

**The Department of Health and Human Services
And
The Department of Justice
Health Care Fraud and Abuse Control Program
Annual Report for Fiscal Year 2018**

May 2019

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GENERAL NOTE

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

EXECUTIVE SUMMARY

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a national Health Care Fraud and Abuse Control Program (HCFAC or the Program) under the joint direction of the Attorney General and the Secretary of the Department of Health and Human Services (HHS)¹, acting through the Inspector General, designed to coordinate federal, state and local law enforcement activities with respect to health care fraud and abuse. In its twenty-second 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.

During Fiscal Year (FY) 2018, the Federal Government won or negotiated over \$2.3 billion in health care fraud judgments and settlements², in addition to other health care administrative impositions. As a result of these efforts, as well as those of preceding years, \$2.3 billion was returned to the Federal Government or paid to private persons in FY 2018. Of this \$2.3 billion, the Medicare Trust Funds³ received transfers of approximately \$1.2 billion during this period, in addition to the \$232 million in Federal Medicaid money that was similarly transferred separately to the Treasury as a result of these efforts.

Enforcement Actions

In FY 2018, the Department of Justice (DOJ) opened 1,139 new criminal health care fraud investigations. Federal prosecutors filed criminal charges in 572 cases involving 872 defendants. A total of 497 defendants were convicted of health care fraud-related crimes during the year. Also in FY 2018, DOJ opened 918 new civil health care fraud investigations and had 1,203 civil health care fraud matters pending at the end of the fiscal year. In FY 2018, FBI investigative efforts resulted in over 812 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 207 health care fraud criminal schemes.

In FY 2018, investigations conducted by HHS' Office of Inspector General (HHS-OIG) resulted in 679 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid, and 795 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 2,712 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 (1,012) or to other health care programs (255), for patient abuse or neglect (201), and as a result of State healthcare licensure revocations (996). HHS-OIG also issued numerous

¹ Hereafter, referred to as the Secretary.

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

³ The Medicare Trust Funds is the collective term for the Medicare Hospital Insurance (Part A) Trust Fund and the Supplemental Medical Insurance (Part B) Trust Fund.

audits and evaluations with recommendations that, when implemented, would correct program vulnerabilities and save Medicare and Medicaid funds.

Sequestration Impact

Due to the 2018 sequestration of mandatory funding, DOJ, FBI, HHS, and HHS-OIG had fewer resources to fight fraud and abuse of Medicare, Medicaid, and other health care programs. A total of \$20.2 million was sequestered from the HCFAC program in FY 2018, for a combined total of \$135.7 million sequestered in the past five years. Including funds sequestered from the FBI and the FY 2013 discretionary HCFAC sequester, \$191.4 million has been sequestered in the past five years.

STATUTORY BACKGROUND

The Annual Report of the Attorney General and the Secretary detailing expenditures and revenues under the Health Care Fraud and Abuse Control Program for Fiscal Year 2018 is provided as required by Section 1817(k)(5) of the Social Security Act.

The Social Security Act Section 1128C(a), as established by the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191, HIPAA or the Act), created the Health Care Fraud and Abuse Control Program, a far-reaching program to combat fraud and abuse in health care, including both public and private health plans.

As was the case before HIPAA, amounts paid to Medicare in restitution or for compensatory damages must be deposited in the Medicare Trust Funds. The Act requires that an amount equaling recoveries from health care investigations – including criminal fines, forfeitures, civil settlements and judgments, and administrative penalties – also be deposited in the Trust Funds.

The Act appropriates monies from the Medicare Hospital Insurance Trust Fund to an expenditure account, called the Health Care Fraud and Abuse Control Account (the Account), in amounts that the Secretary and Attorney General jointly certify as necessary to finance anti-fraud activities. The maximum amounts available for certification are specified in the Act. Certain of these sums are to be used only for activities of the HHS-OIG, with respect to the Medicare and Medicaid programs. In FY 2006, the Tax Relief and Health Care Act (TRHCA) (P.L. 109-432, §303) amended the Act so that funds allotted from the Account are “available until expended.” TRHCA also allowed for yearly increases to the Account based on the change in the consumer price index for all urban consumers (all items, United States city average) (CPI-U) over the previous fiscal year for fiscal years for 2007 through 2010.⁴ In FY 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act (P.L. 111-148, ACA) extended permanently the yearly increases to the Account based upon the change in the consumer price index for all urban consumers, or CPI-U.

In FY 2018, the Secretary and the Attorney General certified \$286.2 million in mandatory funding to the Account after accounting for sequester reductions of \$20.2 million to the total appropriation. Additionally, Congress appropriated \$745 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 2018. (Separately, the FBI, which is discussed in the appendix, received \$134.5 million from HIPAA, after accounting for mandatory sequester reductions.) Under the joint direction of the Attorney General and the

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

Secretary, the Program's goals are:

- (1) To coordinate federal, state and local law enforcement efforts relating to health care fraud and abuse with respect to health plans;
- (2) To conduct investigations, audits, inspections, and evaluations relating to the delivery of and payment for health care in the United States;
- (3) To facilitate enforcement of all applicable remedies for such fraud; 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.
- (3) This annual report fulfills the above statutory requirements.

Additionally, this report fulfills the requirement in the annual discretionary HCFAC appropriation (Public Law 115-141 "Consolidated Appropriations Act, 2018") 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 2018, \$2.3 billion was deposited with the Department of the Treasury and CMS, transferred to other federal agencies administering health care programs, or paid to private persons during the fiscal year. Monetary results from these transfers and deposits are provided in the table below:

Monetary Results: Total Transfers / Deposits by Recipient FY 2018	
Department of the Treasury	
Deposits to the Medicare Trust Fund, as required by HIPAA:	
Gifts and Bequests	\$0
Amount Equal to Criminal Fines	1,897,113
Civil Monetary Penalties	49,208,054
Asset Forfeiture	56,632,467
Penalties and Multiple Damages	556,473,088
Subtotal	664,210,722
Centers for Medicare and Medicaid Services	
HHS/OIG Audit Disallowances: Recovered–Medicare	113,927,142
Restitution/Compensatory Damages*	437,779,171
Subtotal	551,706,313
Total Transferred to the Medicare Trust Funds	\$1,215,917,035
Restitution/Compensatory Damages to Federal Agencies	
TRICARE	\$34,452,969
HHS/OIG	14,870,959
Office of Personnel Management	2,581,753
Other Agencies	170,666,903
Subtotal	222,572,584
Centers for Medicare and Medicaid Services	
Federal Share of Medicaid	231,975,821
HHS/OIG Audit Disallowances: Recovered–Medicaid	318,148,231
Subtotal	550,124,052
Total	\$772,696,636
Relators' Payments**	\$321,909,653
GRAND TOTAL MONETARY RESULTS***	\$2,310,523,324

*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-second year of operation, the Secretary and the Attorney General certified \$286.2 million in mandatory funding as necessary for the Program, after accounting for mandatory sequester reductions of \$20.2 million as required by law. Additionally, Congress appropriated \$745 million in discretionary funding. See allocation by recipient below:

FY 2018 ALLOCATION OF HCFAC APPROPRIATION				
Organization	Mandatory Allocation ⁵	Discretionary Allocation	Funds Sequestered	Total Allocation
Department of Health and Human Services				
Office of Inspector General ⁶	\$213,896,374	\$84,398,000	(\$13,453,597)	\$284,840,777
Office of the General Counsel	7,147,000	0	0	7,147,000
Administration for Community Living ⁷	0	18,000,000	0	18,000,000
Food and Drug Administration	5,853,177	0	0	5,853,177
Centers for Medicare & Medicaid Services	12,000,000	566,766,000	0	578,766,000
Unallocated Funding	3,933,117	0	(2,573,161)	1,359,956
Subtotal	242,829,668	669,164,000	(16,026,758)	895,966,910
Department of Justice				
United States Attorneys	\$29,497,487	\$21,000,000	\$0	\$50,497,487
Civil Division ⁸	19,641,199	16,639,000	0	36,280,199
Criminal Division	6,939,338	18,387,000	0	25,326,338
Civil Rights Division	3,335,652	7,558,000	0	10,893,652
Justice Management Division	30,942	0	0	30,942
Federal Bureau of Investigation	0	11,422,000	0	11,422,000
Office of the Inspector General	0	830,000	0	830,000
Unallocated Funding	4,200,583	0	(4,200,583)	0
Subtotal	63,645,201	75,836,000	(4,200,583)	135,280,618
TOTAL⁹	\$306,474,869	\$745,000,000	(\$20,227,341)	\$1,031,247,528

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

⁶ In addition, HHS-OIG obligated \$7.1 million in funds received as “reimbursement for the costs of conducting investigations and audits and for monitoring compliance plans” as authorized by section 1128C(b) of the Social Security Act, 42 U.S.C. § 1320a-7c(b).

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

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

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

Overall Recoveries

During this fiscal year, the Federal Government won or negotiated over \$2.3 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 \$2.3 billion was returned to the Federal Government or private persons. Of this \$2.3 billion, the Medicare Trust Funds received transfers of approximately \$1.2 billion during this period; and another \$232 million in Federal Medicaid money was transferred to the Treasury separately as a result of these efforts.¹⁰

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

The return on investment (ROI) for the HCFAC program over the last three years (2016-2018)) is \$4.00 returned for every \$1.00 expended.¹¹ 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.

It is important to note that the ROI does not capture the full impact of the results of the Program. For example, criminal action, from either a search warrant, an indictment or an arrest, prevents the defendant from continuing to defraud federal health care programs. Therefore, this ROI calculation that relies on actual recoveries and collections, does not represent the effect of preventing future fraudulent payments. Further, the threat of oversight alone can have a sentinel impact that prevents future bad actors from defrauding Medicaid, Medicare and other federal health care benefit programs.

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.

¹⁰ Note that some of the judgments, settlements, and administrative actions that occurred in FY 2018 will result in transfers in future years, just as some of the transfers in FY 2018 are attributable to actions from prior years

¹¹ The three-year average return on investment includes a downward adjustment to the savings assumed in the FY 2017 Report on HCFAC Recoveries. The FY 2017 OIG Audit Disallowances were corrected by reducing them from \$365.2 million to \$175.6 million. The updated FY 2017 three year average return on investment (2015-2017) is \$4.1 returned for every \$1.00 expended.

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 target doctors and physicians who prescribe opioids outside the scope of legitimate medical practice**, and often charge Medicare and Medicaid for these visits and prescriptions.
- **To highlight best practices by providers and public sector employees** who are dedicated to ending waste, fraud, and abuse in Medicare.
- **To build upon existing partnerships between DOJ and HHS, such as our Medicare Fraud Strike Force Teams**, to reduce fraud and recover taxpayer dollars.

Since its creation, 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. In 2017, DOJ formed an Opioid Fraud and Detection Unit and, in collaboration with HHS-OIG, selected twelve federal judicial districts to participate in the program. In August 2018, DOJ and HHS added a two additional Medicare Fraud Strike Forces in Newark and Philadelphia to combat health care fraud and illegal opioid prescriptions. The end of FY2018 also saw the preparation for the launch of the Appalachian Regional Prescription Opioid Strike Force (ARPO SF), which was announced by then-Attorney General Sessions on October 25, 2018. ARPO operates in 9 federal districts: Southern District of Ohio, the Western District of Kentucky, the Eastern District of Kentucky, the Northern District of West Virginia, the Southern District of West Virginia, the Western District of Tennessee, the Middle District of Tennessee, the Eastern District of Tennessee and the Northern District of Alabama. Its goal is to investigate and charge medical professionals with the illegal prescription of opioids.

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 a 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. The number of participants has increased to 112 public, private and state partner organizations at the end of FY 2018.

The HFPP commenced or completed studies using multiple partners' data to address fraud, waste and abuse in FY 2018, providing partners with detailed results that can be used for corrective actions within their organizations. The HFPP also released a public white paper on fraud and abuse in clinical laboratory services in May 2018 and continued its efforts to foster collaboration among partners by hosting four in-person information-sharing sessions and an Annual Executive Board meeting. These meetings were used to share fraud schemes and provider alerts, provide updates on law enforcement activities, and strategize on how to broaden the HFPP's impact in the private and public sectors. See HFPP section below for more information on HFPP activities

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 now operate Medicare Fraud Strike Force's in fourteen strike forces, in 24 districts across the United States including Miami, Orlando, and Tampa, Florida; Los Angeles, California; Detroit, Michigan; Houston and Dallas, Texas; Brooklyn, New York; Baton Rouge and New Orleans, Louisiana; Chicago, Illinois; Newark, New Jersey; and Philadelphia, Pennsylvania, along with a Corporate Strike Force located in Washington, D.C. The Newark/Philadelphia location was just added this fiscal year as part of the Newark/Philadelphia Regional Strike Force. FY 2019 will see the addition of two new ARPO strike forces covering 9 additional districts, based out of Nashville, Tennessee, and Fort Mitchell, Kentucky.

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 2018 include¹²

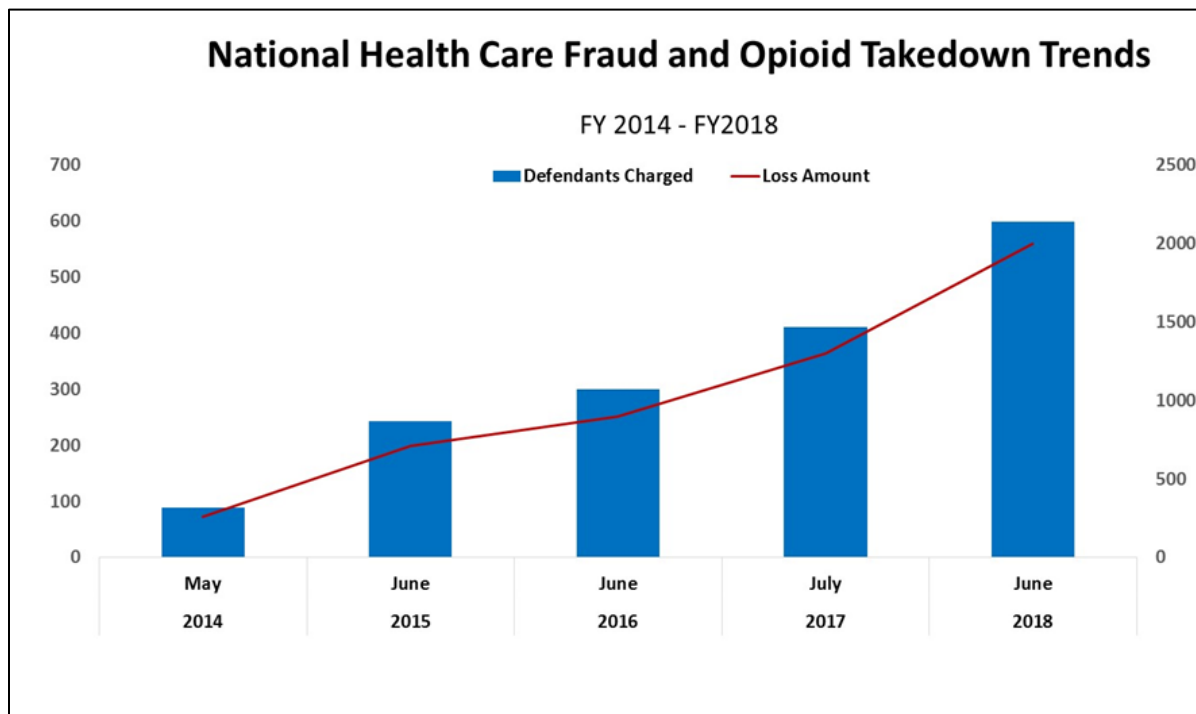
- Filed 313 indictments, informations and complaints involving charges filed against 600 defendants who allegedly billed federal health care programs more than \$2.6 billion;
- Obtained 312 guilty pleas negotiated and 19 jury trials litigated, with guilty verdicts against 25 defendants; and
- Secured imprisonment for 307 defendants sentenced, averaging more than 53 months of incarceration.

Since its inception, Strike Force prosecutors filed more than 1,750 cases charging more than 3,800 defendants who collectively billed the Medicare program approximately \$15 billion; 2,643 defendants pleaded guilty and 338 others were convicted in jury trials; and 2,424 defendants were sentenced to imprisonment for an average term of approximately 50 months. 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 360 criminal and civil (representing over 60 U.S. Attorney's Offices) and law enforcement personnel from FBI, DEA, HHS-OIG, IRS Criminal Investigation, and Defense Criminal Investigative Service (DCIS), U.S. Postal Service (USPS), and the Department of Veterans Affairs - OIG. 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 50 districts, including the 12 districts selected for the Attorney General's Opioid Fraud and Abuse Detection Unit initiative.

In addition, the 2018 National Health Care Fraud Takedown involved more than 600 charged defendants across 58 federal districts with an estimated loss to federal health care programs of approximately \$2 billion, including 165 doctors, nurses, and other licensed medical professionals. The following chart shows the national health care fraud takedown trends from FY 2014 to FY 2018.

¹² The accomplishments figures presented in the bullets include all reported Strike Force cases handled by DOJ



A review of the Part A and Part B CMS data shows that Medicare spending in Strike Force cities has decreased by hundreds of millions of dollars, which highlights the deterrent effect of prosecuting health care fraud, in addition to the monies recovered, and the monies prosecutions have prevented from going out the door.

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 focuses 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 has funded 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 are participating 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. This is in addition to the ARPO initiative, which launched at the beginning of FY 2019.

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 October 2017, three defendants in the District of Arizona were sentenced to 33 months, 24 months, and 18 months in prison, respectively, and ordered to pay more than \$3 million in restitution. The Defendants falsely billed Arizona's Health Care Cost Containment System (AHCCCS) for tens of thousands of medical transports that never occurred, generating more than \$3 million in fraudulent payments from AHCCCS. AHCCCS is Arizona's Medicaid agency that offers health care programs to low-income Arizona residents. The Defendants owned and operated Diné Transport, which purported to provide non-emergency medical transportation for AHCCCS recipients on the Navajo reservation. Approximately 95 percent of the claims submitted by Diné Transport between March 2013 and July 2013 were false.

In April 2018, the Quality Improvement Coordinator for Mauran Ambulance Inc. (Mauran) of San Fernando, California was sentenced to 36 months in prison. Mauran was an ambulance transportation company operating in the greater Los Angeles area that provided non-emergency services to Medicare beneficiaries, many of whom were dialysis patients. As part of his plea, the Defendant admitted that between June 2011 and April 2012, he conspired with other Mauran employees to submit claims to Medicare for ambulance transportation services for individuals who did not need such services. The Defendant also admitted that he and his co-conspirators instructed Mauran emergency medical technicians to conceal the patients' true medical conditions by altering paperwork and creating fraudulent reasons to justify the ambulance services.

In August 2018, East Texas Medical Center Regional Healthcare System, Inc. and East Texas Medical Center Regional Health Services, Inc. (together, "ETMC"), and their affiliated ambulance company, Paramedics Plus, LLC, agreed to pay \$20.7 million to resolve civil FCA allegations that ETMC and Paramedics Plus offered kickbacks to Emergency Medical Services Authority (EMSA) aimed at securing a lucrative ambulance services contract in the state of Oklahoma. EMSA, a quasi-municipal entity, separately agreed to pay \$250,000 based on its ability to pay. The former president and CEO of EMSA agreed to pay \$80,000, also based on his ability to pay. Of the over \$21 million recovery, the defendants paid \$2.9 million to resolve Oklahoma state Medicaid liability.

In January 2018, AmeriCare Ambulance Service, Inc., and its sister company, AmeriCare ALS, Inc. (collectively, AmeriCare), agreed to pay \$5.5 million to resolve civil FCA allegations that they defrauded Medicare by billing for medically unnecessary ambulance transportation services. From January 2008 through December 2016, AmeriCare allegedly submitted fraudulent claims to Medicare and TRICARE for Basic Life Support (BLS), nonemergency ambulance transports that were not medically justified. AmeriCare had created thousands of false reports and other

documentation during this time period in a failed effort to support this illicit practice.

(SF) In April, June, July, and September 2018, the owner of an ambulance company, three employees, and an employee of a dialysis treatment center were sentenced for their roles in a scheme to submit claims to Medicare for unnecessary ambulance transportation services. The owner was sentenced to 46 months in prison and ordered to pay \$3.1 million in restitution, jointly and severally with his co-defendants, after he pleaded guilty to one count of conspiracy to commit health care fraud. The company's quality improvement coordinator received 36 months in prison. The operations manager received 9 months in prison. The dispatch supervisor was sentenced to three years of probation. An administrator of a dialysis center who received kickbacks in exchange for patient referrals received 10 months in prison. The defendants and their co-conspirators concealed Medicare beneficiaries' true medical conditions at the time of transport by altering the requisite paperwork and creating fraudulent reasons to justify services. Medicare was fraudulently billed \$6.6 million and paid \$3.1 million on the false and fraudulent claims.

Clinics

In March 2018, the owner of a clinic and his coconspirator were sentenced in the Eastern District of North Carolina to 40 months and 30 months in prison, respectively for submitting fraudulent claims to Medicaid. The clinic, Christian Medical Center, Inc., was a purported provider of outpatient behavioral services in eastern North Carolina. In truth, Christian Medical was a shell company or "false front" with no legitimate business operations by this point. Among other things, the conspirators purchased stolen Medicaid beneficiary information and used it to prepare and electronically file the fraudulent claims on Christian Medical's behalf through Medicaid's NCTracks system.

(SF) In April 2018, the owner of a home health clinic and two physical rehabilitation clinics was sentenced to 97 months in prison. The co-owner of one of the clinics was sentenced to 120 months in prison. A patient recruiter was sentenced to 17 months in prison, and a man who helped money launder for the scheme was sentenced to 18 months in prison. The defendants were ordered to pay over \$4 million in restitution. The defendants submitted approximately \$10 million in false and fraudulent claims to Medicare and Blue Cross Blue Shield.

In June 2018, the CEO of a Texas clinic was sentenced in the Southern District of Texas to 233 months in prison and ordered to pay more than \$14 million in restitution. According to testimony, the clinic submitted millions in false and fraudulent claims for physical therapy services. Testimony from former employees revealed that the clinic had as many as 30 – 60 patients a day and that employees did not know what the patients were doing in the main treatment area because they were busy in the back doing massages, electrical stimulation treatments and ultrasound treatments.

In June 2018, Healogics, Inc. agreed to pay up to \$22.5 million to settle civil FCA allegations that it knowingly caused wound care centers to bill Medicare for medically unnecessary services. Healogics, a Florida-based company, manages nearly 700 hospital-based wound care centers across the country. Medicare covers hyperbaric oxygen therapy (HBO), a modality in which the

entire body is exposed to oxygen under increased atmospheric pressure, as an adjunctive therapy to treat certain chronic wounds. The settlement resolved allegations that from 2010 through 2015, Healogics knowingly submitted or caused the submission of false claims to Medicare for medically unnecessary or unreasonable HBO therapy.

Dental

In January 2018, dental management company Benevis LLC (formerly known as NCDR LLC) and more than 130 of its affiliated Kool Smiles dental clinics, for which Benevis provides business management and administrative services, agreed to pay the United States \$14.2 million to resolve civil FCA allegations that they knowingly submitted false claims for payment to state Medicaid programs for medically unnecessary dental services performed on children insured by Medicaid. The United States alleged that between January 2009 and December 2011, Benevis and Kool Smiles clinics knowingly submitted false claims to state Medicaid programs for medically unnecessary pulpotomies (baby root canals), tooth extractions, and stainless steel crowns, in addition to seeking payment for pulpotomies that were never performed. The United States alleged that Kool Smiles clinics routinely pressured and incentivized dentists to meet production goals through a system that disciplined “unproductive” dentists and awarded “productive” dentists with substantial cash bonuses based on the revenue generated by the procedures they performed. In addition, the United States further alleged that Kool Smiles clinics located in Texas knowingly submitted false claims to the Texas Medicaid Program for First Dental Home, a program intended to provide a comprehensive package of dental services aimed at improving the oral health of children under three years of age. In addition to the federal recovery, Kool Smiles paid \$9.6 million to resolve state Medicaid liability.

Device Companies

In November 2017, the operators of a medical device company were sentenced in the Eastern District of Louisiana to 46 months and 25 months in prison, respectively, and ordered to pay more than \$2.3 million in restitution in connection with a \$38 million fraud scheme centering around the distribution of “talking glucose meters” that were not medically needed and were often not even requested. The defendants operated Care Concepts, LLC (Care Concepts) and Choice Home Medical Equipment and Supplies (Choice). According to court documents, the defendants paid kickbacks to workers at call centers in California and South Carolina, from which operators would cold-call Medicare recipients to convince them to accept talking glucose meters and related supplies. From 2007 through 2015, the defendants caused thousands of claims to be submitted to Medicare through Care Concepts and Choice, virtually all of which were fraudulent.

In March 2018, Massachusetts-based medical device manufacturer Alere, Inc. and its subsidiary Alere San Diego (collectively, “Alere”) agreed to pay the United States \$28.3 million to resolve civil FCA allegations that Alere caused hospitals to submit false claims to federal health care programs by knowingly selling materially unreliable point-of-care diagnostic testing devices. The United States alleged that between January 2006 and March 2012, Alere knowingly sold such devices, which are intended to aid in the diagnosis of acute coronary syndromes, heart failure, drug overdose, and other serious conditions. The devices were frequently used in

emergency departments where timely decisions are critical to ensuring proper patient care. According to the government's allegations, Alere received complaints from health care providers that certain devices it sold produced erroneous results that had the potential to create false positives and false negatives that adversely affected clinical decision-making. The company failed to take appropriate corrective actions until FDA inspections prompted a nationwide product recall in 2012. In addition to the federal recovery, Alere paid \$4.8 million to resolve state Medicaid liability.

In July 2018, AngioDynamics, Inc., based in Latham, New York, agreed to pay the United States \$10.9 million to resolve civil FCA allegations that the company caused healthcare providers to submit false claims to federal healthcare programs relating to the use of two medical devices—LC Bead, which was FDA-cleared only for use as an embolization device, and the Perforator Vein Ablation Kit, which was FDA-cleared only for the treatment of superficial veins. From May 2006 through December 2011, AngioDynamics served as the U.S. distributor for Biocompatibles plc, the manufacturer of LC Bead, and the government alleged that AngioDynamics marketed LC Bead for use as a drug-delivery device in combination with chemotherapy drugs. AngioDynamics personnel routinely claimed that this particular use of LC Bead, which FDA had twice declined to approve, was “better”, “superior”, “safer”, and “less toxic” than alternative treatments, even though there was insufficient clinical evidence to support the truthfulness of these claims. The government also alleged that AngioDynamics instructed healthcare providers to use inaccurate billing codes when submitting claims for such uses. In addition to the federal recovery, AngioDynamics paid \$600,000 to resolve state Medicaid liability.

Diagnostic Services

In January 2018, the U.S. District Court for the District of Delaware entered judgment in the amount of \$16.2 million against Orthopaedic and Neuro Imaging LLC (ONI) for submitting false claims for Medicare reimbursement under the civil FCA. Under the terms of the judgment, ONI's owner is jointly and severally liable for \$6.1 million. ONI operated independent diagnostic testing facilities in Delaware and Maryland. The United States' complaint alleged that ONI and its owner knowingly submitted false claims to Medicare by administering contrast dye during magnetic resonance imaging (MRI) scans on patients without proper supervision by a physician. Contrast dye is a chemical that is injected intravenously into the body to make certain tissues more clearly visible on an MRI.

