of Orthopedic Services for Moore Orthopedic Clinic established a fake DME company, Creative Casting Concepts (CCC). The director then submitted false invoices to Moore and Providence, representing that CCC was providing orthopedic boots when they were not. The director recruited an accomplice to put their name on CCC in order to keep Moore from learning of the director's connection. The accomplice helped manage a bank account and post office box. In 2015, upon the original director's retirement, the new director of Moore agreed to continue to submit fake invoices. All three defendants—the two directors and the accomplice—pled guilty and were sentenced to incarceration or probation, and restitution and forfeiture of \$2.8 million also was ordered.

### **Electronic Health Records**

In January 2017, an associate of the Vice Lords street gang was sentenced in the Eastern District of Michigan to 48 months in prison for witness tampering by obtaining and disclosing the private health information of 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 his brother and fellow gang member, and while employed at the medical facility, the defendant accessed this database on at least 15 occasions to search for three shooting victims, he admitted. The defendant then provided information, including dates of birth, phone numbers, addresses, and information pertaining to relatives of these victims to his brother. The defendant admitted that he knew his brother wanted this information to locate these relatives and prevent them from cooperating in the investigation and prosecution of the Vice Lords shooting.

In May 2017, eClinical Works (ECW) and certain employees agreed to pay \$155 million to resolve a civil FCA lawsuit filed in Vermont alleging that ECW had misrepresented the capabilities of its software. Through the Electronic Health Records (EHR) Incentive Program, HHS offers financial incentive payments to healthcare providers that adopt certified EHR technology and meet certain requirements relating to their use of the technology. To obtain certification for their product, EHR software vendors must attest that their product satisfies the requirements for certification and pass testing by an accredited independent certifying entity approved by HHS. The government contended that ECW falsely obtained certification for its EHR software by concealing from its certifying entity that its software did not comply with the requirements for certification. For example, the government alleged that to pass certification testing, the company modified its software by "hardcoding" only the drug codes required for testing. ECW's software also allegedly did not accurately record user actions in an audit log, and in certain situations did not reliably record diagnostic imaging orders or perform drug interaction checks. As a result of these and other deficiencies in its software, ECW allegedly caused the submission of false claims for federal incentive payments based on the use of ECW's software. The United States also alleged that ECW paid unlawful kickbacks to certain customers in exchange for promoting its product. Under the terms of the settlement agreement, ECW and three of its founders were jointly and severally liable for \$154,920,000, and three ECW



employees (a software developer and two project managers) paid a total of \$80,000. Also as part of the settlement agreement, ECW agreed to enter into a 5-year CIA with HHS-OIG.

### **Health Maintenance Organization**

In May 2017, CareCore National LLC (“CareCore”), a benefits management company, agreed to pay \$45 million to resolve federal civil FCA allegations that CareCore authorized medical diagnostic procedures paid for with Medicare and Medicaid funds without assessing whether the procedures fell within national coverage criteria. The government alleged that CareCore, which performs prior authorization review for diagnostic procedures on behalf of many insurers, including those providing insurance through Medicare Part C and Medicaid Managed Care, failed to review prior authorization requests in a timely fashion, and in order to avoid contractual penalties for failing to timely process the requests, CareCore instituted a practice of improperly approving the requests. Between 2007 and 2014, CareCore improperly authorized over 200,000 diagnostic procedures. In addition to the federal recovery, CareCore also paid \$9 million to resolve state Medicaid liability.

Also in May 2017, Freedom Health Inc., a Florida-based provider of managed care services, agreed to pay approximately \$31.7 million to settle civil FCA allegations that Freedom Health engaged in illegal schemes to maximize their payment from the government in connection with their Medicare Advantage plans. The government alleged that Freedom Health submitted or caused others to submit unsupported diagnosis codes to CMS, which resulted in inflated reimbursements in connection with two of their Medicare Advantage plans operating in Florida. The government also alleged that Freedom Health made material misrepresentations to CMS regarding the scope and content of its network of providers (physicians, specialists and hospitals) in its application to CMS to expand into new counties in Florida and in other states. As part of the settlement agreement, Freedom Health agreed to enter into a 5-year CIA with HHS-OIG. In June 2017, the former general counsel of WellCare, Inc., pled guilty in the Middle District of Florida to one count of making a false statement to the Florida Medicaid Program. In 2011, the defendant and four other individuals were indicted on various federal criminal violations relating to a scheme to defraud the Florida Medicaid program (from the summer of 2003 through the fall of 2007) by making false and fraudulent statements relating to expenditure information for behavioral health care services. The indictment alleged the ways in which the defendants falsely and fraudulently schemed to submit inflated expenditure information in the company’s annual reports to AHCA in order to reduce the WellCare HMOs’ contractual payback obligations for behavioral health care services. As part of the plea, the defendant in this case admitted that, along with others, to knowingly and willfully causing the submission of the false 2006 expenditure report to the Florida Medicaid program.

### **Home Health Providers**

*(SF)* In October 2016, the owner and medical director of Christian Home Health Agency (Christian) in New Orleans were sentenced to 8 years and 6 years in prison, respectively, after being convicted of health care fraud for billing Medicare for home health services that were not medically necessary or were not provided, based upon false certifications of medical necessity. The vast majority of these patients did not require home health care services, and the medical

director falsely claimed that beneficiaries who were never examined were qualified to receive these services. They were ordered to pay a combined \$9 million in restitution.

*(SF)* In November 2016, two co-owners of 16 home health care agencies in the Detroit area were sentenced after being convicted of health care fraud and conspiracy to pay and receive health care kickbacks. According to evidence presented at trial, the defendants, from October 2004 through 2011, obtained patients by paying cash kickbacks to recruiters, who in turn paid cash to patients to induce them to sign up for home health care with their agencies. The owners also paid kickbacks to physicians to refer patients to the companies for home health care services that were medically unnecessary and were not provided. One defendant was sentenced to 30 years in prison and ordered to pay \$40.4 million in restitution, while the other was sentenced to 8 years in prison and ordered to pay \$38.1 million in restitution.

In May 2017, four individuals were sentenced in the Northern District of Ohio for their roles in an \$8 million health care fraud conspiracy in which participants provided forged documents and fraudulent forms to bill for services that were not provided. The defendants worked in some capacity for Just Like Familiee II, Inc., and Just Like Familiee III, Inc., which the defendants incorporated in 2005 and 2006, respectively, to provide home health services for elderly and disabled clients. Together they defrauded Medicaid, Medicare and the Department of Veteran Affairs out of more than \$8 million as a result of the conspiracy in which they prepared and submitted forged or false records in support of previously submitted and reimbursed billings for patients they did not actually provide face-to-face services. The sentences ranged from 8 months home confinement to 10 years in prison. In addition, the defendants were ordered to pay more than \$8 million in restitution.

*(SF)* In June 2017, a mother and daughter who secretly co-owned and operated seven HHAs in the Miami, Florida area were sentenced to over 10 years in prison and ordered to pay over \$22.9 million in restitution. The mother was sentenced to 11 years and 3 months in prison for health care fraud and conspiracy to commit health care fraud. The daughter was sentenced to 12 years and 7 months in prison for conspiracy to commit health care fraud and wire fraud. As part of their guilty pleas, the defendants admitted to paying patient recruiters bribes and kickbacks in exchange for referring Medicare beneficiaries to their home health agencies; fraudulently concealing their ownership interests in the agencies from Medicare; and laundering millions of dollars of fraud proceeds.

In August 2017, a doctor was sentenced in the Northern District of Texas to 35 years in prison and ordered to pay approximately \$268 million in restitution to Medicare and Medicaid for his role in a large-scale, sophisticated health care fraud scheme. The defendant, through his medical practice, instructed his staff to certify fraudulent Plans of Care (POCs), also known as 485's, which were not medically necessary. The POCs indicated to Medicare and Medicaid that a doctor had reviewed the treatment plan and deemed it medically necessary, and certifying that the patient required home health services, which were only permitted to be provided to those individuals who were homebound and required, among other things, skilled nursing. This process was repeated for thousands of POCs, and the defendant's office included a "485 Department," essentially a "boiler room" to affix fraudulent signatures and certifications. At trial, the government presented evidence that the defendant's practice processed and approved

POCs for 11,000 unique Medicare beneficiaries from more than 500 different home health agencies.

(SF) Also in August 2017, the owner and operator of five Houston-area HHAs was sentenced to 40 years in prison and ordered to pay \$17.8 million in restitution. A registered nurse who worked for one of these HHAs was sentenced to 5 years in prison and ordered to pay \$4.7 million in restitution. The owner and operator pleaded guilty to money laundering, and both defendants pleaded guilty to conspiracy to commit health care fraud. As part of the defendants' \$17 million Medicare and Medicaid fraud scheme, they paid kickbacks to patient recruiters and office employees for hundreds of patient referrals. They also paid kickbacks to physicians to certify patients for medically unnecessary home health and personal attendant services. This case was the largest personal attendant services scheme investigated and tried in Texas history.

## **Hospice Care**

In March 2017, top executives of Passages Hospice, which was at one time one of the largest hospices in Illinois, were sentenced on fraud and obstruction of a federal audit charges. The former administrator and co-owner of Passages was sentenced to 6 years and 6 months in prison for charges relating to falsely billing Medicare for intensive hospice services despite multiple red flags that the billing was improper. Other executives received prison sentences after pleading guilty to obstructing a federal audit, and a former marketing director pleaded guilty to violating the Anti-Kickback Statute. The United States also intervened in the three companion civil qui tam cases, alleging that the defendant submitted false and inflated claims to both Medicare and Medicaid. Among other types of fraud, Passages and its administrator falsely claimed that a large proportion of their hospice patients were on a high level of care called general inpatient care, even though they knew that the patients neither were qualified for nor were receiving that type of care. The government entered into a consent judgment and settlement with the defendant for \$18 million to resolve state and federal FCA liability and also filed a treble damages proof of claim in the bankruptcy case initiated by the now-defunct Passages entity.

In April 2017, International Tutoring Services, LLC, f/k/a International Tutoring Services, Inc., and d/b/a Hospice Plus; Goodwin Hospice, LLC; Phoenix Hospice, LP; Hospice Plus, L.P.; and Curo Health Services, LLC f/k/a Curo Health Services, Inc. agreed to pay approximately \$12.1 million to settle federal civil FCA allegations that they paid kickbacks in exchange for patient referrals. The government alleged that Hospice Plus, Phoenix Hospice, and Goodwin Hospice, which are now consolidated under the Hospice Plus brand and operate primarily in and around Dallas, Texas, paid kickbacks to a physician house call company and medical providers in violation of the Anti-Kickback Statute to induce referrals of hospice patients. In addition to the federal recovery, the defendants paid approximately \$105,000 to resolve state Medicaid liability.

In July 2017, defendants—a co-owner of the defunct Home Care Hospice, Inc. (HCH) and his wife— agreed to pay money and release their interest in property valued at over \$7 million to settle FCA allegations that they and HCH falsely claimed and received taxpayer dollars for hospice services that were either unnecessary or never provided. The government alleged the defendants knowingly submitted false claims and records (including fabricated records) to Medicare for purported hospice care for patients who were not terminally ill and thus not eligible for the Medicare hospice benefit and knowingly submitted or caused the submission of false

claims and records (including fabricated records) to Medicare for crisis care services that were not necessary or not actually provided. Additionally, a jury found one defendant guilty of, and two others pled guilty to, related criminal charges. In a prior settlement in 2015 to resolve FCA allegations, the other co-owner and his wife agreed to pay \$400,000 and release their interests in funds and properties owned jointly with the now-settling co-owner. With this settlement, the funds and properties are now fully released to the United States.

In August 2017, a Cleveland, Mississippi doctor was sentenced to 3 years and 3 months in prison followed by 3 years supervised release and ordered to pay \$1.9 million in restitution to the Medicare program. The sentencing stems from the doctor's guilty plea to a multi-count indictment charging him with referring patients to hospice that were not hospice appropriate and receiving kickbacks. The doctor admitted to referring patients who were not hospice appropriate to Milestone Hospice and Sandanna Hospice which led to \$1.9 million in Medicare payments to Milestone and Sandanna. The doctor also admitted to receiving payments from the hospice owner.

### **Hospitals and Health Systems**

In December 2016, South Miami Hospital, Inc. (SMH), entered into a settlement agreement to resolve its civil FCA liability for submitting claims to Medicare, Medicaid, TRICARE, and Federal Employee Health Benefit Programs for medically unnecessary electro physiology studies, echo cardiograms, tilt-table tests, implantable cardiovascular-defibrillators, biventricular pacemakers, atrioventricular optimizations, and other procedures. SMH is an acute care hospital owned and operated by Baptist Health System of South Florida. SMH agreed to pay \$12 million to resolve its liability under the FCA. As part of the settlement agreement, SMH agreed to enter into a 5-year CIA with HHS-OIG.

In February 2017, TeamHealth Holdings, a successor in interest to IPC Healthcare Inc., f/k/a IPC The Hospitalist Inc. (IPC) agreed to pay \$57.5 million to settle federal civil FCA allegations that IPC billed federal health care programs for higher and more expensive levels of medical service than were actually performed. The government alleged that IPC encouraged its hospitalists – medical professionals whose primary focus is the medical care of hospitalized patients – to bill for a higher level of service than actually provided. IPC's scheme to improperly maximize billings allegedly included corporate pressure on hospitalists with lower billing levels to “catch up” to their peers. In addition to the federal recovery, TeamHealth agreed to pay approximately \$3.5 million to resolve state Medicaid liability. As part of the settlement agreement, IPC agreed to enter into a 5-year CIA with HHS-OIG.

In May 2017, hospitals Mercy Hospital Springfield f/k/a St. John's Regional Health Center, and its affiliate, Mercy Clinic Springfield Communities f/k/a St. John's Clinic (collectively, “Mercy”) agreed to pay \$34 million to resolve civil FCA allegations in the Western District of Missouri that they engaged in improper financial relationships with referring physicians. The government alleged that the hospital and clinic submitted false claims to Medicare for chemotherapy services rendered to patients who were referred by oncologists. Allegedly the oncologists' compensation was, in part, determined by a formula that improperly took into account the value of their referrals to defendants. As part of the settlement agreement, Mercy agreed to enter into a 5-year CIA with HHS-OIG.

In June 2017, PAMC, Ltd. and Pacific Alliance Medical Center Inc., which owns California-based Pacific Alliance Medical Center, agreed to pay \$31.9 million to settle federal civil FCA allegations that they were involved in improper financial relationships with referring physicians. These relationships allegedly violated the Anti-Kickback Statute and the Stark Law and took the form of (1) arrangements under which the defendants paid above-market rates to rent office space in physicians' offices, and (2) marketing arrangements that provided undue benefit to physicians' practices. In addition to the federal recovery, PAMC and Pacific Alliance Medical Center paid \$10 million to resolve state Medicaid liability. As part of the settlement agreement, PAMC and Pacific Alliance Medical Center agreed to enter into a 5-year CIA with HHS-OIG.

Also in June 2017, a financial advisor who was a part owner of Physicians Alliance ACO, LLC,—an Accountable Care Organization (ACO)—was sentenced in the Western District of Arkansas to 12 years and 6 months in prison, ordered to pay \$5.7 million in restitution, and ordered to pay a \$5.7 million judgment. In January 2013, Physicians Alliance entered into an advanced payment agreement with HHS-CMS. The agreement called for payments to Physicians Alliance totaling \$2.6 million. The payments were based on projected savings to the Medicare and Medicaid programs. The defendant diverted investment client funds and advance payment monies to himself and his other businesses. The defendant embezzled more than \$8 million in client funds and \$750,000 in advance payment monies from Physicians Alliance.

### **Identity Theft**

In April 2017, the leader of a criminal organization in New York pled guilty to racketeering, conspiracy to commit health care fraud, bank fraud, money laundering, and identity theft, and was sentenced to 17 years and 6 months in prison, and ordered to pay \$20 million in restitution and \$20 million in forfeiture. The leader and his co-defendants stole the identities of doctors, set up fake medical clinics in their names, and then stole identities of patients so that Medicare could be billed for fictitious medical treatments. Sixteen defendants involved in the scheme were previously sentenced to a combined 51 years and 1 month in prison.

### **Laboratories**

In October 2016, NeuroScience, Inc., its founder, and Pharmasan Labs, Inc. (collectively, "defendants"), entered into a settlement agreement to resolve allegations that they submitted false claims to Medicare and TRICARE for urinary transmitter testing. From January 2008 through January 2014, the defendants allegedly violated Clinical Laboratory Improvement Amendments (CLIA) regulations by intentionally subjecting certain Pharmasan as-measured urinary neurotransmitter test results to a "shift factor" that they had not validated pursuant to CLIA regulations. In addition, the government contended that, during this same period, the defendants applied invalidated reference ranges to urinary neurotransmitter test results. The defendants agreed to pay \$6.1 million to resolve their liability under the civil FCA.

In November 2016, MedNet, Inc., a Ewing, New Jersey-based remote cardiac monitoring company, entered into a settlement agreement to resolve allegations that, from March 2006 through January 2014, it entered into "fee-for-service" or "direct-bill" agreements with certain hospital and physician clinic customers. Under these agreements, MedNet allegedly charged a

fee to customers for certain services that they performed in connection with two types of cardiac monitoring. MedNet allowed the customers to bill Medicare directly for these same services and permitted the customers to retain the reimbursements they received from Medicare. However, the Medicare reimbursement allegedly exceeded the fee that MedNet charged the customers. The government contended that these arrangements resulted in a net profit to MedNet's customers who were part of these agreements and provided remuneration to these customers to induce referrals from the customers for MedNet's services in violation of the Anti-Kickback Statute. The defendant agreed to pay \$1.3 million to resolve its liability under the FCA.

