

**The Department of Health and Human Services
And
The Department of Justice**

**Health Care Fraud and Abuse Control Program
Annual Report for Fiscal Year 2019**

June 2020

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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-third 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) 2019, the Federal Government won or negotiated over \$2.6 billion in health care fraud judgments and settlements,² in addition to other health care administrative impositions. As a result of these efforts, as well as those of preceding years, \$3.6 billion was returned to the Federal Government or paid to private persons in FY 2019. Of this \$3.6 billion, the Medicare Trust Funds³ received transfers of approximately \$2.5 billion during this period, in addition to the \$148.6 million in Federal Medicaid money that was similarly transferred separately to the Treasury due to these efforts.

Enforcement Actions

In FY 2019, the Department of Justice (DOJ) opened 1,060 new criminal health care fraud investigations. Federal prosecutors filed criminal charges in 485 cases involving 814 defendants. A total of 528 defendants were convicted of health care fraud-related crimes during the year. Also in FY 2019, DOJ opened 1,112 new civil health care fraud investigations and had 1,343 civil health care fraud matters pending at the end of the fiscal year. FBI investigative efforts resulted in over 558 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 151 health care fraud criminal schemes.

In FY 2019, investigations conducted by HHS's Office of Inspector General (HHS-OIG) resulted in 747 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid, and 684 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 2,640 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 (1,194) or to other health care programs (335), for patient abuse or neglect (238), and as a result of state health care licensure revocations (576). HHS-OIG also issued numerous audits and evaluations with recommendations that, when implemented, would correct program vulnerabilities and save Medicare and Medicaid funds.

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.

Sequestration Impact

Due to the FY 2019 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 \$19.5 million was sequestered from the HCFAC program in FY 2019, for a combined total of \$139.6 million in mandatory funds sequestered in the past seven years. Including funds sequestered from the FBI (\$64.8 million in the past seven years), \$204.4 million has been sequestered from mandatory HCFAC funds since FY 2013.

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 2019 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 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 2019, the Secretary and the Attorney General certified \$294.3 million in mandatory funding to the Account after accounting for sequester reductions of \$19.5 million to the total appropriation. Additionally, Congress appropriated \$765 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 2019. (Separately, the FBI, which is discussed in the appendix, received \$138.3 million from HIPAA, after accounting for \$9.1 million in mandatory sequester reductions.) Under the joint direction of the Attorney General and the Secretary, the Program’s goals are:

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

- (1) To coordinate federal, state and local law enforcement efforts relating to health care fraud and abuse with respect to health plans;
- (2) To conduct investigations, audits, inspections, and evaluations relating to the delivery of and payment for health care in the United States;
- (3) To facilitate enforcement of all applicable remedies for such fraud; and
- (4) To provide education and guidance regarding complying with current health care law.

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

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

This annual report fulfills the above statutory requirements.

Finally, this report fulfills the requirement in the annual discretionary HCFAC appropriation (Public Law 115-245, Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019) 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 2019, \$3.6 billion was deposited with the Department of the Treasury and Centers for Medicare & Medicaid Services (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 2019	
Department of the Treasury	
Deposits to the Medicare Trust Fund, as required by HIPAA:	
Gifts and Bequests	\$0
Amount Equal to Criminal Fines	14,927,760
Civil Monetary Penalties	64,381,876
Asset Forfeiture	37,095,907
Penalties and Multiple Damages	815,368,976
Subtotal	\$931,774,520
Centers for Medicare & Medicaid Services	
HHS/OIG Audit Disallowances: Recovered–Medicare	\$627,175,115
Restitution/Compensatory Damages*	972,433,406
Subtotal	\$1,599,608,521
Total Transferred to the Medicare Trust Funds	\$2,531,383,041
Restitution/Compensatory Damages to Federal Agencies	
TRICARE	\$28,458,032
HHS/OIG	11,274,490
Office of Personnel Management	6,803,485
Veterans Benefits Administration	4,819,453
Other Agencies	18,482,522
Subtotal	\$72,014,930
Centers for Medicare & Medicaid Services	
Federal Share of Medicaid	148,603,792
HHS/OIG Audit Disallowances: Recovered–Medicaid	578,933,010
Subtotal	\$727,536,802
Total	\$799,551,732
Relators' Payments**	\$254,579,804
GRAND TOTAL MONETARY RESULTS***	\$3,585,514,577

*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-third year of operation, the Secretary and the Attorney General certified \$294.3 million in mandatory funding as necessary for the Program, after accounting for mandatory sequester reductions of \$19.5 million as required by law. Additionally, Congress appropriated \$765 million in discretionary funding. See allocation by recipient below:

FY 2019 ALLOCATION OF HCFAC APPROPRIATION				
Organization	Mandatory Allocation⁵	Discretionary Allocation	Funds Sequestered	Total Allocation
Department of Health and Human Services				
Office of Inspector General	\$223,319,949	\$87,230,000	(\$12,939,025)	\$297,610,924
Office of the General Counsel	7,289,940	0	0	7,289,940
Administration for Community Living	0	18,000,000	0	18,000,000
Food and Drug Administration	5,959,166	0	0	5,959,166
Centers for Medicare & Medicaid Services	8,500,000	581,389,000	0	589,889,000
Unallocated Funding	3,540,110	0	(2,474,743)	1,065,367
Subtotal	\$248,609,165	\$686,619,000	(\$15,413,768)	\$919,814,397
Department of Justice				
United States Attorneys	\$29,851,009	\$27,000,000	\$0	\$56,851,009
Civil Division ⁶	19,101,188	21,935,740	0	41,036,928
Criminal Division	10,150,000	21,972,450	0	32,122,450
Civil Rights Division	1,891,937	2,599,133	0	4,491,070
Justice Management Division	125,942		0	125,942
Federal Bureau of Investigation	0	4,375,621	0	4,375,621
Office of the Inspector General	0	498,056	0	498,056
Unallocated Funding	4,039,919	0	(4,039,919)	0
Subtotal	\$65,159,995	\$78,381,000	(\$4,039,919)	\$139,501,076
TOTAL⁷	\$313,769,160	\$765,000,000	(\$19,453,687)	\$1,059,315,473

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

⁶ The Elder Justice Initiative, managed by the Civil Division, is included in the Civil Division figures.

⁷ 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 \$2.6 billion in judgments and settlements and attained additional administrative impositions in health care fraud cases and proceedings. As a result of these efforts, as well as those of preceding years, approximately \$3.6 billion was returned to the Federal Government or private persons. Of this \$3.6 billion, the Medicare Trust Funds received transfers of approximately \$2.5 billion during this period; another \$148.6 million in Federal Medicaid money was transferred to the Treasury separately due to these efforts.⁸

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

The return on investment (ROI) for the HCFAC program over the last three years (2017–2019) is \$4.2 returned for every \$1.00 expended.⁹ 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 Strike Force teams are a key component of HEAT. The mission of HEAT is:

⁸ Note that some of the judgments, settlements, and administrative actions that occurred in FY 2019 will result in transfers in future years, just as some of the transfers in FY 2019 are attributable to actions from prior years

⁹ The three-year average ROI includes a downward adjustment to the savings assumed in the FY 2017 Report on HCFAC Recoveries. The FY 2017 HHS-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) was \$4.1 returned for every \$1.00 expended.

- **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 the government 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 its 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 12 Federal judicial districts to participate in the program. In August 2018, DOJ and HHS added two additional Strike Forces in Newark and Philadelphia to combat health care fraud and illegal opioid prescriptions. In October 2018, the Attorney General announced the launch of the Appalachian Regional Prescription Opioid (ARPO) Strike Force 8. ARPO operates in 10 Federal judicial districts in Alabama, Kentucky, Ohio, Tennessee, Virginia, and West Virginia. Its goal is to investigate and charge medical professionals with the illegal prescription of opioids. A year later, in August 2019, Assistant Attorney General Brian Benczkowski announced the creation of the Rio Grande Valley/San Antonio Strike Force, in partnership with the Southern and Western Districts of Texas. Like other Strike Forces, the Rio Grande Valley/San Antonio Strike Force will utilize data analytics and other investigative techniques to identify and prosecute health care fraud in the region. HEAT activities have also expanded to include significant involvement from State Medicaid Fraud Control Units (MFCUs), which play a critical role in the many fraud cases involving both Medicare and Medicaid. A total of 30 MFCUs participated in both the 2017 and 2018 National Health Care Fraud Takedowns and four MFCUs participated in the 2019 ARPO Surge Takedown. Strike Force efforts also led to nine takedowns conducted in August/September 2019 involving opioids, health care fraud, medical professionals, telemedicine, and compounding pharmacies. A total of 12 MFCUs participated in the nine takedowns conducted in August/September 2019.