In March 2018, Natera, Inc., a California-based diagnostic company, agreed to pay more than \$11 million dollars to resolve civil FCA allegations in the Western District of Kentucky that it improperly billed TRICARE for its test (including optional panels that screened for microdeletion syndromes). Further, during dates of service of January 1, 2013, through December 31, 2016, the defendant improperly billed TRICARE for non-invasive prenatal screening of certain microdeletion syndromes when TRICARE did not reimburse for this screening. During the same period, defendant improperly billed TRICARE, FEHBP, and Medicaid for its test and for its non-invasive prenatal screening of certain microdeletion syndromes, by using an improper code which misrepresented the services the company was billing to these programs. Lastly, during the same dates of service, the company billed

TRICARE, FEHBP, and Medicaid for its test (including optional panels that screened for microdeletion syndromes) for patients with low-risk pregnancies.

In May 2018, an individual was convicted of conspiracy to commit health care fraud and kickbacks, sentenced to 10 years in prison, and ordered to pay \$9 million in restitution, joint and several. The individual and his co-defendants engaged in a \$13 million conspiracy to falsely bill Medicare and Medicaid for medically unnecessary diagnostic tests. According to court documents, from January 2006 through July 2015, the individual ran several false clinics in Houston and Conroe, Texas. He paid marketers to bring patients to the clinics for a battery of diagnostic tests and blood work, regardless of medical need. The individual paid the marketers approximately \$100 for each patient brought to his clinics; in turn, the marketers paid the patients approximately \$50 each. The individual employed a physician who approved the testing and allowed his physician number to be used in the Medicare billing process to support the tests. Seven defendants involved in the scheme were previously sentenced to a combined 7 years 4 months and 2 days in prison, and ordered to pay \$5.5 million in restitution, joint and several. One additional defendant is awaiting sentencing. This case was worked jointly with the FBI and MFCU.

Drug Companies

In December 2017, United Therapeutics Corporation (UT), based in Silver Spring, Maryland, agreed to pay \$210 million to resolve civil FCA allegations in the District of Massachusetts that UT used a foundation, which claims 501(c)(3) status for tax purposes, as a conduit to pay the co-pay obligations of thousands of Medicare patients taking its pulmonary arterial hypertension (PAH) drugs. The settlement resolved allegations that, from 2010 to 2014, UT violated the FCA by paying kickbacks to Medicare patients through donations it made to Caring Voice Coalition (CVC). CVC, in turn, allegedly used the donations to pay copayments for patients in order to induce the patients to use UT's drugs. The government alleged that UT routinely obtained data from CVC detailing how much CVC spent for patients who were using UT's drugs and that UT used this data to decide how much money to donate to CVC. Essentially, the government alleged that UT used CVC as a conduit to pay the copayments of Medicare patients who were using UT's drugs. As part of the resolution, UT entered a 5-year Corporate Integrity Agreement (CIA) with OIG.

In April 2018, Canada Drugs and certain affiliated entities were sentenced in the District of Montana to forfeit \$29 million, to pay a fine of \$5 million, and to five years of probation. The company's CEO was sentenced individually to pay a fine of \$250,000 and to five years of probation with the first six months in home confinement. The sentencing stemmed from the company's practice of shipping to health care providers in the United States prescription drugs that were unapproved in the United States, labelled with foreign languages, and that lacked adequate instructions for use. Further investigation revealed that various entities affiliated with Canada Drugs were smuggling unapproved and misbranded drugs intended for sale in foreign countries into the United States, including for sale to providers in Montana. To facilitate its sales, Canada Drugs purchased other companies engaged in this business and used the brand names, drug inventories, and customer lists of those companies to further its illegal

operations. In order to avoid detection, Canada Drugs and its affiliated companies falsified customs forms concerning the value of the drugs shipped into the United States.

In May 2018, Pfizer Inc. (Pfizer) agreed to pay more than \$23.85 million to resolve civil FCA allegations associated with donations it made to a 501(c)(3) foundation, which operated funds that pay the copayments of certain patients, including Medicare patients. Specifically, Pfizer resolved allegations that, from 2012 through 2016, it used the foundation as a conduit to pay the copayments of Medicare patients taking Sutent, Inlyta, and Tikosyn, in violation of the Anti-Kickback Statute. As part of the resolution, Pfizer entered into a 5-year CIA with provisions relating to arrangements and interactions between Pfizer and any third party patient assistance program to which Pfizer donates. The CIA also requires Pfizer to implement controls and monitoring designed to promote true independence from any patient assistance program to which it donates.

Drug Distributor

In September 2018, AmerisourceBergen Corporation and its subsidiaries AmerisourceBergen Specialty Group (ABSG), AmerisourceBergen Drug Corporation (ABDC), Oncology Supply Company (OSC), and Medical Initiatives Inc. (MII) (collectively, “ABC”) paid \$581.8 million to resolve civil FCA allegations that it improperly repackaged oncology-supportive injectable drugs into pre-filled syringes and then distributed those syringes to physicians treating vulnerable cancer patients. The United States alleged that ABC sought to profit from the excess drug product or “overfill” contained within the original FDA-approved sterile vials for these drugs by establishing a pre-filled syringe program through a subsidiary that it claimed was a pharmacy. As part of this operation, ABC purchased original vials from their respective manufacturers, broke their sterility, pooled the contents, and repackaged the drugs into pre-filled syringes. The United States alleged that ABC never submitted any safety, stability, or sterility data to the FDA to show that its operation ensured the safety and efficacy of the repackaged drug products. It further alleged that, at times, these pre-filled syringes were prepared in non-sterile conditions, contaminated with bacteria and other unknown particles, and lacked the required quality and purity. In addition, by harvesting the overfill, ABC was able to create more doses than it bought from the original vial manufacturers. The United States alleged that ABC’s scheme enabled it to bill federal health care programs for the same vial more than once. The settlement also resolves allegations that ABC gave kickbacks in the form of general pharmacy credits to physicians to induce them to purchase a drug through the pre-filled syringe program. In addition to the federal recovery, ABC agreed to pay \$43.2 million to resolve state Medicaid liability.

Durable Medical Equipment (DME)

In November 2017, two individuals were convicted of conspiracy to commit health care fraud for their role in directing a \$38 million Medicare fraud scheme. The defendants operated Care Concepts, LLC and Choice Home Medical Equipment and Supplies. According to court documents, the defendants paid kickbacks to workers at call centers from which operators would cold-call Medicare recipients to convince them to accept talking glucose meters and related supplies. From 2007 through 2015, the defendants caused thousands of claims to be submitted to Medicare, virtually all of which were fraudulent. One individual was sentenced to 3 years and

10 months in prison and ordered to pay \$1.3 million in restitution, while the other individual was sentenced to 2 years and 1 month in prison and ordered to pay \$988,593 in restitution. Two defendants involved in the scheme were previously sentenced to a combined 1 year and 1 day in prison and ordered to pay \$133,807 in restitution.

In April 2018, Rotech Healthcare Inc., a Florida-based respiratory equipment supplier, agreed to pay \$9.7 million to resolve civil FCA allegations by knowingly submitting false claims for portable oxygen contents to Medicare. Medicare covers rentals of portable and stationary oxygen equipment for up to 36 months and allows suppliers to bill monthly for oxygen to be used with that equipment for up to 24 additional months after the rental period. Between January 2009 and March 2012, the United States alleged that the company automatically billed Medicare for portable oxygen contents for all Medicare beneficiaries after the 36-month rental period, without verifying that the beneficiaries used or needed portable oxygen, and without obtaining the requisite proof of delivery. The company continued this practice despite knowing that it resulted in the submission of claims for portable oxygen contents that were ineligible for reimbursement.

In August 2018, Lincare, Inc., a durable medical equipment company headquartered in Clearwater, Florida, agreed to pay more than \$5 million to resolve civil FCA allegations in the Southern District of Illinois that it violated the Anti-Kickback Statute. The government alleged that, from 2011 to 2017, the company attempted to gain a competitive advantage in the marketplace by unlawfully waiving or reducing co-insurance, co-payments, and deductibles for beneficiaries who participated in a Medicare Advantage Plan operated through a private insurer. The government alleged that the company's practices violated the Anti-Kickback Statute, and further caused the submission of false claims for payments to Medicare.

(SF) In September 2018, the vice president of a number of medical device companies pleaded guilty to conspiracy to commit health care fraud, mail fraud, and wire fraud for his role as the leader of a scheme to defraud Medicare Part D pursuant to a Rule 11(c)(1)(C) plea agreement, which was provisionally accepted by the court and which includes a term of 60 months imprisonment and restitution of \$1.6 million. The defendant impersonated his brother as the owner of a then-defunct pharmacy and billed Medicare Part D for prescriptions for himself, his wife, and his two brothers, though the prescriptions were never actually ordered or dispensed. The defendant's wife also pleaded guilty to one count of health care false statements for her role in the scheme.

Electronic Health Records

In December 2017, 21st Century Oncology Inc. (21st Century), which is headquartered in Fort Myers, Florida, and certain of its subsidiaries and affiliates, agreed to pay \$26 million to resolve claims in the Middle District of Florida related to its use of Electronic Health Records (EHR) systems. The settlement resolved conduct that was self-disclosed by the company regarding payments made by the government as part of the Medicare EHR Incentive Program. Under the Program, physicians who attest to their meaningful use of certified EHR technology may receive incentive payments and avoid downward adjustments to certain Medicare claims. As part of its self-disclosure, 21st Century reported that it knowingly submitted, or caused the submission of,

false attestations to CMS concerning employed physicians' use of EHR software. The company further reported that, in support of the attestations, its employees falsified data regarding the company's use of EHR software, fabricated software utilization reports, and superimposed EHR vendor logos onto the reports to make them look legitimate. The settlement also resolved civil FCA allegations that 21st Century submitted, or caused the submission of, claims for certain services provided pursuant to referrals from physicians with whom they had improper financial relationships in violation of the Stark Law.

Managed Care

(SF) In November 2017, a former HMO executive was sentenced in the Middle District of Florida to 6 months in prison, followed by a three-year term of supervised release that includes one year of home confinement, for making a false statement to the Florida Medicaid Program. The Court also ordered him to pay a \$50,000 fine. The sentence stemmed from allegations that the HMO, under the direction of the executive and others, engaged in healthcare fraud. The fraud counts alleged that the executive and his co-defendants had executed and attempted to execute both a scheme to defraud the Florida Medicaid Program through Florida's Agency for Health Care Administration ("AHCA"), and a scheme to obtain, by means of false and fraudulent pretenses and representations, money under the custody or control of the program.

In August 2018, two individuals and a corporation they owned in the Eastern District of Louisiana were indicted in connection with the operation of a multiple employer welfare arrangement. The indictment alleged fraud and false statements in the marketing and sale of group health care coverage by the MEWA causing losses exceeding \$41 million. The scheme involved the sale of health care coverage to employers based upon false representations that the health plan was funded by a loan arrangement which would greatly lower the employers' and their contributing employees' taxable income. In fact, there was no loan arrangement and no participant contributions. The defendants collected more than \$21 million in fees from employers and contributing employees. In addition, the defendants caused at least \$20 million in federal FICA taxes to be underpaid as well as a significant amount of personal income taxes, amounts for which the employer-clients and employee-participants may be individually responsible.

In September 2018, HealthCare Partners Holdings LLC, doing business as DaVita Medical Holdings LLC (DaVita), agreed to pay \$270 million to resolve civil FCA liability that it provided inaccurate information that caused Medicare Advantage Organizations (MAOs) to receive inflated Medicare payments. The settlement resolved voluntary disclosures made by DaVita of various practices that were instituted by HealthCare Partners, a large California-based independent physician association that DaVita acquired in 2012, that caused MAOs to submit incorrect diagnosis codes to CMS and obtain inflated payments in which DaVita and HealthCare Partners shared. For example, HealthCare Partners disseminated improper medical coding guidance instructing its physicians to use an improper diagnosis code for a particular spinal condition that yielded increased payments from CMS. The settlement also resolved allegations made by a whistleblower that HealthCare Partners engaged in "one-way" chart reviews in which it scoured its patients' medical records for diagnoses its providers may have failed to record. It then submitted these "missed" diagnoses to MAOs to be used by them in obtaining increased

Medicare payments. At the same time, it ignored inaccurate diagnosis codes that should have been deleted and that would have decreased Medicare payment or required the MAOs to repay money to Medicare. DaVita is headquartered in El Segundo, California.

Home Health Providers

In November 2017, the co-owner and operator of two home health agencies, was convicted of conspiracy to commit health care fraud. The owner and operator was sentenced to 6 years and 8 months in prison, and ordered to pay restitution of \$45 million, joint and several, for her participation in an elaborate health care fraud scheme. According to court documents, from January 2006 through June 2012, the owner and her co-defendants enlisted and paid patient recruiters kickbacks and bribes in exchange for the referral of Medicare beneficiaries to the two home health agencies to receive home health and physical therapy services that were not medically necessary, not provided, or both. Two additional defendants involved in the scheme were previously sentenced to a combined 11 years and 8 months in prison and ordered to pay a portion of the \$45 million in restitution, as well as an additional \$27 million in restitution.

(SF) In November 2017, a registered nurse was sentenced to 120 months in prison and ordered to pay \$17.1 million in restitution. The registered nurse and his co-conspirators were involved in a scheme to recruit patients to receive home health services that were not medically necessary, not provided, or both. The registered nurse also paid kickbacks to physicians who would falsely certify in a plan of care that the Medicare beneficiaries were under their care and confined to the home when they were not. The registered nurse pled guilty in April 2017.

(SF) In December 2017, the owner of a home health agency was sentenced in absentia to 80 years in prison after pleading guilty for his role in a \$13 million dollar Medicare fraud scheme and for filing false tax returns. His wife and co-owner was sentenced to 75 years in prison following a jury trial. The owners and their co-conspirators paid kickbacks to patient recruiters for referring Medicare beneficiaries to the home health agency and to beneficiaries for allowing the home health agency to bill Medicare. The owner falsified medical records and directed others to falsify records to make it appear as though the Medicare beneficiaries qualified for and received home health services when the beneficiaries did not. Three other defendants pleaded guilty or were convicted based on their roles at the home health agency. A physician was sentenced to time served with three years of home confinement. Two patient recruiters were sentenced to time served with three years of supervised release and 33 months in prison, respectively.

In December 2017, five co-conspirators were convicted of charges resulting from their involvement in a scheme to defraud Medicare. In all, they were sentenced to a combined 13 years and 7 months in prison, and ordered to pay \$27.5 million in restitution, joint and several. The defendants conspired to operate multiple fraudulent home health care agencies and a rehab facility. According to court documents, from about January 2010 through about May 2015, the defendants were involved in a scheme to recruit patients to receive unnecessary home health visits. Specifically, the defendants paid kickbacks and bribes to patient recruiters in exchange for the referrals of Medicare beneficiaries to serve as patients at the home health care agencies, which then billed Medicare for services that were not medically necessary, not provided, or both.

The defendants also paid kickbacks and bribes for home health prescriptions and plans of care, which falsely represented that Medicare beneficiaries qualified for home health services when, in fact, they did not. Three defendants involved in the scheme were previously sentenced to a combined 13 years and 9 months in prison and ordered to pay \$34.2 million in restitution, joint and several. One additional defendant is a fugitive in Cuba.

(SF) In February 2018, the owner of more than twenty home health agencies was sentenced to 240 months in prison and ordered to pay \$66.4 million in restitution, jointly and severally with his co-defendants, after pleading guilty to one count of conspiracy to commit health care fraud and wire fraud. A patient recruiter for the home health agencies, who also owned a medical clinic and two home health agencies of her own, was sentenced to 180 months in prison.

Another patient recruiter, who also was the owner of two home health agencies, was sentenced to 115 months in prison. A Miami man who helped launder the proceeds of the scheme was sentenced to 71 months in prison. The defendants and their co-conspirators paid illegal bribes and kickbacks to patient recruiters in return for the referral of Medicare beneficiaries, many of whom did not need or qualify for home health services to these agencies. Medicare paid approximately \$66 million on those claims.

(SF) In August and September 2018, two physicians and the owner of a home health agency were each sentenced on multiple counts of conspiracy and health care fraud and ordered to pay \$6.5 million in restitution. One physician was sentenced to 132 months in prison following trial. A physician who pled guilty was sentenced to 27 months in prison following a guilty plea. The home health agency owner was sentenced to 42 months in prison. A fourth defendant, the owner of a physician clinic, has yet to be sentenced after a guilty plea. The defendants paid and received kickbacks in exchange for patients and billed Medicare more than \$8.9 million for services that were medically unnecessary, never provided, and/or not otherwise reimbursable. Additionally, certain defendants provided prescriptions for opioid medications to induce patient participation in the scheme.

(SF) In September 2018, the co-owner and administrator of a home health agency was sentenced to 24 months in prison, ordered to pay over \$2.2 million in restitution, and ordered to forfeit over \$1.1 million. Her co-owner is scheduled to be sentenced in November 2018. The co-owners participated in a health care fraud conspiracy that resulted in Medicare paying at least \$2.2 million on false and fraudulent claims. The owners and their co-conspirators paid kickbacks to doctors and patient recruiters in exchange for patient referrals, billed Medicare for services that were medically unnecessary, and caused patient files to be falsified to justify the fraudulent billing. Five other co-defendants are scheduled to be sentenced from October through December 2018.

Hospice Care

In October 2017, Vitas Hospice Services LLC, Vitas Healthcare Corporation, and corporate parent Chemed Corporation (collectively, “Vitas”) agreed to pay \$75 million to resolve civil FCA allegations that Vitas submitted false claims for hospice services to Medicare. The settlement resolved allegations that between 2002 and 2013 Vitas knowingly submitted or caused to be submitted false claims to Medicare for services to hospice patients who were not terminally

ill and for continuous home care services that were not necessary, not actually provided, or not performed in accordance with Medicare requirements. This settlement represents the largest-ever FCA recovery with a hospice provider. Vitas also paid \$500,000 to Illinois to resolve state FCA allegations pertaining to the Illinois Medicaid program.

In June 2018, Caris Healthcare LLC and Caris Healthcare, L.P. (collectively, “Caris”), a for-profit hospice chain, agreed to pay \$8.5 million to resolve civil FCA allegations in the Eastern District of Tennessee that it admitted and recertified patients for hospice care that were ineligible for the hospice benefit. The government’s complaint alleged that, in an effort to meet the aggressive admissions and census targets set by the company, Caris admitted patients whose medical records did not support a terminal prognosis. The government’s complaint further alleged that when Caris was alerted to the ineligibility of these patients — via internal audits, concerns raised by its Chief Medical Officer, and recommendations of its nurse employees who actually examined the patients — Caris not only continued to submit hospice claims to Medicare for the patients, but also took no meaningful action to determine whether it had previously received improper payments for these and other patients that should have been returned to Medicare.

Hospitals and Health Systems

In December 2017, EmCare, Inc., a Dallas-based subdivision of Envision Healthcare Corporation that provides physicians to hospitals to staff their Emergency Departments, agreed to pay \$29.8 million to resolve civil FCA allegations that, from 2008 to 2012, EmCare received remuneration from Health Management Associates (HMA), formerly a U.S. hospital chain headquartered in Naples, Florida, to increase Medicare admissions at HMA hospitals by recommending admission for patients whose medical care should have been billed as outpatient or observation services. These recommendations allegedly caused the medically unnecessary admission of Medicare beneficiaries.

In August 2018, William Beaumont Hospital, a regional hospital system based in the Detroit, Michigan area, agreed to pay \$82.7 million to resolve civil FCA allegations that it had improper relationships with eight referring physicians, resulting in the submission of false claims to the Medicare, Medicaid, and TRICARE programs. The settlement resolves allegations that between 2004 and 2012, Beaumont provided compensation substantially in excess of fair market value and free or below-fair market value office space and employees to certain physicians to secure their referrals of patients in violation of the Anti-Kickback Statute and the Stark Law. The settlement also resolves claims that Beaumont allegedly misrepresented that a CT radiology center qualified as an outpatient department of Beaumont in claims to federal health care programs. In addition to the federal recovery, Beaumont paid \$1.8 million to Michigan resolve state Medicaid liability.

In August 2018, California-based Prime Healthcare Services, Inc., Prime Healthcare Foundation, Inc., and Prime Healthcare Management, Inc. (collectively Prime), and Prime’s Founder and Chief Executive Officer agreed to pay the United States \$65 million to resolve civil FCA allegations that 14 Prime hospitals in California knowingly submitted false claims to Medicare by admitting patients who required only less costly, outpatient care and by billing for more

expensive patient diagnoses than the patients had (a practice known as “up-coding”). Under the settlement agreement, Prime’s Founder and CEO agreed to pay \$3,250,000 and Prime agreed to pay \$61,750,000. The settlement resolved allegations that from 2006 through 2013, Prime engaged in a deliberate corporate-driven scheme to increase inpatient admissions of Medicare beneficiaries who originally presented to the emergency departments at 14 Prime hospitals in California. The government claimed that the inpatient admission of these beneficiaries was not medically necessary because their symptoms and treatment needs should have been managed in a less costly outpatient or observation setting. The settlement also resolved allegations that, from 2006 through 2014, Prime engaged in up-coding by falsifying information concerning patient diagnoses, including complications and comorbidities, in order to increase Medicare reimbursement.

In September 2018, Kalispell Regional Healthcare along with six subsidiaries and related entities – Kalispell Regional Medical Center, HealthCenter Northwest LLC, Flathead Physicians Group LLC, Northwest Horizons LLC, Northwest Orthopedics & Sports Medicine LLC, and Applied Health Services Inc. (collectively, “KRH entities”) – agreed to pay \$24 million to resolve allegations that they violated the civil FCA by paying physicians more than fair market value, and by conspiring to enter into arrangements that improperly induced referrals. Between 2010 and 2018, the KRH entities allegedly violated the Stark Law by paying excessive full-time compensation to more than 60 physician specialists – many of whom worked far less than full-time. Additionally, the United States alleged that several of the KRH entities paid excessive compensation to physicians and provided administrative services at below fair market value to induce referrals in violation of the Anti-Kickback Statute.

In September 2018, Health Management Associates, LLC (HMA), formerly a U.S. hospital chain headquartered in Naples, Florida, agreed to pay over \$260 million to resolve criminal charges and civil claims relating to a scheme to defraud the United States. The government alleged that HMA knowingly billed government health care programs for inpatient services that should have been billed as outpatient or observation services, paid remuneration to physicians in return for patient referrals, and submitted inflated claims for emergency department facility fees. As part of the criminal resolution, HMA entered into a three-year Non-Prosecution Agreement (NPA) with the Criminal Division’s Fraud Section, through its Corporate Strike Force, in connection with a corporate-driven scheme to defraud Federal health care programs by unlawfully pressuring and inducing physicians serving HMA hospitals to increase the number of emergency department patient admissions without regard to whether the admissions were medically necessary. The scheme involved HMA hospitals billing and obtaining reimbursement for higher-paying inpatient hospital care, as opposed to observation or outpatient care, from federal health care programs, increasing HMA’s revenue. Under the terms of the NPA, HMA will pay a \$35 million monetary penalty. In addition, an HMA subsidiary, Carlisle HMA, LLC, formerly doing business as Carlisle Regional Medical Center, agreed to plead guilty to one count of conspiracy to commit health care fraud. HMA also agreed to pay \$216 million as part of a related civil settlement which resolved civil FCA allegations that HMA admitted patients to hospitals who required only less costly, outpatient care; billed federal health care programs for services referred by physicians to whom HMA provided remuneration in return for patient referrals; billed federal health care programs for services referred by physicians with whom the facilities had improper financial relationships; leased space to a physician at a below-market rent; and sought

reimbursement for falsely inflated emergency department facility charges. Of the \$223.5 million that HMA agreed to pay to resolve the civil allegations, \$7.2 million was paid to certain states to resolve state Medicaid liability.

Identity Theft

In October 2017, an individual was convicted of health care fraud, making false statements regarding health care fraud, and aggravated identity theft for his role in a sophisticated scheme to defraud Medicare by committing identity theft. According to the investigation, the individual stole the identities of five retired and semi-retired physicians along with their Medicare provider numbers used to submit claims for services provided to patients. The individual utilized fake passports, driver's licenses, and other identification documents to establish bank accounts, mailing addresses, and phone answering services in the names of the victim physicians to give the appearance that the physicians were in practice and providing medical care to deceased beneficiaries in different locations around the country. From June 2011 through December 2016, the individual submitted fraudulent claims to Medicare for purportedly providing medical services. The individual had the money paid by Medicare deposited into the bank accounts he controlled in the victim doctors' names. The doctors, as a result of the individuals' crimes, received bills from the IRS for unpaid taxes and from Medicare for repayment of the apparently fraudulent claims. The individual was sentenced to 13 years and 5 months in prison and ordered to pay \$1.6 million in restitution.

Laboratories

In December 2017 Primex Clinical Laboratories, LLC (Primex) and the CEO and owner of DNA Stat, LLC (DNA Stat) agreed to pay \$3.5 million and \$270,000, respectively, to resolve civil FCA allegations that they paid kickbacks in exchange for laboratory referrals for patient pharmacogenetic testing. Primex is a licensed clinical laboratory providing clinical diagnostic testing services, including pharmacogenetic testing. DNA Stat was a laboratory management company that employed sales representatives and licensed pharmacists. Primex and DNA Stat entered into a services agreement related to pharmacogenetic testing services. From June 2013 through March 2016, Primex and DNA Stat allegedly were involved in several kickback schemes, including a scheme where the defendants created the appearance of paying physicians to provide clinical study data for a Primex-sponsored study related to pharmacogenetic testing when, in fact, the physicians were being paid for referring patients for the testing. Primex and DNA Stat also allegedly provided physicians with in-office medical technicians to do work related to the Primex-sponsored study in an effort to induce those physicians to order pharmacogenetic tests from Primex.

In May 2018, the United States District Court in the District of South Carolina entered judgment for the United States in the amounts of \$111.1 million against the former CEO of Health Diagnostics Laboratory Inc. (HDL) and two individuals who marketed tests for HDL and Singulex, Inc., and for an additional \$3 million against the two marketers. HDL was a blood testing laboratory based in Richmond, Virginia; Singulex is based in Alameda, California. The judgment followed the January 31, 2018, jury verdict finding the three individuals liable for violating the civil FCA by paying remuneration to physicians in exchange for patient referrals, in

violation of the Anti-Kickback Statute, and causing the two laboratories to bill Medicare and TRICARE for medically unnecessary testing. During a two-and-a-half week jury trial held in Charleston, South Carolina, the government introduced evidence that the defendants paid physicians remuneration disguised as “processing and handling fees” for each patient they referred to HDL and Singulex. The government also introduced evidence that the kickback scheme induced physicians to refer patients to HDL and Singulex for medically unnecessary tests, which were then billed to Medicare and TRICARE.

Nursing Homes and Facilities

In October 2017, Catholic Health System, Inc., Home & Community Based Care (Catholic Health) agreed to pay \$6 million to resolve civil FCA allegations that it knowingly caused false claims to be submitted to Medicare. Catholic Health operated and provided long-and short-term skilled nursing care and post-acute care to seniors at Father Baker Manor, the McAuley Residence, and St. Frances Williamsville (collectively described herein as the “Subject Facilities”). The agreement resolves allegations that between January 1, 2007, and December 31, 2014, Catholic Health submitted, or caused to be submitted, false claims to Medicare for rehabilitation therapy services at the Ultra High Resource Utilization Group level it administered to beneficiaries that were unreasonable, not medically necessary, and unsupported by the medical records at its Subject Facilities. As part of the resolution, Catholic Health agreed to enter into a 5-year CIA to resolve its liability.