In April 2017, Quest Diagnostics agreed to pay \$6 million to settle civil FCA allegations that Berkeley HeartLab Inc. made payments to physicians and patients to induce the use of Berkeley for blood testing services for medically unnecessary tests in violation of the Anti-Kickback Statute. The government alleged that Berkeley paid kickbacks to referring physicians disguised as "process and handling" fees. The government also alleged that Berkeley paid kickbacks to patients by routinely waiving copayments owed by certain patients who were legally required to pay for part of their tests. The government further alleged that these illegal practices resulted in medically unnecessary cardiovascular tests being charged to federal health care programs.

### **Nursing Homes and Facilities**

In October 2016, Life Care Centers of America Inc. and its owner agreed to pay, over a period of time, \$145 million to settle civil FCA allegations that Life Care, which is based in Cleveland, Tennessee, caused skilled nursing facilities (SNFs) to submit false claims to Medicare and TRICARE for rehabilitation therapy services that were not reasonable, necessary, or skilled. The government alleged that Life Care submitted false claims for rehabilitation therapy by engaging in a systematic effort to increase its Medicare and TRICARE billings. Medicare reimburses SNFs at a daily rate that reflects the skilled therapy and nursing needs of their qualifying patients. The highest level of Medicare reimbursement for SNFs is for "Ultra High" patients who require a minimum of 720 minutes of skilled therapy from two therapy disciplines (e.g., physical, occupational, speech), one of which has to be provided five days a week. The government alleged that Life Care instituted corporate-wide policies and practices designed to place as many beneficiaries in the Ultra High reimbursement level irrespective of the clinical needs of the patients, resulting in the provision of unreasonable and unnecessary therapy to many beneficiaries. Life Care also allegedly sought to keep patients longer than was necessary in order to continue billing for rehabilitation therapy. Life Care owns and operates more than 220 SNFs across the country; this is the largest civil FCA settlement with a SNF chain. As part of the settlement agreement, Life Care agreed to enter into a 5-year CIA with HHS-OIG.

In June 2017, Genesis Healthcare Inc., headquartered in Kennett Square, Pennsylvania, agreed to pay, over a period of time, \$53.6 million to settle civil FCA allegations that companies and facilities acquired by Genesis caused the submission of false claims to government health care programs for medically unnecessary physical therapy and hospice services, and grossly substandard nursing care. The government alleged that the companies and facilities acquired by Genesis billed (1) for more therapy minutes than the patients actually received, for providing therapy longer than medically necessary, and at a higher Resource Utilization Group (RUG) level than necessary; (2) for hospice services for patients who were not terminally ill and therefore not eligible for the Medicare hospice benefit; (3) for outpatient therapy services that

were not medically necessary or unskilled in nature; and (4) for nursing home services that were grossly substandard and/or worthless and therefore ineligible for payment.

In July 2017, Reliant Care Group and affiliated entities agreed to pay \$8.3 million to resolve claims in the Eastern District of Missouri under the civil FCA for providing unnecessary physical, speech, and occupational therapy to nursing home residents. The government alleged that from January of 2008 through April of 2014, Reliant billed Medicare for unnecessary physical, speech and occupational therapy provided to nursing home residents who had a relatively high level of independence and who were residing in a skilled nursing facility primarily because of a psychiatric condition. The government further alleged that some Reliant Care Rehabilitative Services management pressured therapists to provide therapy to residents even when the therapists believed that the therapy was not medically necessary. As part of the settlement agreement, Reliant agreed to enter into a 5-year CIA with HHS-OIG.

Also in July 2017, Ohio-based Foundations Health Solutions Inc., Olympia Therapy Inc., and Tridia Hospice Care Inc., and two of their executives, agreed to pay \$19.5 million to settle civil FCA allegations pertaining to the submission of false claims for medically unnecessary rehabilitation therapy and hospice services to Medicare. The government alleged that Olympia and the corporate successor to Foundations Health Solutions provided therapy services at excessive levels to increase Medicare reimbursement for those services. The government also alleged that Tridia submitted false claims to Medicare for hospice services provided to patients who were ineligible for the Medicare hospice benefit because Tridia failed to conduct proper certifications or medical examinations. As part of the settlement agreement, Foundations Health Solutions agreed to enter into a 5-year CIA with HHS-OIG.

## **Pharmacies**

In October 2016, Omnicare, Inc. agreed to pay approximately \$20.3 million to settle federal civil FCA allegations that it solicited and received kickbacks from pharmaceutical manufacturer Abbott Laboratories in exchange for promoting the prescription drug Depakote for nursing home patients. Nursing homes rely on consultant pharmacists, such as those employed by Omnicare, to review their residents' medical charts at least monthly and make recommendations to their physicians about what drugs should be prescribed for those residents. The government alleged that Omnicare solicited and received kickbacks from Abbott in exchange for recommending that physicians prescribe Depakote, an anti-epileptic drug manufactured by Abbott, to elderly nursing home residents. In addition to the federal recovery, Omnicare also paid approximately \$7.8 million to resolve state Medicaid liability. Omnicare, which was acquired by Rhode Island-based CVS Health Corporation after the conduct at issue, is the nation's largest nursing home pharmacy. As part of the settlement agreement, CVS agreed to enter into a 5-year CIA with HHS-OIG.

In November 2016, the owner of two Miami pharmacies and her son, a registered agent of one of the pharmacies, were sentenced after pleading guilty to a fraud scheme that paid Medicare beneficiaries and patient recruiters for prescriptions that were medically unnecessary. The owner acknowledged that she directed her co-conspirators to make kickback payments and write and cash checks for the purpose of facilitating kickback payments and concealing fraud proceeds. Her son admitted that he participated in the conspiracy by writing checks to money launderers to

obtain cash to pay the kickbacks to Medicare beneficiaries. The defendants were sentenced to a combined 12 years and 6 months in prison and ordered to pay \$11 million in restitution. Two other defendants involved in the scheme were previously sentenced to a combined 3 years in prison and ordered to pay \$10.9 million in restitution.

In January 2017, Walgreens Co., a nationwide retail pharmacy chain, agreed to pay approximately \$46.2 million to settle federal civil FCA allegations that Walgreens enrolled hundreds of thousands of government health care program beneficiaries in its prescription savings club program in violation of the Anti-Kickback Statute. The government alleged that Walgreens provided government beneficiaries with discounts and other monetary incentives under the prescription savings club program to induce them to patronize Walgreens for all of their prescription drug needs. In addition to the federal recovery, Walgreens also paid approximately \$3.8 million to resolve state Medicaid liability.

*(SF)* Also in January 2017, the owner and operator of New Pharmacy Discount Corp. was sentenced to 4 years in prison and was ordered to pay over \$5 million in restitution, joint and several. The defendant pled guilty to conspiracy to commit health care fraud and conspiracy to pay and receive health care kickbacks. The defendant paid kickbacks in exchange for Medicare and Medicaid beneficiaries' unique identifying information. The information was then used to submit claims to Medicare and Medicaid for prescription drugs that were medically unnecessary, never provided to the beneficiaries, and never purchased by New Pharmacy Discount Corp.

In March 2017, the owner of two northwest Alabama pharmacies was sentenced to 6 months home confinement, order to pay a \$2.5 million fine, and prohibited from working in a pharmacy for a year for obstructing a Medicare audit. The pharmacies operated as both compounding and retail pharmacies. According to the defendant's plea with the government, he obstructed a 2012 audit of his pharmacy's claims for Medicare reimbursement on compounded prescriptions by submitting falsified and misleading documents stating that medications in tablet or capsule form were used as ingredients for compounded prescriptions.

*(SF)* In August 2016, eight defendants were indicted in Tampa, Florida in a sprawling, complex compounding pharmacy fraud conspiracy involving multiple pharmacies, numerous business entities, and over \$125 million in proceeds from a fraud scheme that affected private and government payers. The defendants included a pharmacist, a podiatrist, and several self-described businessmen. The fraud scheme was executed in numerous ways, including through inventory shorting, illegal kickbacks, illegitimate use of "front" pharmacies, and illegitimate prescriptions, all of which resulted in the submission of over \$600 million in claims. The government seized numerous vehicles and a 50-foot speedboat. Of the eight defendants, six have pled guilty, most recently in June 2017, and one defendant was sentenced to 4 years and 3 months in prison. Trial for the two remaining defendants is scheduled for November 2017.

### **Physical Therapy**

In June 2017, Union Treatment Center ("UTC"), a medical and physical therapy provider with clinics in Austin, Killeen, San Antonio, and Corpus Christi, agreed to pay \$3 million to settle civil FCA allegations. The government alleged that UTC and its executives submitted false claims to the Office of Workers' Compensation Programs under the guise that they were treating



injured American workers pursuant to the Federal Employees' Compensation Act (FECA). UTC claimed to specialize in treating workplace injuries. The company marketed itself to patients covered by the FECA program, targeting in particular unionized postal workers in Austin and San Antonio and civilian Army employees in the Corpus Christi area. However, the government asserted that, between January 2009 and December 2012, UTC fraudulently billed the FECA program for services it did not render; routinely overcharged for medical examinations; falsely inflated the time patients spent in therapy; and billed for unnecessary services and supplies. The government also accused UTC of offering, paying, soliciting, and receiving kickbacks in exchange for patient referrals.

### **Physician and Other Practitioners**

In October 2016, Hudson Valley Hematology-Oncology Associates, R.L.L.P. (Hudson), agreed to pay \$5.3 million to resolve Hudson's civil FCA liability for improperly submitting claims to Medicare and Medicaid. From June 2010 through June 2015, Hudson allegedly routinely waived co-payments without an individualized determination of financial hardship or exhaustion of reasonable collection efforts and billed Medicare and Medicaid for evaluation and management services, even though Hudson did not provide any significant, separately identifiable services to the beneficiaries. As part of the settlement agreement, Hudson agreed to enter into a 5-year CIA with HHS-OIG.

In January 2017, a Brea, California man who operated rehabilitation clinics in Walnut, Torrance and Los Angeles and defrauded Medicare out of approximately \$3 million by billing for unneeded or unnecessary services was sentenced to 10 years and 1 month in prison. The defendant was convicted in October 2016 of eight counts of health care fraud, nine counts of receiving kickbacks for health care referrals, and two counts of aggravated identity theft. Convictions arose out of a Medicare fraud scheme involving physical therapy clinics. The defendant owned physical therapy clinics operated by companies called Hong's Medical Management, Inc., CMH Practice Solution, and HK Practice and Solution, Inc. As part of the scheme, the defendant recruited Medicare beneficiaries and provided uncovered services like massage and acupuncture for them. Even though the beneficiaries did not receive actual physical therapy, the defendant's co-conspirators billed Medicare for physical therapy, and then funneled more than 50 percent of the reimbursement funds back to the defendant. During the course of the scheme, the defendant and his co-conspirators received reimbursements from Medicare in the amount of \$2.9 million. Eight other defendants pleaded guilty for their roles in the Medicare fraud scheme involving these clinics.

In February 2017, a pain management physician who owned clinics in Kentucky and Georgia agreed to the entry of a \$20 million consent judgment to settle federal civil FCA allegations that he billed federal health care programs for surgical monitoring services that he did not perform and for medically unnecessary diagnostic tests. On October 24, 2016, the physician was sentenced to 3 years and 2 months in prison and 3 years of supervised release in connection with this conduct.

(SF) In April 2017, after a three-week trial, a jury in the Eastern District of Michigan convicted a medical doctor and a medical billing company co-owner of conspiracy to commit wire fraud and health care fraud and three counts of health care fraud for their roles in a \$28 million Medicare

fraud scheme. According to the evidence presented at trial, from 2008 to 2014, the defendants submitted fraudulent claims for services – mainly nerve block injections – that they knew had not been provided. After Medicare subjected the medical doctor defendant’s claims to pre-payment review in 2009, the defendants conspired to circumvent Medicare’s fraud investigation by recruiting family members and employees to serve as straw owners of the defendants’ companies. The medical doctor used the proceeds of the fraud for international travel and to purchase part ownership of a Canadian professional basketball team. In September 2017, the billing company co-owner was sentenced to 10 years in prison. The medical doctor is scheduled to be sentenced in November 2017.

*(SF)* In June 2017, a Detroit-area medical biller was sentenced to 4 years and 2 months in prison and ordered to pay \$3.2 million in restitution for her involvement in a \$7.3 million Medicare and Medicaid fraud scheme. After a week-long trial, a jury convicted the defendant of one count of conspiracy to commit wire fraud, health care fraud, and mail fraud, and one count of mail fraud. The evidence at trial showed that the defendant submitted fraudulent bills on behalf of a co-conspirator physician for services she knew could not have been rendered, and for services she knew had not been rendered as billed. In exchange, the physician paid the defendant six percent of the total billings to Medicare and Medicaid. The physician pled guilty to a \$33 million Medicare fraud scheme and was sentenced in March 2017 to 8 years and 5 months in prison.

*(SF)* In September 2017, a doctor was sentenced to 8 years and 1 month in prison and ordered to pay \$4.8 million in restitution after being convicted of conspiracy to commit health care fraud and wire fraud. As part of the defendant’s multi-faceted health care fraud scheme, he received kickbacks in exchange for referring Medicare beneficiaries to pharmacy owners, signing plans of care and prescriptions for home health care services, and prescribing controlled substances, including opioids, to patients and patient recruiters who did not need them. The defendant also submitted claims to Medicare for services that he did not render.

### **Prescription Drugs / Medicare Part D**

In October 2016, an osteopathic doctor was sentenced to 30 years in prison and ordered to pay \$342,504 in restitution for operating a “pill mill” out of his medical offices. The defendant worked with Pagan’s Motorcycle Club, an outlaw gang known for violence and drug dealing, writing fraudulent prescriptions for oxycodone and other drugs, while the Pagans recruited “pseudo-patients” to buy the fraudulent prescriptions. After filling the prescriptions, the Pagans resold the pills on the street. From March 2012 to January 2015, the defendant distributed more than 700,000 pills containing oxycodone and other Schedule II controlled substances in furtherance of the conspiracy. Eight additional defendants involved in the scheme were sentenced to a combined 49 years and 10 months in prison. Five defendants have pleaded guilty and are awaiting sentencing.

*(SF/USAO)* In March 2017, an owner of a medical clinic in the Central District of California was sentenced to 4 years and 3 months in prison and was ordered to pay \$1.9 million in restitution, joint and several, after being found guilty at trial of conspiracy to commit health care

fraud and 11 counts of filing false tax returns. The defendant, whose wife was the doctor at the medical clinic, sold false prescriptions in the names of his wife's patients to a co-conspirator pharmacist. The pharmacist then submitted false claims to insurance companies for drugs that were never dispensed. The defendant also filed false federal tax returns, underreporting income of over \$2.9 million. As a condition of supervised release, the court ordered the defendant to pay the IRS over \$900,000 in unpaid taxes.

In June 2017, Rhine Drug Company and its owner agreed to pay a total of \$2.2 million to resolve allegations in the Southern District of Georgia that they violated the FCA and the Controlled Substances Act (CSA) by submitting claims to Medicare for drugs that Rhine Drug Company did not dispense to patients. In addition, the United States alleged that Rhine violated the CSA by failing to keep proper records for a number of substances, including opioids. As part of the settlement agreement, Rhine Drug Company agreed to enter into a 3-year Integrity Agreement (IA) with HHS-OIG.

From 2006 through August 2013 in New York, multiple co-defendants conducted a scheme to defraud Medicaid, Medicare, and the New York State-funded AIDS Drug Assistance Program ("ADAP") through the purchase and sale of illegally diverted prescription drugs. In May 2017, one defendant pleaded guilty to conspiracy to commit wire and health care fraud and was ordered to pay \$7.5 million in restitution, joint and several. Two defendants involved in the scheme were previously sentenced to a combined 3 years and 1 month in prison and ordered to pay \$7.5 million restitution, joint and several. To date, 4 co-defendants have been excluded from participation in Federal health care programs for a combined 102 years.

### **Psychiatric and Psychological Testing and Services**

(SF) In April 2016, a prominent Kentucky attorney, a former Social Security Administration (SSA) Administrative Law Judge (ALJ), and a clinical psychologist were charged in an 18-count indictment with, among other offenses, conspiracy to commit wire fraud and mail fraud. The defendants defrauded the SSA by creating and submitting falsified medical evidence to support favorable SSA disability determinations. As a result of defendants' fraud scheme, claimants represented by the attorney obtained improper disability benefits. The SSA paid the attorney over \$7.5 million in representative fees and paid the claimants more than \$70 million in disability benefits that the SSA subsequently determined they were not entitled to receive. The total value of the social security benefits conferred upon the claimants associated with this scheme exceeded \$600 million over the claimants' lifetimes. In March 2017, the attorney pleaded guilty to theft of government money and paying illegal gratuities. Immediately prior to sentencing, the attorney fled the jurisdiction and remains at large. Nevertheless, in July 2017, he was sentenced, *in absentia*, to 12 years in prison and was ordered to pay approximately \$106 million in restitution. In April 2017, the ALJ pled guilty to receiving illegal gratuities, and he was sentenced to 4 years in prison and was ordered to pay \$93 million in restitution. The psychologist proceeded to trial in June 2017. After a week-long trial, the jury found the psychologist guilty of conspiracy to commit mail fraud and wire fraud, and making false statements. He is scheduled to be sentenced in September 2017.

In May 2017, St. Joseph's Hospital Health Center, which operates a Comprehensive Psychiatric Emergency Program (CPEP) in Syracuse, New York, paid \$4.8 million to resolve civil FCA

allegations that the hospital routinely up-coded its CPEP emergency room visits and improperly billed for services rendered by nurse practitioners that failed to satisfy the requirement that a physician have a face-to-face encounter with the patient. Previously, in August 2016, St. Joseph's paid \$3.2 million to resolve allegations that it violated the federal and New York False Claims Acts by presenting false claims for payment to the state Medicaid program for mobile crisis outreach services rendered by unqualified staff.