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, HHS-OIG compliance program guidance documents and trainings for providers, ongoing 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. Moreover, HHS-OIG offers a Compliance Resource Portal on its website, which includes special fraud alerts, videos, and other resources directed at various segments of the health care industry. 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 2019, more than 300 prosecutors and law enforcement agents attended the program. Prescription opioid fraud and abuse training was also provided to the USAO community and DOJ agency partners during the fiscal year.

Health Care Fraud Prevention Partnership (HFPP)

The Health Care 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 144 public, private, and state partner organizations at the end of FY 2019. Collectively, these organizations represent more than 215 million covered lives, equivalent to more than 3 in 4 insured Americans. Thirty-four of the current partners are actively submitting claim level data, representing 100 million individuals, or more than 1 in 3 insured Americans.

The HFPP commenced or completed studies using multiple partners' data to address fraud, waste and abuse in FY 2019, providing partners with detailed results that can be used for corrective actions within their organizations. The HFPP continued its efforts to foster collaboration among partners by hosting 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 in the CMS section for more information on HFPP activities.

Strike Forces

The first 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 inter-agency 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, DOJ and HHS now operate 15 Health Care Fraud and Prescription Opioid Strike Forces in 24 districts across the United States, including Los Angeles, California; Miami and Tampa/Orlando, Florida; Chicago, Illinois; Ft. Mitchell, Kentucky; Baton Rouge and New Orleans, Louisiana; Detroit, Michigan; Brooklyn, New York; Newark, New Jersey/Philadelphia, Pennsylvania; Nashville, Tennessee; and Houston, San Antonio, and Dallas, Texas; along with a Corporate Strike Force located in Washington, D.C. In FY2019, the Strike Force program expanded to include the Appalachian Regional Prescription Opioid (ARPO) Strike Force, a joint effort between DOJ, HHS, FBI, DEA, and state law enforcement to combat health care fraud and the opioid epidemic. The ARPO Strike Force is based in two hubs, Ft. Mitchell, Kentucky and Nashville, Tennessee, and originally covered nine federal districts. Following the first ARPO takedown in April 2019, ARPO was expanded to include a tenth district—the Western District of Virginia. In August 2019, Assistant Attorney General Brian Benczkowski announced the creation of the Rio Grande Valley/San Antonio Strike Force, in partnership with the Southern and Western Districts of Texas. Strike Force activities have also expanded to include significant involvement from State MFCUs, which play a critical role in the many fraud cases involving both Medicare and Medicaid.

Each 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, including USAO accomplishments, during FY 2019 included:¹⁰

- Filing 359 indictments, informations and complaints involving charges against 673 defendants who allegedly billed federal health care programs more than \$5.1 billion;
- Obtaining 323 guilty pleas negotiated and 33 jury trials litigated, with guilty verdicts against 35 defendants; and
- Securing imprisonment for 340 defendants sentenced, averaging nearly 49 months of incarceration.

Since its inception, Strike Force prosecutors filed more than 1,920 cases charging more than 4,200 defendants who collectively billed the Medicare program approximately \$19.1 billion; 2,800 defendants pleaded guilty and 361 others were convicted in jury trials; and 2,587 defendants were sentenced to imprisonment for an average term of approximately 51 months. Medicare payment trends demonstrate the positive impact of Strike Force enforcement and prevention efforts.

Increased outreach and coordination by Strike Force partners at the national, regional, state, and local levels is another positive measure that reflects the overall impact of the HCFAC program. In April, the ARPO Strike Force Takedown involved 60 charged defendants, including 53 medical professionals, and over 32 million pills, across 11 federal districts. To ensure patients impacted by law enforcement operations maintained continuity of care, this Takedown