In June 2018, Signature Healthcare, LLC (Signature), a company that operates approximately 115 skilled nursing facilities, agreed to pay \$30 million to resolve civil FCA allegations associated with its submission of false claims to Medicare for unnecessary rehabilitation therapy. Specifically, the settlement agreement resolves allegations that, from January 1, 2011, through September 30, 2015, Signature billed the highest reimbursement level (Ultra High Resource Utilization Group) for patients for periods exceeding 30 days. Signature’s corporate policies and practices allegedly encouraged the provision of unnecessary therapy untethered to the individual clinical needs of patients. Additionally, the settlement agreement resolves allegations that, from January 1, 2011 and June 1, 2013, Signature improperly submitted Pre-admission Evaluation Certifications that were photocopied or had forged physician signatures in order to illegally obtain reimbursement from Tennessee’s Medicaid program. As part of the resolution, Signature agreed to enter into a company-wide 5-year CIA.

Pharmacies

In December 2017, DaVita Rx, LLC (DaVita Rx), a nationwide pharmacy that specializes in serving patients with severe kidney disease, entered into a settlement agreement to resolve allegations that it billed Federal health care programs for prescription medications that were never shipped, that were shipped but subsequently returned, and that did not comply with requirements for documentation of proof of delivery, refill requests, or patient consent. In addition, the settlement also resolves allegations that DaVita Rx paid financial inducements to Federal health care program beneficiaries in violation of the anti-kickback statute. Specifically, DaVita Rx allegedly accepted manufacturer copayment discount cards in lieu of collecting copayments from Medicare beneficiaries, routinely wrote off unpaid beneficiary debt, and

extended discounts to beneficiaries who paid for their medications by credit card. These allegations relating to improper billing and unlawful financial inducements were the subject of self-disclosures by DaVita Rx and a subsequently filed whistleblower lawsuit. DaVita Rx repaid approximately \$22.2 million to federal healthcare programs following a self-disclosure and agreed to pay an additional \$38.3 million to the United States as part of the settlement agreement. In addition to the federal recovery, DaVita Rx paid \$3.2 million to resolve state Medicaid liability.

In December 2017, Kmart Corporation, a wholly owned subsidiary of Sears Holdings Corporation, agreed to pay \$32.3 million to the United States to settle civil FCA allegations that in-store pharmacies in Kmart stores failed to report discounted prescription drug prices to Medicare Part D, Medicaid, and TRICARE. In addition to the federal recovery, Kmart agreed to pay \$9.8 million to resolve state Medicaid and insurance liability.

(SF) In January 2018, a pharmacy owner, a physician, and a patient recruiter were convicted at trial for their involvement in a kickback scheme. The doctor and other co-conspirators prescribed expensive pain and scar creams costing up to \$17,000 per bottle in return for kickback payments. The pharmacy owner then billed TRICARE for the medically-unnecessary pain and scar creams, and TRICARE paid approximately \$4.3 million on the claims. The pharmacy owner was sentenced to 13 years in prison and ordered to forfeit approximately \$340,000 worth of real property and two cashier's checks worth \$25,000 each. The patient recruiter was sentenced to 2 years. The physician was sentenced to 3 years of probation, which is currently being appealed by the United States.

(SF) In August 2018, the owner and the pharmacist-in-charge of a Mississippi compounding pharmacy pleaded guilty to one count of conspiracy to commit health care fraud. The pharmacy received approximately \$240 million in reimbursements from TRICARE and other health care benefit programs for dispensing compounded medications that were medically unnecessary and ineffective. The pharmacist and his co-conspirators selected formulas for compounded medications based on reimbursement rates rather than medical efficacy. They also failed to collect beneficiary copayments and paid copayments on behalf of beneficiaries. More than \$29 million has been seized and is being forfeited to the United States. The pharmacist is scheduled to be sentenced in October 2018.

(SF) Between December 2017 and April 2018, seven individuals were sentenced for their roles in a \$150 million compounding pharmacy fraud scheme. From approximately October 2012 through December 2015, the co-conspirators manipulated billing codes and submitted claims for pharmaceutical ingredients they did not have, chiefly for compounded pain creams and scar creams, to private insurance companies, Medicare, and TRICARE. They also paid kickbacks and bribes in exchange for prescriptions and patient identifying information to further the scheme. The pharmacies submitted approximately \$633 million in claims for compounded medications and received approximately \$157 million on the claims. The president and owner of a pharmacy was sentenced to 15 years in prison and ordered to pay \$54 million in restitution. His seven co-defendants were sentenced to between 1 year and a day and 66 months in prison. The defendants also were ordered to forfeit a combined equity of over \$7.6 million in the real properties, cars, and boats.

Physical Therapy

(SF) In February, March, and July 2018, six defendants were sentenced after pleading 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 fraudulent health services, including physical and occupational therapy services. A medical biller was sentenced to 18 months in prison. A therapist manager was sentenced to 36 months in prison. An officer worker at the clinic was sentenced to 18 months in prison. The three agreed to pay a total of over \$17 million in restitution. The operator and manager of a Brooklyn clinic, who also served as an ambulette driver and the president and owner of purported management companies used to launder approximately \$1.8 million to pay kickbacks to patients, was sentenced to 46 months in prison followed by 3 years of supervised release and order to pay \$1.8 million in restitution. Two co-owners of Brooklyn-area medical clinics were each sentenced to a year in prison and ordered to pay \$1.1 million in restitution. The owners were ordered to pay \$151,000 and \$115,000 in restitution respectively. From 2008 through 2011, the defendants and others executed falsified patient charts and medical billing documents. They paid patient recruiters and patients cash kickbacks to receive treatment, including physical and occupational therapy. The defendants billed Medicare and Medicaid over \$55 million and were paid over \$26 million for medically unnecessary treatments. Together with these defendants, over 20 individuals have pled guilty for their participation in similar schemes perpetrated at these and other clinics.

In July 2018, Southern SNF Management, Inc., Rehab Services in Motion d/b/a Dynamic Rehab and nine affiliated skilled nursing facilities in Florida and Alabama agreed to pay \$10 million to resolve civil FCA allegations that they submitted or caused the submission of false claims to Medicare for medically unnecessary rehabilitation therapy services. The United States alleged that between October 2009 and December 2013, Southern SNF, Dynamic Rehab and the nine skilled nursing facilities' corporate policies and practices encouraged the provision of medically unreasonable and unnecessary therapy without regard for patients' individual clinical needs.

Physician and Other Practitioners

(SF) In February 2018, a surgeon who practiced at several hospitals in Brooklyn and surrounding areas was sentenced to 13 years in prison and ordered to pay restitution and to forfeit over \$7 million following a jury trial for health care fraud, falsification of medical records, and money laundering. Medicare was fraudulently billed more than \$85 million for incision-and-drainage and wound debridement procedures that the surgeon did not perform. The surgeon also wired more than a million dollars of fraud proceeds overseas.

(SF) In February 2018, a physician was sentenced to 72 months in prison and ordered to forfeit \$1.7 million after a jury convicted him for his role in a \$10.4 million conspiracy to defraud the Medicare program. The office manager pleaded guilty and was sentenced to 18 months in prison. The physician accepted kickbacks from his co-conspirators in exchange for referring Medicare patients for electromyogram tests (EMGs), some of which were unnecessary, and physical therapy performed by unlicensed individuals. The physician then disguised the payments as "rent" and set up a shell company to hide this illegal scheme.

In June 2018, Health Quest Systems, Inc., Health Quest Medical Practice, P.C. ("HQMP"), Health Quest Urgent Medical Care Practice, P.C., ("HQUC") (collectively "Health Quest"); and Putnam Health Center ("PHC") entered into a settlement agreement to resolve their FCA liability. From April 1, 2009 through June 23, 2015, Health Quest submitted claims for evaluation and management services but did not sufficiently document the services to support the level of service billed. As a result, the services were billed two levels higher than supported by the medical record. From April 1, 2011 through August 2014, Health Quest submitted claims for home health services that lacked sufficient medical records to support the claim, including documentation of a face-to-face encounter with a physician. From March 1, 2014 through December 31, 2014, Health Quest subsidiary hospital, PHC, submitted allegedly false claims for inpatient and outpatient services referred to PHC by two orthopedic physicians, in alleged violation of the Physician Self-Referral Law. The two physicians had a direct financial relationship with PHC for providing administrative services and received compensation from PHC. The United States alleged their compensation exceeded the fair market value for the services, and thereby violated the Physician Self-Referral Law, which prohibits a hospital from billing Medicare for certain services referred by physicians with whom the hospital has an improper compensation arrangement. The United States further alleged that one purpose of the excessive compensation was to induce the above referrals to PHC, in violation of the Anti-Kickback Statute. Health Quest and PHC agreed to pay \$15.6 million and enter into a 5-year CIA.

In September 2018, the District Court for the Eastern District of Missouri entered a civil judgment in the amount of \$5.5 million against a neurosurgeon, his fiancée, and their professional corporations DS Medical and Midwest Neurosurgeons. Previously, in November 2017, a federal jury sitting in St. Louis, Missouri found that the couple conspired to violate the civil FCA and also violated the FCA and the Anti-Kickback Statute. The government's complaint and evidence at trial established that the neurosurgeon, who practiced through his professional corporation Midwest Neurosurgeons, used spinal implants when performing spinal fusion surgeries. His fiancée started a spinal implant distributorship business called DS Medical in November 2008, after which he began using DS Medical as his spinal implant distributor for most of his spinal implant surgeries from 2009 through 2012. His fiancée then received commissions on the expensive implants that he purchased from her company.

(SF) In September 2018, a physician was convicted by a jury of one count of conspiracy to commit health care fraud and three counts of false statements relating to health care matters. A clinic operator was convicted of one count of conspiracy to commit health care fraud and six counts of health care fraud. Another clinic operator was convicted of one count of conspiracy to commit health care fraud and three counts of health care fraud. The defendants conspired to sell false medical orders signed by the physician and other documents certifying patients for home health services to home health agencies. Co-conspirators at the home-health agencies then used the false and fraudulent paperwork to bill Medicare. The defendants also billed Medicare for purported physician services that were actually provided by an unlicensed practitioner, if at all. In total, Medicare paid approximately \$17 million on the claims. Sentencing is scheduled for December 2018.

(SF) In September and November 2018, a physician and owner of a medical billing company

were sentenced following a jury trial of one count of conspiracy to commit health care fraud and wire fraud and three counts of health care fraud. The physician was sentenced to 180 months in prison followed by 3 years of supervised release. The owner was sentenced to 120 months in prison followed by 3 years of supervised release. The pair were ordered to pay approximately \$9.1 million in restitution, and the court issued a preliminary order of forfeiture for the same amount. The charges stemmed from the defendants' involvement in a \$26 million fraud scheme in which they billed for services, including nerve block injections that were not provided and conspired to evade Medicare's prepayment review.

Prescription Drugs / Medicare Part D

Between October 2017 and February 2018, three Doctors were convicted of multiple counts regarding controlled substances and health care fraud for their participation in a scheme to illegally sell prescriptions for controlled substances. The investigation disclosed that from about February 2012 through August 2016, two of the Doctors owned substance-abuse clinics in Philadelphia, while the third Doctor worked at a nearby substance-abuse clinic. The three and other doctors sold prescriptions for Suboxone and Klonopin to drug dealers and drug addicts in exchange for cash payments. Drug dealers openly sold controlled substances inside the clinics and on the street immediately outside. The physicians did not perform medical or mental health examinations of their patients as required by law to legally prescribe these controlled substances. Virtually every customer who visited the clinics received the maximum daily doses of Suboxone and Klonopin regardless of the customer's medical or mental health history. The three Doctors were sentenced to a combined 4 years and 1 day in prison; ordered to pay \$39,199 in restitution; joint and several; and ordered to forfeit \$153,193.

In December 2017 and February 2018, two co-conspirators connected with the health clinic Advance Care Services (ACS), were convicted of charges resulting from their involvement in an unlawful prescription drug operation. In all, they were sentenced to a combined 10 years in prison and ordered to pay \$2.5 million in restitution, joint and several. The co-conspirators—an ACS physician and a patient recruiter—conspired to operate a fraudulent medical practice. ACS purported to be a pain management and HIV infusion clinic; however, the actual scheme involved patient recruiters bringing “patients” to the clinic to obtain medically unnecessary prescriptions for controlled substances. Medicare was billed for medical examinations and tests that were not conducted properly or at all. According to statements made at the plea hearing and evidence submitted at sentencing, the ASC physician often took advantage of the female “patients” who received controlled-substance prescriptions by sexually molesting or harassing them. The ASC physician was responsible for illegally distributing more than 700,000 dosage units of Hydrocodone, more than 240,000 dosage units of Alprazolam, and more than 2 million milliliters of promethazine with codeine cough syrup, worth more than \$15 million on the street market. Three other defendants involved in the scheme were previously sentenced to a combined 6 years and 5 months in prison and ordered to pay \$2.5 million in restitution (joint and several).

Superseding indictments returned in January and May 2018 charged seven individuals, including two leaders in Italy, for their roles in a Racketeering Influenced Corrupt Organization (RICO) which illegally operated pain clinics in Tennessee and Florida. Defendants were charged with

RICO conspiracy and drug trafficking conspiracy to distribute and dispense oxycodone, oxymorphone and morphine outside the scope of professional practice and not for a legitimate medical purpose and resulting in deaths. Additional charges included maintenance of drug-involved premises, distribution of oxycodone resulting in death, conspiracy to defraud the United States through the solicitations and receipt of illegal health care kickbacks and money laundering. The criminal enterprise is alleged to have operated clinics in Tennessee and Florida which generated revenues of over \$21 million and prescribed in excess of 880 billion milligrams of oxycodone. Trial is scheduled in FY 2019.

(SF) In March 2018, a New Orleans-area woman pleaded guilty to one count of conspiracy to unlawfully distribute and dispense oxycodone and to obtain oxycodone by fraud. The defendant admitted to using a physician's stolen prescription template to create hundreds of fraudulent prescriptions for oxycodone in her name and in the names of others. She further admitted that she was responsible for approximately 25,620 tablets of oxycodone distributed on the black market. The defendant is scheduled to be sentenced in November 2018.

(SF) In September 2018, the physician and the owner of a pain management clinic each were sentenced to 35 years in prison after a jury found them guilty of one count of conspiracy to unlawfully distribute controlled substances and three counts of unlawfully distributing and dispensing controlled substances. From March 2015 through July 2017, the physician and the owner ran a clinic that operated as an illegal pill mill and produced daily profits often in excess of \$30,000 that they divided between themselves. The physician wrote prescriptions for hydrocodone, a Schedule II controlled substance, and carisporodal, a Schedule IV controlled substance—a dangerous drug cocktail with no known medical benefit. Altogether, the physician wrote approximately 18,252 prescriptions for over 2.1 million dosage units of hydrocodone and approximately 15,649 prescriptions for over 1.3 million dosage units of carisporodal. “Crew leaders” ferried patients to the clinic, sometimes as many as 60 per day, so that the physician could write prescriptions for controlled substances in exchange for cash.

(SF) In September 2018, a physician was sentenced to 78 months in prison to be followed by three years of supervised release, ordered to forfeit \$4,800, and ordered to pay a \$250,000 fine after a jury convicted him of participating in a conspiracy to distribute a controlled substance. From January 2014 through October 2017, the physician and his co-conspirators performed sham consultations with cash-paying patients and improperly prescribed opioids and narcotics, including Oxycodone, Oxycontin, and Percocet, in exchange for cash payments. The physician provided his co-conspirators with pre-signed prescriptions to use in his absence. An employee at the physicians' office was sentencing to serve 24 months in prison to be followed by three years of supervised release and ordered to pay \$396,428 in restitution, jointly and severally. A second employee was sentenced to serve 18 months in prison to be followed by three years of supervised release and ordered to pay \$396,428 in restitution. A third employee was sentenced to time-served, three years of supervised release, and ordered to pay \$132,142 in restitution.

Psychiatric and Psychological Testing and Services

In November 2017, Region 8 Mental Health Services (Region 8) agreed to pay a lump sum of

\$6.9 million, plus approximately \$1.7 million based on the anticipated value of six properties, to resolve allegations that it violated the civil FCA by submitting false claims to Medicaid. Region 8 provides a variety of mental health services to children and adults located in five counties in Mississippi. The settlement resolves allegations that, from October 2004 through December 2010, Region 8 submitted false claims for services to Medicaid beneficiaries enrolled in its preschool Day Treatment program that it did not provide or that were not provided by qualified individuals. Medicaid defines Day Treatment as “a behavioral intervention program, provided in the context of a therapeutic milieu, which provides children/adolescents with serious emotional disturbances the intensity of treatment necessary to enable them to live in the community.”

(SF) In September 2018, a Houston psychiatrist was sentenced to over 12 years in prison and ordered to pay \$22 million in restitution after a jury convicted him for his involvement in a \$155 million Medicare fraud scheme involving false claims for psychiatric services. From 2006 to February 2012, the psychiatrist indiscriminately admitted and readmitted patients into a partial hospitalization program causing false and fraudulent claims for intensive outpatient psychiatric treatment to be submitted to Medicare. The psychiatrist falsified medical records and signed false documents to make it appear as if patients qualified for, required, and actually received the intensive psychiatric services. The psychiatrist also personally billed Medicare for psychiatric services he did not provide. The psychiatrist was personally responsible for over \$55 million of the \$155 million billed to Medicare. Fifteen other defendants, including administrators, patient recruiters, and group home owners, have been sentenced from 5 to 45 years for their roles in this case.

In July 2018, Early Autism Project, Inc. (EAP), South Carolina’s largest provider of behavioral therapy for children with autism, entered into an FCA settlement agreement resolving allegations that: (1) between January 1, 2009 and December 31, 2016, EAP submitted claims payable by the South Carolina Medicaid Waiver program for Early Intensive Behavioral Intervention therapy services by Consultants and Lead Therapists that either misrepresented the services provided or where services were not provided at all; and (2) between April 1, 2012, and July 9, 2016, EAP submitted claims to the Defense Health Agency for one-on-one Applied Behavioral Analysis therapy services that either misrepresented the services provided or where services were not provided at all. EAP agreed to pay \$8.8 million, and ChanceLight, Inc., for itself and on behalf of EAP, its wholly-owned subsidiary, entered into a 5-year CIA.

Other Medicare and Medicaid Matters

In November 2017, an individual was convicted of making false statements to Federal agents and was sentenced to 6 months in prison. The individual owned and operated group homes in the Houston, Texas area. The individual engaged in a scheme to defraud Medicare by receiving kickbacks in exchange for referring her group home residents for home health services.

(SF) In September 2018, a prominent Kentucky attorney was sentenced to 180 months in prison consecutive to a 144-month sentence previously imposed in a companion case, and ordered to pay more than \$70 million in restitution. He pleaded guilty to conspiracy to defraud the United States, conspiracy to retaliate against an informant, and conspiracy to escape from custody. The attorney and his co-conspirators defrauded the Social Security Administration of more than

\$600 million by creating and submitting falsified medical evidence to support favorable disability determinations by the Social Security Administration. As a result of the scheme, the Social Security Administration paid more than \$70 million on fraudulent disability claims, and Medicare paid more than \$50 million in health care benefits to individuals the Social Security Administration subsequently determined were not entitled to receive benefits.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

A certain portion of the funds appropriated under HIPAA are, by law, set aside for Medicare and Medicaid activities of HHS-OIG. In FY 2018, the Secretary and the Attorney General jointly allotted \$190.4 million to HHS-OIG after accounting for a sequester reduction of \$13.6 million. OIG was allocated an additional \$10.1 million in HCFAC mandatory funds from the Secretary. Additionally, Congress appropriated \$84.4 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 they served. HHS-OIG pursues this vision through independent oversight of HHS programs and operations and by providing HHS and Congress with objective, reliable information for use in policymaking. HHS-OIG assesses the Department's performance, administrative operations, and financial stewardship. HHS-OIG also 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 combating 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 2018, HHS-OIG investigations resulted in 679 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid; and 795 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 2018, HHS-OIG excluded a total of 2,712 individuals and entities, the details of which are below.

In FY 2018, 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 and Tampa, Florida; Dallas and Houston, Texas; Los Angeles, California; Detroit, Michigan; Brooklyn, New York; Baton Rouge and New Orleans, Louisiana; Chicago, Illinois; and Newark, New Jersey/Philadelphia, Pennsylvania; along with a Corporate Strike Force in Washington, D.C. HHS-OIG supports 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 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.¹³

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 2018, 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 \$25.6 billion–\$25.0 billion in Medicare savings and \$675 million 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 \$13 to \$1.¹⁴

¹³ As of October 2018, OIG has assigned Special Agents to support 13 prosecutors with the newest addition of the Appalachian Regional Prescription Opioid Strike Force

¹⁴ 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.

Additional information about savings achieved through such policy and procedural changes may be found in the HHS-OIG fall Semiannual Report to Congress, online at <http://oig.hhs.gov>.

OIG Priority Outcomes

With a \$1 trillion portfolio to oversee, HHS-OIG sets priority outcomes to achieve the greatest impact across HHS's diverse programs. For each priority outcome area, HHS-OIG executives and senior-level staff develop strategies, drive action, unleash organizational creativity, and measure impact to provide solutions and improve outcomes for HHS programs and beneficiaries. HHS-OIG's current priority outcome areas were selected on the basis of past and ongoing work, top challenges facing HHS as identified annually by HHS-OIG, ability to collect data, and ability to influence outcomes. HHS-OIG's initial priority outcome areas fall into two broad categories:

1. Minimize risks to beneficiaries

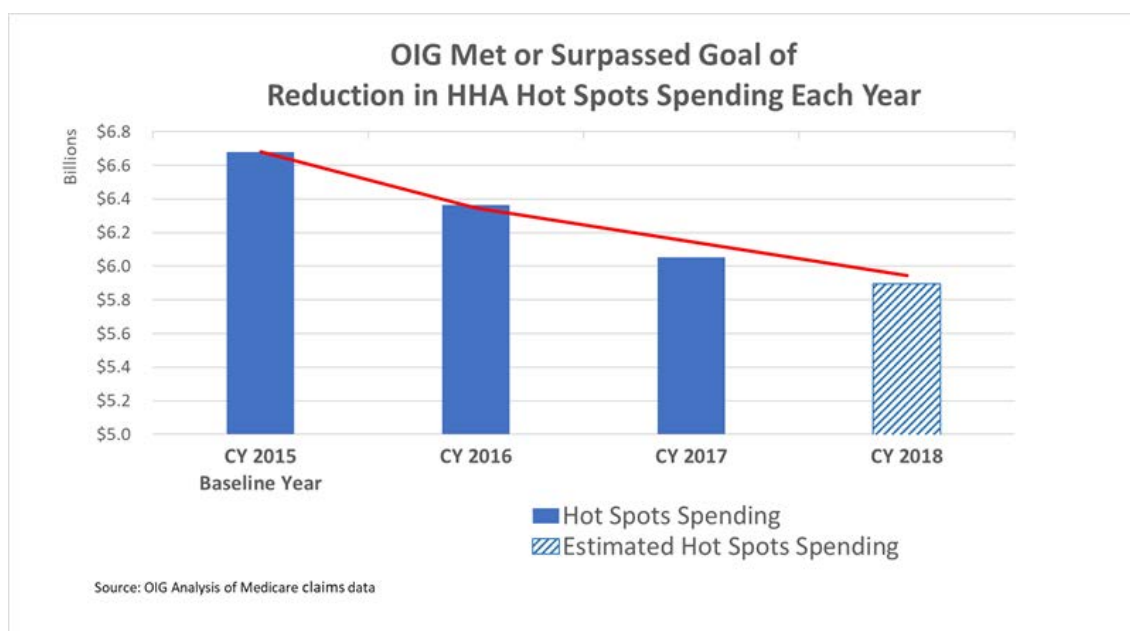
- Protect beneficiaries from prescription drug abuse, including opioids
- Ensure health and safety of children served by HHS grants

2. Safeguard programs from improper payments and fraud

- Promote patient safety and accuracy of payment in home and community settings
- Strengthen Medicaid protections against fraud and abuse

These priority outcome areas reflect only some of the important work HHS-OIG performs. They address key vulnerabilities identified in the HHS publication, *Top Management and Performance Challenges*.

For instance, OIG has long recognized the Medicare home health benefit as a program area vulnerable to fraud, waste, and abuse. In the baseline year for this effort, Medicare reimbursed over 11,000 distinct home health agencies (HHAs) for almost 7 million episodes of home health care, totaling approximately \$18.7 billion. Using data analytics, OIG identified four geographic areas—Florida, Texas, and select areas in Southern California and the Midwest—that have large numbers of home health providers with characteristics that OIG determined, based on its previous data analysis, to be suspect. OIG efforts contributed to a 9 percent decrease in home health payments in the four geographic hot spots from CY 2015 to CY 2017. Nationally, the decrease in home health spending over this same time was 2 percent. OIG continues to monitor the progress of HHA spending in these hot spots and has surpassed the HHA spending reduction goal each year to date.



Enforcement

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.

Combating 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 June 2018, HHS-OIG participated with Federal, State, and local partners (including 30 MFCUs) in the National Health Care Fraud Takedown, described in more detail elsewhere in this report. More than 600 defendants in 58 Federal districts were charged with participating in fraud schemes involving about \$2 billion in false billings to Medicare and Medicaid. Among those charged, 165 defendants (including 32 doctors) were charged in cases involving the illegal distribution of opioids. HHS-OIG also issued exclusion notices to 587 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 providing data on the extent to which Medicare Part D beneficiaries receive extreme amounts of opioids or appear to be "doctor shopping". 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.

Program Exclusions

One important mechanism for safeguarding the care provided to program beneficiaries is through

exclusion of providers and suppliers who have engaged in crimes related to Medicare or Medicaid, patient abuse or neglect, financial misconduct, or controlled substances, or as a result of license revocation. This list of conduct is not exhaustive but identifies the most prevalent causes underlying HHS-OIG's exclusions of individuals or entities. The effect of an HHS-OIG exclusion is that no Federal health care program payment may be made for any items or services furnished (1) by an excluded person or (2) at the medical direction or on the prescription of an excluded person. HHS-OIG completed the deployment of a new service for Medicaid Fraud Control Units to report convictions through a central web based portal for exclusion. HHS-OIG is also responsible for reinstating providers who apply and have met the requirements of their exclusions.

In FY 2018, HHS-OIG excluded a total of 2,712 individuals and entities. In addition to those mentioned in the Program Accomplishments section above, exclusion actions by HHS-OIG included:

- In November 2017, HHS-OIG excluded an individual for a minimum period of 30 years. The individual was an administrator at Passages Hospice, LLC. According to court documents, from August 2009 to September 2009, the administrator altered patient files to make visits that were at the routine level appear to have been general inpatient services for purposes of Medicare payment. General inpatient services, which are paid at a higher rate than routine care services, were not medically necessary and were not provided. The administrator pleaded guilty to conspiracy to commit an offense against the United States and was sentenced to 2 years and 4 months in prison and ordered to pay \$9 million in restitution, joint and several among other defendants.
- In November 2017, HHS-OIG excluded an individual for a minimum period of 50 years. The individual was a pharmacist who owned RX Discount Pharmacy. According to evidence presented at trial, from January 2010 through December 2015, the pharmacist sold prescription pain pills without a legitimate medical purpose and sold pseudoephedrine, knowing or having reason to believe that it was being used to manufacture methamphetamine. Many of the pharmacist's customers visited pain clinics in other states to obtain illegitimate prescriptions from irreputable clinics. The pharmacist would charge \$600 to \$1,000 to fill the prescriptions, which included excessive amounts of oxycodone. According to trial testimony, the pharmacist also sold multiple boxes of pseudoephedrine at a time, for excessively high prices, to drug addicts and traffickers. A jury convicted the individual on 71 counts involving the illegal dispensing of oxycodone, hydrocodone, and pseudoephedrine, and sentenced him to 30 years in prison.
- In May 2018, HHS-OIG excluded a doctor for a minimum period of 75 years. The doctor was excluded based on his convictions on multiple counts of criminal sexual conduct. From about July 1998 to about May 2015, the doctor sexually abused patients in his position as the lead doctor for the USA Women's gymnastics team. It was his job to medically treat the gymnasts on the team, and during those treatment sessions, the doctor would sexually touch the victims. The doctor was sentenced to 40 to 175 years in prison on the basis of his conviction in the 30th Judicial Circuit Court of Ingham County,

Michigan, and 40 to 125 years in prison for his conviction in the 56th Judicial Circuit Court of Eaton County, Michigan. The doctor was also convicted in the United States District Court of Western Michigan of receipt and attempted receipt of child pornography, possession of child pornography and destruction and concealment of records and tangible objects. In addition, the doctor's license to practice as an osteopath was revoked by the Michigan Department of Licensing and Regulatory Affairs. HHS-OIG had previously excluded the doctor in 2017 based on his suspension from the Michigan Department of Health and Human Services.