(SF) Also in May 2017, a jury convicted a psychiatrist of conspiracy to commit health care fraud and five counts of health care fraud for his role in a \$158 million Medicare fraud scheme. The evidence at trial showed that, over the course of 6 years, the psychiatrist and others defrauded Medicare by submitting false and fraudulent claims for partial hospitalization program (PHP) services, which are intensive outpatient treatments for patients with severe mental illness. The psychiatrist indiscriminately admitted and readmitted patients into PHPs. Many of these patients were unable to participate in the treatment, and therefore did not qualify for the services, because they suffered from severe Alzheimer's or dementia. The 15 defendants involved in this scheme have either pled guilty or been tried and convicted. The psychiatrist is scheduled to be sentenced in October 2017.

(SF) In July 2017, a clinical psychologist and his mother, both of whom owned and operated several psychological services companies, were sentenced to 15 years and 7 years, respectively, and ordered to pay \$13.8 million in restitution. After a 7-day trial, the defendants were convicted of conspiracy to commit health care fraud and conspiracy to make false statements related to health care matters. According to evidence presented at trial, the defendants' companies contracted with nursing homes in Alabama, Florida, Louisiana, and Mississippi to allow clinical psychologists to provide psychological services to nursing home residents. The defendants caused these companies to bill Medicare for hours of psychological testing services that these nursing home residents did not need or, in some instances, did not receive. Between 2009 and 2015, the defendants submitted over \$25.2 million in claims to Medicare, and a significant amount of these claims were fraudulent. Medicare paid \$13.8 million on the fraudulent claims.

### **Other Medicare and Medicaid Matters**

(SF) In July 2017, the owner of Tri-County Network, his deputy, and five physicians were indicted on various charges for their involvement in a \$132 million Medicare fraud scheme. The Tri-County Network included five medical clinics, a laboratory, and a physical therapy company. The defendants conspired to prescribe medically unnecessary controlled substances, some of which were sold on the street, and to require Medicare beneficiaries, some of whom were addicted to controlled substances, to submit to medically unnecessary injections, drug testing, and other procedures. The owner also solicited illegal kickbacks for medically unnecessary referrals by the physicians to other providers, such as laboratories, diagnostic companies, and home health agencies. The owner concealed his involvement from Medicare by placing the clinics in the name of straw owners and sought to circumvent Medicare's investigation by opening new clinics when Medicare suspended the billing privileges of existing clinics. He used the fraud proceeds to sit courtside at NBA basketball games, make \$6.6 million investments, and finance the construction of a \$6.8 million house. Over \$12 million in fraudulently obtained assets have been seized, and trial is scheduled for April 2018.



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# DEPARTMENT OF HEALTH AND HUMAN SERVICES

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## 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 2017, the Secretary and the Attorney General jointly allotted \$185.9 million to HHS-OIG after accounting for a sequester reduction of \$13.8 million. OIG was allocated an additional \$6 million in HCFAC mandatory funds from the Secretary. Additionally, Congress appropriated \$82.1 million in discretionary funding for HHS-OIG HCFAC activities.

The HHS-OIG mission is to protect the integrity of HHS programs and the health and welfare of the people they serve. As established by the [Inspector General Act of 1978](#), HHS-OIG is an independent and objective organization that fights fraud, waste, and abuse and promotes efficiency, economy, and effectiveness in HHS programs and operations. HHS-OIG's vision is to drive positive change in HHS programs and in the lives of the people served by these programs. HHS-OIG pursues this vision through independent oversight of HHS programs and operations and by providing HHS and Congress with objective and reliable information for use in policymaking. HHS-OIG assesses the Department's performance, administrative operations, and financial stewardship. HHS-OIG evaluates risks to HHS programs and recommends recovery of misspent funds and program improvements. The law enforcement component of HHS-OIG investigates fraud and abuse against HHS programs and holds wrongdoers accountable for their actions.

With respect to HCFAC funds, HHS-OIG focuses on combatting Medicare and Medicaid fraud, waste, and abuse, including in priority areas, such as protecting beneficiaries from prescription drug abuse, including opioid abuse; enhancing program integrity in non-institutional care settings, such as home health and hospice; and strengthening Medicaid program integrity, including working with state partners to enhance the effectiveness of the Medicaid Fraud Control Units (MFCUs). HHS-OIG is working to strengthen oversight of the Medicare Advantage program.

As the leading oversight agency specializing in health care fraud, HHS-OIG employs a multi-disciplinary approach and uses data-driven decision-making to produce outcome-focused results. HHS-OIG leverages sophisticated data analysis to identify and target potential fraud schemes and areas of program waste and abuse and to provide quality, timely, and actionable data to frontline staff, as well as to its government and, as appropriate, private sector partners. HHS-OIG combines data analysis, field intelligence, and state-of-the art investigative techniques to combat fraud and abuse.

### Results

In FY 2017, HHS-OIG investigations resulted in 788 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid; and 818 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 2017, HHS-OIG excluded a total of 3,244 individuals and entities, the details of which are below.

In FY 2017, HHS-OIG continued to staff and support Medicare Strike Force operations working 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. Among other fraudulent conduct, 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 government health care programs. The continued support of Medicare Strike Force operations is a top priority for HHS-OIG. HHS-OIG has also collaborated with DOJ and assigned special agents to support the Opioid Fraud and Abuse Detection Units.

HHS-OIG also provides critical support in the establishment and ongoing work of the new Opioid Fraud and Abuse Detection Units established by the Attorney General in collaboration with HHS-OIG, FBI, and DEA. These units focus specifically on opioid related health care fraud using data to identify and prosecute individuals, such as prescribers of opioids, and entities, such as clinics, pill mills, and pharmacies, which are contributing to the opioid epidemic. HHS-OIG has assigned Special Agents to support 12 prosecutors identified by DOJ to focus solely on investigating and prosecuting opioid related health care fraud cases.

Investigations, audits, and evaluations frequently reveal vulnerabilities, misspent funds, 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 may recommend legislative proposals or other corrective actions that, when enacted or implemented, close loopholes and reduce improper payments or conduct. The savings from these efforts can be substantial. For FY 2017, 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 \$24.4 billion—\$23.2 billion in Medicare savings and 1.2 billion in savings to the federal share of Medicaid. HHS-OIG's expected recoveries from its involvement in health care audits and investigations totaled \$4.7 billion, which resulted in a return on investment (ROI) of \$14 to \$1.<sup>13</sup>

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>.

## **Enforcement**

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<sup>13</sup> This ROI uses a 3-year average of expected recoveries, fines, penalties, and stolen and misspent funds relating to HHS-OIG's health care oversight and is compared with HHS-OIG's annual obligations. This ROI differs from the HCFAC ROI, which uses actual dollars returned to the government.

HHS-OIG works with its law enforcement partners to conduct criminal and civil investigations involving the Medicare and Medicaid programs and participates in the settlement of False Claims Act cases, including through the negotiation of Corporate Integrity Agreements (CIAs). HHS-OIG works with the MFCUs to address fraud and abuse in the Medicaid program. Examples of this enforcement work appears elsewhere in this report. In addition to investigating criminal and civil matters, HHS-OIG administers the exclusion program and imposes civil monetary penalties for a variety of health care related offenses.

### Combatting the Opioid Epidemic

Fighting the opioid crisis and protecting beneficiaries from prescription drug abuse is among HHS-OIG's top priorities. Opioids related matters are a substantial portion of HHS-OIG's investigations. In July 2017, HHS-OIG participated with Federal, State, and local partners (including 31 MFCUs) in the National Health Care Fraud Takedown, described in more detail elsewhere in this report. More than 400 defendants in 41 Federal districts were charged with participating in fraud schemes involving about \$1.3 billion in false billings to Medicare and Medicaid. Among those charged, 120 defendants (including 27 doctors) were charged in cases involving the illegal distribution of opioids. HHS-OIG also issued exclusion notices to 295 doctors, nurses, and other providers on the basis of conduct related to opioid diversion and abuse. Further, HHS-OIG developed and released a data brief about the Part D program identifying prescribers with questionable opioid prescribing patterns and beneficiaries at high risk. In collaboration with DOJ, FBI, and DEA, HHS-OIG has assigned agents and contributed data analysis to support the Opioid Fraud and Abuse Detection Units.

### 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 2017, HHS-OIG excluded a total of 3,244 individuals and entities. Among these were exclusions based on criminal convictions for crimes related to Medicare and Medicaid (1,281) or to other health care programs (309); for patient abuse or neglect (266); or as a result of licensure revocations (973). 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 2017. In addition to those mentioned in the Program Accomplishments section above, exclusion actions by HHS-OIG included:

Home Health Providers (District of Columbia) – In December 2016, the owner of Global Healthcare, Inc. was excluded for a minimum period of 55 years. The owner had previously had her nursing license revoked and was excluded from all federal health care programs in March 2000. Using a different name, the owner fraudulently gained approval as a provider in the Medicaid program and from August 2009 through February 2014, led a scheme to bill Medicaid for services that were not provided, including using phony time sheets, patient files and employment files. The owner was convicted of health care fraud, money laundering, and other charges stemming from this scheme, and was sentenced to 10 years in prison and ordered to pay \$80.6 million in restitution, joint and several. The original exclusion from March, 2000 also remains in place.



Nursing Home and Facilities (Virginia) – In December 2016, a licensed nurse aide was excluded for a minimum period of 30 years. According to court documents, while working in a nursing home, the nurse aide sexually assaulted an 84-year old patient. The patient was not alert, nonverbal, and suffered from dementia. The nurse aide was sentenced to 22 years in prison based on his conviction for rape. In addition, the Virginia State Board of Nursing revoked his license to practice as a nurse aide.

Nursing Home and Facilities (Minnesota) – In June 2017, a nursing assistant was excluded for a minimum period of 20 years. According to court documents, the nursing assistant sexually assaulted a patient at a nursing facility. The patient had dementia and Alzheimer's disease and was completely dependent on caretakers due to advanced dementia. The nursing assistant was sentenced to 8 years in prison based on a conviction for criminal sexual conduct.

Clinics (New York) – In July 2017, a former outpatient drug rehabilitation program provider was excluded from all Federal health care programs for 50 years. The provider agreed to resolve False Claims Act allegations that it submitted claims to Medicaid for services predicated on illegal kickbacks and services not rendered. As a part of settlement, the provider admitted that, between 2006 and 2014, it induced beneficiaries to use its outpatient programs by providing the beneficiaries with subsidized housing. The provider also admitted that, between 2008 and 2011, it paid operators of other short-term residences to condition residency at their residences on enrollment in and attendance at one of the provider's outpatient programs. The provider also admitted that, in 2010, it directed employees to falsify records to reflect that counselors had treated certain Medicaid beneficiaries. As part of settlement, the provider, which is currently in Chapter 7 bankruptcy, agreed that the United States will receive a \$50.5 million bankruptcy claim.

### 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. In FY 2017, HHS-OIG concluded cases involving approximately \$49.1 million in CMPs. Examples include:

Dental (New Jersey) – In January 2017, a New Jersey dentist agreed to pay \$1.1 million in assessments and penalties and be excluded from participation in all Federal health care programs for a period of 50 years. The dentist is a New Jersey dentist who was previously excluded due to the suspension of his license to practice dentistry in 1999. HHS-OIG alleged that the dentist knowingly presented or caused to be presented to Medicaid claims for items or services he knew or should have known were false or fraudulent or otherwise not provided as claimed; knowingly presented or caused to be presented to Medicaid claims for items or services furnished by an excluded person; and was the owner and managing employee of an entity that was participating while he was excluded from participating in Federal health care programs.

Hospitals and Health Systems (Connecticut) – In April 2017, Hartford Hospital and its sister hospital, Midstate Medical Center, agreed to pay more than \$2.8 million in assessments and penalties for submitting claims between February 2009 and March 2015 where patients received home health services within three days of the patient’s release from Hartford Hospital that were improperly coded as a discharge rather than as a post-acute care transfer.

Hospitals and Health Systems (South Carolina) – In June 2017, AnMed agreed to pay \$1.2 million to resolve its potential liability under EMTALA, the largest such settlement in HHS-OIG’s 30-year enforcement of the statute. HHS-OIG alleged that, between April 2012 and July 2013, AnMed violated EMTALA by failing to provide appropriate medical screening examinations and stabilizing treatment to patients who presented to the emergency department (ED) with psychiatric conditions. Specifically, HHS-OIG alleged that, despite the availability of on-call psychiatrists and open beds in its psychiatric unit, AnMed kept 35 individuals in its ED pursuant to a longstanding policy of not admitting involuntary patients to its psychiatric unit. These 35 individuals, who suffered from serious psychiatric disorders, were kept in AnMed’s ED for 6 to 38 days each until they were discharged or transferred to another medical facility.

### 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:

In September 2016, Kindred Healthcare, Inc., the Nation’s largest provider of post-acute care, including hospice and home health services, paid a penalty of more than \$3 million for failing to comply with a CIA. The CIA was the result of allegations involving claims for hospice services that were medically unnecessary and claims for continuous or crisis care services when the patients were not experiencing a crisis. The penalty for violating the CIA resulted from Kindred’s failure to correct improper billing practices in the fourth year of the 5-year agreement. HHS-OIG made several unannounced site visits to Kindred facilities and found ongoing violations. Specifically, CIA-required audits performed by Kindred’s internal auditors in 2013, 2014, and 2015 found that the company and its predecessors failed to implement policies and procedures required by the CIA, and that poor claims submission practices led to significant error rates and overpayments by Medicare.

### **Audits and Evaluations**

OIG promotes the economy, effectiveness, and efficiency of HHS programs through a program of audits and evaluations. HHS-OIG uses a dynamic work planning process and makes

adjustments throughout the year to meet evolving 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 addition, HHS-OIG considers a number of factors, including:

- Mandatory requirements for HHS-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.

Among HHS-OIG's audit and evaluation findings in FY 2017 were the following, organized by outcome:

#### Preventing Fraud

*State Use of Express Lane Eligibility for Medicaid and CHIP Enrollment:* HHS-OIG examined the benefits and barriers to State use and expansion of Express Lane Eligibility (ELE) and found that States that used ELE to expedite and simplify enrollment in Medicaid and CHIP adopted variations of three models, with more than half adopting an automated model that requires minimal action from staff and beneficiaries. All 14 States that used ELE reported benefits, and some States reported that they rely heavily on ELE. Eleven States reported that they encountered barriers when they implemented ELE, but reported that they overcame these barriers through strong partnerships and integrated eligibility systems. Despite largely positive experiences using ELE, 5 of the 14 States that adopted ELE discontinued its use. HHS-OIG concluded that ELE appears to meet the intended objective of easing the eligibility and enrollment process and did not identify any significant impediments to continuing to allow voluntary use of ELE once States and CMS have corrected process problems and gaps in oversight identified by HHS-OIG audits of ELE enrollments. (OEI-06-15-00410)

*Managed Long-Term Care Payments:* HHS-OIG found that New York improperly claimed reimbursement for 36 of 100 payments made to Medicaid Managed Long-Term Care (MLTC) plans that were reviewed. HHS-OIG also found that if New York develops procedures to monitor MLTC plans for compliance with requirements in its contracts and ensure that future contracts include provisions that allow it to recover payments when plans do not comply with contract requirements, \$1.4 billion (\$717 million Federal share) could have been saved during the 1-year audit period. (A-02-15-01026)

*Suspension of Medicaid Payments for Cases with Credible Fraud Allegations:* HHS-OIG found that Florida did not always suspend Medicaid payments to providers that had credible fraud allegation cases in accordance with legal requirements. Of the 95 cases reviewed, Florida did not suspend Medicaid payments for 54 cases. HHS-OIG recommended that Florida should

update its policies and procedures to ensure that it suspends Medicaid payments to providers with credible fraud allegations, which could have prevented \$40 million (Federal share) from being at risk. (A-04-14-07046)

*Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2014 Average Sales Prices:* CMS lowered Part B reimbursement for 14 drugs, saving Medicare and its beneficiaries \$24 million over 1 year based on 2014 data. This finding highlights the success of HHS-OIG's mandated quarterly comparisons of average sales prices with average manufacturer prices and implementation of CMS's current price-substitution policy. HHS-OIG continues to recommend that CMS expand the price-substitution criteria. CMS did not concur with the recommendation to expand the price-substitution policy and believes that more experience with this policy is needed before it can be expanded. (OEI-03-16-00540)

*Availability of T-MSIS Data:* HHS-OIG found that after failing to meet the implementation deadline of January 2014, CMS and States reported that technological problems and competing priorities caused further delays with T-MSIS. CMS indicated that it expects that all States will be reporting to T-MSIS by the end of 2017. As of December 2016, 21 States were submitting data. As States and CMS work together to submit data into T-MSIS, they continue to raise concerns about the completeness and reliability of the data. Because of CMS's history of delaying target dates for implementation, HHS-OIG is concerned that CMS and States will delay further rather than address these outstanding challenges. (OEI-05-15-00050)

*CMS Validation of Hospital Inpatient Quality Reporting Program Data:* HHS-OIG found that for payment year 2016, CMS met its regulatory requirement by validating sufficient hospital inpatient quality reporting program data, which are used to adjust payments based on quality. However, CMS made limited use of analytics, which can help identify gaming of quality data. CMS concurred with our recommendation, which was to make better use of analytics to ensure the integrity of hospital-reported quality data and the resulting payment adjustments (OEI-01-15-00320)

*Use of Medicaid Payment Suspensions:* Most Medicaid agencies (41 of 56) reported imposing 10 or fewer payment suspensions in fiscal year 2014. Medicaid agencies reported significant challenges related to imposing payment suspensions, which appear to have limited States' use of this program integrity tool. CMS concurred with our recommendation to provide additional technical assistance to help Medicaid agencies fully utilize Medicaid payment suspensions as a program integrity tool. (OEI-09-14-00020)

*Medicaid Fraud Control Units Fiscal Year 2016 Annual Report:* HHS-OIG's MFCU FY 2016 Annual Report highlights the statistical accomplishments of the 50 MFCUs during FY 2016. HHS-OIG found that FY 2016 continued a trend of increasing numbers of convictions. Just over one-third of the 1,564 MFCU convictions involved personal care services attendants. Fraud cases accounted for 74 percent of the MFCU convictions, while 26 percent involved patient abuse or neglect. MFCUs reported 998 civil settlements and judgments, almost half of which involved pharmaceutical manufacturers. MFCUs reported almost \$1.9 billion in criminal and civil recoveries. In an appendix to the report, HHS-OIG summarizes beneficial practices by the MFCUs that were identified in onsite review reports published between FYs 2011-2016. (OEI-09-17-00210)

## Analyzing Payment Trends and Detecting Potential Fraud

*Impact of High-Price Drugs on Payments for Medicare Part D Catastrophic Coverage:* HHS-OIG found that high-price drugs are increasing Federal payments for Medicare Part D catastrophic coverage. Federal payments for Part D catastrophic coverage exceeded \$33 billion in 2015, which is more than triple the amount paid in 2010. Spending for high-price drugs contributed significantly to this growth. Moreover, 10 high-price drugs accounted for nearly one-third of all drug spending for catastrophic coverage in 2015. The issue of high-price drugs is not exclusive to catastrophic coverage; it affects the entire Part D benefit and can lead to higher costs for patients. Securing the future of the Part D program while ensuring that patients have access to needed drugs is a complex issue that calls for a multifaceted approach. (OEI-02-16-00270)

*Improper Payments for Chiropractic Services:* HHS-OIG has previously found that Medicare made improper payments for chiropractic services that were medically unnecessary, incorrectly coded, insufficiently documented, or not documented. In this audit, HHS-OIG found that most Medicare payments for chiropractic services did not comply with Medicare requirements. An estimated \$358.8 million (82 percent) of the \$438.1 million paid by Medicare for chiropractic services was found to be unallowable. These overpayments occurred because CMS's controls were not effective in preventing payments for medically unnecessary chiropractic services. (A-09-14-02033)

*Rebates for Physician-Administered Drugs:* HHS-OIG conducted reviews in California and Virginia to determine whether States are complying with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs dispensed to enrollees of Managed Care Organizations (MCOs). HHS-OIG found that California claimed an estimated \$7.3 million in Federal reimbursement that was unallowable and \$35.2 million that may have been unallowable because it did not comply with Federal Medicaid requirements. Virginia did not bill manufacturers for an estimated \$2.9 million in rebates. (A-09-15-02035; A-03-15-00201)

*Medicare Payments to Acute-Care Hospitals for Outpatient Services:* HHS-OIG found that Medicare did not appropriately pay acute-care hospitals any of the \$51.6 million for outpatient services reviewed, and beneficiaries were held responsible for unnecessary deductibles and coinsurance of \$14.4 million. Medicare overpaid the acute-care hospitals because the system edits that should have prevented or detected the overpayments were not working properly. If the system edits had been working properly since 2006, Medicare could have saved almost \$100 million, and beneficiaries could have saved \$28.9 million in deductibles and coinsurance. (A-09-16-02026)

*Medicare's 2-Midnight Hospital Policy:* HHS-OIG identified several vulnerabilities in hospital billing under Medicare's 2-midnight policy, including a large number of potentially inappropriate short inpatient stays and an increased number of beneficiaries in outpatient stays paying more and having limited access to skilled nursing facility (SNF) services compared to inpatients. These findings raise concerns about the cost to Medicare and beneficiaries. (OEI-02-15-00200)

*Concerns about Extreme Use and Questionable Prescribing of Opioids:* HHS-OIG found that one out of every three beneficiaries received a prescription opioid through Medicare Part D in 2016. Half a million beneficiaries received high amounts of opioids during the year and almost 90,000 beneficiaries who were at serious risk of opioid misuse or overdose. These 90,000 beneficiaries either received extreme amounts of opioids or appeared to be doctor shopping. Moreover, 401 prescribers had questionable prescribing patterns for beneficiaries who are at serious risk. Ensuring the appropriate use and prescribing of opioids is essential to protecting the health and safety of beneficiaries and the integrity of Part D. (OEI-02-17-00250)

*Medicare Payments for Clinical Diagnostic Laboratory Tests:* Medicare paid \$6.8 billion under Part B for lab tests in 2016, a total that changed very little over 3 years. The top 25 tests by Medicare payments totaled \$4.3 billion and represented 63 percent of all Medicare payments for lab tests in 2016. More than half of payments for the top 25 tests went to 1 percent of labs. Congress mandated that HHS-OIG monitor Medicare payments for lab tests and publicly release an annual analysis of the top 25 lab tests by Medicare payments. Changes in the Medicare payment rates for these 25 tests could have a significant impact on overall Medicare spending for lab tests when the new payment system for lab tests goes into effect in 2018. Our data brief contains no recommendations. (OEI-09-17-00140)

### Identifying Misspent Funds and Addressing Improper Payments

*Improper Payments for Incarcerated Beneficiaries:* The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires CMS to establish policies and implement claim edits to ensure that payments are not made for Medicare services rendered to incarcerated beneficiaries. HHS-OIG found that CMS's policies and procedures did not allow CMS to detect and recoup improper payments to beneficiaries who were incarcerated. CMS has not taken steps to determine whether any of the \$34.6 million in potentially improper payments (for claims for incarcerated beneficiaries) made in 2013 and 2014 should have been denied. HHS-OIG also found that CMS's planned corrective revisions to its policies and procedures do not comply with Medicare requirements. When CMS implements its revised policies and procedures, it will, according to CMS officials, further adjudicate the \$34.6 million in claims. However, because the data that CMS plans to use will be incomplete, these efforts will not identify all improper payments. (A-07-15-01158)

*Unallowable School-Based Medicaid Administrative Costs:* In prior reviews of school-based and community-based administrative costs that States allocated to Medicaid using random moment sampling (RMS), HHS-OIG identified significant overpayments. As part of Medicaid risk assessment, HHS-OIG found that North Carolina and Mississippi used statistically invalid RMS in allocating costs to Medicaid and did not promptly submit to HHS for review their cost allocation plan (CAP) amendments describing their new random moment time study (RMTS) methodology. As a result, North Carolina claimed almost \$107.5 million (almost \$53.8 million Federal financial participation) and Mississippi claimed almost \$42.4 million (almost \$21.2 million Federal financial participation) in unallowable school-based Medicaid administrative costs for Federal FYs 2010 through 2012. (A-04-15-00101; A-04-15-00103)

*Capitation Payments for Deceased Beneficiaries:* The Florida Statewide Medicaid Managed Care Program pays MCOs to provide covered health care services in return for a monthly fixed

payment for each eligible beneficiary (capitated payment). In 2014, nearly all of Florida's Medicaid beneficiaries were moved into managed care. HHS-OIG found that Florida did not always stop making capitation payments after a beneficiary's death, despite its efforts to identify and recover any overpayments. HHS-OIG estimated that Florida made overpayments to MCOs totaling \$26.2 million (\$15.4 million Federal share) during the audit period. (A-04-15-06182)

*Vulnerabilities Remain in the Medicare Outlier Payment Methodology:* HHS-OIG found that for the period October 2003 through March 2011, Medicare contractors did not always refer cost reports that qualified for reconciliation, and CMS did not always ensure that Medicare contractors reconciled the outlier payments associated with cost reports that had been referred. Our previous reviews identified 465 cost reports that qualified for reconciliation of outlier payments. (A-07-14-02800)

*Enhancements Needed in the Tracking and Collection of Medicare Overpayments Identified by ZPICs and PSCs:* Zone Program Integrity Contractors (ZPICs) and Program Safeguard Contractors (PSCs) referred a total of \$559 million dollars in overpayments to Medicare Administrative Contractors (MACs) in fiscal year 2014; however, the dollar amounts referred varied widely across ZPICs and PSCs. MACs did not collect 80 percent of the \$482 million they sought to collect from these overpayment referrals. MACs' collection rate varied depending on the type of claim, with home health and hospice overpayments having just an 11 percent collection rate. Furthermore, ZPICs, PSCs, and MACs continue to experience challenges in tracking referrals and collections of overpayments. Because CMS began transitioning PSCs and ZPICs to Unified Program Integrity Contractors (UPICs) in 2016, our recommendations included these new contractors. CMS concurred with four of our recommendations: share best practices across ZPIC- and UPIC-referred overpayments; identify strategies to increase MACs' collection of ZPIC- and UPIC-referred overpayments; work with ZPICs, UPICs, and MACs to create a standard report format both for overpayment referral reports and overpayment collection reports; and require ZPICs, UPICs, and MACs to use a unique identifier for each overpayment. CMS did not state whether it concurred or did not concur with our recommendation to implement the surety bond requirement for home health providers and consider the feasibility of implementing surety bonds for other providers based on their level of risk. (OEI-03-13-00630)

### Promoting Quality and Safety in Health Care

*Incidents of Potential Abuse or Neglect at Skilled Nursing Facilities:* This memorandum alerts CMS to the preliminary results of an HHS-OIG ongoing review of potential abuse or neglect of Medicare beneficiaries in skilled nursing facilities (SNFs) and is part of the office's ongoing efforts to detect and combat elder abuse. HHS-OIG identified 134 Medicare beneficiaries whose injuries may have been the result of potential abuse or neglect that occurred from January 1, 2015, through December 31, 2016. HHS-OIG also found that a significant percentage of these incidents may not have been reported to law enforcement. As a result, HHS-OIG determined that CMS has inadequate procedures to ensure that incidents of potential abuse or neglect of Medicare beneficiaries residing in SNFs are identified and reported. (A-01-17-00504)

*Correcting Deficiencies at Nursing Homes:* HHS-OIG found that that Arizona did not always verify nursing homes' correction of deficiencies, as required under Federal regulations, identified during surveys in 2014 in accordance with Federal requirements. HHS-OIG estimated that

Arizona did not verify nursing homes' correction of deficiencies in accordance with Federal requirements for 361 (56 percent) of the 650 deficiencies identified during surveys in 2014. Arizona's practice for less serious deficiencies was to accept the nursing homes' correction plans as confirmation of substantial compliance without obtaining the required evidence of correction. This is part of an ongoing series of reviews of States' verification of correction of deficiencies. (A-09-16-02013)

*Critical Incidents Involving Beneficiaries with Developmental Disabilities:* HHS-OIG found that Maine did not comply with Federal Medicaid waiver and State requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities. Maine failed to demonstrate that it has a system to ensure the health, welfare, and safety of the 2,640 Medicaid beneficiaries with developmental disabilities covered by the Medicaid waiver. (A-01-16-00001)

*Tracking Costs for Recalled or Prematurely Failed Medical Devices:* HHS-OIG determined that Medicare costs related to the replacement of recalled or prematurely failed medical devices could not be identified and tracked using only the claim data. HHS-OIG estimated that services related to the replacement of seven recalled and prematurely failed medical devices cost Medicare \$1.5 billion and accrued \$140 million in beneficiary copayment and deductible liabilities during calendar years 2005 through 2014. (A-01-15-00504)

*Investigations of Nursing Home Complaints:* HHS-OIG found that nursing home complaints rose by one-third across States from 2011 to 2015. During the period reviewed, States conducted nearly all the required onsite investigations for the two most serious levels of complaints. Although almost all States conducted most of their onsite investigations within required timeframes, a few States fell short. This data brief raises questions about how some States respond to complaints, as these responses could have serious consequences for nursing home residents in those States. To ensure the health and safety of nursing home residents, CMS must remain vigilant and assist the States that are falling short in meeting timeframes for investigations of complaints. (OEI-01-16-00330)

## **Other HHS-OIG Fraud and Abuse Prevention Activities**

### Data Analytics

As described above, HCFAC funding supported HHS-OIG's continued enhancement of HHS-OIG's technology and data analysis capabilities for detecting health care fraud. For example, HHS-OIG continues to use data mining, predictive analytics, trend evaluation, and modeling approaches to better analyze and target the oversight of the Medicare and Medicaid programs. Multi-disciplinary teams use near real 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 our HEAT and other partners, HHS-OIG's data analysis supports a highly effective combination of cutting edge technologies and traditional skills to fight against fraud, waste, and abuse.

### **Industry Outreach and Guidance**



HHS-OIG strives to cultivate a culture of compliance in the health care industry through various educational and outreach efforts.

### 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 2017, the HHS-OIG, in consultation with DOJ, issued 9 advisory opinions and modified 1 advisory opinions. A total of 352 advisory opinions and 21 modifications to advisory opinions have been issued, and 4 opinions terminated, during the 21 years of the HCFAC program.

### Collaborations with Private Sector Partners

HHS-OIG regularly engages with public stakeholders to combat fraud. For example, HHS-OIG is an active partner in the Healthcare Fraud Prevention Partnership (HFPP), described in more detail elsewhere in this report, and with the National Healthcare Anti-Fraud Association, both of which are public-private partnerships that address health care fraud by sharing data and information for the purposes of detecting and combatting fraud and abuse in health care programs. HHS-OIG frequently shares information about prescription-drug fraud schemes, trends, and other matters related to health care fraud, as appropriate. As a further example, HHS-OIG has collaborated with the DEA to provide anti-fraud education at numerous Pharmacy Diversion Awareness Conferences held across the United States. The conferences were designed to assist pharmacy personnel with identifying and preventing diversion activity. Since 2013, HHS-OIG has presented at conferences in 50 States and Puerto Rico.

## **Centers for Medicare & Medicaid Services**

In FY 2017, CMS was allocated \$20.8 million by HHS, which is comprised of \$18.2 million in new FY 2017 mandatory HCFAC funding and \$2.6 million in prior year mandatory funding, and appropriated \$569.1 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 2017, Congress required HHS to fully fund the Administration for Community Living's (ACL) Senior Medicare Patrol's activity. Therefore, \$18 million of CMS's \$569.1 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 other Medicaid program integrity activities, the Fraud Prevention System, Recovery Audit Contractor activities, and prior authorization initiatives are discussed in detail in separate reports. CMS will also submit an annual 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 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 fraud, waste, and abuse and improving payment accuracy.

During FY 2017, 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 fraud, waste, and abuse. 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 2010<sup>14</sup> (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 potentially fraudulent providers and suppliers, reduce the administrative and compliance burden on legitimate providers and suppliers, and prevent potential fraud so that funds are not diverted from providing beneficiaries with access to quality health care.

CMS has invested considerable resources in systems and initiatives related to data and analytics to prevent or rapidly identify fraud, waste, and abuse. During FY 2016, CMS developed the next generation system of the FPS, known as 2.0, which was implemented in 2017. FPS 2.0 improves model development, decreases time to market for models and edits, and expands CMS analytic capabilities.

The FPS helped CMS identify or prevent \$527.1 million in inappropriate payments during FY 2016, which resulted in a ROI of \$6.3 to 1.<sup>15</sup> Since CMS implemented the original FPS technology in June 2011, the FPS has identified or prevented almost \$2.0 billion in inappropriate payments by discovering new leads or contributing to existing investigations. During FY 2016, the FPS models generated 688 leads that were included in the Zone Program Integrity Contractor's workload, resulting in 476 new investigations and augmented information for 212 existing investigations. (FY 2017 numbers not available at time of this report.)

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<sup>14</sup> Public Law 111-240.

<sup>15</sup> During FY 2016, CMS operated the FPS (FPS 1.0) and simultaneously developed FPS 2.0, which is the next generation of the FPS. FPS 2.0 became operational in FY 2017, so there were no savings associated with it in FY 2016. The \$6.3 to \$1 ROI includes costs associated with both FPS 1.0 and the development of FPS 2.0. If the FPS 2.0 costs are excluded from the calculation, the ROI would be \$8.2 to \$1.

## Suspensions

In FY 2017, CMS continued its use of statutory 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 there is reliable information that an overpayment exists. During FY 2017, there were 551 payment suspensions that were active at some point during the fiscal year. Of the 551 payment suspensions, 252 new payment suspensions were imposed during FY 2017.

## National Correct Coding Initiative

### *Medicare*

Given the volume of claims processed by Medicare each day and the significant cost associated with conducting medical review of an individual claim, CMS uses automated edits to help prevent improper payment without the need for manual intervention. The National Correct Coding Initiative (NCCI) program consists of edits designed to reduce improper payments in Medicare Part B. CMS originally implemented the NCCI program in the Medicare program in January 1996 using Procedure-to-Procedure (PTP) edits to ensure accurate coding and reporting of services by physicians. PTP edits prevent inappropriate payment for billing code pairs that should not be reported together by the same provider for the same beneficiary for the same date of service. In addition to PTP edits, CMS established the Medically Unlikely Edit (MUE) program in 2007 as part of the NCCI program to reduce the Medicare Part B paid claims improper payment rate. MUEs prevent payment for an inappropriate number/quantity of the same service on a single day.

Since October 2008, CMS has made public and posted all PTP edits and the majority of MUEs on the CMS website. To prevent misuse or manipulation by fraudulent or abusive individuals and entities, CMS does not publish certain edits. The use of PTP edits developed through the NCCI program saved the Medicare program \$186.9 million during the first nine months of FY 2017. In addition, MUEs saved the Medicare program \$359.8 million during the first nine months of FY 2017.

### *Medicaid*

Section 1903(r) of the required CMS to notify states by September 1, 2010 which NCCI methodologies are compatible with claims filed with Medicaid. It also required states to use these methodologies to process applicable Medicaid claims filed on or after October 1, 2010.<sup>16</sup> CMS has worked closely with state Medicaid agencies to implement the NCCI methodologies in their Medicaid programs. Complete and correct implementation of NCCI methodologies in state Medicaid programs will be a long-term undertaking by both CMS and the states. However, CMS use of the Medicaid NCCI methodologies in states' adjudication of Medicaid claims produces significant savings in federal and state Medicaid program expenditures based on

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<sup>16</sup> 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>.

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, the [Medicaid National Correct Coding Initiative Technical Guidance Manual](#), which compiles, organizes, and integrates CMS requirements for state implementation for the Medicaid NCCI methodologies. Similar to that for Medicare, this document is continually refined, with revised edit tables published quarterly. The Medicaid NCCI edits include Medicare compatible edits and Medicaid specific NCCI edits. These resources are located on [The National Correct Coding Initiative in Medicaid website](#).