- In June 2018, HHS-OIG excluded a psychiatrist for a minimum period of 15 years. According to court documents, from about January 2008 to about March 2014, the psychiatrist engaged in a conspiracy to defraud the Office of Workers' Compensation Program (OWCP), which is a component of the Department of Labor, through the submission of millions of false claims. The psychiatrist and his co-conspirators would create templates and patient reports purportedly reflecting patients' status, history, treatment, or progress that would be submitted to OWCP randomly. These created records would then be used to bill OWCP for false claims for services that were never provided. The psychiatrist pleaded guilty to conspiracy to commit health care fraud and was sentenced to 10 months in prison and ordered to pay approximately \$2.3 million in restitution.

Civil Monetary Penalties

HHS-OIG has the authority to seek civil monetary penalties (CMPs), assessments, and exclusion against an individual or entity based on a wide variety of prohibited conduct. Three common ways that HHS-OIG seeks CMPs, assessments, and exclusion are described below. In the first half of FY 2018 (October 1, 2017 to March 31, 2018), HHS-OIG concluded cases involving more than \$35.5 million in CMPs and assessments.

Affirmative Litigation and Exclusion

HHS-OIG may seek a CMP or exclusion against individuals or entities that present claims to Federal health care programs that the individual or entity knows or should know are for items or services that were not provided as claimed or were false or fraudulent. HHS-OIG may also seek a CMP or exclusion against individuals or entities who knowingly and willfully violate the Anti-Kickback Statute by: (1) offering or paying remuneration, directly or indirectly, to induce referrals of Federal health care program business; or (2) soliciting and receiving remuneration, directly or indirectly, in return for referrals of Federal health care program business.

Affirmative litigation examples include:

- In December 2017, a doctor and his medical practice, The Female Pelvic Medicine Institute of Virginia, P.C. (FPMI), agreed to pay more than \$1.4 million and enter into a 3-year IA to resolve their potential liability under the Civil Monetary Penalty Law (CMPL) for submitting claims to Federal health care programs for items or services that FPMI knew or should have known were not provided as claimed or were false or fraudulent. Specifically, HHS-OIG alleged that the M.D. and FPMI submitted claims for

pelvic floor therapy services that were provided by unqualified individuals; diagnostic electromyography services under CPT Code 51784 that had not been performed pursuant to the indicated code's requirements; unbundled biofeedback procedures; and "incident to" services that lacked the required physician supervision level. OIG also alleged that the M.D. and FPMI submitted claims for electromyography services under CPT Code 51784 and anorectal manometry services under CPT Codes 91120 and 91122 that were not supported by the medical record. This resolution resulted from HHS-OIG's collaboration with the Consolidated Data Analytics Center.

- In June 2018, Comanche County Hospital Authority d/b/a Comanche County Memorial Hospital (CCHA), agreed to pay \$566,806 to resolve its potential liability under the CMPL related to allegations that CCHA submitted claims to Medicare for emergency ambulance transportation to destinations such as skilled nursing facilities and patient residences that should have been billed at the lower non-emergency rate. Additionally, during HHS-OIG's investigation, CCHA discovered and disclosed that it submitted claims to Medicare for emergency ambulance transportation that were not medically reasonable or necessary. CCHA also disclosed that it submitted claims to Medicare for transports where the documentation for the transport was not consistent with the patient's condition, and therefore did not support the documented medical necessity for the transport. This settlement resulted from collaboration between the Office of Counsel to the Inspector General (OCIG) and HHS-OIG's Consolidated Data Analysis Center. OCIG has settled eight affirmative CMPL cases based on this type of conduct since September 2016.

Patient Dumping

HHS-OIG may also seek a CMP against any hospital that negligently violates its obligations under the Emergency Medical Treatment and Labor Act (EMTALA), known as the "patient dumping" statute, which requires a hospital to stabilize and treat, or appropriately transfer if the hospital lacks the specialized capabilities necessary to stabilize the person, anyone who presents to the emergency department with an emergency medical condition.

Patient dumping examples include:

- In December 2017, Cambridge Health Alliance (CHA) agreed to pay \$90,000 to resolve its potential liability under EMTALA. OIG alleged that CHA violated EMTALA when it failed to screen a patient after she presented on hospital property in medical distress. Specifically, HHS-OIG alleged that a patient who was experiencing a severe asthma attack presented to CHA's Somerville Hospital Campus, but was unable to gain entry to the ambulance bay doors. The patient called 911, which notified the hospital's responding nurse. HHS-OIG alleged that CHA was negligent in its search for the patient, looking only briefly outside without leaving the ambulance bay door or searching the sidewalk located just steps from the doors. The patient had collapsed on a bench adjacent to the ambulance doors. Ultimately, the 911 dispatchers sent emergency responders to the hospital who found the patient in full cardiac arrest and no longer breathing. The

patient was brought inside the hospital in grave condition, and 6 days later died of hypoxic brain injury.

- In January 2018, Piedmont Newton Hospital (PNH) agreed to pay \$52,414 to resolve its potential liability under EMTALA. HHS-OIG alleged that PNH violated EMTALA when it failed to provide an appropriate medical screening exam and stabilizing treatment to a patient (TMK) and inappropriately transferred TMK to another hospital. Specifically, HHS-OIG alleged that TMK arrived at PNH complaining of left-sided pleuritic chest pain and abdominal pain. PNH's emergency department (ED) physician observed that her abdomen was diffusely firm with hypoactive bowel sounds, and ordered blood tests, which revealed that TMK's lactic acid and bleeding and clotting time were elevated beyond normal limits. The ED physician learned that TMK had undergone dilation and curettage two days earlier. The ED physician ordered an acute abdominal series with chest x-ray for TMK, which showed a large amount of intraperitoneal air under her right diaphragm, suggesting bowel perforation. The ED physician consulted with the on-call surgeon, who recommended transferring TMK to the other hospital where she previously underwent the dilation and curettage procedure. The other hospital agreed to accept the transfer and asked that TMK be airlifted to their facility. The ED physician's notes revealed that TMK had a perforated bowel and her condition was critical at the time of transfer. Upon her arrival at the other hospital, TMK was in septic shock and appeared on the verge of a respiratory collapse. She was immediately intubated and taken to the operating room for a resection and colostomy. TMK's condition worsened and she died later that day due to septic shock with multi-organ failure.
- In April 2018, Covenant Medical Center (Covenant) entered into a \$90,000 settlement agreement with HHS-OIG to resolve allegations that it violated EMTALA when it failed to provide an adequate medical screening examination and stabilizing treatment for a patient and then inappropriately transferred him to another hospital. The patient, a 54-year-old man, arrived by ambulance to Covenant's Emergency Department (ED) complaining of shortness of breath, chest pain, and diaphoresis. The ED physician screened the patient and consulted the on-call cardiologist. The patient's condition worsened, and he was intubated. On advice of the on-call cardiologist, the ED physician began transcutaneous pacing. The ED physician did not request the on-call cardiologist present to the ED nor did the on-call cardiologist present to the ED to examine and treat the patient. The ED physician requested transfer to a nearby hospital for placement of a transvenous pacemaker. The patient was transferred to the receiving hospital nearly three hours after he presented to Covenant's ED. The receiving hospital placed a transvenous pacemaker on the patient, but he expired shortly after. OIG alleged that Covenant's on-call cardiologist was capable of providing a transvenous pacemaker.

Self-Disclosure

HHS-OIG maintains the Self-Disclosure Protocol whereby providers may voluntarily identify, disclose, and resolve instances of potential fraud involving Federal health care programs for resolution under the Civil Monetary Penalties Law (CMPL).

Self-disclosure examples include:

- In January 2018, after self-disclosing conduct to HHS-OIG, Shands Jacksonville Medical Center, Inc. d/b/a UFHealth Jacksonville and University of Florida Jacksonville Physicians, Inc. (collectively, “UFHealth”), agreed to pay more than \$4.4 million to resolve its liability under the CMPL. Specifically, HHS-OIG alleged that UFHealth presented false claims to Medicare and Medicaid for hospital and professional services associated with surgical procedures performed by an ophthalmologist at UF Health Jacksonville, from April 8, 2010, through April 7, 2016, when the records did not support medical necessity for the procedures performed.
- In July 2018, after self-disclosing conduct to HHS-OIG, St. Agnes Healthcare, Inc. (St. Agnes), agreed to pay more than \$2.2 million to resolve its liability under the CMPL. Specifically, HHS-OIG alleged that, from February 1, 2011, through July 1, 2017, St. Agnes paid a physician excessive compensation in the forms of an inflated salary and improper incentive and administrative payments to induce his referrals of Federal health care program patients.
- In April 2018, after self-disclosing conduct to HHS-OIG, BenchMark Rehabilitation Partners, LLC, BenchMark Growth Partners, LLC, BenchMark Premier Partners, LLC, BenchMark East Partners, LLC, BenchMark Development Partners, LLC, and BenchMark West Partners, LLC (collectively, “BenchMark”), agreed to pay more than \$3.1 million to resolve its alleged liability under the CMPL. Specifically, HHS-OIG alleged that BenchMark submitted claims to Medicare and TRICARE for time-based outpatient rehabilitation therapy services provided to Medicare and TRICARE beneficiaries when BenchMark’s therapists did not provide constant attendance or direct one-on-one contact because the therapy services were provided concurrently with another Medicare or TRICARE beneficiary.
- In May 2018, after self-disclosing conduct to HHS-OIG, HVHC LLC, Visionworks of America, Inc., Visionary Properties, Inc., Visionworks, Inc., Empire Vision Center, Inc. (collectively, “Visionworks”), agreed to pay more than \$3.6 million to resolve its alleged liability under the CMPL. Specifically, HHS-OIG alleged that Visionworks paid excess remuneration to certain optometrists in the form of space and equipment leases that were below fair market value and/or by failing to collect one or more rental amounts under space and equipment leases, in violation of the Anti-Kickback Statute.

Corporate Integrity Agreements (CIA) and Enforcement

Many health care providers elect to settle their cases before litigation. HHS-OIG provides information on its website that identifies how it evaluates future risk to Federal health care programs from providers who settle health care fraud cases (called the “Fraud Risk Indicator”). 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 examples below:

- In July 2018, pursuant to HHS-OIG's authority under the CIA between HHS-OIG and eClinicalWorks, LLC (ECW), HHS-OIG issued a \$132,500 stipulated penalty for ECW's failure to timely report patient safety issues to HHS-OIG as reportable events. In May 2017, ECW, one of the nation's largest vendors of electronic health records (EHR) software, agreed to pay \$155 million and entered into a CIA to resolve ECW's alleged FCA liability when ECW concealed from its customers that its software did not comply with the requirements for "meaningful use" certification. The CIA requires ECW to retain an Independent Software Quality Oversight Organization, which evaluates ECW's software quality control systems, to provide notice to its customers of any safety related issues, and to maintain on its customer portal a comprehensive list of such issues and any steps users should take to mitigate potential patient safety risks. The CIA requires ECW to notify OIG of certain reportable events, including patient safety issues. The CIA stipulates that failure to timely report qualifying events may result in the assessment of penalties. ECW's failure to comply with the reportable events provision of the CIA resulted in HHS-OIG imposing the \$132,500 stipulated penalty.
- Chatsworth Park Health Care Center (Chatsworth), Palm Terrace Care Center (Palm Terrace), and Park Ridge Care Center (Park Ridge)—skilled nursing facilities (SNFs) affiliated with North American Health Care, Inc. (NAHC)—paid a total of \$843,106.04 to resolve their CMPL liability for employing or contracting with individuals who were excluded from participation in Federal health care programs to provide items or services for which payment may be made under such programs. Specifically, the settlement agreements resolve allegations that (1) Chatsworth employed an excluded individual from May 1, 2014, through December 19, 2016; (2) Palm Terrace employed an excluded individual from January 24, 2006, through January 31, 2017; and (3) Park Ridge contracted with an excluded individual from May 20, 2012, through November 20, 2016. NAHC disclosed this conduct to HHS-OIG pursuant to its obligations under its CIA with HHS-OIG. NAHC entered into the CIA in 2016 in connection with its settlement of FCA liability based on the alleged provision of medically unnecessary rehabilitation therapy services provided to patients at SNFs that had service agreements with NAHC.

Audits and Evaluations

HHS-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);
- Strategic goals;
- Top management and performance challenges facing HHS;
- Work to be performed in collaboration with partner organizations;
- Management's actions to implement recommendations from previous reviews; and
- Timeliness.

HHS-OIG's audit and evaluation findings in FY 2018 are listed below and organized by the following targeted issue areas:

- Preventing fraud;
- Analyzing payment trends and detecting potential fraud;
- Identifying misspent funds and addressing improper payments; and
- Promoting quality and safety in health care.

Program Integrity and Preventing Fraud

Weaknesses Exist in Medicaid Managed Care Organizations' Efforts to Identify and Address Fraud and Abuse. OIG found that managed care organizations (MCO) play an increasingly important role in fighting fraud and abuse in Medicaid, yet weaknesses exist in their efforts to identify and address fraud and abuse. Although the number of cases varied widely, some MCOs identified and referred few cases of suspected fraud or abuse to the State in 2015. In addition, MCOs took actions against providers suspected of fraud or abuse but did not typically inform the State, including when MCOs terminated provider contracts for reasons associated with fraud or abuse. Finally, MCOs did not always identify and recover overpayments, including those associated with fraud or abuse. At the same time, selected States employ a number of strategies to address MCOs' weaknesses and improve MCO efforts. (OEI-02-15-00260)

2017 Performance Data for the Senior Medicare Patrol Projects. The Senior Medicare Patrol (SMP) projects receive grants from the Administration for Community Living to recruit and train retired professionals and other senior citizens to prevent, recognize, and report health care fraud, errors, and abuse. In 2017, the 53 SMP projects had a total of 6,130 active team members who

conducted a total of 26,429 group outreach and education events, reaching an estimated 1.9 million people. In addition, the projects had 226,261 individual interactions with, or on behalf of, a Medicare beneficiary. The projects reported \$2,010,475 in expected Medicare recoveries, which came primarily from one project that prompted law enforcement to open an investigation that resulted in a settlement with a hospice company. The SMP projects also reported \$211,749 in cost avoidance and \$44,468 in savings to beneficiaries and others. (OEI-02-18-00130)

MS Ensured That Medicare Shared Savings Program Beneficiaries Were Properly Assigned: Beneficiaries Were Assigned to Only One Accountable Care Organization and Were Not Assigned to Other Shared Savings Programs. The ACA established the Medicare Shared Savings Program (MSSP) to facilitate coordination and cooperation among providers and suppliers to: (1) improve quality of care for Medicare fee-for-service beneficiaries; and (2) reduce health care costs. Eligible providers and suppliers may voluntarily participate in the MSSP by creating or joining an accountable care organization (ACO). Beneficiary assignment is the basis for many key MSSP operations, such as determining an ACO's financial performance and reporting quality measures after each performance year. The designated ACO is responsible for the quality and cost of care of its assigned Medicare beneficiaries during a performance year. ACOs may be eligible to receive additional payments (i.e., shared savings payments) if they reduce health care costs and meet certain quality performance standards. ACOs may also be responsible for a portion of any shared losses. CMS complied with Federal requirements when assigning beneficiaries to ACOs in the MSSP during Performance Years 2013 through 2015 by ensuring that MSSP beneficiaries were assigned to only one ACO and were not assigned to other savings programs. (A-09-17-03010)

Medicare Needs Better Controls to Prevent Fraud, Waste, and Abuse Related to Chiropractic Services. This portfolio presents an overview of program vulnerabilities identified in prior OIG audits, evaluations, investigations, and legal actions related to chiropractic services in the Medicare Program. It consolidates the findings and issues identified in that work and discusses recommendations from prior reports that have not been implemented or have been implemented ineffectively. In addition, this portfolio provides information to help CMS understand the need for effective controls over chiropractic services. (A-09-16-02042)

Medicare Advantage Encounter Data Show Promise for Program Oversight, but Improvements Are Needed. CMS collects detailed information from MA organizations regarding each service provided to beneficiaries in the MA program. This information is known as MA encounter data. Overall, 28 percent of MA encounter records that HHS-OIG reviewed from the first quarter of 2014 had at least 1 potential error, but CMS reported correcting the majority of these records. With CMS's subsequent correction, only 5 percent of the records in HHS-OIG's review would contain a potential error. Some of these errors may raise concerns about the legitimacy of services documented in the data, such as records that lacked a beneficiary last name or a valid identifier for the billing provider. Only a few MA organizations submitted half of the encounter records that had a potential error. CMS does not require MA organizations to submit certain provider identifiers used in program integrity reviews, and these were frequently absent from encounter data. Furthermore, CMS has not tracked how MA organizations responded to edits that reject data, i.e., "reject edits," nor has it established performance measures to monitor MA organizations' submission of records with missing or invalid data. (OEI-03-15-00060)

Reliance on Unverified Patient Lists Creates a Vulnerability in Home Health Surveys. HHS-OIG found that some patient lists supplied by home health agencies (HHAs) were missing Medicare beneficiaries, allowing them to be excluded from surveyor inspections. HHS-OIG also found that surveyors cannot comprehensively verify that HHA-supplied patient lists are complete at the time they conduct their surveys. While HHS-OIG's analysis does not demonstrate that these providers were engaged in fraudulent activity, it does illustrate a vulnerability that HHAs could exploit to conceal fraudulent activity or health and safety violations. However, existing data sources may be useful tools for both surveyors and CMS. HHS-OIG encouraged CMS to explore actions to mitigate this vulnerability. (OEI-05-16-00510)

CMS Ensured Nearly All Part D Drug Records Contained Valid Prescriber Identifiers in 2016. Nearly all prescription drug event (PDE) records for Part D drug claims in 2016 contained valid prescriber National Provider Identifiers (NPIs). Prescriber identifiers are a valuable program integrity safeguard as they enable CMS and Part D plan sponsors to determine if legitimate practitioners have prescribed drugs for enrollees. The Medicare Access and the Children's Health Insurance Program (CHIP) Reauthorization Act of 2015 requires that, beginning in 2016, pharmacy claims for covered Part D drugs must contain valid prescriber NPIs. Additionally, the law requires the HHS Secretary to establish procedures for determining the validity of these prescriber NPIs and requires HHS-OIG to submit to Congress a report on the effectiveness of these procedures no later than January 1, 2018. The evaluation report fulfills HHS-OIG's mandate under the CHIP Reauthorization Act. The report concludes that the system edits that CMS currently has in place to check PDE records are effective in ensuring the validity of the vast majority of Part D prescriber NPIs. (OEI-03-17-00040)

Medicaid Fraud Control Units: Investigation and Prosecution of Fraud and Beneficiary Abuse in Medicaid Personal Care Services. MFCUs investigate and prosecute Medicaid provider fraud and patient abuse or neglect under State law. HHS-OIG conducted this study to provide data on MFCU investigations, indictments, and convictions involving fraud and patient abuse in Medicaid personal care services (PCS). HHS-OIG found that during the review period, PCS fraud cases were a substantial and growing percentage of MFCU cases and outcomes. In FY 2015, fraud cases involving PCS providers or attendants constituted 12 percent of total investigations. From FY 2012 through FY 2015, fraud cases involving PCS providers or attendants constituted 38 percent of indictments and 34 percent of convictions. HHS-OIG also found that during this time, indictments increased 56 percent and convictions increased 33 percent. HHS-OIG found that MFCUs have made recommendations to States for strengthening PCS oversight. Finally, HHS-OIG found that, in MFCUs' efforts to protect beneficiaries receiving PCS services, they are constrained by their ineligibility to receive Federal funding to investigate and prosecute complaints of beneficiary abuse or neglect in non-facility settings (such as beneficiaries' homes). The findings suggest that PCS remain vulnerable to fraud and support the need for greater oversight of Medicaid PCS. (OEI-12-17-00500)

Analyzing Payment Trends and Detecting Potential Fraud in Medicaid

Ohio Received Millions in Unallowable Bonus Payments, Kansas Received Millions in Unallowable Bonus Payments. Under the CHIP Reauthorization Act of 2009, States receive bonus payments to offset the costs of increased enrollment of children in Medicaid. These two

reports are part of a series of reviews that HHS-OIG conducted to determine whether these bonus payments were allowable. Both Ohio and Kansas overstated their current enrollment in their bonus requests to CMS because they included individuals who did not qualify because of their basis-of-eligibility category. As a result of the States' overstated enrollment numbers, CMS overpaid Ohio \$29.5 million and Kansas \$17.8 million in bonus payments. Ohio and Kansas did not concur with HHS-OIG's findings or recommendations to refund the excess payments. (A-04-16-08049, A-04-16-08050)

North Carolina Did Not Comply with Federal and State Requirements When Making Medicaid Cost-Sharing Payments for Professional Medical Services. States must make medical assistance available for Medicare deductibles, coinsurance, and copayments (cost-sharing) for certain individuals who are dually eligible to be enrolled in both Medicare and Medicaid. In North Carolina, Medicaid is required to make cost-sharing payments at the lesser of the cost-sharing amount or the Medicaid allowable payment. North Carolina did not comply with Federal and State requirements when making Medicaid cost-sharing payments for professional medical services. On the basis of its sample results, HHS-OIG estimated that North Carolina made at least \$63 million in improper Medicaid cost-sharing payments and claimed Federal reimbursement of at least \$41.2 million for these payments. These improper payments occurred because North Carolina did not program its Medicaid Management Information System (MMIS) to calculate Medicaid cost-sharing payments for professional medical services in accordance with the State's required cost-sharing payment methodology. ([A-04-16-04054](#))

New Jersey Claimed Hundreds of Millions in Unallowable or Unsupported Medicaid School-Based Reimbursement. New Jersey did not follow Federal regulations and CMS guidance when it developed its payment rates for Medicaid school-based services and, as a result, claimed \$300.5 million in unallowable costs. New Jersey claimed an additional \$306.2 million in reimbursement using payment rates developed with unsupported costs. Among its findings, HHS-OIG determined that: (1) New Jersey's contractor changed school employees' responses to time studies to indicate that their activities were directly related to providing Medicaid services when the responses indicated the activities were unrelated; (2) New Jersey improperly incorporated into its payment rates more than \$400 million owed to the school employees' pension fund despite not having made scheduled payments to the fund in nearly 20 years; and (3) salaries of some employees who did not provide health-related services were incorporated into the payment rates. In addition, New Jersey did not maintain documentation related to the time studies, which it used to identify the percentage of time personnel provided particular services. (A-02-15-01010)

Texas Did Not Appropriately Spend Some State Balancing Incentive Payments Program Funds. Texas appropriately spent \$272.4 million of the \$284.4 million in Balancing Incentive Payments Program (BIPP) funds it received. Of the remaining \$12 million, Texas inappropriately spent \$6.3 million for medical service rate increases that did not benefit Medicaid recipients and did not spend \$5.7 million in BIPP funds before the end of the funding period. Additionally, Texas did not separately track BIPP funds or follow CMS instructions for extending the funding period. (A-06-15-00041)

New York Did Not Correctly Determine Medicaid Eligibility for Some Newly Enrolled Beneficiaries. New York did not always determine Medicaid eligibility for newly eligible beneficiaries in accordance with Federal and State requirements. In HHS-OIG's sample of 130 beneficiaries, New York correctly determined eligibility for 90 beneficiaries. However, it did not determine eligibility for 37 beneficiaries in accordance with Federal and State requirements and did not provide supporting documentation to verify beneficiaries were newly eligible for the remaining 4 potentially ineligible beneficiaries. The total exceeds 130 because 1 beneficiary was found to be ineligible for one determination period and found to be potentially ineligible for another determination period. On the basis of its sample results, HHS-OIG estimated that New York made Federal Medicaid payments of \$26.2 million on behalf of 47,271 ineligible beneficiaries. (A-02-15-01015)

California Made Medicaid Payments on Behalf of Newly Eligible Beneficiaries Who Did Not Meet Federal and State Requirements. For HHS-OIG's sample of 150 beneficiaries who were newly eligible for Medicaid, California made Medicaid payments on behalf of 112. However, for the remaining 38 beneficiaries, California made payments on behalf of ineligible beneficiaries (e.g., a woman who did not meet eligibility requirements for the newly eligible group because she was pregnant) and potentially ineligible beneficiaries (e.g., a beneficiary who may not have met the residency requirement). On the basis of its sample results, HHS-OIG estimated that California made Medicaid payments of \$738.2 million (\$628.8 million Federal share) on behalf of 366,078 ineligible beneficiaries and \$416.5 million (\$402.4 million Federal share) on behalf of 79,055 potentially ineligible beneficiaries. These deficiencies occurred because California's eligibility determination systems lacked the necessary system functionality and eligibility caseworkers made errors. HHS-OIG also identified a weakness in California's procedures related to determining eligibility of individuals who may not have intended to apply for Medicaid. (A-09-16-02023)

New Jersey Claimed Federal Medicaid Reimbursement for Children's Partial Hospitalization Services That Did Not Meet Federal and State Requirements. HHS-OIG estimated that New Jersey improperly claimed at least \$54.7 million in Federal Medicaid reimbursement for children's partial hospitalization services that did not meet Federal and State requirements. New Jersey did not comply with Federal and State requirements for all 100 of the claims in HHS-OIG's sample, including 94 that contained more than one deficiency. For all 100 claims, HHS-OIG found that services provided were not documented or adequately supported. For 81 claims, services were provided at a facility not licensed by New Jersey's hospital licensing agency to provide outpatient hospital services. For 48 claims, providers did not meet the minimum staff-to-client ratio requirement for group therapy services. For 16 claims, services were provided by staff members who did not meet qualification requirements. Finally, for 10 claims weekly progress notes were not maintained. As a result, the quality of care provided to the children at these providers might have been inadequate. The deficiencies occurred because New Jersey did not ensure that children's partial hospitalization services were provided by appropriately licensed hospitals. Also, New Jersey did not adequately monitor the children's partial hospitalization program to ensure that providers complied with Federal and State requirements. (A-02-16-01008)

New York Did Not Comply With Federal Grant Requirements for Claiming Marketplace Contract Costs to Medicaid and the Children's Health Insurance Program. New York did not always follow Federal requirements for claiming Maximus contract costs to Medicaid and CHIP. Specifically, New York claimed unallowable costs totaling as much as \$954,521 (as much as \$852,992 in unallowable profit fees and \$101,529 in unallowable general and administrative costs and related profit fees). This occurred because New York did not establish a basis for the profit fee rate with its contractor, Maximus, Inc., and did not require Maximus to retroactively adjust the calculation of its profit fee and general and administrative costs by removing project costs that should not have been subject to these charges. (A-02-15-01014)

Potential Misclassifications Reported by Drug Manufacturers May Have Led to \$1 Billion in Lost Medicaid Rebates. HHS-OIG found that drug manufacturers may have misclassified 3 percent of drugs in the Medicaid Drug Rebate Program (rebate program). These potential misclassifications may have led to \$1.3 billion in lost Medicaid rebates and demonstrate the opportunity for CMS to improve its oversight of classification data in the rebate program. (OEI-03-17-00100)

Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs. Arkansas did not invoice manufacturers for rebates associated with \$9.9 million (Federal share) in physician-administered drugs. Arkansas improperly claimed Federal reimbursement for single-source drugs and top-20 multiple-source drugs. Also, Arkansas did not submit the utilization data necessary to secure rebates for all other physician-administered drug claims totaling \$1.4 million (Federal share). (A-06-16-00018)

Arizona Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations. Arizona did not bill for and collect from manufacturers estimated rebates of \$36.7 million (\$25.6 million Federal share) for physician-administered drugs. Arizona did not always bill for and collect rebates from manufacturers because it did not have a system edit to ensure that National Drug Codes (NDCs) or valid NDCs were submitted for physician-administered drugs before October 1, 2012. (A-09-16-02031)

Identifying Misspent Funds and Addressing Improper Payments

CMS Paid Practitioners for Telehealth Services That Did Not Meet Medicare Requirements. Medicare paid a total of \$17.6 million in telehealth payments in 2015, compared with \$61,302 in 2001. Medicare telehealth payments include a professional fee, paid to the practitioner performing the service at a distant site, and an originating-site fee, paid to the facility where the beneficiary receives the service. HHS-OIG analyzed 2014 and 2015 (its audit period) telehealth claims and found that more than half of the professional telehealth claims paid by Medicare did not have matching originating-site facility fee claims. Therefore, we focused our review on telehealth claims billed through a distant site that did not have a corresponding originating-site fee. CMS paid practitioners for some telehealth claims associated with services that did not meet Medicare requirements. For 31 of the 100 claims in its sample, telehealth services did not meet requirements. The deficiencies that we identified occurred because CMS did not ensure that: (1) there was oversight to disallow payments for errors for which telehealth claim edits could not be implemented; (2) all contractor claim edits were in place; and (3) practitioners were aware of

Medicare telehealth requirements. (A-05-16-00058)

Most Medicare Claims for Replacement Positive Airway Pressure Device Supplies Did Not Comply with Medicare Requirements. Most Medicare claims that durable medical equipment (DME) suppliers submitted for replacement positive airway pressure (PAP) device supplies did not comply with Medicare requirements. Of the 110 claims in HHS-OIG's sample that Medicare paid in 2014 and 2015, 86 claims did not comply with Medicare requirements. Based on its sample results, HHS-OIG estimated that Medicare made overpayments of almost \$631.3 million for replacement PAP device supply claims that did not meet Medicare requirements. These overpayments occurred because CMS oversight of replacement PAP device supplies was not sufficient to ensure that suppliers complied with Medicare requirements or to prevent payment of claims that did not meet those requirements. Without periodic reviews of claims for replacement supplies, Medicare contractors were unable to identify suppliers that consistently billed claims that did not meet Medicare requirements or to take remedial action. (A-04-17-04056)

CMS Did Not Detect Some Inappropriate Claims for Durable Medical Equipment in Nursing Facilities. HHS-OIG found that CMS allowed \$18.4 million in Medicare payments for inappropriate claims for DME provided during SNF stays not covered by Medicare, and may also have allowed additional inappropriate claims for DME provided in Medicaid-only nursing facilities. CMS requires facilities to provide DME as a standard part of nursing care, and does not permit separate Medicare payment for DME except when Medicaid-only nursing facilities serve as beneficiary homes. CMS uses two payment edits designed to identify and reject inappropriate claims, but neither edit rejected the claims because SNFs and DME suppliers did not submit full and accurate information required for processing. ([OEI-06-16-00380](#))

The MEDIC Produced Some Positive Results but More Could be Done to Enhance its Effectiveness. While the Medicare Drug Integrity Contractor's (MEDIC) reported recoveries resulted in a positive return on investment (\$3 in recoveries for every \$1 invested in 2017), CMS has no measures that specifically assess the MEDIC's effectiveness. CMS directed the MEDIC to devote more resources to proactive data analysis and administrative actions in 2014 and 2015, which led to a sharp increase in proactive data analysis, but a decrease in the MEDIC resources available to follow up on the results of these analyses. As a result, there have been fewer MEDIC investigations and referrals to law enforcement agencies, including OIG. Through its increased proactive analyses, the MEDIC provided thousands of high-risk leads involving drugs, including opioids, to plan sponsors from 2014 through 2017. The impact of these activities, however, cannot be measured as plan sponsors are not required to report to CMS the actions taken in response to these leads. In addition, MEDIC staff described numerous barriers that limit the MEDIC's overall impact. ([OEI-03-17-00310](#))

Setting Medicare Payment Rates for Clinical Diagnostic Laboratory Tests: Strategies to Ensure Data Quality. The Protecting Access to Medicare Act of 2014 (PAMA) requires CMS to set Medicare Part B payment rates for clinical diagnostic laboratory tests (lab tests) using private sector payment rates. Under PAMA, labs report private payer rates for lab tests to CMS every 3 years. To provide oversight, PAMA mandated that HHS-OIG monitor Medicare payments for lab tests and CMS's implementation of the new payment system. CMS issued new payment rates for lab tests that took effect on January 1, 2018. Payment rates decreased for 75 percent of

lab tests, which are generally in line with savings estimated in previous HHS-OIG reports. During the initial implementation of the new payment system, labs experienced some one-time challenges complying with the new data-reporting requirement. However, CMS's limited data quality assurance efforts present an ongoing risk and HHS-OIG identified strategies to help CMS ensure that future payment rates are based on complete and accurate data. (OEI-09-17-00050)

Medicare Improperly Paid Providers for Nonemergency Ambulance Transports to Destinations Not Covered by Medicare. Medicare made improper payments of \$8.7 million to providers for nonemergency ambulance transports to destinations not covered by Medicare. The majority of the improperly billed claim lines (59 percent) were for transports to diagnostic or therapeutic sites, other than a physician's office or a hospital that did not originate from SNFs. As of the publication of this report, the total improper payment amount of \$8.7 million included claim lines outside of the 4-year claim-reopening period. (A-09-17-03018).

Medicare Improperly Paid Providers for Items and Services Ordered by Chiropractors. Medicare payments for selected items and services ordered by chiropractors did not comply with Federal requirements. Specifically, for calendar years 2013 through 2016, Medicare improperly paid providers \$6.7 million. Medicare overpaid providers because CMS's claim-processing edits were not fully effective in preventing overpayments. CMS did not begin using these edits to deny claims until January 2014. Of the improper payments for HHS-OIG's audit period, 89 percent were for items and services provided before CMS's implementation of the edits. (A-09-17-03002)

Medicare Made Improper and Potentially Improper Payments for Emergency Ambulance Transports to Destinations Other Than Hospitals or Skilled Nursing Facilities. Medicare payments to providers for emergency ambulance transports did not comply or potentially did not comply with Federal requirements. Specifically, for calendar years 2014 through 2016, Medicare made improper and potentially improper payments totaling \$1.9 million: (1) improper payments of \$975,154 for transports to destinations that were not covered by Medicare for either emergency or nonemergency ambulance transports; and (2) potentially improper payments of \$928,092 for transports that may not have met Medicare coverage requirements or might have been paid by Medicare as nonemergency ambulance transports. (A-09-17-03017)

Medicare Improperly Paid Hospitals Millions of Dollars for Intensity-Modulated Radiation Therapy Planning Services. Payments for outpatient intensity-modulated radiation therapy (IMRT) planning services did not comply with Medicare billing requirements. On the basis of HHS-OIG's sample results, it estimated that Medicare overpaid hospitals nation-wide as much as \$21.5 million for complex simulations billed during our audit period (calendar years 2013 through 2015). In addition, HHS-OIG identified \$4.2 million in potential overpayments for other IMRT planning services that were not included in its sample. In total, Medicare overpaid hospitals as much as \$25.8 million during HHS-OIG's audit period. For IMRT planning services billed in the 2 years after our audit period (for calendar years 2016 and 2017), HHS-OIG identified an additional \$3.7 million in potential overpayments for complex simulations and \$1.7 million for other IMRT planning services. In total, Medicare overpaid hospitals as much as \$5.4 million after HHS-OIG's audit period. (A-09-16-02033)

Medicare Payments for Clinical Diagnostic Laboratory Tests in 2017: Year 4 of Baseline Data. Medicare paid \$7.1 billion under Part B for lab tests in 2017, a total that changed very little over 4 years. The top 25 tests by Medicare payments totaled \$4.5 billion and represented 64 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. The new payment system for lab tests took effect on January 1, 2018, and resulted in significant changes to the Medicare payment rates for lab tests. (OEI-09-18-00410)

Round 2 Competitive Bidding for Oxygen: Continued Access for Vast Majority of Beneficiaries. HHS-OIG found that Medicare payments for oxygen equipment and contents continued for the vast majority of beneficiaries in both Round 2 bidding areas and non-bidding areas, indicating that the Competitive Bidding Program likely did not disrupt their access. The percentage of beneficiaries for whom Medicare payments did not continue was slightly higher in Round 2 bidding areas than in non-bidding areas, which may or may not indicate disruptions in receiving needed oxygen equipment and contents for a very small proportion of beneficiaries. (OEI-01-15-00041)

Round 2 Competitive Bidding for Enteral Nutrition: Continued Access for Vast Majority of Beneficiaries. HHS-OIG found that Medicare payments for enteral nutrition supplies continued for the vast majority of beneficiaries in both Round 2 bidding areas and non-bidding areas, indicating that the Competitive Bidding Program likely did not disrupt their access. The percentage of beneficiaries for whom Medicare payments did not continue was slightly higher in Round 2 bidding areas than in non-bidding areas, which may or may not indicate disruptions in receiving needed enteral nutrition supplies for a very small proportion of beneficiaries. (OEI-01-15-00042)

Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials. High overturn rates when beneficiaries and providers appeal denials, and CMS audit findings about inappropriate denials, raise concerns that some beneficiaries and providers may not be getting services and payment that Medicare Advantage Organizations (MAOs) are required to provide. These findings are particularly concerning because beneficiaries and providers almost never use the appeals process designed to ensure access to care and payment. (OEI-09-16-00410)

Texas Did Not Make Increased Primary Care Provider Payments and Claim Reimbursement in Accordance With Federal Requirements. Texas did not always make increased Medicaid payments to providers and claim reimbursement in accordance with Federal requirements. Of the \$721 million in Federal funds that it received, Texas inappropriately received \$20.7 million because it: (1) incorrectly claimed the 100-percent matching rate for payments that were only eligible for the regular matching rate; and (2) made payments that were unallowable. Additionally, HHS-OIG is setting aside \$1.1 million in Federal funds Texas received for payments that exceeded the providers' actual billed charges. Providers did not complete the billed charges field for some payment data with meaningful amounts, so HHS-OIG could not determine the correct payment amounts for the data. (A-06-15-00045)

Most of New York's Claims for Federal Reimbursement for Monthly Personal Emergency Response Service Charges Did Not Comply with Medicaid Requirements. New York provides Personal Emergency Response Services (PERS) to eligible Medicaid beneficiaries through contracts negotiated between local social services districts (local districts) and PERS providers. Payment for PERS includes a monthly service charge for monitoring agency services. For 87 of the 100 claims in HHS-OIG's sample, New York claimed Federal reimbursement for PERS monthly service charge claims that did not comply with Medicaid requirements. On the basis of sample results, HHS-OIG estimated that New York improperly claimed at least \$5.5 million in Federal Medicaid reimbursement. New York's ineffective oversight of the PERS program leaves the program vulnerable to misuse of Federal funds and could potentially place beneficiaries at risk of harm. (A-02-15-01019)

New York Claimed Federal Reimbursement for Consumer-Directed Personal Assistance Services That Did Not Meet Medicaid Requirements. New York's consumer-directed personal assistance program (CDPAP) includes personal care, home health, and nursing services. New York claimed Federal Medicaid reimbursement totaling more than \$579 million for CDPAP services provided from January 2012 through June 2016. For 27 of 120 sampled claims, New York claimed Federal reimbursement for CDPAP services claims that did not meet Medicaid requirements. New York also claimed reimbursement for services provided after a 6-month authorization period had lapsed. This occurred because New York did not effectively monitor the CDPAP for compliance with certain CDPAP requirements. Based on sample results, HHS-OIG estimated that New York improperly claimed at least \$74.8 million in Federal Medicaid reimbursement during our audit period. New York's lack of effective monitoring of the CDPAP leaves the program vulnerable to misuse of Federal funds and could potentially place beneficiaries at risk of harm. (A-02-16-01026)

Virginia Did Not Claim Some Medicaid Administrative Costs for Its Medallion 3.0 Waiver Program in Accordance With Federal Requirements. Of the \$220 million (Federal share) in administrative costs claimed for Virginia's waiver program in State FYs 2016 and 2017, Virginia correctly claimed \$211.2 million (Federal share). However, we found that Virginia claimed \$7.7 million (Federal share) in unallowable waiver program administrative costs not identified in its Cost Allocation Plan (CAP). In addition, Virginia incorrectly claimed \$1.2 million (Federal share) in administrative costs that were misclassified as waiver program administrative costs. The misclassified expenditures did not directly benefit the waiver program but directly benefited a separate public welfare program, Virginia's Children's Health Insurance Program. (A-03-17-00200)

California Claimed Millions of Dollars in Unallowable Federal Medicaid Reimbursement for Specialty Mental Health Services. California did not always comply with Federal and State requirements when claiming Federal reimbursement for specialty mental health services (SMHS) expenditures. On the basis of its sample results, HHS-OIG estimated that California claimed at least \$180.6 million in unallowable Federal reimbursement. California claimed unallowable Federal reimbursement because its oversight was not effective in ensuring that its SMHS claims complied with Federal and State requirements. Although California issued guidance and provided training and technical support to its county-run managed care mental health plans (health plans), the plans continued to report to California unallowable expenditures as allowable

expenditures. In addition, although California's triennial reviews were effective in identifying unallowable expenditures, California did not ensure that adequate corrective action was taken. HHS-OIG found repeat deficiencies at some health plans. (A-09-15-02040)

California Created a Medicaid Program Vulnerability by Reporting Placeholders That Did Not Represent Actual Expenditures Supported by Documentation. California reported SMHS placeholders totaling \$47.5 million for FY 2013 that did not represent actual expenditures supported by documentation. California did not have policies and procedures to ensure that supporting documentation for the placeholders was: (1) available at the time the Form CMS-64 (the CMS-64) was filed; and (2) retained. California's reporting of placeholders created a program vulnerability: California could have withdrawn funds related to the unsupported placeholders that CMS had not acted to defer before the 60-day deadline as required by Federal regulations or to disallow. According to its placeholder record, California reported for FY 2013 additional placeholders totaling \$1.2 billion for other types of Medicaid expenditures. (A-09-15-02027)

Alaska Received Millions in Unallowable Bonus Payments. Under the Children's Health Insurance Program Reauthorization Act of 2009, Congress appropriated \$3.2 billion for qualifying States to receive bonus payments to offset the costs of increased enrollment of children in Medicaid. Some of the bonus payments that Alaska received for the audit period were not allowable in accordance with Federal requirements. While most of the data used in Alaska's bonus payment calculations were in accordance with Federal requirements, Alaska overstated its FYs 2009 through 2013 current enrollment in its bonus requests to CMS because it included individuals who did not qualify because of their basis-of-eligibility category. As a result of the overstated current enrollment numbers, CMS overpaid Alaska almost \$8.9 million in bonus payments. (A-04-17-08059)

Opioid Use in Medicare Part D Remains Concerning. HHS-OIG found that nearly one in three beneficiaries received a prescription opioid through Medicare Part D in 2017, a slight decrease from 2016. Overall Part D spending for opioids also decreased, from \$4.0 billion in 2016 to \$3.4 billion for opioids in 2017. This decrease was due in part to declining prices. Almost 460,000 beneficiaries received high amounts of opioids in 2017, fewer than in 2016. Of these, about 71,000 beneficiaries were at serious risk of opioid misuse or overdose, also fewer than in 2016. These 71,000 beneficiaries received extreme amounts of opioids or appeared to be doctor shopping. Moreover, almost 300 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-02-18-00220)

Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2018. HHS-OIG found that the rate of Part D plan formularies' inclusion of the drugs commonly used by dual eligible (i.e., individuals who are eligible for both Medicare and Medicaid) is high, with some variation. Because some variation exists in formularies' inclusion of these drugs and in their application of utilization management tools to the drugs, some dual eligibles may need to use alternative methods to access the drugs they take. (OEI-05-18-00240)

Analysis Toolkit: Calculating Opioid Levels to Identify Patients at Risk of Misuse or Overdose. This toolkit provides detailed steps for using prescription drug claims data to analyze patients' opioid levels and identify certain patients who are at risk of opioid misuse or overdose. It is based on the methodology that HHS-OIG has developed in its extensive work on opioids. It is intended to assist its partners, such as Medicare Part D plan sponsors, private health plans, and State MFCUs, with analyzing their own prescription drug claims data to help combat the opioid crisis. (OEI-02-17-00560)

Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio. Hospice use has grown steadily over the past decade, with Medicare paying \$16.7 billion for this care for 1.4 million beneficiaries in 2016. However, HHS-OIG has identified vulnerabilities in the program. HHS-OIG found that hospices do not always provide needed services to beneficiaries and sometimes provide poor quality care. Also, beneficiaries and their families and caregivers do not receive crucial information to make informed decisions about care. Further, hospices' inappropriate billing costs Medicare hundreds of millions of dollars. Lastly, the current payment system creates incentives for hospices to minimize their services and seek beneficiaries who have uncomplicated needs. ([OEI-02-16-00570](#))

Questionable Billing for Compounded Topical Drugs in Medicare Part D. HHS-OIG found that Medicare Part D spending for compounded topical drugs was 24 times higher in 2016 than it was in 2010 and that nearly 550 pharmacies had questionable Part D billing for compounded topical drugs in 2016. This explosive growth and identification of pharmacies raises concerns about fraud and abuse. ([OEI-02-16-00440](#))

Open Payments Data: Review of Accuracy, Precision, and Consistency in Reporting. The Open Payments program promotes transparency by making available to the public the financial relationships that physicians and teaching hospitals have with applicable manufacturers and group purchasing organizations. Of 11.9 million records published on the Open Payments website for 2015, less than 1 percent were missing required data elements. Although the Open Payments data elements reported to CMS were complete overall, HHS-OIG identified records that contained inaccurate, imprecise, or inconsistent information. The Open Payments program can benefit the public only if the data reported are complete and accurate. As such, potential issues with these data may undermine the public benefit of this program. (OEI-03-15-00220)

CMS's Policies and Procedures Were Generally Effective in Ensuring That Prescription Drug Coverage Capitation Payments Were Not Made After the Beneficiaries' Dates of Death. CMS had policies and procedures in place that were generally effective in ensuring that capitation payments to Medicare Advantage organizations' prescription drug plans and stand-alone prescription drug plans (collectively referred to as "sponsors") for Medicare Part D coverage were not made on behalf of deceased beneficiaries after the individuals' dates of death. These policies and procedures generally ensured that CMS did not make improper capitation payments on behalf of deceased beneficiaries when its data systems indicated at the time of a monthly capitation payment that the beneficiaries in question had died. CMS did not, however, identify and recoup all improper capitation payments. As of March 7, 2017, CMS had not recouped \$1.1 million associated with 65,398 separate capitation payments. For HHS-OIG's audit period, these improper payments represented .0004 percent of the total capitation payments made to sponsors

and .097 percent of the total adjustments that CMS made after receiving information on beneficiaries' dates of death. (A-07-16-05088)

CMS Did Not Always Provide Accurate Medicaid Unit Rebate Offset Amounts to State Medicaid Agencies. CMS did not always provide accurate Medicaid unit rebate offset amounts (UROAs) to States from 2010 through 2014 in accordance with Federal guidance. (Under the Medicaid drug rebate program, drug manufacturers enter into rebate agreements with the Federal Government and pay rebates to States. Amounts collected by the States that are attributable to increased rebates mandated by recent legislation—UROAs—are applied against the amounts that the Federal Government pays to the States.) CMS did not update the quarterly UROA information that it sent to the States to include changes to the UROAs when covered drugs' best prices changed but the unit rebate amounts stayed the same. The States would have used these incorrect UROA amounts to calculate rebates, which would have resulted in incorrect rebate amounts being claimed. (A-07-17-06074)

Increases in Reimbursement for Brand-Name Drugs in Part D. HHS-OIG found that Part D reimbursement for brand-name drugs increased at a pace greater than the rate of inflation while utilization for these drugs decreased. Specifically, total reimbursement for all brand-name drugs in Part D increased 77 percent from 2011 to 2015, while utilization decreased 17 percent across the 5 years. Continued increases in reimbursement for brand-name drugs may have long-term effects on Medicare and its beneficiaries, especially those beneficiaries who need access to expensive maintenance drugs. (OEI-03-15-00080)

Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2016 Average Sales Prices. Based on 2016 data, CMS lowered Part B reimbursement for 16 drugs, saving Medicare and its beneficiaries \$13.1 million over 1 year. 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. ([OEI-03-18-00120](#))

Opioids in Ohio Medicaid: Review of Extreme Use and Overprescribing. HHS-OIG found that more than 700 beneficiaries are at serious risk of prescription opioid misuse or overdose and that nearly 50 prescribers stood out by ordering opioids for more of these beneficiaries than other prescribers. HHS-OIG's results underscore the tenacity of the opioid crisis and the importance of Ohio's ongoing commitment to addressing it. HHS-OIG encourages Ohio to continue its ongoing efforts to explore new strategies to address its opioid crisis and look for ways to improve its existing strategies. (OEI-05-18-00010)

CMS's Policies and Procedures Were Generally Effective in Ensuring That Capitation Payments Were Not Made After Beneficiaries' Dates of Death. CMS had policies and procedures in place that were generally effective in ensuring that capitation payments to Medicare Advantage organizations for Medicare Parts A and B services were not made on behalf of deceased beneficiaries after the individuals' dates of death. During CY 2012 through 2015, CMS received updated beneficiary date-of-death information and then made approximately 1.8 million adjustments to capitation payments, thereby recouping \$2.96 billion from Medicare Advantage organizations for Parts A and B capitation payments that had been made on behalf of

beneficiaries who had died. CMS did not, however, identify and recoup all improper capitation payments. As of March 7, 2017, CMS had not recouped \$2.4 million associated with 1,817 capitation payments that were made on behalf of 978 beneficiaries. For HHS-OIG's audit period, these improper payments represented .0004 percent of the total capitation payments made to Medicare Advantage organizations and .08 percent of the total adjustments that CMS made after receiving information on beneficiaries' dates of death. (A-07-16-05087)

CMS Generally Met Requirements in Round 2 of the DMEPOS Competitive Bidding Program. CMS usually selected Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers, calculated the sampled DMEPOS single-payment amounts (SPAs), and monitored suppliers in accordance with its established procedures and applicable Federal requirements. HHS-OIG determined that CMS consistently followed its established program procedures and applicable Federal requirements for 192 of the 215 winning suppliers associated with the sampled SPAs reviewed. While the overall effect on Medicare payments to suppliers was relatively small, HHS-OIG determined that CMS did not consistently follow its established procedures and applicable Federal requirements for selecting suppliers during the bid process for 23 of the 215 winning suppliers. This affected 99 of the 240 sampled SPAs. On the basis of HHS-OIG's sample, HHS-OIG estimated that CMS paid suppliers \$182,000 less than they would have received without any errors, or less than 0.03 percent of the \$553.7 million paid under Round 2 during the last 6 months of 2013. (A-05-14-00049)

CMS Did Not Adequately Address Discrepancies in the Coding Classification for Kwashiorkor. Providers incorrectly billed diagnosis code 260 for Kwashiorkor for inpatients who did not have the disease. In separately issued reports, HHS-OIG reviewed the medical records for a total of 2,145 inpatient claims at 25 providers and found that all but 1 claim incorrectly included the diagnosis code for Kwashiorkor, resulting in overpayments in excess of \$6 million. The ICD-9 coding classification contained a discrepancy between the tabular list and the alpha index on the use of diagnosis code 260, which may have resulted in other diseases being assigned this code. CMS did not have adequate policies and procedures in place to address this discrepancy, resulting in a total potential loss of approximately \$102 million during CYs 2006 through 2014. Even though CMS was aware of the discrepancy, it did not take any separate action to address it. While previous reviews successfully returned \$5.7 million to the Medicare Trust Fund, HHS-OIG estimates that Medicare could have saved approximately \$102 million from CYs 2006 through 2014 if the coding discrepancy had been immediately corrected. (A-03-14-00010)

Wisconsin Physicians Service Paid Providers for Hyperbaric Oxygen Therapy Services That Did Not Comply with Medicare Requirements. Hyperbaric oxygen (HBO) therapy involves giving a high concentration of oxygen within a pressurized chamber in which the patient intermittently breathes in 100-percent oxygen. Wisconsin Physicians Service (WPS) paid 73 providers for HBO therapy services that did not comply with Medicare requirements. WPS made payments for HBO therapy that did not always comply with Medicare requirements because it had limited policies and procedures in place to ensure that it made correct payments. Based on its sample results, HHS-OIG estimated that WPS overpaid providers in Jurisdiction 5 \$42.6 million during the audit period for HBO therapy that did not comply with Medicare requirements. (A-01-15-00515)

Medicare Improperly Paid Providers for Specimen Validity Tests Billed in Combination with Urine Drug Tests. Medicare improperly paid 4,480 clinical laboratories and physician offices a total of \$66.3 million for specimen validity tests billed in combination with urine drug tests. CMS officials explained that medically necessary tests used to diagnose certain conditions (which include the same tests that can be used to validate urine specimens) that are performed on the same day as a urine drug test for a single beneficiary should be a rare occurrence. The improper payments occurred because providers did not follow existing Medicare guidance, and CMS's system edits were not adequate to prevent payment for specimen validity tests billed in combination with urine drug tests. Although CMS implemented a system edit designed to identify and prevent these improper payments, HHS-OIG still identified \$1.8 million in improper payments from April 1 through December 31, 2016. At this observed rate, these improper payments would total \$12.1 million over a 5-year period. (A-09-16-02034)

Hospitals Did Not Comply with Medicare Requirements for Reporting Certain Cardiac Device Credits. All 296 payments reviewed for recalled cardiac medical devices did not comply with Medicare requirements for reporting manufacturer credits. Medicare contractors incorrectly paid hospitals \$7.7 million for cardiac device replacement claims rather than the \$3.3 million they should have been paid, resulting in potential overpayments of \$4.4 million. For all payments reviewed, manufacturers issued reportable credits to hospitals for recalled cardiac medical devices, but the hospitals did not adjust the claims with the proper condition codes, value codes, or modifiers to reduce payment as required. The overpayments occurred because Medicare controls were not sufficient to ensure that hospitals properly reported manufacturer credits for cardiac devices. (A-05-16-00059)

Excluding Non-Covered Versions When Setting Payment for Two Part B Drugs Would Have Resulted in Lower Drug Costs for Medicare and its Beneficiaries. HHS-OIG found that CMS and a Federal court interpret the law to require the inclusion of average sales prices for noncovered versions in limited circumstances when setting payment amounts for Part B drugs. As a result, the inclusion of noncovered versions of two drugs caused Medicare and its beneficiaries to pay an extra \$366 million from 2014 through 2016. (OEI-12-17-00260)

Many Inpatient Rehabilitation Facility Stays Did Not Meet Medicare Coverage and Documentation Requirements. Inpatient rehabilitation facilities (IRFs) did not comply with all Medicare coverage and documentation requirements specified for reasonable and necessary care. For 175 of 220 stays that HHS-OIG sampled, which corresponded to 135 IRFs, medical record documentation did not support that IRF care was reasonable and necessary in accordance with Medicare's requirements. Based on its sample results, HHS-OIG estimated that Medicare paid IRFs nation-wide \$5.7 billion in 2013 for care to beneficiaries that was not reasonable and necessary. (A-01-15-00500)

Promoting Quality and Safety in Health Care

Follow-up Review: CMS's Management of the Quality Payment Program. CMS continued its progress toward implementing the Quality Payment Program (QPP), a set of clinician payment reforms designed to put increased focus on the quality and value of care. During 2017, CMS made significant efforts to address the two vulnerabilities that HHS-OIG identified in its 2016

management review— developing IT systems and preparing clinicians to participate in the QPP. CMS appears on track to deploy the IT systems needed for data submission by January 1, 2018. Regarding clinician readiness, CMS has conducted outreach, communicated eligibility information, issued subregulatory guidance, awarded technical assistance contracts, and established a Service Center to respond to questions. Clinician feedback demonstrates widespread awareness of the QPP, but also uncertainty about eligibility, data submission, and other elements of the program. Regarding emerging challenges, HHS-OIG found that CMS has not yet developed a comprehensive program integrity plan. HHS-OIG identified two vulnerabilities that are critical for CMS to address in 2018: (1) if clinicians do not receive sufficient technical assistance, they may struggle to succeed under the QPP or choose not to participate; and (2) if CMS does not develop and implement a comprehensive QPP program integrity plan, the program will be at greater risk of fraud and improper payments. (OEI-12-17-00350)

Minnesota Did Not Comply With Federal Waiver and State Requirements for 18 of 20 Family Adult Foster Care Homes Reviewed

Minnesota did not comply with Federal waiver and State requirements in overseeing homes that serve vulnerable adults who receive services through the program. We determined that 18 of the 20 homes we reviewed did not comply with 1 or more State licensing requirements. Specifically, we found 64 instances of noncompliance related to health and safety and administrative requirements. County licensor supervisors stated that instances of noncompliance occurred mainly because of low staffing levels and a lack of training opportunities for license holders (providers) and county licensors. Additionally, specific State licensing requirements on the necessity of safeguarding hazardous materials were unclear.