#### Integrated Data Repository and the 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 prescription 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. The IDR contains Medicare Part A, Part B (including DME), Part C (encounter), and Part D paid claims beginning with January 2006, both before and after final payment. This allows for prepayment analytics on historical data to develop models for use in the FPS.

CMS continues to integrate new data sources into the IDR. CMS has added Shared Systems location data for pre-adjudicated claims, claims submitter, and medical review utilization data.

CMS is also working to incorporate state Medicaid data into the IDR through standard T-MSIS data formats, 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 in conjunction with the IDR 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.

#### The Command Center

The Command Center opened in July 2012 and provides an opportunity for Medicare and Medicaid policy experts, law enforcements officials from HHS-OIG and the DOJ, including the Federal Bureau of Investigation (FBI), state law enforcement officials, clinicians, and CMS fraud investigators to collaborate before, during, and after the development of fraud leads in real time. 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 2017, 25 missions were conducted in the Command Center that included participants from CMS and CMS partners, including the FBI.

## 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. Zone Program Integrity Contractors (ZPICs)/Program Safeguard Contractors (PSCs)/Unified Program Integrity Contractors (UPICs) 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 2017 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.

### **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, or if applicable, 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 programs and ensure that only eligible providers are caring for beneficiaries and receiving payment.

### Medicare Provider Screening and Site Visits

CMS implemented additional screening provisions through a final rule<sup>17</sup> published by the Federal Register on February 2, 2011. CMS' regulation establishes 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. Providers and suppliers designated in the "limited" risk category undergo verification of licensure and a wide range of database checks to ensure compliance with all provider- or supplier-specific requirements. Providers and suppliers designated in the "moderate" risk category are subject to all the requirements in the "limited" screening level, in addition to unannounced site visits. Providers and suppliers in the "high" risk category are subject to all of the requirements in the "limited" and "moderate" screening levels, in addition to fingerprint-based criminal background checks (FCBCs). For Medicare, CMS began phasing in the fingerprinting requirements on August 6, 2014. In FY 2017, CMS denied approximately 1,259 enrollments and revoked 19 enrollments as a result of the FCBCs or a failure to respond.

The Advanced Provider Screening system (APS) automatically screens all current and prospective providers and suppliers against a number of data sources, including provider and supplier licensing and criminal records to identify and highlight potential program integrity issues for proactive investigation by CMS. In FY 2017, APS resulted in more than 2.6 million screenings. These screenings were composed of more than 21,700 actionable License Continuous Monitoring alerts, and more than 60 actionable Criminal Continuous Monitoring alerts, which resulted in approximately 176 Criminal revocations and over 590 Licensure revocations.

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<sup>17</sup> 76 FR 5862 (Feb. 2, 2011).

Site visits are a screening mechanism used to prevent questionable providers and suppliers from enrolling or maintaining enrollment in the Medicare program. The CMS-authorized site-visit contractors validate that the provider or supplier complies with Medicare enrollment requirements during these visits. In FY 2017, the initiative resulted in 75,568 site visits conducted by the National Site Visit Contractor (NSVC), which conducts site visits for most Medicare FFS providers and suppliers, and 17,745 conducted by the National Supplier Clearinghouse (NSC), which conducts site visits for Medicare DME suppliers. This work resulted in 227 revocations due to non-operational site visit determinations for all providers and suppliers.

CMS's provider screening and enrollment initiatives in Medicare have had a significant impact on removing ineligible providers from the program. In FY 2017, CMS deactivated 177,525 enrollments, and revoked 2,831 enrollments. Site visits, revalidation, and other initiatives have contributed to the deactivation<sup>18</sup> and revocation<sup>19</sup> of more than one million enrollment records since CMS started implementing these screening and enrollment requirements.

### Enrollment Special Study

The Enrollment Special Study 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 by CMS 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, 2017, the Medicare Administrative Contractor covering Florida (First Coast Service Operations) had conducted 17,558 site visits to verify providers' and suppliers' operational status, deactivated 596 practice locations, and revoked or denied 1,433 providers. CMS saved \$21.6 million from prepayment medical record review.

### Medicaid Screening and Enrollment

As part of its oversight role in Medicaid, CMS works closely with state Medicaid Agencies (SMAs) to provide regulatory guidance, technical assistance, and other support with respect to provider enrollment. SMAs can comply with Medicaid screening requirements by using CMS' screening results for dually-enrolling providers, thus eliminating the need and burden associated with states re-screening such applicants. States may use Medicare screening data, including site visits, payment of application fees, and FCBCs. For Medicaid-only FFS providers, SMAs at a minimum must follow the same risk-based screening procedures followed by Medicare when enrolling Medicare providers and suppliers.

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<sup>18</sup> 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.

<sup>19</sup> Revocation means the provider's or supplier's billing privileges are terminated. See 42 CFR 424.535.

During FY 2017, CMS continued to expand 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. Additionally in FY 2017, CMS launched the PECOS State's page and included provider enrollment information such as Medicare enrollment status, recent change of ownership information, reassignments, Medicare risk levels, and more. CMS also shares HHS-OIG exclusion data with states. Since May 2016, CMS has offered 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 updates to the MPEC in FY2017, 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 (MII). The FY 2017 course schedule included a seminar in April 2017 that focused exclusively on provider screening and enrollment compliance provisions in statute. More information on the MII can be found at: <https://www.justice.gov/mii>.

### Provider Enrollment Moratoria

CMS has used the authority provided to the Secretary in section 1866(j)(7) of the Social Security Act to temporarily prevent the enrollment of new Medicare, Medicaid, and CHIP providers and suppliers, including categories of providers and suppliers, where the Secretary has determined such moratoria are necessary to combat fraud, waste, or abuse. In July 2013, CMS announced temporary moratoria on the enrollment of new Home Health Agencies (HHAs) and Part B ground ambulance suppliers in Medicare in three "fraud hot spot" metropolitan areas of the country: in and around Miami, Florida, and Chicago, Illinois (HHAs and HHA Sub-units) and in and around Houston, Texas (Part B ground ambulance suppliers). The moratoria also applied to Medicaid and CHIP. CMS exercised this authority again on January 2014, CMS extended these moratoria by 6 months and expanded the moratoria to include HHAs in the areas surrounding Fort Lauderdale, Florida; Dallas and Houston, Texas; and Detroit, Michigan, and Part B ground ambulance suppliers in and around Philadelphia, Pennsylvania. CMS continued to extend these moratoria in 6-month increments and nearby New Jersey counties. The moratoria have since

been extended at 6-month intervals and to date, remain in place in all of the above-mentioned locations.

In July 2016, CMS announced the 6-month extension and statewide expansion of the moratoria on the enrollment of HHAs in Florida, Illinois, Michigan, and Texas and of Part B non-emergency ambulance suppliers in Texas, New Jersey, and Pennsylvania. In addition, it announced the lifting of the moratoria on all Part B emergency ground ambulance suppliers. These moratoria and changes also applied to Medicaid and CHIP.

In conjunction with the extension and expansion of the moratoria, CMS implemented the Provider Enrollment Moratoria Access Waiver Demonstration (PEWD) for HHAs and Part B non-emergency ground ambulance suppliers in moratoria-designated geographic locations. The PEWD also applies to Medicaid and CHIP. The PEWD includes heightened screening and investigations of certain providers and suppliers, and allows CMS to support an expansion to state-wide moratoria by addressing the operational concerns that have surfaced throughout the moratoria and providing possible exceptions to a statewide moratorium based primarily on beneficiary access to care, so long as the provider passes the enhanced screening measures.

In January 2017, and again in July 2017, CMS extended these moratoria for an additional six months. On August 25, 2017, the President of the United States signed the Presidential Disaster Declaration for several counties in the State of Texas due to Hurricane Harvey. As a result of the President's declaration, CMS carefully reviewed the potential impact of continued moratoria in Texas, and decided to lift the temporary enrollment moratorium on Medicare Part B non-emergency ground ambulance suppliers in Texas in order to aid in the disaster response, effective September 1, 2017. The lifting of the moratorium also applied to Medicaid and CHIP in Texas. A notification that CMS lifted the moratorium was published on the CMS website and became effective on September 1, 2017. In accordance with § 424.570(d), CMS also published a document in the Federal Register to announce this action.

In each moratorium area, CMS prohibited the new enrollment of HHAs and ground ambulance suppliers while taking administrative actions, such as deactivations and revocations of HHAs and ground ambulance companies, as well as worked with law enforcement to support investigations and prosecutions.

### **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 and other funding sources 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. Utilizing technical assistance and education through CMS' Medicaid Technical Advisory Groups, voluntary state assistance site visits, provider screening and enrollment strategies, onsite focused program integrity reviews, consolidation of provider audits and investigations through the five newly awarded



Unified Program Integrity Contractors, and through desk 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.

CMS provides 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. CMS also ensures all 50 states and the territories received technical assistance with moving through the Enterprise Life Cycle (ELC) Gate Review Process, including any associated consults. States received assistance with project management, implementation, and operations. Technical artifacts required by statute were analyzed and tracked to assess state progress. Gap analyses were done on a regular basis and risk registers were studied to identify opportunities for improvement. In addition, CMS geared numerous tasks 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 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 beneficiary eligibility for Medicaid and CHIP under the current law, in August 2013 and October 2015, CMS released guidance announcing temporary changes to PERM eligibility reviews. For FYs 2015 through 2018, CMS did not conduct the eligibility measurement component of PERM in order to update the eligibility component measurement methodology and related PERM program regulation. In place of these PERM eligibility reviews, all states are required to conduct eligibility review pilots that provide more targeted, detailed information on the accuracy of eligibility determinations to: provide state-by-state programmatic assessments of the performance of new processes and systems in adjudicating eligibility; identify strengths and weaknesses in operations and systems leading to errors; and test the effectiveness of corrections and improvements in reducing or eliminating those errors. During this time, for the purpose of computing the overall national improper payment rate, the Medicaid and CHIP eligibility component improper payment rates are held constant at the FY 2014 national rate of 3.11 percent and 4.22 percent, respectively. In July 2017, CMS issued a final rule (CMS-6068-F) that made changes to the eligibility measurement component of the PERM program, and the eligibility measurement component will resume for reporting in 2019.

In the Department of Health and Human Services FY 2017 Agency Financial Report (AFR), CMS reported the national Medicaid improper payment rate that is based on measurements conducted in FYs 2015, 2016, and 2017. The FY 2017 national Medicaid improper payment rate is 10.10 percent, representing \$36.73 billion in gross improper payments. The FY 2017 national improper payment rates by component are 12.87 percent for Medicaid FFS, and 0.30 percent for Medicaid managed care. As noted above, 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 decreased from 10.48 percent in FY 2016 to 10.10 percent in FY 2017.

Since FY 2014, the Medicaid improper payment rate has been driven by errors due to state non-compliance with provider screening, enrollment, and National Provider Identifier (NPI) requirements. Compliance with provider screening, enrollment, and NPI requirements for the 17 states measured in FY 2017 improved and CMS saw a decrease in improper payments related to non-compliance. The Medicaid FFS improper payment rate for non-compliance with these requirements decreased for these states from 5.74 percent in 2014 to 4.03 percent in 2017. Although the 17 states reviewed this year had better compliance results compared to their previously measured cycle, non-compliance with the provider screening, enrollment, and NPI requirements is still a major contributor to the improper payment rate. Additionally, improper payments due to no or insufficient medical documentation increased in FY 2017.

CMS also reported in the FY 2017 AFR the national CHIP improper payment rate that is based on measurements conducted in FYs 2015, 2016, and 2017. The FY 2017 national CHIP improper payment rate is 8.64 percent, representing \$1.24 billion in gross improper payments. The national improper payment rates by component are 10.29 percent for CHIP FFS and 1.62 percent for CHIP managed care. As noted above, 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 7.99 percent in FY 2016 to 8.64 percent in FY 2017.

The increase was due to continued state difficulties coming into compliance with the provider screening, enrollment, and NPI requirements described in Medicaid above. The CHIP FFS

improper payment rate for non-compliance with these requirements increased for these states from 4.69 percent in 2014 to 5.73 percent in 2017. A higher percentage of CHIP providers are not enrolled in Medicare and, therefore, there are more CHIP providers where states are not able to rely on Medicare's screening in lieu of conducting state screening. Additionally, there was an increase in managed care improper payments in FY 2017 due to recipients that aged out of CHIP, yet continued to receive medical coverage.

### 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 approximately 54 active demonstrations for which federal outlays an estimated \$109 billion in FY 2015. The Medicaid portfolio of section 1115 demonstrations continues to grow 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.

CMS staff activities in 2017 included implementing a new budget neutrality calculation policy under which projected expenditures that are compared to estimated demonstration costs are now based on more current and realistic expenditure growth assumptions. CMS also implemented 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 and ongoing participation on a taskforce to develop a phased approach to building standard operating procedures and reporting tools to strengthen section 1115 fiscal and program monitoring, including a new budget neutrality workbook to support state reporting and CMS review and a demonstration monitoring template for states.

CMS staff continue to work 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 continue to support a CMS IT contractor further advance an information management system that is beginning to strengthen federal monitoring and analysis of performance trends across states and over time. The third version of this system was recently released and staff are being trained on it.

### Medicaid/CHIP Financial Management Project

Under the Medicaid/CHIP Financial Management Project, funding specialists, including accountants and financial analysts, worked to improve CMS' financial oversight of the Medicaid Program and CHIP. In FY 2017 through the continued efforts of these specialists, CMS removed an estimated \$2.7 billion (with approximately \$647 million recovered and \$2.1 billion resolved) of approximately \$9.5 billion identified in questionable Medicaid costs.

Furthermore, an estimated \$457 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.

#### National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC)

The NBI MEDIC has national jurisdiction related to Part C and Part D benefits and 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.

In the first nine months of FY 2017, NBI MEDIC Part C referrals resulted in sentences ordering restitution of \$2.7 million according to FY 2017 notifications from law enforcement. In addition, in the first nine months of FY 2017, NBI MEDIC Part D referrals resulted in sentences ordering restitution of \$38.0 million and \$2.5 million in fines according to FY 2017 notifications from law enforcement. The NBI MEDIC was responsible for assisting the HHS-OIG and the Department of Justice (DOJ), through data analysis and investigative case development, in achieving arrests, indictments, and convictions, from FY 2017 notifications. As a result of the NBI MEDIC’s data analysis projects including Part D plan sponsor self-audits, HHS recovered \$5.0 million in the first nine months of FY 2017 from Part D sponsors.

#### 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 2017, 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, CMS also has the 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.

CMS has greatly increased the level of transparency with respect to audit materials, the performance of audits, and the results of those audits, including any enforcement actions that may result. CMS believes 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 money penalties (CMP),
- Intermediate sanctions (i.e., suspension of marketing, enrollment, payment), and
- Terminations.

### Part C Benefits Review Activities

Each year, CMS requires Part C organizations to submit bids and plan benefit packages detailing how their Part C plans will provide coverage to beneficiaries for the following year. About 4,000 Part C plans submitted plan benefit packages and project to cover more than 20 million beneficiaries in contract year 2018 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 CMS's 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 are conducted 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 of each year. 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 in accordance with 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 organizations 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 2.7 billion encounter data records (EDRs).

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 organizations.

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 and 2017 CMS continued that transition and will ultimately use encounter data as the sole source of plan-submitted diagnosis information.

#### Encounter Data Oversight and Integrity Activities

Since complete and accurate encounter data are integral to risk adjustment payments and other uses of encounter data, CMS has developed an encounter data oversight and integrity plan to support efforts to ensure the completeness and accuracy of the MA data that are collected by CMS. This plan is aligned with direction provided by the GAO and lays out an incremental approach to assess and drive encounter data submission and quality over multiple years. Major components of the plan include: outreach, analysis, monitoring, and compliance of MAOs' encounter data submissions.

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

Each year, CMS publishes a national improper payment rate for Medicare Part C and Part D in accordance with the IPIA, as amended by IPERA and IPERIA.

The Part C gross improper payment estimate reported for FY 2017 (based on the 2015 payment year) is 8.31 percent or \$14.35 billion. The Part C methodology estimates improper payments resulting from errors in beneficiary risk scores. The primary component of most beneficiary risk scores is based on clinical diagnoses submitted by the plan. If the diagnoses submitted to CMS are not supported by medical records, the risk scores will be inaccurate and result in payment errors. The Part C estimate is based on medical record reviews conducted under CMS' annual National Risk Adjustment Data Validation (RADV) process, where CMS identifies unsupported diagnoses and calculates corrected risk scores.

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

- **Contract-Level Audits:** Contract-level RADV audits are CMS' primary corrective action to recoup overpayments. RADV verifies, through medical record review, the accuracy of enrollee diagnoses submitted by Part C organizations for risk adjusted payment. CMS expects that payment recovery will have a sentinel effect on the quality of risk adjustment

data submitted by plans for payment, as contract-level RADV audits increase the incentive for Part C organizations to submit valid and accurate diagnosis information, and encourage Part C organization to self-identify, report, and return overpayments they have received. Payment recovery for the pilot audits has been completed, totaling \$13.7 million (\$5.4 million was recovered in FY 2014, \$5.0 million in FY 2013, and \$3.4 million in FY 2012). After completing the pilots, contract-level RADV audits of payment years 2011 through 2013 are in various stages of the audit process. For example, payment year 2013 audits continued in FY 2017, and CMS will initiate payment year 2014 audits in FY 2018. Furthermore, CMS expects to conduct recoveries for the 2011 and 2012 contract-level RADV audits (which began in FY 2014 and FY 2015, respectively) in FY 2018, which will be the first reviews to recoup funds based on extrapolated estimates.

- **Overpayment Recoveries Related to Regulatory Provisions:** As required by the Social Security Act, CMS regulations specify MA organizations report and return overpayments that they identify. In FY 2017, MA organizations reported and returned approximately \$78.7 million in self-reported overpayments. CMS believes that this requirement will reduce improper payments by encouraging MA organizations to submit accurate payment information.
- **Recovery Audit Contractor:** Section 1893(h) of the Social Security Act required the implementation of a Medicare Part C RAC program. CMS previously published a solicitation for comments and, in 2014, issued a request for proposal; however, no proposals were received. In 2015, CMS issued a request for information and reviewed comments received. Currently, CMS is exploring how to fit the Medicare Part C RAC program into the larger Medicare Part C program integrity efforts, and examining refinements that can be made to the operations of RACs such that their activities do not excessively burden plans.
- **Training:** Historically, CMS has conducted fraud, waste, and abuse in-person and webinar training sessions for MA plans. Only one training session for MA plans was conducted in FY 2017 due to procurement activities that were underway and the termination of contractor support in mid-FY 2017. In late FY 2017, CMS procured a new contractor to support this initiative and will resume training in FY 2018.

The Part D gross improper payment estimate reported for FY 2017 (based on CY 2015) is 1.67 percent or \$1.3 billion, which represents payment error related to prescription drug event (PDE) data. CMS measures the inconsistencies between the information reported on PDEs and the supporting documentation submitted by Part D sponsors: prescription record hardcopies (or medication order, as appropriate), and detailed claims information. Based on these reviews, each PDE in the audit sample is assigned a gross drug cost error, which is simulated onto a representative sample of beneficiaries to determine the Part D improper payment estimate.

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. For example, CMS continued to offer training sessions with detailed instructions for Part D sponsors submitting documentation to support their Prescription Drug Events (PDEs) as part of the improper payment estimation process. Historically, CMS has also conducted fraud, waste, and abuse in-person and webinar training sessions for Part D sponsors. Only one fraud, waste, and abuse training session for Part D sponsors was conducted in FY 2017 due to procurement activities that were underway and the termination of contractor support in mid-FY 2017. In late FY 2017, CMS procured a new contractor to support this initiative, and will resume trainings in FY 2018.
- **Outreach:** CMS continued formal outreach to plan sponsors for invalid/incomplete documentation. CMS distributed Final Findings Reports to all plan sponsors participating in the national payment error estimate. This report provided feedback on the number of PDE records successfully validated, and, if applicable, identified PDEs that CMS had determined were not substantiated by supporting documentation and therefore found to be in error.
- **Overpayment Recoveries Related to Regulatory Provisions:** As required by the Social Security Act, CMS requires that Part D sponsors report and return overpayments that they identify. CMS believes the overpayment statute and regulation contribute to increased attention paid by Part D sponsors to data accuracy. In FY 2017, Part D sponsors reported and returned approximately \$2.8 million in self-reported overpayments.

### CMS Marketplace Program Integrity

Program integrity is an increasing concern in the Health Insurance Exchanges – both in the Federally Facilitated Exchange (FFE) and the State-Based Exchange (SBE). In FY 2017, CMS’s exchange integrity team performed investigations work to identify areas of fraud and abuse in the Exchanges to include pilots to test the value of consumer complaints and identify leads that could result in administrative action, test the value of monitoring the license status of insurance agents once they register with CMS, and identify areas that appear to have a higher risk of fraud and abuse. CMS will continue these activities in FY 2018, including implementing an Exchange Program Integrity Contractor (EPIC) to facilitate analysis and investigations.

### **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 CMS's 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. The MACs 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.

## 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 overall mission of the HFPP is to position itself as a leading body of empowerment for the healthcare industry to reduce fraud, waste, and abuse by:

- Providing an unparalleled cross-payer data source, representing the full spectrum of the healthcare industry, to enable the performance of sophisticated data analytics and information-sharing for the benefit of all Partners;
- Achieving meaningful participation by Partners and establishing strategic collaborations with diverse stakeholders; and
- Leveraging Partnership resources and relationships to generate real-time, comprehensive approaches that materially impact efforts to reduce healthcare fraud, waste, and abuse.

In FY 2017, the HFPP reached a membership level of 85 Partner organizations, an increase of 23 percent since FY 2016. Membership is comprised of nine federal agencies, 12 associations, 44 private payers, and 20 state and local partners.

In FY 2017, the HFPP expanded its study methodology to collect frequently updated data, including personally identifiable information (PII) and protected health information (PHI). Over 5 billion professional claim lines were submitted by Partners in FY 2017 for the purpose of conducting cross-payer analyses, and at the end of FY 2017, the HFPP had commenced or completed 15 studies since program inception. These cross-payer studies enable the HFPP to proactively identify vulnerabilities in real time, significantly increasing the value of membership to all Partner organizations. The HFPP is currently using professional claims but is planning to expand to collect institutional, pharmacy, and dental claims in the future.

The HFPP uses a diverse variety of approaches to identify vulnerabilities in Partner data. These methods include standard searches to detect anomalies that may implicate the existence of fraud, waste, and abuse; scanning of incoming claims information against existing data sets, such as lists of deactivated providers; creation of reference files that list providers that may be suspect

based on known risks; and creation of informational content to support stakeholders in addressing vulnerabilities (e.g., white papers). Some studies initiated in FY 2017 include the identification of:

- Services billed under an “impossible day” scenario (including evaluation and management services, psychotherapy services, and physical and occupational therapy services),
- Referring providers with no prior relationship treating that patient,
- Excessive holiday and weekend billing, and
- Deactivated providers that continue to submit claims for payment.

Additionally, in January 2017, the HFPP released a White Paper entitled “Healthcare Payer Strategies to Reduce the Harms of Opioids: The Healthcare Fraud Prevention Partnership’s Commitment to the Management of Opioid Misuse and Opioid Use Disorder.” The White Paper describes best practices for serious consideration by all healthcare payers and other relevant stakeholders to effectively address and minimize the harms of opioids while ensuring access to medically-necessary therapies and reducing fraud, waste, and abuse.

### Open Payments

Open Payments is a statutorily required, national transparency program designed to provide the public with information regarding the financial relationships between the health care industry (applicable manufacturers and group purchasing organizations (GPOs), including pharmaceutical and medical device manufacturers) and health care providers (physicians and teaching hospitals). Open Payments data includes payments and other transfers of value (such as gifts, honoraria, consulting fees, research grants, and travel reimbursements) that drug or device companies provide to physicians and teaching hospitals, as well as the ownership and investment interests held by physicians or their immediate family members in these companies.

The Department of Health and Human Services (HHS) is required to collect and display this information, which is self-reported by industry, annually on a public website. The public can search, download, and evaluate the reported data.

In Fiscal Year 2017, CMS published \$8.18 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 11.96 million total records attributable to 631,000 physicians and 1,146 teaching hospitals. Payments in the three major reporting categories included:

- \$2.80 billion in general (i.e., non-research related) payments,
- \$4.36 billion in research payments, and
- \$1.02 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 40.77 million records, accounting for \$24.94 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 2017, HHS allocated \$18 million in HCFAC appropriations, plus an additional \$571,899 in carryover funding from FY 2016 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 beginning in FY 2016. In FY 2017, ACL was allocated \$18 million from CMS's 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 states and territories include the District of Columbia. In FY 2017, ACL awarded \$15.48 million in grant funding to SMPs nationwide, an increase of 5 percent over FY 2016. 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 rural areas of the state.

SMP projects use this funding to educate and empower Medicare beneficiaries to prevent, detect, and report Medicare fraud, errors, and abuse. ACL (and SMPs) have also recently partnered with CMS to identify potential fraud trends related to the new Medicare cards CMS will begin issuing to all beneficiaries starting in April 2018. In FY 2017, SMPs conducted 2,408 group outreach and education events and 4,167 individual interactions to educate beneficiaries about the new Medicare cards and related scams. To date, SMP projects have reported new Medicare card-related scams in four states.

Each year, the HHS Office of the Inspector General (HHS-OIG) completes an annual performance report on the SMP projects. In CY 2016, the 53 SMP projects had a total of 6,157 active team members (including volunteers, staff, and partners) who contributed more than 413,395 hours of work in support of the SMP program. These team members conducted 26,307 group outreach and education events to teach beneficiaries how to prevent, detect, and report Medicare fraud, errors, and abuse, reaching an estimated 1.5 million people. In addition, the projects had 195,386 individual interactions with, or on behalf of, beneficiaries in order to help resolve instances of suspected fraud, errors, or abuse. For 2016, the SMP projects reported \$163,904 in cost avoidance on behalf of Medicare, Medicaid, beneficiaries, and others. Savings to beneficiaries and others totaled \$53,449. Expected Medicare recoveries totaled \$2,672. Further, two projects provided information to Federal prosecutors that resulted in settlements totaling an additional \$9.2 million in expected Medicare recoveries.

Since SMP's inception, the program has educated over 36.6 million beneficiaries through 361,000 group education and outreach sessions. 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 2017 report on the SMP program:

*We note that 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 potentially substantial savings derived from a sentinel effect whereby Medicare beneficiaries' scrutiny of their bills reduces fraud and errors.*

ACL recognizes the importance of measuring the value of the SMP program impact to the fullest degree possible. To that end, ACL awarded a three-year research grant to Tufts University to measure the value of SMP prevention activities. Tufts 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 value of SMP prevention efforts, however further research and analysis is needed. In FY 2018, ACL's evaluation contractor will begin follow-up work to attempt to replicate and expand upon these results.

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 2017, ACL awarded a new, three-year grant to the National SMP Resource Center. 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. In FY 2017, ACL worked with SMPs to prioritize and implement ongoing system improvements to ensure SIRS continues to meet their needs and best support 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 was to develop new, efficient, and sustainable approaches for ensuring high-quality, culturally competent service delivery to help educate consumers to prevent health care fraud. These projects concluded 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 SMP Customer Satisfaction Survey received OMB approval in August 2017. Survey implementation will begin in late 2017 and continue over a three-year period. Each SMP project will be 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 and determine how the program can be improved to provide better service to Medicare beneficiaries. Survey results will be available at the national level, as well as for each individual SMP project.

## **Office of the General Counsel**

In FY 2017, the Office of the General Counsel (OGC) was allocated \$7 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's 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 2017, OGC was involved in a wide range of HCFAC efforts that resulted in Government recoveries of over \$1.8 billion in judgments, settlements, or other types of recoveries, savings, or receivables as described elsewhere in this report.

### HEAT

During FY 2017, OGC was involved in HEAT initiatives and worked closely with other HEAT members to combat fraud, waste, and abuse in the Medicare and Medicaid programs by providing advice on the myriad legal issues presented as the Federal Government implements innovative anti-fraud programs 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 federal court challenges that were brought as a result of HEAT

initiatives. OGC's involvement in HEAT also included advising CMS on provider and supplier revocations, payment suspensions, and recoupments, and defending the administrative appeals that resulted.

#### FCA and Qui Tam Actions

OGC supported DOJ in assessing FCA 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 helping DOJ focus Federal Government resources on matters 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 2017, OGC participated in FCA and related matters that recovered over \$1.6 billion for the Federal Government. The types of FCA cases in which OGC worked collaboratively with DOJ included: provider billing for services not rendered, marketing activity by device manufacturers that resulted in payment for items that do not qualify as payable durable medical equipment (DME), physician self-referral violations, billing by skilled nursing facilities for services that were not reasonable or necessary, improper approval of prior authorization requests, "incident to" and clinical supervision violations, provider upcoding, false certification of electronic health record capabilities, and Medicare Advantage matters, especially relating to risk adjustment issues.

#### Provider/Supplier Suspensions and Enrollment Revocations or Denials

Payment suspensions play a critical role in protecting against the abuse of program funds. OGC continuously advises CMS on whether to suspend payments to Medicare providers and suppliers and defended the suspensions when challenged through the appeal process. In FY 2017, 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, physicians, and diagnostic testing facilities. OGC also represented CMS when providers or suppliers appealed denials of enrollment or revocation actions. In FY 2017, OGC represented CMS in appeals before the HHS Departmental Appeals Board and in U.S. district court.

#### Part C and Part D Compliance

During FY 2017, OGC continued to provide extensive advice to CMS on a variety of Part C and Part D-related contract compliance issues, including identifying enforcement options against plan 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, CMP notices, and non-renewal or termination notices.

#### Civil Monetary Penalties

CMS has the responsibility of administering numerous CMP provisions enacted by Congress to combat fraud, waste, and abuse by enforcing program compliance and payment integrity. In FY 2017, 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 assisted HHS in developing an agency-wide Interim Final Rule that adjusts for inflation all CMP amounts authorized by statute and regulations under the Social Security Act as required under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act, Pub. L. 114-74).

#### 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 2017, 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 2017, 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's efforts include: providing counsel to the CMS "Innovation Center" on program integrity issues regarding new and existing 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 notices related to extending provider and supplier enrollment moratoria; assisting CMS in developing fraud-related sections of a new Medicare payment rule applicable to clinical diagnostic laboratory tests reimbursed under the Clinical Laboratory Fee Schedule; and helping CMS interpret and implement a new regulation that addresses concerns about fraud, waste, and abuse in the Part D program by requiring prescribers of Medicare Part D covered drugs to enroll Medicare.

#### Physician Self-Referral

OGC provided guidance to CMS and DOJ in navigating the complexities of the Stark physician self-referral law. This consultation helped build stronger cases and focus investigatory efforts, leading to successful results for the Government. In FY 2017, OGC provided extensive counsel to CMS in its ongoing implementation of the Medicare Physician Self-Referral Disclosure Protocol, which was created 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 600.

#### Medicare Secondary Payer (MSP) Workload

OGC's efforts to recover Medicare's conditional payments that are the primary responsibility of other payers directly support the HCFAC statutory goal of facilitating the enforcement of all applicable legal remedies for program fraud and abuse. During FY 2017, OGC has been successful in establishing the right to recover over \$9.2 million for Medicare under the MSP program.

#### 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 Medicare provider agreements as executory contracts, and petitioning for administrative costs where appropriate. In FY 2017, OGC asserted CMS's interests in numerous bankruptcy and receivership actions involving physicians, hospitals, independent diagnostic test facilities, DME suppliers, skilled nursing facilities, and home health agencies, collecting or establishing the right to collect over \$10.5 million in recoveries involving bankrupt providers and suppliers.

#### 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 2017, 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 challenging 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 2017 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 and 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 2017, \$4.4 million in HCFAC funding was made available for the U.S. Food and Drug Administration (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, which furthers FDA's public health mission by protecting the public from potentially dangerous medical products, helping to reduce health care costs, in most cases before they are incurred, and deterring 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 200 criminal HCFAC investigations. In FY 2017, FDA's seventh full fiscal year of HCFAC Program activity, OCI, through its PFP, opened 46 criminal investigations, including investigations involving drug compounders, clinical trials, and foreign and domestic medical-product manufacturers. These investigations consist of allegations involving:

- Questionable manufacturing practices of a foreign-based drug firm involving possible violations regarding application fraud, data integrity, data manipulation, and product adulteration.
- Questionable manufacturing practices of drug compounding facilities, involving possible violations of misbranding and/or adulteration.
- Questionable manufacturing practices of drug and medical devices ultimately causing public safety risks, involving possible violations of misbranding and/or adulteration.
- Clinical trial fraud, involving individuals suspected of falsifying/manipulating clinical trial data or conducting clinical trials without FDA oversight.
- Application fraud, involving individuals or companies who either submitted false/fraudulent information to FDA in order to obtain approval/clearance or did not submit the required information to legally market drugs, devices or biologics.
- Fraudulent marketing schemes.

As noted in previous requests, the types of criminal investigations conducted through the PFP are typically complex investigations, such as application fraud and marketing fraud, requiring extensive document review. It is not unusual for these complex fraud investigations to last for five years or more from initiation to conclusion. Yet investigations under the PFP have produced numerous prosecutions

For example, in November 2016, a PFP investigation resulted in a 40 count indictment of a sales representative of a Tennessee company, who devised a scheme to defraud health insurance companies of more than \$5 million, by using false and/or invalid prescriptions for patients with no pre-existing medical condition or need for the treatments. The defendant pled guilty to one count of wire fraud in September 2017.

In March 2017, a PFP investigation resulted in the conviction of an owner and head pharmacist of a compounding pharmacy that infected 750 people with mold and resulted in 64 deaths. After a nine week trial, a federal jury convicted the owner of racketeering and mail fraud. This owner and head pharmacist was sentenced in June 2017 to nine years in prison and three years of supervised release. In September 2017, the owner was ordered to forfeit assets totaling over \$7.5 million. A second supervisory pharmacist at this same compounding pharmacy was convicted by a federal jury in October 2017, of racketeering, racketeering conspiracy, mail fraud, and introduction of misbranded drugs into interstate commerce. In this case, fourteen defendants in total were charged and three of them pled guilty to charges in 2016.

Also in March 2017, the co-owner and chief operating officer of a Wisconsin drug manufacturer

pled guilty to one count of introducing a misbranded drug into interstate commerce, in connection with the shipment of sterile products that were contaminated with harmful bacteria. It was suspected that these contaminated products may have caused unexpected skin infections in numerous patients, including two children who developed sepsis after exposure to the product. The defendant was sentenced to probation in June 2017, and was ordered to pay approximately \$35,000 in restitution.

In June 2017, the owner of an Indiana compounding pharmacy and his compliance director were both indicted in connection with distributing over- and under-potent drugs, and for defrauding the United States by obstructing the lawful functions of the FDA. The compliance director pled guilty in July 2017. The owner pled not guilty and has a trial set for April 2018.

Furthermore, FDA believes that various investigations already initiated under the PFP may lead to future judicial action that may include criminal prosecution and monetary recoveries. These investigations include several foreign drug manufacturers under investigation for data integrity and other manufacturing violations which could possibly pose a risk to the public's health and safety. Sixty percent of generic drugs in the United States come from foreign manufacturers.