Minnesota partially concurred with our recommendations that they (1) ensure that the 64 instances of noncompliance with health and safety and administrative requirements identified in this report are corrected; and (2) work with counties to ensure the health and safety of vulnerable adults by considering staffing standards and caseload thresholds for county agencies. Minnesota also fully concurred with recommendations that they (1) review training opportunities available to providers and county licensors and improve or increase them as needed; and (2) insurance that Minnesota guidance accurately reflects administrative requirements related to hazardous materials. In addition, Minnesota outlined its plans for corrective actions, which include updating State guidance and developing training materials and licensor training specific to home safety. (A-05-16-00044)

Minnesota Did Not Comply With Federal Waiver and State Requirements for All 20 Adult Day Care Centers Reviewed; Illinois Did Not Comply With Federal Waiver and State Requirements at 18 of 20 Adult Day Service Centers Reviewed; Mississippi Did Not Comply With Federal Waiver and State Requirements at All 20 Adult Day Care Facilities Reviewed

Minnesota, Illinois, and Mississippi did not comply with Federal waiver and State requirements in overseeing providers that serve vulnerable adults receiving adult day care services. In Minnesota, we found 200 instances of noncompliance with health and safety and administrative requirements at all 20 of the centers we reviewed. In Illinois, we found 105 instances of noncompliance at 18 of the 20 centers we reviewed. In Mississippi, we found 564 instances of

noncompliance at all 20 of the centers we reviewed.

Minnesota said that the instances of noncompliance occurred because low staffing levels did not allow State licensors to make relicensing visits every 2 years. Additionally, Minnesota and the centers indicated that there was a need to develop templates for administrative records that the State requires. Illinois said that most instances of noncompliance occurred because center personnel did not have sufficient training on State requirements. Although Illinois offers initial training to new centers, more State-led training is needed for established centers. According to Mississippi, budget reductions and low auditor staffing levels limited its oversight and monitoring of provider facilities, staffing, and training, and the lack of State licensing requirements contributed to provider noncompliance.

Minnesota, Illinois, and Mississippi concurred with our recommendations that they (1) ensure that the instances of noncompliance with health and safety and administrative requirements are corrected and (2) improve their oversight of staffing, training, and administration. ([A-05-17-00009](#), [A-05-17-00028](#), [A-04-17-00116](#))

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 several approaches for monitoring and analyzing health care payments and trends, and sophisticated data analytics and statistical modeling target the oversight of the Medicare and Medicaid programs. OIG has developed analytic tools to automate work formerly conducted by multi-disciplinary teams. These tools use near real time data to examine Medicare data for high-risk providers, conduct peer comparisons, to calculate ratios of allowed services as compared with national averages, as well as other assessments. When united with the expertise of 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

HIPAA established 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 2018, the HHS-OIG, in consultation with DOJ, issued 14 advisory opinions and rescinded one advisory opinion. A total of 366 advisory opinions and 21 modifications to advisory opinions have been issued, four opinions have been terminated, and one opinion has been rescinded during the 22 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 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.

HHS-OIG also engages with the industry to promote best practices for compliance. For example, HHS-OIG hosted a roundtable with industry compliance professionals to discuss methods for measuring the effectiveness of compliance programs. The ideas discussed at the roundtable were compiled into a resource guide for other industry participants to consider when evaluating their own compliance programs. In addition to the compliance roundtable, HHS-OIG regularly presents at various health care compliance conferences throughout the country.

Centers for Medicare & Medicaid Services

In FY 2018, CMS received an allocation of \$12.0 million by HHS and appropriated \$584.8 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 2018, Congress required HHS to fund the Administration for Community Living's (ACL) Senior Medicare Patrol's activity. Therefore, \$18.0 million of CMS's \$584.8 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 (FFS) and Medicaid improper payment rate measurement and other Medicaid program integrity activities, 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. CMS's approach to program integrity is guided by four major principles:

- **Prevention** - Increase CMS's capability to stop improper claims before they are paid by enhancing existing processes and increasing analytic capabilities.
- **Detection** - Foster collaboration with HCFAC partners, including various components of HHS, DOJ, states, and other stakeholders with a shared interest in the integrity of the national health care system.
- **Recovery** - Identify and recover overpayments. CMS will continue to work with its contractors and partners, including the HHS/OIG, DOJ, state agencies for survey and certification, and state Medicaid agencies to pursue appropriate corrective actions such as restitution, fines, penalties, damages, and program suspensions or exclusions.
- **Transparency and Accountability** - Develop and deploy a comprehensive program integrity communication plan to share key messages and information with internal and external stakeholders. Performance measures are also being developed to evaluate operations and outcomes against other CMS reporting activities.

During FY 2018, CMS continued to integrate Medicare and Medicaid efforts and provide technical assistance and education to states, providers, and other stakeholders; and 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, recovery actions, and outreach and education.

Unified Program Integrity Contractor (UPIC)

In FY 2016, CMS began consolidating the Medicare and Medicaid program integrity functions performed by the Zone Program Integrity Contractors (ZPICs), including Medicare-Medicaid Data Match (Medi-Medi) activities, and the Audit Medicaid Integrity Contractors (MICs) into the Unified Program Integrity Contractors (UPICs). The UPICs merge these separate contracting functions into a single contractor, in a geographic area, with responsibility to conduct program integrity audit and investigation work across Medicare and Medicaid operations. The UPIC structure provides CMS with a flexible contracting vehicle to address the complex landscape of program integrity. Currently, all UPICs are fully operational and are carrying out program integrity activities in five jurisdictions: Midwest, Northeast, West, Southeast and Southwest.

Fraud Prevention System (FPS)

The Fraud Prevention System is the predictive analytics technology required under the Small Business Jobs Act of 2010¹⁵ (SBJA). FPS analyzes FFS claims using sophisticated algorithms to

¹⁵ Public Law 111-240.

target investigative resources; generate alerts for suspect claims or providers and suppliers; and provide information to facilitate and support investigations of the most egregious, suspect, or aberrant activity. HHS uses the FPS information to prevent and address improper payments using a variety of administrative actions, including claim denials, payment suspensions, Medicare billing privilege revocations, and law enforcement referrals. In March 2017, HHS updated the FPS to modernize the system and user interface, improve model development time and performance measurement, and expand program integrity capabilities.

During FY 2017, the FPS models generated 416 leads that were included in the ZPIC and UPICs' workload, resulting in 172 new investigations and augmented information for 244 existing investigations. (FY 2018 numbers were not available at the time of this report.)

National Correct Coding Initiative (NCCI)

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) consists of edits designed to reduce improper payments in Medicare Part B. NCCI Procedure-to-Procedure (PTP) edits prevent inappropriate payment for billing code pairs that should not be reported together by the same provider for the same beneficiary and date of service. NCCI Medically Unlikely Edits (MUEs) prevent payment for an inappropriate quantity of the same service rendered by the same provider for the same beneficiary on the same date of service. During the first nine months of FY 2018, NCCI PTP edits and MUEs saved the Medicare program \$176.7 million and \$328.6 million, respectively.

Medicaid

Section 1903(r) of the Social Security Act requires states to use NCCI methodologies to process applicable Medicaid claims. CMS continues to provide assistance for state Medicaid agencies to use NCCI methodologies in their Medicaid programs.

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 data), and Part D paid claims beginning with January 2006, both before and after final payment. This allows for 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 Transformed Medicaid Statistical Information System (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 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 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 2018, 30 missions were conducted in the Command Center that included participants from CMS and CMS partners, including the FBI.

Durable Medical Equipment (DME) Initiatives

DME suppliers pose a high risk of fraud to the Medicare program and CMS has undertaken an aggressive strategy to address this risk. ZPICs and UPICs and Program Safeguard Contractors (PSCs) have continued to conduct site visits and interviews of DME suppliers, providers, and beneficiaries receiving DME products in high billing areas for DME supplies and products. In FY 2018 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, and suppliers from entering either program. CMS is committed to maintaining operational excellence in its provider enrollment and 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 rule¹⁶ published by the Federal Register on February 2, 2011. CMS's 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 unannounced site visits in addition to all the requirements in the "limited" screening level. Providers and suppliers in the "high" risk category are subject to fingerprint-based criminal background checks (FCBCs) in addition to all of the requirements in the "limited" and "moderate" screening levels. For Medicare, CMS began phasing in the fingerprinting requirements on August 6, 2014. In FY 2018, CMS denied approximately 771 enrollments and revoked five 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 2018, APS resulted in more than 1 million screenings. These screenings generated more than 29,000 potential licensure alerts, and more than 560 criminal alerts for potentially fraudulent providers for further review by CMS. Such review resulted in approximately 119 criminal revocations and over 250 licensure revocations.

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 2018, the initiative resulted in 38,484 site visits conducted by the National Site Visit Contractor (NSVC), which conducts site visits for most Medicare FFS providers and suppliers, and 34,155 conducted by the National Supplier Clearinghouse (NSC), which conducts site visits for Medicare DME suppliers. This work resulted in about 140 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 2018, CMS deactivated over 158,000 enrollments, and revoked about 1,950 enrollments. Site visits, revalidation, and other initiatives have contributed to the deactivation¹⁷ and revocation¹⁸ of more than one million enrollment records since CMS started implementing these screening and enrollment requirements.

¹⁶ 76 FR 5862 (Feb. 2, 2011).

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

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

Provider Enrollment, Chain and Ownership System (PECOS)

PECOS is the system of record for all Medicare Provider/Supplier enrollment data, which includes Part A, Part B, and DME. It is the Internet-based system that providers and suppliers use to enroll, revalidate, or make changes to their enrollment information in the Medicare FFS program. PECOS stores all information furnished by providers and suppliers; tracks all enrollment processing and the results of Medicare Administrative Contractor (MAC) evaluation; and provides feeds to FFS claims payment systems which are used in processing all claims. Medicare FFS claims processing cannot occur without provider/supplier enrollment information from PECOS. All provider/supplier updates and validations, both systematic and those performed manually by MACs, are stored and sent by PECOS. It is integrated with and supports multiple enterprise systems and CMS operations such as the Promoting Interoperability Programs and DMEPOS competitive bidding, providing direct access to information on the relationships between individuals and organizations stored in enrollment records. The Promoting Interoperability Programs system cannot function without PECOS and it is the base data used by FPS and groups such as ZPICs, RACs, OIG, and State PI Programs.

PECOS is the source for vetting CMS's Accountable Care Organization programs and models and provides information that is used as a primary factor to determine program and model eligibility. PECOS supports data transparency through interfacing with programs such as: Open Payments, Physician Compare, and Nursing Home Compare, and also supports CMS data management initiatives through Master Data Management (MDM) and IDR. State Medicaid programs also rely on data-sharing efforts to support requirements for screening providers. CMS is focused on transitioning PECOS to a modernized, enterprise resource that is a platform for all provider/supplier enrollments across Medicare, Medicaid, and emerging programs. This single platform is intended to allow for streamlining and consistency in user workflows, as well as the ability to standardize interfaces with systems internal and external to CMS.

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's Medicare 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 must at a minimum follow the same risk-based screening procedures followed by Medicare when enrolling Medicare providers and suppliers.

During FY 2018, 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, enhancing the 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, publishing additional guidance in the Medicaid Provider Enrollment Compendium (MPEC), continuing monthly Technical Assistance Group (TAG) calls, and establishing a TAG call dedicated solely to screening and enrolling Medicaid managed

care network providers.

CMS shares the Medicare provider enrollment record via the PECOS administrative interface and in bulk data extracts from PECOS. Additionally CMS launched the PECOS State's page in January 2017, and included provider enrollment information such as Medicare enrollment status, site visit information, fingerprint results, change of ownership information, reassignments, Medicare risk levels, and more. Since May 2016, CMS has offered the 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 has made enhancements to this service, which include tailoring the type of comparison to meet a state's specific needs (for example, comparing provider ownership information between Medicare and Medicaid). Lastly, in FY 2018, CMS launched the Data Exchange (DEX) system, which is used to share data among CMS and the separate Medicaid programs of every state. The new system stores all state-submitted terminations as well as all Medicare revocations, and HHS-OIG exclusion data, and enhances collaboration, improves reporting, and creates transparency through this process.

CMS 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 FY2018, which is sub-regulatory guidance designed to assist states in applying certain regulatory requirements. The most recent update focuses on applying screening and enrollment requirements to the Medicaid managed care network provider population.

Medical Review

- Accuracy reviews
CMS uses the Medical Review Accuracy Contractor (MRAC) to conduct medical reviews of determinations made by the MACs and Supplemental Medical Review Contractor (SMRC). CMS performs a number of accuracy reviews using clinicians; however, the MRAC is able to complete more accuracy reviews and provides additional analysis to CMS.
- Prior Authorization
In a final rule, CMS established an initial Master List of certain Durable Medical Equipment Prosthetic Orthotic Supplies (DMEPOS) that are frequently subject to unnecessary utilization and established a prior authorization process for these items. CMS announced the first two codes for two types of power wheelchairs subject to prior authorization as a condition of payment, which began on March 20, 2017, in four states. Prior authorization for these codes expanded nationally on July 17, 2017. DME MACs review requests for prior authorization for the noted items, communicate decisions with suppliers and physicians, and provide ongoing education and customer service. In FY 2018, CMS transitioned the Power Mobility Device demonstration into the national program.
- Comparative Billing Reports
Comparative Billing Reports (CBRs) allow providers the opportunity to view and compare their billing patterns to those of their peers. They provide an educational opportunity for

providers and allow them to have an additional tool for any self-audit efforts they undertake. Currently, CBRs are mailed or faxed to providers. Since 2011, CBRs have been issued on topics such as physical therapy, opioids, and orthoses claims. Typically CBRs are sent to the 5,000 highest-billing providers per topic and are selected based on contractor metrics to determine the outlier providers. Topics are based on GAO/OIG reports, Comprehensive Error Rate Testing program findings and through agency and contractor data analysis.

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, will improve the CMS and state's ability 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. States participate in and receive technical assistance and education from CMS through;

- Medicaid Technical Advisory Groups
- Voluntary state assistance site visits
- Webinars
- Provider screening and enrollment strategies
- Onsite focused program integrity reviews
- Consolidation of provider audits and investigations through the five Unified Program Integrity Contractors
- 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.

Health and Welfare Special Review Teams

The Health and Welfare Special Review Teams (H&W SRT) project began in late September 2018. The purpose of this project is to ensure that state quality monitoring methodologies are efficiently and effectively preventing, detecting, and remediating all instances of abuse and/or neglect to beneficiaries in home and community based settings including group homes, and assisted living programs. The H&W SRT will develop an overall strategy for identifying, preventing, and addressing any systemic problems in the states' implementation of and compliance with health & safety oversight systems within these settings.

Medicaid Enterprise System

State Medicaid agencies develop, implement, operate and maintain information technology systems to support their program operations. The systems generally include eligibility and enrollment, managed care payment, encounter data and/or claims processing, pharmacy management, etc. These systems work in concert with one another and must adhere to Federal regulation¹⁹ and guidance, including the Medicaid Information Technology Architecture (MITA) framework, several standards and conditions²⁰, and certification criteria. Adhering to these mandates promotes the consistency of business and technical processes and IT platforms, as well as standards across the Medicaid Enterprise.

CMS provides independent technical assistance to states 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. Required technical artifacts are analyzed and tracked to assess state progress. Gap analyses are done on a regular basis and risk registers are studied to identify opportunities to better ensure project success. As systems enter production operations (aka “go-live”), they are reviewed in-depth by CMS to ensure that the system functions appropriate to implement the policy requirements (e.g., for provider enrollment or for eligibility and enrollment, etc). Certain state systems also undergo a certification review conducted by CMS as an additional step in ensuring proper operation.

Federal and state governments have invested heavily in the development and operations of Medicaid claims processing and information retrieval systems that engage in high volume transactions. In 2016, CMS released an update to the MMIS Certification process in the form of MECT 2.0 to ensure a more comprehensive analysis of CMS funded state systems functionality. Moving forward, CMS is focused on increasing accountability and state flexibility by creating an outcomes based oversight model to state systems certification. This approach will focus on producing timely and accurate claims payment results, properly screening and enrolling providers, member management, and comprehensive data analytics and reporting capabilities including timely and accurate submissions of required federal reporting such as T-MSIS.

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

¹⁹ Mechanized Claims Processing and Information Retrieval Systems (90/10) Final Rule
(<https://www.federalregister.gov/documents/2015/12/04/2015-30591/medicaid-program-mechanized-claims-processing-and-information-retrieval-systems-9010>)

²⁰ <https://www.medicaid.gov/medicaid/data-and-systems/mita/index.html>

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 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 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 place of these PERM eligibility reviews, CMS required all states to conduct Eligibility Review Pilots (ERP) 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. For the purpose of computing the overall national improper payment rate, the Medicaid and CHIP eligibility component improper payment rates were held constant at the FY 2014 national rate of 3.11 percent and 4.22 percent, respectively.

CMS also used the ERP to test updated PERM eligibility processes, and prepare states for the resumption of the PERM eligibility component measurement. Based on result from the pilots, CMS published a final rule¹⁹ that updated the eligibility component measurement methodology. (82 FR 31158, July 5, 2017²¹). CMS resumed the eligibility component measurement under such final rule requiring states to do PERM reviews triennially and will report an updated national eligibility improper payment estimate in FY 2019. The agency also set forth the standards for a new Medicaid Eligibility Quality Control program which provides states additional opportunities to review Medicaid eligibility determinations and determine areas for corrective actions in years that they are not required to do PERM reviews.

In the HHS FY 2018 Agency Financial Report (AFR), CMS reported the national Medicaid improper payment rate that is based on measurements conducted in FYs 2016, 2017, and 2018. The FY 2018 national Medicaid improper payment rate was 9.79 percent, representing \$36.25 billion in gross federal improper payments. The FY 2018 national improper payment rates by component are 14.31 percent for Medicaid FFS, and 0.22 percent for Medicaid managed care. As noted above, the Medicaid eligibility component improper payment rate was held constant at the FY 2014 reported rate of 3.11 percent. The Medicaid improper payment rate decreased from 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. The majority of improper payments have been cited on claims where a newly

²¹ 82 FR 31158, July 5, 2017

enrolled provider had not been appropriately screened by the state, a provider did not have the required NPI on the claim, or a provider was not enrolled. Although these errors remain a driver of the Medicaid rate, state compliance has improved, as the Medicaid FFS improper payment rate for these errors decreased from 9.27 percent in FY 2017 to 7.21 percent in FY 2018.

While the screening errors described above are for newly enrolled providers, states are also required to screen providers upon revalidation of enrollment. States are required to revalidate the enrollment of all providers at least every 5 years and must have completed the revalidation process of all existing providers by September 25, 2016. In FY 2018, CMS measured the first cycle of states for compliance with requirements for provider screening at revalidation. Improper payments cited on claims where a provider had not been appropriately screened at revalidation is a new major source of error in the Medicaid improper payment rate. CMS will complete the measurement of all states for compliance with provider revalidation requirements in FY 2020.

CMS also reported in the FY 2018 AFR the national CHIP improper payment rate that is based on measurements conducted in FYs 2016, 2017, and 2018. The FY 2018 national CHIP improper payment rate was 8.57 percent, representing \$1.4 billion in gross federal improper payments. The national improper payment rates by component are 12.55 percent for CHIP FFS and 1.24 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 decreased from 8.64 percent in FY 2017.

The majority of CHIP improper payments have been cited on claims where a newly enrolled provider or a provider due for revalidation had not been appropriately screened by the state or a provider did not have the required NPI on the claim (see above Medicaid section for further description of CMS's review of these errors). State compliance with screening requirements has not improved for CHIP. 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.

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 40 active demonstrations representing estimated federal outlays in the amount of \$288.7 million in FY 2016. 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 activities in FY 2018 included releasing a State Medicaid Director Letter documenting CMS's approach to various aspects of Medicaid 1115 budget neutrality calculations. It includes recent changes in budget neutrality policy that CMS has been implementing which base project expenditures that are compared to estimated demonstration costs to more current and realistic expenditure growth assumptions. CMS is also continuing to implement its revised uncompensated care pools policy which resizes the states' uncompensated care (UC) pools based

on data submitted by states, reflecting charity care only, on the Hospital and Hospital Health Care Complex Cost Report. CMS does not provide UC funds to substitute for payment that could be provided by Medicaid through payment of appropriate rates. In addition, CMS continues to build and test standard operating procedures and reporting tools to strengthen section 1115 fiscal and program monitoring and internal controls, including a new budget neutrality workbook that is being rolled out to states in the Fall, and demonstration monitoring templates for states.

CMS continues to work closely with technical assistance contractors to build performance measurement sets for high priority demonstrations such as for substance use disorders and community engagement. CMS also works 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 to further advance an information management system introducing stronger and more reliable internal controls, and that is beginning to strengthen federal monitoring and analysis of performance trends across states and over time. The fifth version of this system was recently released.

Home and Community-Based Services Rate Review and Fiscal Integrity Project

The Rate Review and Fiscal Integrity Project improves the efficiency and effectiveness of rate setting oversight and financial reporting for the Programs of All-inclusive Care for the Elderly (PACE), and Home and Community Based Services (HCBS) waiver and state plan programs. Project tasks include rate methodology review and analysis, assessing compliance with statute and regulations, data compilation and validation, and education and training for states and CMS staff. Specifically this includes:

- Ensuring that states are in compliance with the HCBS assurances as described in Section 1915(c) of the Act
- Analyzing states fiscal integrity systems; conducting analyses of HCBS personal care services requirements and tracking and trending states' protections against waste, fraud, and abuse
- Providing education and training related to financial accountability, rate development, and pre and post payment review methods
- Conducting environmental scans of states' incident management systems to identify methods to detect unnecessary and/or recurrent hospitalizations and methods for monitoring the health and safety of Medicaid participants

As of September 6, 2018, 181 reviews of HCBS waivers for 41 states were completed in FY 2018 and reports with findings pertaining to the waivers' fiscal and quality components were compiled for each. Twenty PACE reviews spanning 17 states and a pilot survey of states' incident management systems were also completed during this time. Findings from these reviews are aggregated in an annual report each year which helps inform technical assistance activities and guide program improvements. Since 2016, 21 presentations have been completed and made available to state staff via technical assistance calls and web posting. They covered topics such as fiscal protections in personal care services, preventing unallowable costs in HCBS programs,

financial accountability of HCBS, rate sufficiency, and HCBS rate development.

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 2018, NBI MEDIC Part C referrals resulted in sentences ordering forfeitures of \$2.1 million, while Part D referrals resulted in sentences ordering restitution of \$10.0 million according to FY 2018 notifications from law enforcement. Through data analysis and investigative case development, the NBI MEDIC continued in FY 2018 to assist the HHS-OIG and DOJ in achieving arrests, indictments, and convictions. As a result of the NBI MEDIC's data analysis projects including Part D plan sponsor self-audits, HHS recovered \$3.1 million in the first nine months of FY 2018 from Part D sponsors.

Medicare Parts C and D Marketing Oversight

Each year CMS- analyzes Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents and 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 ANOC or 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.

In FY 2018, CMS issued a total of 35 notices of non-compliance (NONCs) to 27 parent organizations as part of a timeliness review. Twenty NONCs were issued to plans that failed to enter dates their ANOCs or EOCs were mailed, nine NONCs were issued for incorrect coding of ANOC or EOC materials, and six were issued for failing to send timely ANOCs or EOCs to enrollees.

There were a total of 13 NONCs issued to 13 parent organizations during the accuracy review. The NONCs were based on substantive inaccuracies (e.g., benefits, cost-sharing) contained in ANOC or EOC documents issued to Medicare enrollees.

Program Audit

CMS conducts program audits of Parts C and 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 CMS's resources, program audits in 2018, 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 which 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 Medicare Parts C and D. .

Compliance and Enforcement

CMS has a number of tools, including the imposition of administrative enforcement actions, to encourage program compliance. These actions include:

- Civil money penalties (CMPs)
- Intermediate sanctions (i.e., suspension of marketing, enrollment, payment)
- CMS initiated contract terminations

CMS has the authority to take enforcement or contract termination actions against a Part C or Part D plan sponsor for program violations, including:

- Substantially failing to comply with program and/or contract requirements
- Performance under a 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
- Failure to substantially meet the applicable conditions of the Medicare Part C and D program

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. More than 4,800 Part C plans submitted plan benefit packages on June 4, 2018 and project to cover more than 22.0 million beneficiaries in contract year 2019. 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 for enrollees in Part C and protects beneficiaries from very high out of pocket medical costs.
- Service Category Cost-Sharing Standards —Each year, CMS evaluates the cost-sharing plans include in their bids and plan benefit packages to ensure 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 under FFS. 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 carefully conducted by CMS 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 1st 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

In the FY 2009 inpatient prospective payment system (IPPS) final rule, CMS revised regulations to require Part C organizations to submit encounter data for each item and service provided to Part C plan enrollees. Consistent with such regulations, CMS requires Part C organizations to submit encounter data for dates of service beginning January 3, 2012. Part C organizations are required to submit data for all institutional, professional, and DME services provided to Part C plan enrollees on or after that date. CMS established and maintains the Encounter Data System

(EDS) to collect and process encounter data. To date, the EDS has collected over 3.8 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 Encounter Data Processing System (EDPS) will allow CMS to make more accurate payments reflecting the patterns of care and the predicted costs of diseases for Part C enrollees. 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 in FY 2015, CMS began to use encounter data as an additional source of diagnoses to risk adjust payments to Part C organizations. In CY 2016, CMS continued the transition and calculated risk scores using both Risk Adjustment Processing System (RAPS) and encounter data, with RAPS-based risk scores weighted at 90% and encounter data-based risk scores weighted at 10 percent. CMS has continued transitioning the reliance on diagnoses from encounter data in payment. In calendar year 2019, CMS will continue to increase the use of encounter data for calculating risk scores with encounter data-based risk scores receiving a weight of 25 percent and RAPS-based risk scores a weight of 75 percent. CMS anticipates ultimately using 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 Part C 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 Part C plans' encounter data submissions.