Finally, FDA continues to train its employees to maximize the agency's ability to prevent and detect fraud involving medical products. In December 2016, FDA conducted a training session to FDA regulatory personnel attending the annual Clinical Bioresearch Monitoring training. These personnel routinely conduct inspections of clinical trials to ensure the protection of research subjects and the integrity of data submitted to FDA in support of a marketing application. Those inspections may uncover fraud. This training assists in teaching FDA regulatory personnel how to identify fraud and develop skills in collecting evidence that may result in a potential criminal case. In March 2017, FDA conducted a one day training session for newly hired criminal investigators and current supervisors covering PFP-related topics. In July 2017, 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 included legal training by OGC-FDD on the Federal Food, Drug, and Cosmetic Act.

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# DEPARTMENT OF JUSTICE

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## United States Attorneys

In FY 2017, the United States Attorneys' Offices (USAOs) were allocated \$71.6 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 2017, the Office of Legal Education (OLE) offered Certified Fraud Examiner Training, which was attended by approximately 40 analysts, auditors, investigators, and paralegals, and which provided training on a variety of topics related to health care fraud. The Criminal Division Fraud Section also held its annual 2017 National Health Care Fraud Training Conference that was attended by 130 Assistant United States Attorneys representing almost 60 districts. In addition, the Executive Office for United States Attorneys (EOUSA) presented multiple webinars during FY 2017 focusing on health care fraud issues. Many AUSAs, analysts, auditors, investigators, and paralegals participated in other federal, state, and private health care fraud seminars.

## **Criminal Prosecutions<sup>20</sup>**

In FY 2017, the USAOs opened 967 new criminal health care fraud investigations and filed criminal charges in 439 cases involving 720 defendants. During that same time period, 639 defendants were convicted of health care fraud-related crimes during the year.

## **Civil Matters and Cases<sup>21</sup>**

In FY 2017, the USAOs opened 948 new civil health care fraud investigations and had 1,086 civil health care fraud matters pending at the end of the fiscal year.

## **Civil Division**

In FY 2017, the Civil Division received approximately \$24.1 million in FY 2017 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 civil 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 every year since FY 2010.

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. These matters included allegations of hospitals, drug and device manufacturers, and pharmacies paying kickbacks to health care providers, including physician practices and hospitals, for referrals of patients, drugs, or devices (such as the Shire, Forest, Omnicare, and Walgreens 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 Mylan matter discussed earlier in this report) and

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<sup>20</sup> FY 2017 numbers are actual data through the end of September 2017. This data includes records classified either with the primary or tertiary 03G – Health Care Fraud program code.

<sup>21</sup> FY 2017 numbers are actual data through the end of September 2017. This data includes those records classified under with the FRHC – Health Care Fraud civil code.

marketing and selling products based on misleading or false information (the Biocompatibles and Novo Nordisk matters discussed earlier).

The Fraud Section's recoveries for AKS claims remained significant this year. 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 Department's largest recovery for a violation of the AKS was from Shire Pharmaceuticals LLC. The Department also recovered close to a hundred million dollars from hospitals and health systems for allegedly paying unlawful remuneration to clinics and physician practice groups. Similarly, the Department pursued matters involving alleged violations of the Stark Law, which 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 (including the Mercy Hospital matter discussed earlier).

The Fraud Section has continued to pursue matters in which providers bill federal health care programs for medically unnecessary services or services not rendered as billed. Such cases involve allegations that providers, including skilled nursing facilities, ambulance companies, and hospices, billed for services that the patients did not need (such as Life Care, Olympia Therapy, Medstar, and Genesis discussed above). Other cases involved allegations that providers such as hospitals billed federal health care programs for higher and more expensive levels of medical service than were actually performed (the IPC matter discussed earlier). The Department is pursuing claims against a hospital chain and its owner, alleging that the hospital chain billed for excessive and unnecessary inpatient hospital services instead of less costly outpatient or observation services. The Section has also committed significant resources to litigating claims against a number of nursing homes and health care providers relating to rehabilitation therapy administered to elderly residents who did not require or could not benefit from such therapy. Similarly, the Department has continued to pursue claims against hospice providers for billing Medicare for patients who did not have a terminal prognosis of six months or less or who received medically unnecessary services.

The Fraud Section is also handling an increasing number of matters related to managed care providers. Such cases include settlements of allegations that the defendants submitted unsupported diagnosis codes to inflate reimbursement (the CareCore and Freedom Health matters discussed previously). In addition, the Section filed suit against the nation's largest Medicare Advantage organization, alleging that the company obtained inflated risk adjustment payments based on untruthful and inaccurate information about the health status of beneficiaries enrolled in certain of the company's Medicare Advantage plans.

The Fraud Section also has successfully sought to hold individuals responsible for defrauding federal health care programs. In one matter, in addition to recovering a significant amount from an electronic health records vendor alleged to have misrepresented the capabilities of the companies' electronic medical records software, the Fraud Section also pursued settlements with certain founders and employees of that company (the ECW matter discussed earlier). In the past year, the Department has pursued a pain management physician who allegedly billed federal health care programs for services and tests that were not performed or were not medically necessary, the owners of pediatric dental practices alleged to have submitted false claims for pediatric dental services not rendered (the MB2 matter discussed earlier), and the owner of a

skilled nursing facility chain alleged to have billed Medicare and TRICARE for rehabilitation therapy services that were not reasonable, necessary, or skilled (the Life Care matter discussed earlier). The Fraud Section also obtained a settlement from a physician and office manager (husband and wife) who implemented a bonus scheme that induced a clinic's family to order unnecessary laboratory tests in violation of the Stark Law.

As the Fraud Section is litigating an increasing number of FCA cases, including the cases described above, to obtain an appropriate resolution, the Fraud Section is devoting additional resources to ensure that these complex cases are presented to the court in a polished and efficient manner. As courts have moved toward the use of technology in the courtroom, the Fraud Section, like other litigating parties, must retain litigation consultants who specialize in courtroom presentation.

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 the 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 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.

Finally, the Elder Justice Initiative, which is overseen by 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](http://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 pharmaceuticals and medical devices 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 the Department's regulations, the Branch is the primary component charged with enforcement of the Food, Drug, and Cosmetic Act in the federal court system. In FY 2017, CPB investigated and resolved a number of cases involving harmful practices that endanger the public health, employing novel tools to prosecute wrongdoers who sell unsafe pharmaceuticals and medical products to the American public. Several examples are discussed below:

In January 2017, the Branch resolved a case against Baxter Healthcare Corporation, which agreed to pay more than \$18 million to resolve criminal and civil liability arising from its failure to follow current Good Manufacturing Practices (cGMP) when manufacturing sterile drug products. Under the Federal Food, Drug, and Cosmetic Act, the failure to follow cGMP renders drugs manufactured under such conditions adulterated. At a plant in North Carolina, Baxter manufactured large-volume sterile intravenous (IV) solutions in a clean room that had high-efficiency particulate absorption (HEPA) filters installed in the ceiling. Air was pushed into the clean room through the HEPA filters. Between July 2011 and November 2012, Baxter manufactured IV solutions in a clean room with moldy HEPA filters, despite the fact that an employee had reported the presence of mold on the HEPA filters to plant management. Baxter distributed the adulterated products it made in that clean room (although there was no evidence that any of the product was actually contaminated with mold). As part of a global resolution, Baxter agreed to a deferred prosecution agreement and to pay a total of \$16 million in criminal monetary penalties and forfeiture. The resolution also included a civil settlement with the federal government, including a payment of approximately \$2.158 million, to resolve allegations that Baxter submitted or caused to be submitted false claims to the Department of Veterans Affairs in violation of the False Claims Act.

The Branch was part of the team that prosecuted the owner and head pharmacist of New England Compounding Center (NECC), Barry Cadden, in 2017. After a 9-week trial, in March 2017, Cadden was convicted by a federal jury of racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead. The charges arise from the 2012 outbreak of fungal meningitis caused by adulterated medicine made at NECC in Framingham, Massachusetts. The 2012 outbreak was caused by



contaminated vials of preservative-free methylprednisolone acetate (MPA) manufactured by NECC. In 2012, 753 patients in 20 states were diagnosed with a fungal infection after receiving injections of MPA manufactured by NECC. Of those 753 patients, the U.S. Centers for Disease Control and Prevention (CDC) reported that 64 patients in nine states died. The outbreak was the largest public health crisis ever caused by a pharmaceutical product.

The ensuing investigation revealed a host of fraudulent and unsafe pharmacy operations at NECC. Cadden directed and authorized the shipping of contaminated MPA to NECC customers nationwide. In addition, he authorized the shipping of drugs before test results confirming their sterility were returned, never notified customers of nonsterile results, and compounded drugs with expired ingredients. Furthermore, certain batches of drugs were manufactured, in part, by an unlicensed pharmacy technician at NECC. Cadden also repeatedly took steps to shield NECC's operations from regulatory oversight by the FDA by claiming to be a pharmacy dispensing drugs pursuant to valid, patient-specific prescriptions. In fact, NECC routinely dispensed drugs in bulk without valid prescriptions. NECC even used fictional and celebrity names on fake prescriptions to dispense drugs. Cadden was sentenced to serve 9 years in prison in June.

Another example of CPB's focus on consumer health and safety is the Novo Nordisk matter, resolved in September of this year. On September 5, 2017, the Department of Justice announced that Danish pharmaceutical manufacturer Novo Nordisk paid an equitable disgorgement of \$12.15 million under the terms of a civil settlement agreement related to the company's failure to comply with a Risk Evaluation and Mitigation Strategy ("REMS") required under the Food, Drug, and Cosmetic Act ("FDCA") for Type II diabetes medication Victoza. Pursuant to the settlement agreement, the United States filed a complaint against Novo Nordisk in the District Court for the District of Columbia. The complaint alleged that shipments of Victoza were misbranded pursuant to the FDCA because Novo Nordisk's sales force made false or misleading statements regarding the potential risk of a rare form of cancer associated with the drug. Those false or misleading statements contradicted the REMS required by FDA as a condition of approval of Victoza to ensure doctors understood the potential risks of the drug. As part of the settlement agreement, the parties requested the court dismiss the complaint. The global resolution also included a False Claims Act settlement of \$46.5 million. This is the first resolution or action of any kind brought for a manufacturer's failure to comply with a REMS.

CPB also has taken a leading role in the Department's efforts to combat elder fraud. With a long record of successfully prosecuting mass-mailing and telemarketing scams that target older Americans, CPB is now coordinating a major Department effort to highlight and advance elder-fraud cases across the country. CPB also is an active participant in the Elder Justice Initiative, furthering law enforcement efforts to combat elder exploitation through training, interagency collaboration, and public events. By protecting and educating seniors susceptible to fraud schemes, CPB's work helps to detect and deter a broad array of scams, including health-care-related frauds.

## **Criminal Division**

In FY 2017, the Criminal Division was allocated \$22.5 million in FY 2017 HCFAC funding to support criminal health care fraud litigation and interagency coordination, which is carried out primarily by the Fraud Section's Health Care Fraud Unit and, to a lesser extent, the Organized Crime and Gang Section.

### **The Fraud Section**

The Fraud Section's Health Care Fraud Unit ("HCF Unit") employs criminal prosecutors who focus exclusively on investigating and prosecuting health care fraud and related offenses. The HCF Unit's core mission is to investigate and prosecute health care fraud schemes that harm the public in two ways. First, a significant number of the HCF Unit's charged cases and active investigations focus on harm to federal health care program beneficiaries, including opioid abuse and drug diversion. Second, all of the cases investigated and prosecuted by the HCF Unit involve substantial losses to federal health care programs and the public fisc. The HCF Unit also supports the U.S. Attorney's Office community by providing legal, investigative and data analytics support, guidance and training on criminal health care fraud matters.

Beginning in March 2007, the Fraud Section, working with the local USAO, the FBI, HHS-OIG, and state and local law enforcement agencies, launched the Medicare Fraud Strike Force in Miami-Dade County, Florida, to investigate and 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. In FY 2017, the HCF Unit provided attorney staffing, litigation support, and leadership and management for the Strike Force program's operations in nine regions: Miami and Tampa/Orlando, Florida; Southern Texas; Southern Louisiana; Los Angeles, CA; Detroit, MI; Chicago, IL; Brooklyn, NY; and Washington, DC (Corporate Strike Force). Since the inception of the Strike Force program in 2007, the HCF Unit and its Strike Force partners have charged 3,286 defendants who have collectively billed the Medicare program more than \$12 billion. In FY 2017 alone, the HCF Unit achieved the following results:

- Filed 102 indictments, criminal informations and complaints involving charges filed against 210 defendants who allegedly collectively billed federal health care programs approximately \$1.5 billion;
- Obtained 160 guilty pleas and litigated 18 jury trials, with guilty verdicts against 18 defendants; and
- Sentenced 166 defendants, with an average sentence of over 63 months.

Each year, the HCF Unit leads and coordinates the National Health Care Fraud Takedown. On July 13, 2017, Attorney General Jeff Sessions and Department of Health and Human Services (HHS) then Secretary Tom Price, M.D., announced the results of the FY 2017 Takedown – the single largest health care fraud law enforcement operation in history - led by the HCF Unit in coordination with 41 U.S. Attorney's Offices and 29 Medicaid Fraud Control Units (MFCUs). This year's Takedown resulted in charges against 412 individuals, including 115 doctors, nurses,

and other licensed medical professionals, involving approximately \$1.3 billion in fraudulent billings of opioids. Of the 412 individuals charged, 120 (including 27 doctors) were charged in cases involving the illegal distribution of opioids. Furthermore, the Centers for Medicare & Medicaid Services (CMS) also suspended a number of providers using its suspension authority as provided in the Affordable Care Act.

The HCF Unit also provided legal guidance to FBI and HHS-OIG agents, health program agency staff, Assistant U. S. Attorneys, and other Criminal Division attorneys on criminal and administrative tools to combat health care fraud. Throughout FY 2017, the HCF Unit'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 HCF Unit 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.

Each year, the HCF Unit coordinates and hosts the National Health Care Fraud Training Conference. The 2017 National Health Care Fraud Training Conference was held in September 2017 in Washington, D.C. and was attended by 310 criminal and civil prosecutors (representing almost 60 U.S. Attorney's Offices) and law enforcement personnel from FBI, DEA, HHS-OIG, IRS Criminal Investigation, and Defense Criminal Investigative Service (DCIS), and provided training on investigative techniques and tools, trial skills, case studies, and persistent and emerging health care fraud schemes.

As part of the HCF Unit's efforts to lead a coordinated, national approach to combating health care fraud, the HCF Unit created and launched the HCF Unit Data Analytics Team in November 2016. This team allows the HCF Unit to better assist prosecutors in effectively and efficiently identifying and prosecuting individuals and entities, and to examine emerging health care fraud trends in the field. The HCF Unit Data Analytics Team also provides U.S. Attorney's Offices with customized HCF data analytic training and ongoing case-specific investigation and prosecution assistance. The HCF Data Analytics Team will continue to strengthen the HCF Unit's partnerships with U.S. Attorney's Offices across the country in combating health care fraud.

The HCF Unit's cases are also increasingly complex, both in the individual Strike Force locations and the Corporate Strike Force. Specifically, the Corporate Strike Force's mission is to investigate and prosecute corporate fraud cases involving major health care providers that operate in multiple jurisdictions, including major regional health care providers operating in the Strike Force cities, with a focus on investigations and prosecutions of individuals. The Corporate Strike Force coordinates with the Civil Division's Fraud Section and Consumer Protection Branch, U.S. Attorney's Offices across the country, state Medicaid Fraud Control Units, the FBI, and HHS-OIG in order to identify, investigate, and prosecute significant

corporate health care fraud cases, including the global resolution with Tenet Healthcare Corporation and related individual prosecutions. In addition, numerous city-based Strike Force prosecutions involve sophisticated money laundering and financial fraud schemes involving the use of shell companies and intermediaries to conceal ownership interests, kickback payments, and assets. The HCF Unit's expertise enables it to pursue these complex cases, many of which involve 100s millions of dollars in fraudulent claims to the Medicare and Medicaid program and TRICARE.

### **The Organized Crime and Gang Section (OCGS)**

The Criminal Division's Organized Crime and Gang Section (OCGS) supports and conducts investigations and prosecutions of health care 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 and supports the use of the Racketeer Influenced and Corrupt Organizations (RICO) statute to combat health care fraud and abuse.

In FY 2017, seven OCGS attorneys were assigned to health care fraud prosecutions and investigations.

In Knoxville, one OCGS attorney worked with the United States Attorney's office on the superseding indictment in a pill-mill prosecution of individuals for operating pain clinics and prescribing vast quantities of opioids outside the scope of professional practice without legitimate medical purposes. The clinics were responsible for generating revenues in excess of \$21 million and prescriptions for approximately 12 million opioid pills and other narcotics. The indictment also charged two pain clinic owners with taking bribes and kickbacks from national drug laboratories for referral of unnecessary urine screenings, causing the labs to submit approximately \$13,564,364 in claims to Medicare for the medically unnecessary tests, and directing bribe and kickback payments through shell companies which appeared to be providing legitimate services to the labs. This case is summarized above in the Highlights of Significant Criminal and Civil Investigations.

In Detroit, an OCGS attorney worked with the United States Attorney's Office to obtain a 48-month sentence 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 Health Records section of the Highlights of Successful Criminal and Civil Investigations.

Additional OCGS attorneys were engaged in investigations of health care fraud and abuse involving several large collectively bargained health plans, third party administrators to private sector health plans, health plans funded through prevailing wage government contracts, a federal prescription drug program and the sale of unapproved pharmaceuticals.

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 RICO statute in prosecutions of Medicare and Medicaid frauds as well as private sector health care frauds.