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

Each year, CMS publishes national improper payment rates 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 2018 (the latest year for which CMS has data, which is based on the 2016 payment year) was 8.10 percent or \$15.55 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 payment error estimate is based on medical record reviews conducted under CMS's 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 three key specific corrective actions described below:

- **Contract-Level Audits:** Contract-level RADV audits are CMS's 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 2018, and CMS will initiate payment year 2014 audits in FY 2019. Furthermore, CMS expects to conduct recoveries for the 2011, 2012, and 2013 contract-level RADV audits in FY 2019.
- **Overpayment Recoveries Related to Regulatory Provisions:** As required by the Social Security Act, CMS promulgated regulations to specify that MA organizations must report and return overpayments that they identify. In FY 2018, MA organizations reported and returned approximately \$64.9 million in self-reported overpayments. CMS believes that this requirement will reduce improper payments by encouraging MA organizations to submit accurate payment information.
- **Training:** Historically, CMS has conducted fraud, waste, and abuse in-person and webinar training sessions for MA plans. In FY 2018 HHS conducted three in-person missions (one in October 2017 and two in April 2018) and a large in-person fraud, waste and abuse training conference in July 2018.

The Part D gross improper payment estimate reported for FY 2018 (based on CY 2016) the latest year for which CMS has data, was 1.66 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 imputed onto the corresponding PDE records of a representative sample of beneficiaries. The estimated error is calculated for this sample of beneficiaries and the result is extrapolated onto the payments of the remaining Part D beneficiaries to determine the Part D improper payment estimate.

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. In FY 2018 HHS conducted three in-person missions (one in October 2017 and two in April 2018) and a large in-person fraud, waste and abuse training conference in July 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 2018, Part D sponsors reported and returned approximately \$2.1 million in self-reported overpayments.

Central Data Abstraction Tool (CDAT)

CMS uses diagnosis information submitted by Medicare Advantage Organizations to risk adjust payments to plans. The more diagnosis information a plan submits, typically the higher their payments from Medicare. Each year, CMS conducts RADV audits to measure the accuracy of the plan-submitted diagnostic information. As required by statute, CMS uses the results of these audits to estimate and recover overpayments for individual Medicare Advantage plans. The Central Data Abstraction Tool is the main system that CMS uses to support the RADV audits.

CMS Exchange Program Integrity

Program integrity is an increasing concern in the Health Insurance Exchanges – both in the Federally facilitated Exchanges (FFE) and the State-Based Exchanges (SBEs). In FY 2018, CMS's Exchange program integrity team performed investigations to identify areas of fraud and abuse in the Exchanges including a review of consumer complaints, verification of licenses for agents and brokers and identification of areas that appear to have a higher risk of fraud and abuse. Reviewing and categorizing consumer complaints allows CMS to identify health insurance policies that should be rescinded, determine whether administrative action can be taken and identify patterns and schemes to share with law enforcement. The agent and broker license verification is used to identify insurance agents and brokers who are enrolling consumers into Qualified Health Plans and confirm that they are registered with CMS to sell plans on the FFEs, have a valid license to sell insurance in the state which they are enrolling consumers, and hold a valid line of authority to sell health insurance products. The purpose of the high risk region analysis is to target analytics and audit activities specific to eligibility and enrollment to areas of the country that are significant outliers in eligibility and enrollment indicators.

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.

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 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.

CMS works with providers, states, and others to protect CMS programs for the future. CMS's work focuses on safeguarding the programs and protecting beneficiaries from fraud, waste and abuse, while also working to minimize unnecessary burden. Providing education and training opportunities that are responsive to stakeholder needs will help protect the financial security of CMS's programs by reducing improper payments and curtailing emerging fraud schemes. By offering regular in-person and virtual events and trainings, as well as clear and concise information online, CMS aims to provide needed information that is responsive to the realities of clinical practice.

In April 2018, CMS launched a new program integrity landing webpage, reflecting a complete overhaul of the previous web presence in its look, feel and content. The webpage represents a one-stop shop for all program integrity stakeholders to easily find the resources they need and learn about program integrity work that CMS does. Over the course of FY 2018, CMS also improved the content and delivery of several key webpages to provide concise and user-friendly information, including updates to the Parts C and D Recovery Audit Program, E-clinical template, Targeted Probe and Educate, Documentation Reduction and Simplification, and Reducing Provider Burden webpages. These webpages now include such enhancements as site-specific navigation, user-friendly language, and the ability of users to interact and communicate with CMS.

CMS also coordinated multiple training events about current Medicare Parts C and D fraud schemes, fraud prevention techniques, and anti-fraud, waste and abuse activities for Medicare Advantage Organizations and Prescription Drug Plans. These sessions integrated group discussions, information-sharing exercises, presentations and panel discussions that focused on the latest fraud, waste and abuse issues for these plans.

To increase transparency and ensure providers, states, beneficiaries and others understand what is happening and why, a core focus for CMS in 2018 was to communicate agency priorities more effectively using infographics, data visualization, and information design. CMS developed several pieces including an Opioid Roadmap outlining efforts to address this issue of national concern; a Medicare Beneficiaries at a Glance Infographic (to learn more: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Beneficiary-Snapshot/Bene_Snapshot.html) , which provides a visual summary of statistics on Medicare beneficiaries, including the types of coverage they have, the services they use, and their satisfaction with the program; a Targeted Probe & Educate process flow visual to explain how the program works; and Data Exchange System (DEX) collateral to summarize user roles and highlight new features of the system. These resources are integrated into various communication channels and used to communicate complex ideas in ways that are easy to digest for stakeholders, including providers, states and the general public. In an effort to reduce opioid misuse, CMS also mailed 8,000 Opioid Safety Commitment posters to select providers to help patients understand the physician's commitment to their pain management needs and the practice's patient safety principles.

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 for the health care industry to reduce fraud, waste, and abuse by:

- Providing an unparalleled cross-payer data source, representing the full spectrum of the health care 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
- Leveraging Partnership resources and relationships to generate real-time, comprehensive approaches that materially impact efforts to reduce health care fraud, waste, and abuse

In FY 2018, the HFPP reached a total membership level of 112 partner organizations, comprised of 9 federal agencies, 12 associations, 61 private payers, and 30 state and local partners.

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). The HFPP has also expanded its study methodology to collect frequently updated data, including personally identifiable information (PII) and protected health information (PHI). The HFPP is currently using professional claims

and is planning to expand to collect institutional, pharmacy, and dental claims in the future.

Over 10 billion professional claim lines were submitted by partners in FY 2018 for the purpose of conducting cross-payer analyses, and by the end of FY 2018, the HFPP has commenced or completed 18 studies since program inception.

Examples of studies initiated in FY 2018 include the identification of:

- Potentially problematic sleep study providers
- Referring providers with no prior relationship treating that patient
- Providers with deactivated National Provider Identifiers (NPIs) that continue to submit claims for payment
- Providers that perform more services during a 24-hour period or during off hours (i.e., weekends and holidays) than would be expected

The HFPP also continued its efforts to foster collaboration among partners in FY 2018 by hosting four in-person information-sharing sessions and an Annual Executive Board meeting. These meetings were used to share fraud schemes and provider alerts, provide updates on law enforcement activities, and strategize on how to broaden the HFPP's impact in the private and public sectors. Additionally, in May 2018, the HFPP released a White Paper entitled "Examining Clinical Laboratory Services: A Review by the Healthcare Fraud Prevention Partnership" The White Paper summarizes common issues and challenges associated with clinical laboratory services fraud and abuse

State Engagement to Address Opioid Overprescribing and Misuse

A critical component of addressing the opioid crisis is to identify and mitigate abusive prescribing practices and overutilization of prescription opioids. In an effort to combat the opioid epidemic, CMS, other federal agencies, and states are collaborating to review and improve; state delivery system reform, treatment programs, and policy. This project is in its infancy and still being fully developed. As of September 2018 New Hampshire has collaborated with CMS in an effort to lead the way to best practices in analyzing and identifying potential data sources, trends, and determining best course of actions for interventions. This pilot project will give CMS a deeper understanding of state data, the various projects implemented, and the lessons learned that can be adapted by other states to bolster their efforts to address program integrity concerns in the opioids crisis.

Open Payments

Open Payments is a statutorily required-national transparency program designed to provide the public with information regarding the financial relationships between applicable manufacturers and group purchasing organizations (GPOs), collectively referred to as reporting entities and 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.

HHS is required to collect and display this information, which is self-reported annually by reporting entities, on the public website public website. The public can search, download, and evaluate the reported data.

In FY 2018, CMS published information regarding \$8.4 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 11.5 million total records attributable to 628,214 physicians and 1,158 teaching hospitals. Payments in the three major reporting categories included:

- \$2.8 billion in general (i.e., non-research related) payments
- \$4.7 billion in research payments
- \$927 million of ownership or investment interests held by physicians or their immediate family members

Since the program's inception in in 2013, CMS has published over 53 million records, accounting for \$33.4 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 2018, HHS allocated

\$18 million in HCFAC appropriations, plus an additional \$142,317 in carryover funding from FY 2017 to the Administration for Community Living (ACL) to support SMP program infrastructure and provide grants to SMPs in 54 states and territories.

Until FY 2016, ACL received funding from a separate Congressional appropriation (the Older Americans Act) to support SMP grants. However, the Consolidated Appropriations Act of 2016 required the SMP program to be fully funded by CMS discretionary HCFAC appropriations beginning in FY 2016. This language was modified in FY 2018 to require that the program be funded at no less than \$17,621,000, still from CMS discretionary HCFAC appropriations. In FY 2018, the Secretary allocated \$18 million from these appropriations to the SMP program.

SMP Project Activities and Outcomes

ACL uses the majority of its HCFAC allocation to fund SMP projects in every state, the District of Columbia, Puerto Rico, Guam, and the U.S. Virgin Islands. During FY 2018, ACL held a new SMP grant competition and awarded \$15.57 million in funding to 54 SMPs nationwide, including eight new SMP grantees. Each SMP grantee received 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 will use this funding to educate and empower Medicare beneficiaries to prevent, detect, and report Medicare fraud, errors, and abuse.

New Medicare Card Initiative

During FY 2018, ACL and SMPs partnered with CMS to identify scams and potential fraud trends related to the new Medicare cards CMS began issuing to all beneficiaries in April 2018. Over the past year, thousands of people have come to SMPs with questions about the new Medicare cards and how to protect themselves. Between October 1, 2017 and August 31, 2018, SMPs held 5,012 outreach events to educate more than 427,000 people about the new Medicare cards and related scams. SMPs also individually counseled 44,000 people about their specific questions and concerns related to the new cards.

Annual SMP OIG Report

Each year, the HHS Office of the Inspector General (HHS-OIG) completes an annual performance report on the SMP projects. In CY 2017, the SMP projects had 6,130 active team members (including volunteers, staff, and partners) who contributed more than 433,728 hours of work in support of the SMP program. These team members conducted 26,429 group outreach and education events to teach beneficiaries how to prevent, detect, and report Medicare fraud, errors, and abuse, reaching an estimated 1.9 million people. In addition, the projects had 226,261 individual interactions with, or on behalf of, beneficiaries in order to help resolve instances of suspected fraud, errors, or abuse. For 2017, expected Medicare recoveries attributable to the SMP projects totaled \$2,010,475. The SMP projects also reported \$211,749 in cost avoidance and \$44,468 in savings to beneficiaries and others. Further, additional Medicare expected recoveries totaled \$53.2 million and additional Medicaid expected recoveries totaled \$1.8 million.

Since SMP's inception, the program has educated over 38.4 million beneficiaries through 387,315 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 May 2018 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.

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 \$126.8 million in savings attributable to the SMP program since its inception in 1997. Further, HHS-

OIG has recognized SMP contributions to other cases that have resulted in \$64.2 million in additional expected Medicare and Medicaid recoveries.

SMP Infrastructure and Program Support

SMP Resource Center

During FY 2018, ACL awarded year two of a 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 of the SMP projects. 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 2018, ACL worked with SMPs to prioritize and implement ongoing system improvements to ensure SIRS continues to meet their needs and best support their programs.

SMP Customer Satisfaction Survey

During FY 2018, ACL implemented the first national survey to ascertain the quality and effectiveness of the services provided by the SMP program. Historically, SMPs have only tracked output and outcome measures, such as number of SMP team members, group outreach and education events, individual interactions, and savings. 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 results from the survey will help measure satisfaction among individuals who attend SMP group education sessions and determine how the program can be improved to better serve Medicare beneficiaries, their families, and caregivers.

ACL's SMP Customer Satisfaction Survey received OMB approval in August 2017. Survey implementation began in early FY 2018 and will continue over a three-year period. One-third of the SMP projects will be surveyed during each year of the project. At the conclusion of the project, survey results will be available at the national level, as well as for each SMP project.

Preliminary national results are positive and include the following findings:

- 97% of participants were satisfied with the SMP group education session they attended
- 97% of participants felt the presentation provided them with useful information
- 96% of participants would recommend the presentation to others, and

- 92% of participants would contact the presenter for help or information

Preliminary results also show that based on what they learned during an SMP group education session, participants report they will take the following actions:

- 84% of participants will hang up on anyone who calls and asks for their Medicare number or personal information;
- 80% of participants will report suspected Medicare fraud, errors, or abuse;
- 80% of participants will share what they learned with their family or friends;
- 76% of participants will review their Medicare Summary Notices (MSNs) or plan statements for possible errors or fraudulent charges; and,
- 10% of participants will take another action.

Final survey results and findings will be available in FY 2020, at the conclusion of the three-year customer satisfaction survey project.

Office of the General Counsel

In FY 2018, HHS allocated the Office of the General Counsel (OGC) \$7.1 million in HCFAC funding to support OGC's program integrity activities. Such activities focused on litigation aimed at the recovery of program funds and review of CMS programs to strengthen them against potential fraud, waste, and abuse. OGC's HCFAC activities in FY 2018 helped the Government establish over \$2.2 billion in judgments, settlements, or other types of recoveries, savings, or receivables.

FCA and Qui Tam Actions

OGC supports DOJ's FCA work by interpreting complex Medicare and Medicaid rules and policies, which assists DOJ in discerning which allegations involve program violations and helps focus Government resources on the matters that are most likely to result in recovery. In addition, OGC provides significant litigation support by assisting DOJ in interviewing and preparing CMS personnel who may act as witnesses and in responding to requests for documents and information.

In FY 2018, OGC worked collaboratively with DOJ and OIG on numerous FCA matters regarding a variety of issues, including: provider billing for services not rendered; falsified statements of medical necessity; sales of unreliable point-of-care diagnostic testing devices; physician self-referral violations; provider upcoding; Medicare Advantage risk adjustment; failure to report discounted prescription drug prices; and misrepresentations under the Medicare Electronic Health Records Incentive Program. OGC efforts on these and other FCA matters in FY 2018 helped the Federal Government recover nearly \$1.98 billion.

Civil Monetary Penalties

CMS is responsible for administering CMP legislation that is aimed at combatting fraud, waste, and abuse. OGC, in turn, advises CMS on its development and imposition of CMPs. OGC also defends CMS in numerous administrative appeals and judicial litigation related to the imposition of CMPs. The decisions in such cases can immediately impact the quality of care provided to affected beneficiaries, save program funds, and set precedents that demonstrate HHS's commitment to policing this area.

OGC obtained several favorable outcomes regarding the imposition of CMPs during FY 2018. For example, OGC assisted CMS in obtaining a CMP recovery against a skilled nursing facility for its failure to educate nurses on policies regarding medication administration and pain management. As a result of such failure, a beneficiary received an incorrect dose of morphine and was hospitalized for an opioid overdose.

Provider/Supplier Suspensions and Enrollment Revocations or Denials

Payment suspensions, enrollment revocations, deactivations and denials all play a critical role in protecting program funds. These actions help protect the trust funds by ensuring that inappropriate providers and suppliers are not given or do not retain the ability to submit claims. OGC assists with this work by: advising CMS on whether to suspend payment to Medicare

providers and suppliers; interpreting CMS enrollment regulations; reviewing proposed enrollment rules, manual changes, and correspondence related to enrollment issues; and providing litigation support and program guidance in defense of suspensions, revocations and denials. For example, in FY 2018, OGC worked with CMS's Center for Program Integrity to develop a coordinated strategy for defending revocations based on improper prescribing practices. OGC also defended the first revocation of a physician based on a pattern or practice of abusive prescribing of Part D drugs. Specifically, OGC argued that the physician at issue put Medicare beneficiaries at risk of harm by prescribing expensive, compounded drugs for general "pain" and "wellness" via telephone.

Part C and Part D Compliance

During FY 2018, OGC provided 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. OGC also continued its review of compliance-related correspondence that CMS issues to Part D sponsors and Part C plans, which include warning letters, corrective action plan letters, intermediate sanctions, CMP notices, and non-renewal or termination notices.

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 over \$20 million in 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 2018, OGC petitioned these agencies to recover funds in matters in which Medicare was a victim of fraud.

Regulatory Review and Programmatic Advice

In FY 2018, OGC advised CMS on a variety of regulatory and program issues aimed at combating fraud and preventing the wrongful disbursement of program funds in the first instance. For example, OGC:

- Provided counsel to CMS on program integrity issues in the MSSP, including advice regarding a proposed rule, program integrity screenings for applicants to the program, and appeals of application denials.
- Reviewed proposed and final rules that eliminate the enrollment requirement in Medicare Parts C and D and replace this requirement with a preclusion list. The preclusion list includes the names of providers or prescribers that are revoked and under a reenrollment bar, or that could be revoked under certain circumstances.
- Continued to counsel the CMS Innovation Center, which is testing innovative payment and service delivery models to reduce expenditures and preserve or enhance quality of care for Medicare, Medicaid, and CHIP beneficiaries. OGC advises the Innovation

Center on topics including, model design, fraud and abuse waivers, the imposition of corrective action plans, participant screening, and recovery of funds for such models.

Physician Self-Referral

In FY 2018, 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. In addition, as discussed above, OGC continued to provide guidance to CMS and DOJ in navigating the complexities of the physician self-referral law in FCA cases. These consultations help build stronger cases and focus investigatory efforts, leading to successful results for the Government.

Medicare Secondary Payer (MSP)

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. As part of this work in FY 2018, OGC assisted DOJ in its efforts to protect federal Medicare and Medicaid interests in federal opioid lawsuits as HHS continues to find ways to abate the opioid epidemic.

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 2018, 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.

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. OGC also

handles change of ownership issues related to bankrupt Medicare providers to ensure successor financial liability and to protect patient health and safety. For example, in FY 2018, OGC attorneys nationwide worked with CMS to help stabilize a national chain of over 100 nursing homes, particularly 65 facilities in Kansas, Nebraska, South Dakota, Arkansas, and Pennsylvania that were put into state receiverships. This required ensuring the proper flow of funds to the receivers to deliver care to the thousands of residents, including the use of federal CMP funds to help bridge funding gaps in some states.

State Medicaid Disallowances

Upon identifying an increasing number of questionable state financing schemes over the past several years designed to maximize federal payments under Medicaid, CMS has taken an increased number of Medicaid disallowances. Correspondingly, OGC continues to see a significant increase in its workload regarding proposed disallowances, requested reconsiderations, and defense against Medicaid disallowance appeals before the Departmental Appeals Board (DAB).

As a result of OGC's advocacy, CMS has prevailed in numerous matters in FY 2018 that have upheld millions of dollars in disallowances. For example, CMS recently prevailed in a \$144.8 million disallowance against Illinois for submitting to CMS inflated claims for Disproportionate Share Hospital (DSH) payments in excess of the applicable limits.

In summary, OGC's efforts in FY 2018 directly supported the HCFAC program's goals. As part of its program integrity work, OGC coordinated with CMS, DOJ and OIG to enforce various statutes and regulations applicable to health care fraud and abuse, to the benefit of the Medicare and Medicaid programs.

Food and Drug Administration Pharmaceutical Fraud Program

In FY 2018, \$5.9 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 239 criminal HCFAC investigations. In FY 2018, FDA's ninth fiscal year of HCFAC Program activity, OCI, through its PFP, opened 38 criminal investigations, including investigations involving drug compounders, clinical trials, and foreign and domestic medical-product manufacturers. The investigations consist of allegations involving:

- Application fraud, involving individuals or companies who may have submitted false or fraudulent information to FDA in order to obtain an approval or clearance; or who did not submit the required information to legally market drugs, devices or biologics.
- Questionable manufacturing practices of a foreign-based drug firm and drug compounding facilities, involving possible data integrity, misbranding, and/or product adulteration.
- Clinical trial fraud, involving possible falsification of study documents and/or fraudulent study subject enrollments.
- Fraudulent marketing schemes, involving the promotion of products through false or misleading claims.

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.

In October 2017, a PFP investigation resulted in the conviction of a supervisory pharmacist of a compounding pharmacy on 77 counts, including racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead. The conviction resulted from a nationwide fungal meningitis outbreak that killed 64 and caused infections in 750 patients. In January 2018, the defendant was sentenced to 96 months in prison and was ordered in March 2018, to forfeit \$175,000 in connection with the conviction. In August 2018, another defendant, an unlicensed pharmacy technician, pleaded guilty to 10 counts of mail fraud, in connection with his employment at the same compounding pharmacy. This investigation is being conducted jointly with the FBI, a Health Care Fraud Unit of a U.S. Attorney's Office, and other federal law enforcement agencies. In total, fourteen defendants were charged in the case.

In November 2017, the former compliance director of an Indiana compounding pharmacy plead guilty to introducing adulterated drugs into interstate commerce and conspiracy to defraud the United States by obstructing the lawful functions of the FDA. The defendant's conviction resulted from distributing over- and under-potent drugs to hospitals and lying to FDA inspectors to conceal out-of-specification drug potency test results.

In June 2018, the founder of a health care and life sciences company, and her former chief operating officer, were indicted on eleven counts of conspiracy and wire fraud charges in connection with the marketing of a laboratory testing device. The two defendants allegedly defrauded doctors, patients, and potential investors, by making false claims concerning the company's ability to provide accurate, fast, reliable, and cheap blood tests and test results.

The indictment alleges that the defendants' misrepresentations and omissions induced hundreds of patients, or their medical insurance companies, to pay for blood tests and test results, causing inaccurate, unreliable, and improperly validated blood results to be delivered to doctors. This investigation is being conducted jointly with the FBI, the U.S. Attorney's Office, and the Postal Inspection Service.

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 drug manufacturers and clinical investigators under investigation for data integrity and other violations which could possibly pose a risk to the public's health and safety.

Finally, FDA continues to train its employees and conduct outreach activities to maximize the agency's ability to prevent and detect fraud involving medical products. In February 2018, FDA conducted health care fraud and PFP training for regulatory personnel at the FDA India Office in New Delhi, India. During this same trip, FDA presented on its anti-fraud efforts and the PFP at an international conference to regulatory partners in the governments of India, Sri Lanka, and Nepal. This overseas training and outreach was conducted to strengthen our international efforts and to expand our global reach to investigate foreign-based manufacturing firms. In March 2018, FDA conducted a one-day training session for newly hired criminal investigators. This training covered health care fraud control and PFP-related topics. In April 2018, FDA conducted a training session on health care fraud 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. In May 2018, FDA conducted a one-day training session for supervisory criminal investigators, covering health care fraud and PFP-related topics. In July 2018, 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 on the Federal Food, Drug, Cosmetic Act.

DEPARTMENT OF JUSTICE

United States Attorneys

In FY 2018, the United States Attorneys' Offices (USAOs) were allocated \$50.5 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 twelve 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 2018, the Office of Legal Education (OLE) offered healthcare fraud training at the National Advocacy Center which was attended by approximately 60 Assistant United States Attorneys and which provided training on a variety of topics related to health care fraud. In addition, OLE offered training on Affirmative Civil Enforcement at the National Advocacy Center; this course was attended by approximately 60 United States Attorneys and provided training on a variety of topics, including topics related to civil healthcare enforcement. The Criminal Division Fraud Section also held its annual 2018 National Health Care Fraud Training Conference that was attended by 120 Assistant United States Attorneys representing almost 61 districts. In addition, the Executive Office for United States Attorneys (EOUSA) presented multiple webinars during FY 2018 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 Prosecutions²²

In FY 2018, the USAOs opened 1,139 new criminal health care fraud investigations and filed criminal charges in 572 cases involving 872 defendants. During that same time period, 497 defendants were convicted of health care fraud-related crimes.

Civil Matters and Cases²³

In FY 2018, the USAOs opened 918 new civil health care fraud investigations and had 1,203 civil health care fraud matters pending at the end of the fiscal year.

Civil Division

In FY 2018, the Civil Division received approximately \$36.3 million in FY 2018 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.

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. First and foremost, the Fraud Section takes seriously matters which raise the potential for patient harm, such as the AmeriSourceBergen matter, which resolved allegations arising from the operation of a facility that improperly repackaged oncology-supportive injectable drugs into pre-filled syringes and improperly distributed those syringes to physicians treating vulnerable cancer patients. Other cases involved allegations of device manufacturers

²² FY 2018 numbers are actual data through the end of September 2018. This data includes records classified either with the primary or tertiary 03G – Health Care Fraud program code.

²³ FY 2018 numbers are actual data through the end of September 2018. This data includes those records classified under with the FRHC – Health Care Fraud civil code.

marketing and selling products that were deficient or based on misleading or false information (the Alere and AngioDynamics matters discussed earlier).

A number of matters included allegations of hospitals, drug and device manufacturers, and pharmacies paying kickbacks to induce referrals of patients, drugs, or devices, which may subvert appropriate medical decision-making, and which violate the Anti-Kickback Statute (AKS) (such as the United Therapeutics, Pfizer, HMA, William Beaumont Hospital, Kalispell, and UPMC Hamot matters discussed above). 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 United Therapeutics, which allegedly used a charity as a conduit to pay kickbacks to induce prescriptions for its drugs. The Department also recovered hundreds of millions of dollars from hospitals and health systems for allegedly paying unlawful remuneration to clinics and physician practice groups.

The Fraud Section has also continued to pursue matters in which providers bill federal health care programs for medically unnecessary services or services not rendered as billed. The Department resolved claims against several hospital chains for allegations that they billed for excessive and unnecessary inpatient hospital services instead of less costly outpatient or observation services (such as the HMA, Prime, EmCare, and Banner Health matters discussed above). Other matters involved allegations that providers, including hospices, skilled nursing facilities, and pediatric dental providers, billed for services that the patients did not need (such as the Vitas, Kool Smiles, and SignatureHealth matters discussed earlier). Other cases involved allegations that providers such as durable medical equipment companies and pharmacies billed federal health care programs for services not rendered (the Rotech and DaVita Rx matters) or for higher and more expensive levels of medical service than were actually performed. 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.

The Fraud Section also has successfully sought to hold individuals responsible for defrauding federal health care programs. A trial in Columbia, South Carolina, resulted in a judgment of more than \$114 million against three individuals involved in a kickback scheme pertaining to blood laboratory testing (the HDL/Singulex matter discussed above). Another trial in St. Louis, Missouri, resulted in a judgment of more than \$5.4 million against two individuals and their respective companies for violating the FCA through a kickback scheme (the DS Medical/Midwest Neurosurgeons matter discussed earlier). Additionally, a number of corporate settlements required individuals, particularly senior executives, to pay a portion of the settlement amount (such as the Prime and Paramedics Plus matters discussed above).

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), including its Office of Counsel, 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), 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, such as the sick and elderly. Among

its top priorities are pursuing cases against those who market unsafe pharmaceuticals, medical devices, and dietary supplements 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 2018, 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 October 2017, a Texas grand jury returned two indictments against five Chinese citizens, two Chinese firms, and American companies Genabolix USA and Max Pharmatech, Inc., in connection with alleged sales of stimulants intended for inclusion in dietary supplements. The indictments alleged that five defendants participated in a scheme to produce and sell dietary supplements containing hidden synthetic stimulants. As part of the scheme, the defendants allegedly shipped DMHA or DMAA, controversial stimulant ingredients that major American dietary supplement retailers will not carry. The indictments alleged the defendants agreed with a confidential government informant to either mislabel the ingredients or otherwise help to hide the true nature of a proposed new dietary supplement from retailers. Three defendants have pleaded guilty in the case. The remaining individual defendants are believed to be in China.

CPB also works to prosecute the fraudulent sales of purported medical devices. Together with the U.S. Attorney's Office, the Branch prosecuted three individuals who marketed and sold light-emitting medical devices as a cure-all to consumers, primarily targeting the elderly. The defendants falsely claimed the device could treat a panoply of conditions, including cancer, HIV, diabetes, and Lou Gehrig's disease. The leader of the scheme continued to defraud consumers even after he was ordered by a federal court to stop. The scheme caused losses of more than \$16 million, mostly from elderly consumers who each paid approximately \$4,000 to \$13,000. In April 2018, the court sentenced the lead defendant to 12 years in prison. The other two co-conspirators were sentenced to 24 months and 15 months of imprisonment, respectively.

The Branch brought numerous actions related to prescription drug manufacturers. In January 2018, Aegerion Pharmaceuticals, Inc., pleaded guilty to violating the FDCA relating to its distribution of a prescription drug, Juxtapid. Following its guilty plea, the District Court sentenced Aegerion to three years of probation, to include the establishment of a \$7.2 million restitution fund. Juxtapid was approved to treat patients with homozygous familial hypercholesterolemia (HoFH), a rare genetic disorder that causes abnormally high levels of LDL-C, or "bad" cholesterol. As part of Juxtapid's approval, FDA required a Risk Evaluation and Mitigation Strategy (REMS) to educate prescribers about the risks of liver toxicity and to restrict access to Juxtapid only to those patients with a clinical or laboratory diagnosis consistent with HoFH. However, Aegerion failed to give health care providers complete and accurate information about HoFH, filed a misleading REMS assessment report with FDA, and distributed Juxtapid as a general treatment for high cholesterol without adequate directions for such use. The plea was part of a global resolution that included a separate consent decree of

permanent injunction to resolve civil liability under the FDCA.

In November 2017, the compliance director of Pharmakon Pharmaceuticals, Inc., an Indiana outsourcing facility that made and distributed compounded drugs for hospitals around the country, pleaded guilty to conspiracy and FDCA charges relating to the alleged distribution of under- and over-potent compounded drugs. The indictment in June 2017 alleged that the compliance director and Pharmakon's president knew of test results showing problems with the drugs. The indictment alleged that in one instance, Pharmakon distributed 2,460-percent potent compounded morphine sulfate, which was administered to children and caused one child to be rushed to treatment by helicopter. The company president is expected to go to trial in December 2018.

The Branch filed a civil complaint and a motion seeking a preliminary injunction in Arkansas against Cantrell Drug Company and its co-owner and Chief Executive Officer, to stop the manufacturing and distribution of adulterated drugs. The complaint alleged that Cantrell, a compounding pharmacy, distributed adulterated drugs and caused drugs to become adulterated. Cantrell initiated voluntary recalls of drug products in 2016 and 2017 due to a lack of sterility assurance. According to the complaint, FDA inspections of the Cantrell facility documented evidence of insanitary conditions and significant deviations from current good manufacturing practice requirements, including records showing the company detected potentially dangerous bacteria in the air and on surfaces used for sterile processing. The district court entered a consent decree of permanent injunction against the firm, which required the pharmacy to undertake remedial measures before it can resume drug manufacture and distribution.

The Branch is taking action to fight the opioid epidemic. CPB worked with the U.S. Attorney's Office for the Northern District of Ohio to file first-of-their-kind civil enforcement actions against two physicians for illegally distributing and dispensing opioids and other controlled substances. The complaints alleged violations of the Controlled Substances Act. The complaint against one of the doctors also alleged numerous False Claims Act violations. The court in both matters granted temporary restraining orders to limit the defendants' ability to distribute or dispense controlled substances. The actions ultimately will seek permanent injunctive relief and civil money penalties.

CPB continued to play a leading role in the Department's efforts to combat elder fraud, which aims to detect and deter a broad array of scams, including health-care-related frauds. The Branch coordinated a major Department "sweep" of elder fraud cases brought across the country. The actions, announced at a press conference by the Attorney General in February 2018, included cases against more than 150 defendants who caused more than half a billion dollars of loss to more than one million victims. The sweep included cases filed by the Department between February 2017 and February 2018, and featured a number of Consumer Protection Branch criminal and civil cases. The Branch also coordinated an education and public outreach campaign that accompanied the sweep announcement.

Criminal Division

In FY 2018, the Criminal Division was allocated \$25.3 million in 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 and illegal prescription opioid 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 2018, the HCF Unit provided attorney staffing, litigation support, and leadership and management for the Strike Force program's operations in twelve regions across the United States including Miami, Orlando, and Tampa, Florida; Los Angeles, California; Detroit, Michigan; Houston and Dallas, Texas; Brooklyn, New York; Baton Rouge and New Orleans, Louisiana; Chicago, Illinois; Newark, New Jersey; and Philadelphia, Pennsylvania, along with a Corporate Strike Force located in Washington, D.C. The Newark and Philadelphia locations were added this fiscal year as part of the Newark/Philadelphia Regional Strike Force, announced by Assistant Attorney General Brian Benczkowski on August 13, 2018, as a joint effort between DOJ, HHS, FBI, and DEA, to combat health care fraud and the opioid epidemic in the District of New Jersey and the Eastern District of Pennsylvania. As noted above, the ARPO SF was launched at the beginning of FY 2019, with preparations beginning at the end of FY 2018. Since the inception of the Strike Force program in 2007, the HCF Unit and its Strike Force partners have charged 3,800 defendants who have collectively billed the Medicare program approximately \$15 billion.

In FY 2018 alone, the HCF Unit achieved the following results:

- Filed 151 indictments, criminal informations and complaints involving charges filed against 326 defendants who allegedly collectively billed federal health care programs approximately \$1.8 billion;

- Obtained 188 guilty pleas and litigated 16 jury trials, with guilty verdicts against 22 defendants; and
- Sentenced 172 defendants, with an average sentence of over 58 months.

Each year, the HCF Unit leads and coordinates the National Health Care Fraud Takedown. On June 25, 2018, Attorney General Jeff Sessions and Department of Health and Human Services (HHS) Secretary Azar, announced the results of the FY 2018 Takedown – the single largest health care fraud law enforcement operation in history – led by the HCF Unit in coordination with 58 U.S. Attorney’s Offices and 30 Medicaid Fraud Control Units (MFCUs). This year’s Takedown resulted in charges against 601 individuals, including 165 doctors, nurses, and other licensed medical professionals, involving approximately \$2.0 billion in false and fraudulent billings to Medicare, Medicaid, TRICARE, and other federal and private insurance programs. Of the 601 individuals charged, 162 (including 32 doctors) were charged in cases involving the illegal distribution of opioids. Furthermore, to prevent further patient harm, the Drug Enforcement Administration (DEA) revoked the DEA registrations for prescribers or had the numbers surrendered for cause, and the Centers for Medicare & Medicaid Services (CMS) 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 2018, 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 2018 National Health Care Fraud Training Conference was held in September 2018 in Washington, D.C. and was attended by 360 criminal and civil prosecutors (representing more than 60 U.S. Attorney’s Offices) and law enforcement personnel from FBI, DEA, HHS-OIG, IRS Criminal Investigation, and Defense Criminal Investigative Service (DCIS), U.S. Postal Service (USPS), and the Department of Veterans Affairs - OIG. The Conference provided training on investigative techniques and tools, trial skills, case studies, and persistent and emerging schemes in both health care fraud and opioid abuse and drug diversion.

As part of the HCF Unit’s efforts to lead a coordinated, national approach to combating health care fraud, the HCF Unit bolstered the HCF Unit Data Analytics Team in FY 2018. 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, opioid fraud, and drug diversion 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.

Furthermore, the HCF Unit's cases are also increasingly complex, both in cases investigated and charged in the individual Strike Force locations and in cases handled by 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 hundreds of millions of dollars in fraudulent claims to the Medicare and Medicaid program and TRICARE.

Based on the Criminal Division, Fraud Section's prosecutions in FY 2018, the below chart sets forth the projected amounts the Medicare Program saved over specific amounts of time. For example, had the defendants charged by the Fraud Section in FY 2018 continued defrauding the Medicare program at the same rate, this would have resulted in an additional \$1.1 billion loss after 3 years, and \$2.4 billion in loss after 10 years. The Impact of Investment shows that over 10 years, every dollar spent on the Criminal Division, Fraud Section in FY 2018, resulted in \$109 in savings to the Medicare program.

Time Frame	Monies Saved	Impact of Investment
1-year	\$442.7 million	\$20 saved/ \$1 spent
3-year	\$1.085 billion	\$49.4 saved/ \$1 spent
5-year	\$1.597 billion	\$72.5 saved/\$1 spent
8-year	\$2.151 billion	\$97.7 saved/\$1 spent
10-year	\$2.419 billion	\$109 saved/\$1 spent

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 provides legal advice and necessary approvals in the use of the Racketeer Influenced and Corrupt Organizations (RICO) statute to combat health care fraud and abuse.

In FY 2018, 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 for the Eastern District of Tennessee on a pill-mill prosecution of individuals illegally operating pain clinics and prescribing vast quantities of opioids. Superseding indictments returned in January and May 2018 charged seven individuals, including two leaders in Italy, for their roles in a Racketeering Influenced Corrupt Organization (RICO) conspiracy and drug trafficking conspiracy to distribute and dispense oxycodone, oxymorphone and morphine outside the scope of professional practice and not for a legitimate medical purpose and resulting in deaths. The indictment also charged maintenance of drug-involved premises, distribution of oxycodone resulting in death, conspiracy to defraud the United States through the solicitations and receipt of illegal health care kickbacks and money laundering. The criminal enterprise is alleged to have operated clinics in Tennessee and Florida which generated revenues of over \$21 million and prescribed in excess of 880 billion milligrams of oxycodone. In total, the partnerships between OCGS and the Eastern District of Tennessee has resulted in the investigation and prosecution of over 140 individuals. Trial is scheduled in FY 2019. This case is summarized above in the Highlights of Significant Criminal and Civil Investigations.

In Washington, D.C., two OCGS attorneys are handling the prosecution of a former union official and an outside lobbyist for health care fraud conspiracy and health care fraud. The union official is alleged to have arranged for the lobbyist to be fraudulently placed on the union's health plan even though the lobbyist was not a full-time employee of the union and therefore not eligible to participate in the health plan. The lobbyist thereafter obtained more than \$66,000 in medical reimbursements to which she was not entitled from the insurance carrier for the plan. Trial is scheduled in FY 2019.

Additional OCGS attorneys were engaged in investigations of health care fraud, kickbacks, embezzlements and other criminal abuses involving large collectively bargained health plans, third party administrators to private sector health plans, pharmacy benefits managers, health plans funded through prevailing wage government contracts, and health plans provided through multiple employer welfare arrangements.

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). Private sector employment-based group health plans are the leading source of health care coverage for individuals not covered by Medicare or Medicaid. OCGS provides litigation

support as requested at any stage of the prosecution from indictment through trial and on appeal.

OCGS attorneys support 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. For example, in August 2018, an OCGS attorney provided assistance to the investigation and indictment in the Eastern District of Louisiana of two individuals operating a multiple employer welfare arrangement. The indictment alleged fraud and false statements in the marketing and sale of group health care coverage causing losses exceeding \$41 million. The scheme involved the sale of health care coverage to employers based upon false representations that the health plan was funded by a loan arrangement which would greatly lower the employers' and their contributing employees' taxable income. In fact there was no loan arrangement and no participant contributions. The defendants collected more than \$21 million in fees from employers and contributing employees. In addition, the defendants caused at least \$20 million in federal FICA taxes to be underpaid as well as a significant amount of personal income taxes, amounts for which the employer-clients and employee-participants may be individually responsible. This case is summarized above in the Highlights of Significant Criminal and Civil Investigations.

OCGS attorneys also 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, FBI and IRS. 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 racketeering enterprises involved in the distribution of opioids, fentanyl, and other pharmaceuticals Medicare and Medicaid frauds, and private sector health care frauds.

Civil Rights Division

In FY 2018 the Civil Rights Division was allocated \$13.933 million in HCFAC funding to support Civil Rights Division litigation activities related to health care fraud and abuse. The Civil Rights Division pursues relief affecting public, residential, and nonresidential health care facilities and service systems, and conducts investigations to eliminate abuse and grossly substandard care in public, Medicare, and Medicaid funded long-term care facilities. Consistent with the ADA's integration mandate set forth in 28 C.F.R. § 35.130(d), the Division also works to prevent the unnecessary segregation of individuals who require health care supports and services. *Olmstead v. L.C.*, 527 U.S. 581 (1999).

The Division plays a critical role in the HCFAC Program. The Special Litigation Section of the Civil Rights Division is the sole DOJ component responsible for enforcing 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 facilities, and initiation of a civil action for injunctive relief to remedy a pattern or practice violation of the Constitution or federal statute. In addition, both the Special Litigation Section and the Disability Rights Section have engaged in interagency coordination with the goal of combatting the misuse of Medicaid funding related to the unnecessary segregation of persons with disabilities.

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 the investigation of allegations of discrimination by public entities against individuals with disabilities, including discrimination in the form of unnecessarily segregating 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 segregation often increases Medicaid costs.

The Educational Opportunities Section of the Civil Rights Division also participates in the HCFA Program to address the use of Medicaid funding for youth with disabilities who are unnecessarily placed in segregated education settings in violation of the ADA. The Special Litigation, Educational Opportunities, and Disability Rights Sections work collaboratively with the USAOs and with HHS.

FY 2018 Accomplishments

Key litigation and enforcement accomplishments in FY 2018 by the Civil Rights Division can be summarized as follows:

- Number of matters in active enforcement: 15;
- Cumulative estimate of individuals with disabilities affected: 55,685; and
- Number of institutional facilities affected: 2,095.

Special Litigation Section

In Fiscal Year 2018, the Special Litigation Section continued monitoring compliance with four statewide settlement agreements and began monitoring a fifth statewide agreement. In addition to these agreements, which benefit thousands of people, the Section continued litigating two large cases involving the alleged unlawful institutionalization of, and denial of community-based services to, individuals with disabilities. During FY 2018, the Section's active enforcement efforts affected more than 1,400 health care facilities in eight states.

In Louisiana, the Division filed a complaint alleging that the State violates the ADA by requiring people with mental illness to receive services in nursing facilities when they qualify for, and could be served in, community-based settings. The Division simultaneously filed a settlement agreement that requires the State to transition people with mental illness from nursing facilities to community-based care where appropriate and not opposed, enhance the community-based

services necessary to support them, and divert other people with mental illness from unnecessary nursing facility admission.

The Section also continued monitoring implementation of settlements in New Hampshire, Virginia and Georgia that are helping individuals with intellectual, developmental, and mental health disabilities avoid unnecessary institutionalization.

In New Hampshire, the State's implementation of the settlement has diverted hundreds of individuals with mental illness from costly hospital admissions through community crisis services; served over 800 people in permanent Supported Housing; provided approximately 1,000 adults with Assertive Community Treatment (ACT) services at any given time; and within the last year, provided over 3,700 people with Supported Employment services, a Substance Abuse and Mental Health Services Administration (SAMHSA) evidence-based practice that assists individuals with disabilities to gain meaningful, competitive employment, self-sufficiency, and independence.

Similarly, in Georgia, the State's implementation of the settlement 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 1,600 adults with ACT services, and provided over 1,200 people with Supported Employment services. Under the settlement, Georgia is also serving an additional 1,700 people with intellectual and developmental disabilities (IDD) through Medicaid home and community-based services to prevent their unnecessary institutionalization or return them to the community from institutional settings.

In Virginia, as a result of the State's implementation of the settlement, more than 4,000 people with IDD who qualify for Medicaid-funded community services have received them; an additional 12,000 people with IDD have received one-time support to assist them in continuing to live in the community; more than 450 people with IDD have been able to live in their own home; and more than 700 individuals have successfully transitioned from state-run residential institutions to community settings.

In Oregon, the Section continued to monitor the 2016 Oregon Performance Plan (OPP), which the State developed in response to the Division's investigation of the State's mental health system. As a result of the State's implementation of the OPP, the State has 35 ACT teams serving over 1,200 individuals, 400 more than in 2016. The State has also expanded peer-delivered services from about 2,100 individuals to over 3,000.

The Section continued to work toward a resolution of the Division's investigative conclusions that: 1) South Dakota fails to serve older adults and people with disabilities in the most integrated setting appropriate to their needs; and 2) West Virginia fails to serve children with mental health conditions in the most integrated setting appropriate to their needs.

The Section continued litigation 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. Trial is expected to occur in FY 2019. The Section also continued litigation against the State of Texas alleging that the State

violates the ADA by unnecessarily institutionalizing persons with intellectual and developmental disabilities in nursing facilities. Trial in this case commenced in October 2018.

Disability Rights Section

In FY 2018, 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 segregation 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 2021 and expand integrated employment opportunities for people with mental illness by providing supported employment services to 2,500 individuals by 2021. 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.

As of June 30, 2018, 2,168 individuals had been diverted or moved from large adult care homes to permanent supported housing. Eight hundred and eighty-nine 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 1,279 individuals moved out of adult care homes into the community. Of the 2,168 individuals who have moved into permanent supported housing, 1,580 (or 73 percent) continue to live and receive services in the community. In addition, 5,279 individuals were receiving ACT services and 1,805 individuals in the agreement's target population had received 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 IDD by 2024, and roughly 3,500 individuals will benefit from changes to the State's employment and day service systems. The State and City of Providence have made significant progress, including meeting or exceeding two of three upcoming Supported Employment placement targets ahead of schedule. Thus far, 786 individuals have obtained competitive, integrated employment over the course of these agreements.

The Section, along with the U.S. Attorney's Office for the Eastern District of New York, continued monitoring the second amended 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 are provided the opportunity to receive services in the most integrated setting appropriate to their needs consistent with the ADA and *Olmstead*. Under the agreement, these individuals can choose to live and

receive services in the community, thus enabling them to live, work, and participate fully in community life. To date, more than 700 former adult home residents are living and receiving services in the community, and more than 2,100 additional adult home residents have expressed interest in doing so. On March 12, 2018, the parties asked the Court to approve a proposed supplement to the second amended settlement agreement. The Court held a fairness hearing regarding the proposed supplement on June 18, 2018, and granted final approval of the supplement on September 6, 2018.

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 IDD obtain competitive integrated employment. The State committed to provide supported employment services and related employment services so that by June 30, 2022, 1,115 working-age individuals receiving sheltered workshop services would newly obtain competitive integrated employment. The State also agreed that by July 1, 2022, it would provide employment services to at least 4,900 youths aged 14 to 24, and Individual Plans for Employment to at least half of those youths. The State has reported that as of March 2018, it had reduced the census of segregated sheltered workshop settings to 664 and the total number of hours worked in such settings to 34,155. The State has also reported that through the end of June 2018, it had provided supported employment services and related employment services so that at least 598 individuals receiving sheltered workshop services have newly obtained competitive integrated employment, 3,102 transition-aged youths have received at least one new employment service, and 2,702 of those youths 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. The appeal was fully briefed on March 1, 2018, and oral argument occurred on October 3, 2018.

Educational Opportunities Section

The Educational Opportunities Section (EOS) has participated in the HCFAC Program for the past four 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.

Office of Inspector General

In FY 2018, the Office of the Inspector General (OIG) was allocated \$0.8 million in HCFAC funding to address health care fraud as it directly impacts DOJ operations. The DOJ spends over \$1 billion a year to provide health care to inmates of the Federal Bureau of Prisons and the U.S. Marshals Service and over \$115 million a year in annual workers' compensation payments related to disabled DOJ employees and informants. To date, the OIG has hired one special agent and two analysts to assist in identifying and investigating health care fraud. This has resulted in the initiation of nine cases for the Investigations Division and also a Procedural Reform Recommendation to the Bureau of Prisons that they move toward electronic billing for health care data at all their facilities.

APPENDIX

Federal Bureau of Investigation

In FY 2018, the FBI was allocated \$134.5 million in funding from HIPAA to support the facilitation, coordination and accomplishment of the goals of the HCFAC Program. This yearly appropriation was used to support 814 positions (487 Agent, 327 Support).

In FY 2018, the FBI initiated 781 new health care fraud investigations and had 2,247 pending investigations. Investigative efforts produced 553 criminal health care fraud convictions and 880 indictments and informations. In addition, investigative efforts resulted in over 812 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 207 health care fraud criminal enterprises.

The FBI is the primary investigative agency involved in the fight against health care fraud that has jurisdiction over both federal and private insurance programs. Health care fraud 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 health care fraud matters.

The FBI seeks to approach the health care fraud 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 health care fraud.

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 health care fraud 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 health care fraud threat through joint investigative efforts; intelligence collection, sharing, and analysis; and the utilization of advanced and sophisticated investigative techniques. FBI field offices participate in health care fraud task forces and/or working groups with partners including local USAOs, 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 health care fraud. HEAT, which is jointly led by the Deputy Attorney General and HHS Deputy Secretary, is comprised of top level law enforcement agents, prosecutors, attorneys, auditors, evaluators, and other staff from DOJ, 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 supports nine Strike Forces located in Miami, Detroit, Houston (also includes McAllen, Texas), New York City (Brooklyn), Tampa, Los Angeles, Chicago, Dallas, Southern Louisiana (Baton Rouge and New Orleans), and two pilot programs in Puerto Rico and Washington, DC area. In 2018, Strike Force teams were established in Philadelphia and Newark. 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 June 2018 DOJ National Health Care Fraud and Opioid Takedown resulting in the charging of 601 subjects, including 165 doctors, nurses and other licensed medical professionals, for their alleged participation in health care fraud schemes involving approximately \$2 billion in false billings. 162 of these individuals, including 76 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.

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 to 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. An example of this was the conviction of a physician in the Miami AOR who billed Medicare more than \$100 million and was paid over \$59 million. The doctor was charged in a multiple-count indictment, including 37 counts of health care fraud. The doctor was found guilty following an eight week trial and was sentenced to 204 months imprisonment and was ordered to pay over \$42 million in restitution. In Detroit, a physician was convicted of conspiracy to commit health care fraud and health care fraud for submitting in excess of over \$26 million in claims to Medicare. The physician was sentenced to 180 months imprisonment and was ordered to pay over \$9 million in restitution. In Dallas, a scheme was uncovered involving illegal kickbacks being paid to numerous home health agencies (HHA) and beneficiaries for the purpose of billing Medicare approximately \$375 million for services neither necessary nor provided. The defendant in this case, a co-owner of an HHA, was sentenced to 120 months imprisonment and ordered to pay over \$23 million in restitution. 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 this was the FBI-led investigation of former CEO of Health Diagnostics Laboratory Inc. (HDL), two marketers of HDL, and Singulex Inc., who were found guilty at trial of violating the Anti-Kickback Statute and the False Claims Act for paying kickbacks to physicians in exchange for patient referrals and causing two laboratories to bill federal health care programs for medically unnecessary testing. The case resulted in a \$114 million settlement to resolve allegations of \$35,074 false claims, worth approximately \$17 million, submitted to Medicare and TRICARE by HDL. The FBI coordinated efforts in this case with DOJ Civil Division's Commercial Litigation Branch; the USAOs in the District of South Carolina, District of Columbia and Middle District of North Carolina; HHS-OIG; OPM-OIG; and DCIS-OIG.

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

individuals and entities for improper prescribing and dispensing practices of controlled substances. These schemes have significant impact on public health and safety. Examples of these types of cases include a Kentucky physician who pled guilty to various counts of conspiracy, unlawful distribution of controlled substances, and health care fraud and was sentenced to 96 months imprisonment. In Philadelphia, an office manager of a clinic operated a large prescription narcotics diversion ring creating and passing more than 2,000 fraudulent prescriptions for Oxycodone. The office manager was sentenced to 168 months imprisonment. 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 health care fraud matters. The FBI has teamed with the DOJ, HHS, and private insurance organizations to provide training in the priority threat areas of health care fraud. Funded training has included innovative methods of employing advanced investigative techniques; basic health care fraud training for FBI Special Agents and professional staff newly assigned to investigate health care fraud; and sessions on new and current health care fraud trends and issues. FBI personnel training opportunities included sessions offered by the FBI, other government agencies and the private sector. In FY 2018, more than 264 FBI health care fraud 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 health care fraud investigations, national initiatives, training, specialized equipment, 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 114).
- 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 2018, including sequester reductions. The FBI also receives a stipulated amount of HIPAA funding for use in support of the Fraud and Abuse Control Program, which is shown below. Separately, CMS receives additional Mandatory Resources under the Medicare Integrity Program (section 1817(k)(4) of the Social Security Act). The inclusion of the activities supported with these funds is not required in this report, and this information is included for informational purposes. Since 2009, Congress has also appropriated annual amounts to help carry out health care fraud and abuse control activities within DOJ and HHS. Those amounts are set forth as Discretionary Resources in the table below and the results of the efforts supported with these funds are contained within this report.

Mandatory Resources²⁴	Fiscal Year 2018
Office of Inspector General	\$190,388,777
Health and Human Services Wedge ²⁵	36,414,133
Medicare Integrity Program ²⁶	877,243,936
<i>MIP/Medicare (non-add)</i>	809,763,633
<i>Medi-Medi (non-add)</i>	67,480,303
Department of Justice Wedge ²	59,444,617
Federal Bureau of Investigation ²⁷	134,525,069
Subtotal, Mandatory HCFAC	1,298,016,532
Discretionary Resources	
Office of Inspector General	\$84,398,000
CMS Program Integrity	584,766,000
<i>Medicare Program Integrity (Non-Add)</i>	482,368,000
<i>Medicaid Program Integrity (Non-Add)²⁸</i>	84,398,000
<i>Senior Medicare Patrols (ACL Non-Add)²⁹</i>	18,000,000
Department of Justice	75,836,000
Subtotal, Discretionary HCFAC	745,000,000
Grand Total, HCFAC	2,043,016,532

²⁴ All mandatory resources are post-sequester.

²⁵ 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.

²⁶ 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.

²⁷ 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.

²⁸ This does not include the Medicaid Integrity Program authorized in the Deficit Reduction Act of 2005, which receives funding separately from the HCFAC account.

²⁹ 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 Common 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

CPI—Center for Program Integrity

CY—Calendar Year

DEA—Drug Enforcement Administration

DME—Durable Medical Equipment

DOJ—The Department of Justice

FBI—Federal Bureau of Investigation

FCA—False Claims Act

FDA—Food and Drug Administration

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

MAO—Medicare Advantage Organization

MFCU—Medicaid Fraud Control Unit

MEDIC—Medicare Drug Integrity Contractors

OCGS—Organized Crime and Gang Section

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

PECOS—Provider Enrollment, Chain and Ownership System

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

UPIC—Unified Program Integrity Contractor

USAO—United States Attorney's Office

ZPIC—Zone Program Integrity Contractor