### **Civil Rights Division**

In FY 2017 the Civil Rights Division was allocated approximately \$9.0 million in FY 2017 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 also works to prevent 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 actions 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 2017 Accomplishments**

Key litigation and enforcement accomplishments in FY 2017 by the Civil Rights Division can be summarized as follows:

- Number of matters in active enforcement: 18;
- Cumulative estimate of individuals with disabilities affected: 42,600; and
- Number of institutional facilities affected: 2,321

### **Special Litigation Section**

In Fiscal Year 2017, the Special Litigation Section made findings regarding the unlawful use of nursing facilities to serve people with mental illness; closed five cases that successfully implemented reforms enabling individuals with intellectual and developmental disabilities and individuals with mental health disabilities to avoid needless institutionalization; continued monitoring compliance with eight statewide settlement agreements and one facility-focused agreement benefiting thousands of people; continued monitoring 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; continued litigating two large cases involving the unlawful institutionalization of, and denial of necessary services to, individuals with disabilities; and opened an investigation into conditions in a public mental health facility and whether a lack of county community alternatives causes unnecessary institutionalization of people with mental health disabilities. 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 13 states as well as the District of Columbia.

In Louisiana, the Division made findings that the state violates the ADA by facilitating the

placement of people with mental illness into nursing facilities when they qualify for, and could be served in, community-based settings. The Division is negotiating a proposed resolution to transition people with mental illness from nursing facilities to appropriate community-based care, enhance the community-based services necessary to support them, and divert other people with mental illness from unnecessary nursing facility admission.

An important aspect of the Division's work is the active enforcement of its agreements and litigation (i.e., ongoing monitoring to ensure agreements are successfully implemented and pursuit of remedial measures where compliance is not occurring). Because of these agreements' scope and complexity, this work typically spans several years. In FY 2017, the Special Litigation Section brought to a successful close five such agreements.

For example, in Tennessee, long-standing litigation regarding institutional and community services for people with intellectual disabilities in the eastern and middle of the state successfully concluded as a result of the Section's persistent compliance work. In June 2017, the State of Tennessee completed the last requirements of an "Exit Plan" negotiated by the parties. In August 2017, the parties filed a joint motion to vacate the case, and the court granted the parties' motion in September.

Another example is the Division's settlement agreement with the State of Delaware, which required the State to provide community-based services for people with serious mental illness who had been unnecessarily institutionalized in the State's psychiatric hospital. This matter concluded after Delaware implemented the agreement on schedule and significantly expanded community-based mental health services to ensure positive individual outcomes in integrated settings. Further, the State created 812 units of permanent Supported Housing, which is a SAMHSA evidence-based practice that reduces hospitalizations, and 15 Assertive Community Treatment ("ACT") teams, a SAMHSA evidence-based practice that reduces contact with institutional settings and enhances the quality of life in the community. The State also implemented a mental health crisis system with mobile crisis teams that divert 80 to 90 percent of callers from hospitalization or criminal justice interaction.

The Section also continued monitoring implementation of 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 other settings.

In New Hampshire, the Section's agreement with the State has enabled the State to divert hundreds of individuals with mental illness from costly hospital admissions through community crisis services; serve over 750 people in permanent Supported Housing; provide close to 1,000 adults with ACT team services; and provide over 3,000 people with Supported Employment services, a SAMHSA evidence-based practice that assists individuals with disabilities to gain meaningful, competitive employment, self-sufficiency, and independence.

Similarly, in Georgia, the Section has continued its oversight of the State's efforts to comply with its court-enforceable agreements. In implementing these agreements, Georgia has diverted hundreds of individuals with mental illness from unnecessary hospital admissions, provided permanent Supported Housing enabling 4,000 people to live successfully in the community, provided approximately 2,500 adults with ACT services, and provided over 2,600 people with Supported Employment services. Under these agreements, Georgia is also serving an additional 1,800 people with IDD through Medicaid home and community-based services to prevent their institutionalization or return them to the community from institutional settings.

In Virginia, the Section also has continued oversight of the State's efforts to comply with a statewide agreement requiring the development of community resources for people with intellectual and developmental disabilities ("IDD") who otherwise would be at risk of institutionalization. As a result of the agreement to date, more than 3,000 people with IDD who qualify for Medicaid-funded community services have received them, an additional 7,000 people with IDD have received one-time supports to assist them in continuing to live in the community, more than 300 people with IDD have been able to live in their own home; and more than 600 individuals have successfully transitioned from state-run institutions to community settings.

In FY 2017, the Section continued monitoring Oregon's implementation of a Performance Plan for Mental Health Services for Adults with Serious and Persistent Mental Illness ("SPMI"). Oregon developed the Plan in response to the Division's investigation of the State's mental health system under the ADA. The Plan memorializes steps the State will take over three years to help individuals with serious and persistent mental illness live successfully in community settings. The Plan required that, by June 30, 2017, the State would increase the number of individuals with SPMI served by ACT teams, from a baseline of 815, to 1,050 individuals served. The State reportedly exceeded the target, with 1,098 people with SPMI served by ACT teams. The Plan required that by June 30, 2017, the State would increase the number of individuals served with mobile crisis services to 3,500 people served. The State reportedly exceeded the target, with 4,383 people served with mobile crisis services. The Plan required that, by June 30, 2017, the State would ensure that 60 percent of individuals discharged from an acute care psychiatric facility would receive a follow up visit with a community mental health provider within 7 days of discharge. The State reportedly exceeded the target, with 71.5 percent of individuals receiving a follow up visit with a community mental health provider within 7 days of discharge. If the State successfully implements the remainder of the Plan's objectives, the Section will close its investigation.

The total number of people benefiting from these Agreements continues to grow, as the population served turns over with time.

The Section continued to negotiate a resolution in FY 2017 with the State of South Dakota regarding the Section's findings 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 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 also 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.

When it has not been possible to reach a negotiated resolution where the Department of Justice has found that individuals' rights have been violated through unlawful institutionalization or unlawful institutional conditions, the Section has litigated those findings. In FY 2017, the Section filed suit against the State of Mississippi, alleging that the State violates the ADA by serving thousands of persons with mental illness in State psychiatric hospitals when they could be served in integrated settings in the community. The litigation is ongoing. Also in FY 2017, the Section continued to pursue litigation against the State of Texas alleging that the State violates the ADA by institutionalizing persons with intellectual and developmental disabilities in nursing facilities. That case is scheduled for trial in June 2018.

### **Disability Rights Section**

In FY 2017, the Disability Rights Section monitored compliance of five settlement agreements, under which more than 16,100 people collectively will obtain relief; investigated whether another state provides services to individuals with physical disabilities in the most integrated setting appropriate to their needs; and continued its litigation of another case involving unnecessary institutionalization of people with disabilities.

The Section continued to monitor the implementation of its settlement agreement with the State of North Carolina, under which the State is providing opportunities to individuals with mental illness in adult care homes to transition to less costly, integrated service settings. Specifically, the State must provide integrated Supported Housing to 3,000 people by July 2020 and expand integrated employment opportunities for people with mental illness by providing Supported Employment services to 2,500 individuals by 2019. These services will allow individuals with mental illness to choose to live and work in the community, while allowing the State to avoid costly institutional settings.

Due to the State's failure to meet intermediate targets, the Section filed a motion to enforce the agreement in January 2017. In September 2017, the court granted the motion in part, found the State had failed to substantially comply with its July 1, 2016 obligations to provide Supported Housing and Supported Employment services, and ordered the parties to submit any agreed-to modifications by October 27, 2017.

As of August 31, 2017, 1,562 individuals had been diverted from or moved from large adult care homes to community-based settings. Six hundred ten individuals were diverted from adult care homes upon discharge from a state psychiatric hospital or upon being considered for admission to an adult care home, and 952 individuals moved out of adult care homes into the community. Of these 1,562 individuals, 1,225 (or 78 percent) continue to live and receive services in the community. In addition, 5,014 individuals were receiving Assertive Community Treatment services and 1,269 individuals in the agreement's target population were receiving Supported Employment services.

The Section 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 2,600 individuals with intellectual and developmental disabilities by 2024, and roughly 3,500 individuals will benefit from systemic changes to the State's employment and day service systems. The Section's enforcement efforts prompted the State to improve its data tracking and increase employment supports and placements. More than 540 individuals have obtained competitive, integrated employment as a result of these agreements.

The Section, along with the U.S. Attorney's Office for the Eastern District of New York, continued monitoring the settlement agreement with the State of New York and private plaintiffs regarding New York's mental health service system. The agreement benefits at least 2,500 people and remedies discrimination by the State in the administration of its mental health service system. Pursuant to the agreement, individuals with serious mental illness who reside in 22 large institutional settings known as adult homes in New York City will be given the opportunity to receive services in the most integrated setting appropriate to their needs consistent with the ADA and *Olmstead*. Under the agreement, such individuals can choose 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 540 adult home residents are living and receiving services in the community, and another 2,000 adult home residents have expressed interest in and are working toward doing so. The parties filed a second amended settlement agreement on May 4, 2017, which the Court approved on May 18, 2017.

The Section is working with class plaintiffs to monitor a settlement agreement with the State of Oregon. Pursuant to the settlement agreement, the State is decreasing its reliance on segregated employment settings and increasing Supported Employment services to help individuals with intellectual and developmental disabilities to obtain competitive integrated employment. The State will provide Supported Employment services so that 1,115 working-age individuals will obtain competitive integrated employment by June 30, 2022. By July 1, 2022, the State will also 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. As of March 2017, the State reduced the census of segregated settings to 1,043 individuals and reduced the total number of hours worked in segregated settings to 53,857. The parties are currently working to confirm the number of new individuals who achieved competitive integrated employment. Finally, as of June 30, 2017, the State reported that 2,453 transition-aged youth received at least one new employment service, and 2,043 of those youth received an Individual Plan for Employment.

The Section continued to litigate *United States v. Florida* (S.D. Fla. 2013), a case in which the United States alleges, among other things, that the State of Florida administers its Medicaid service system for children with significant medical needs in violation of Title II of the ADA by unnecessarily segregating them in nursing facilities, when they could, and want to, be served at home or in other community-based settings. On August 7, 2017, the United States filed a notice of appeal, appealing to the U.S. Court of Appeals for the Eleventh Circuit the Final Order of Dismissal as to the United States, entered on September 20, 2016, and the final order of dismissal of all other claims and parties, entered June 9, 2017.

Separately, a federal district court cited the Department's Statement of Interest and *Olmstead* guidance document in *Ball v. Kasich*, 2:16-cv-282 (S.D. Ohio), a case in which individuals on a wait list for home- and community-based services allege that Ohio's ongoing denial of services has placed them at serious risk of institutionalization. The Statement of Interest responded to the defendants' motion to dismiss a named plaintiff's claims on the ground of ripeness, clarifying that non-institutionalized individuals with disabilities who are not currently receiving state-funded home- and community-based services may bring a claim that a public entity has placed them at serious risk of institutionalization or segregation in violation of Title II's integration mandate. On March 23, 2017, the court denied in part defendants' motion to dismiss and concluded that the plaintiffs' claims were ripe for review.

### **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. The Section's pending litigation against the State of Georgia, alleging that the State is violating Title II of the ADA regarding its use of segregated educational services for approximately 5,000 Georgia students with emotional and behavioral disabilities, has been stayed pending resolution of *United States v. Florida*, noted above.

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# APPENDIX

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## Federal Bureau of Investigation

In FY 2017, the FBI was allocated \$131.3 million in funding from HIPAA and \$4.3 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 (488 Agent, 326 Support).

In FY 2017, the FBI initiated 625 new Health Care Fraud (HCF) investigations and had 2,799 pending investigations. Investigative efforts produced 583 criminal HCF convictions and 793 indictments and informations. In addition, investigative efforts resulted in over 674 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 148 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 has 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 among FBI components, but also with its 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. 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 – to include the rising prescription drug abuse epidemic, 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 threats.

FBI field offices throughout the U.S. address the HCF threat through joint investigative efforts; intelligence collection, sharing, and analysis; and the utilization of advanced and sophisticated investigative techniques. FBI field offices participate in HCF Task Forces and/or working groups with partners including local US Attorney's Office, HHS-OIG, DEA, IRS, FDA, other federal, state, and local law enforcement agencies, 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 developed and supports four initiatives, including the Health Care Fraud Prevention and Enforcement Action Team (HEAT), Large Scale Conspiracies, Major Provider Fraud, and the Prescription Drug Initiative.

HEAT is a DOJ, FBI 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, FBI 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 funding, resource allocation, Strike Force expansion, target identification, training, and operations. The FBI has 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 2017, two pilot Strike Force teams were established in Puerto Rico and the Washington, DC area. In addition to funding agent resources, the FBI funds 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 July 2017 DOJ National Health Care Fraud Takedown resulting in the charging of 412 subjects, including 115 doctors, nurses and other licensed medical professionals, for their alleged participation in health care fraud schemes involving approximately \$1.3 billion in false billings. 120 of these individuals, including 27 doctors, were charged in cases related to the prescription drug opioid threat. 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.

In FY 2017, the FBI led law enforcement efforts to identify judicial districts across the United States that are particularly at risk in the current opioid epidemic. The Attorney General created the Opioid Fraud and Abuse Detection Unit to surge prosecutorial resources to twelve of these judicial districts to prosecute individuals that are contributing the prescription opioid epidemic. As part of this initiative, DOJ appropriated additional funding to the FBI to support the

deployment of dedicated Special Agents to identify, investigate, and prosecute individuals who divert prescription opioids in judicial districts in states such as Tennessee, North Carolina, West Virginia, and Alabama.

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 of a pair of physicians in Alabama on 20 counts including RICO Conspiracy, Conspiracy to Distribute Controlled Substances, and Conspiracy to Commit Health Care Fraud. This conspiracy included double-billing for toxicology screens, kickback payments to the physicians totaling nearly \$80,000 per month, and voluminous controlled prescriptions from both subjects to individuals without medical necessity. The physicians were sentenced to a combined 492 months in prison and over \$30 million in restitution. In Detroit, three physicians was convicted of Conspiracy to Commit Health Care Fraud for submitting false statements, upcoding claims, billing for unnecessary services, and paying kickbacks for over \$17 million in claims to Medicare. In Houston, an 18-month FBI undercover operation collected evidence to ensure prosecution of significant health care fraud encompassing over \$90 million in Medicare losses, incurred by over 200 home health care facilities and four clinics submitting false claims. One Houston physician identified through this operation was sentenced to 480 months in prison for guilty verdicts of Conspiracy to Commit Health Care Fraud and Conspiracy to Commit Money Laundering. The FBI is committed to addressing this type of crime problem through the disruption, dismantlement and prosecution of those involved in criminal enterprises and other organized criminal activities.

The Major Provider Fraud Initiative seeks to identify and target corporate-level groups involved in fraud and abuse schemes with significant billing to health care benefit programs. The related schemes are frequently complex, challenging to identify, and can involve conduct that is nationwide in scope. Extensive resources and coordination are frequently required due to the complexity and scope of the schemes. Qui tams are a significant intelligence source for these types of cases. These investigations frequently involve pharmaceutical manufacturers, hospital corporations, and regional or national medical provider agencies. In addition to the work completed at the field office level, and in response to this substantial threat, the FBI has established a centralized support team to provide investigative assistance on these cases nationwide. An example of these types of cases would include the FBI-led investigation of Tenet Healthcare Corporation, which resulted in a \$513 million settlement (\$368 million civil; \$145 million criminal) to resolve allegations including the payment of over \$12 million in kickback payments to regional clinics for labor and delivery services. 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 would be a Philadelphia doctor convicted, after a six week trial, to 360 months in federal prison for

conspiring with a local chapter of the Pagan Motorcycle Club to divert approximately \$5 million worth of Schedule II controlled pain medications. An Alabama physician was sentenced to 180 months in prison for his role in operating a “pill mill” prescribing Schedule II controlled pain medications for cash. This physician was videoed in a surreptitious recording saying that he was “numb to” the 2 to 3 overdose deaths per week of his patients. With the Attorney General’s allocation of funds to the FBI as part of the Opioid Fraud and Abuse Detection Unit, the FBI is dedicated to prioritizing prescription drug scheme investigations, particularly in at-risk federal judicial districts, with enhanced support from the Prescription Drug Initiative.

The FBI actively provides training and guidance on HCF matters. The FBI has teamed with the DOJ, HHS, and private insurance organizations to provide training in the priority threat areas of HCF. Funded training has included innovative methods of employing advanced investigative techniques; basic HCF training for FBI Special 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 2017, more than 279 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 88).
- 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 2017, 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.

<b>Mandatory Resources<sup>1</sup></b>	<b>Fiscal Year 2017</b>
Office of Inspector General	185,906,325
Health and Human Services Wedge <sup>2</sup>	35,556,811
Medicare Integrity Program <sup>3</sup>	859,238,682
<i>MIP/Medicare (non-add)</i>	793,143,399
<i>Medi-Medi (non-add)</i>	66,095,283
Department of Justice Wedge <sup>2</sup>	58,045,073
Federal Bureau of Investigation <sup>4</sup>	131,334,942
<b>Subtotal, Mandatory HCFAC</b>	<b>1,270,081,834</b>
<b>Discretionary Resources</b>	
Office of Inspector General	82,132,000
CMS Program Integrity	569,068,000
<i>Medicare Program Integrity (Non-Add)</i>	468,936,000
<i>Medicaid Program Integrity (Non-Add)<sup>5</sup></i>	82,132,000
<i>Senior Medicare Patrols (ACL Non-Add)<sup>6</sup></i>	18,000,000
Department of Justice	73,800,000
<b>Subtotal, Discretionary HCFAC</b>	<b>725,000,000</b>
<b>Grand Total, HCFAC</b>	<b>1,995,081,834</b>

<sup>1</sup> All mandatory resources are post-sequester.

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> This does not include the Medicaid Integrity Program authorized in the Deficit Reduction Act of 2005, which receives funding separately from the HCFAC account.

<sup>6</sup> 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

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

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

HEAT—Health Care Fraud Prevention & Enforcement Action Team

HFPP—Health care Fraud Prevention Partnership

HHA—Home Health Agency

HHS—The Department of Health and Human Services

HHS-OIG—The Department of Health and Human Services - Office of the Inspector General

HI—Hospital Insurance Trust Fund

HIPAA — The Health Insurance Portability and Accountability Act of 1996, P.L. 104-191

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