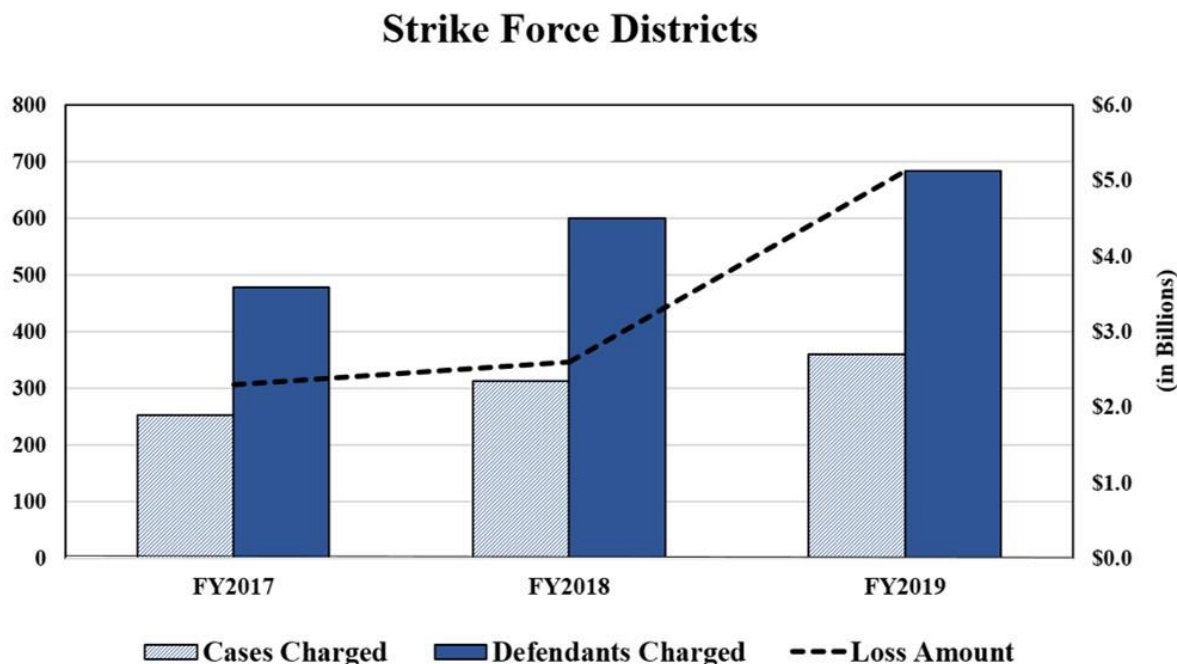
¹⁰ The summary statistics in this document exclude sealed cases.

coordinated an unprecedented public health response, led by the Criminal Division, in partnership with the DEA, HHS-OIG, HHS' Substance Abuse and Mental Health Services Administration (SAMHSA), Centers for Disease Control and Prevention (CDC), and all impacted State Departments of Health. In FY 2019, the Fraud Section's Health Care Fraud Data Analytics Team completed 2,383 data analysis requests in 59 federal districts.

In FY 2019, Strike Forces successfully completed 11 coordinated law enforcement actions.

- On April 9, 2019, 24 defendants, including the CEOs, COOs and others associated with five telemedicine companies, the owners of dozens of durable medical equipment (DME) companies and three licensed medical professionals, were charged in a Telemedicine and DME scheme involving over \$1.2 billion in losses.
- On April 17, 2019, the ARPO Strike Force led its first takedown, resulting in charges against 60 defendants, including 53 licensed medical professionals across 11 federal districts.
- On September 27, 2019, charges involving fraudulent genetic testing were brought against 35 individuals responsible for over \$2.1 billion in losses in one of the largest health care fraud schemes ever charged. Among those charged were 10 medical professionals, including nine doctors.
- From August 28 to September 27, 2019, eight regional takedowns were carried out. These regional takedowns resulted in charges against over 345 individuals who allegedly billed federal health care programs for more than \$1 billion and allegedly prescribed/dispensed approximately 50 million controlled substance pills in Houston, across Texas, the West Coast, the Gulf Coast, the Northeast, Florida and Georgia, and the Midwest. Charges include those against 105 defendants for opioid-related offenses.

The following chart shows the Strike Force trends from FY 2017 to FY 2019¹¹:



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 Assistant U.S. Attorneys (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.

¹¹ Loss Amount is defined as the total that federal health care programs, including Medicare, Medicaid, and VA, were allegedly billed in indicted cases.

Highlights of Significant Criminal and Civil Investigations

Our respective Departments successfully pursued 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 May 2019, the owner of Your Health EMS in Texas pleaded guilty to conspiracy to commit health care fraud and was sentenced to five years and three months in prison and ordered to pay \$1.3 million in restitution. The individual knowingly and falsely billed Medicare and Medicaid for non-eligible transports. Specifically, the individual submitted claims for individual ambulance transports, when in fact, multiple patients were being transported via one ambulance. Moreover, Your Health submitted claims for transporting Medicare patients unauthorized via an ambulance to Partial Hospitalization Programs at various facilities. The individual also billed Medicare for ambulance transportation services when there was no medical necessity. As a result, Your Health falsely billed Medicare for approximately \$2.8 million in ambulance transports and was reimbursed approximately \$1.0 million by Medicare.

In July 2019, Unicare Ambulance LLC and PA Paramedics LLC, d/b/a EasternCare Ambulance, and their owners, agreed to a judgment against them jointly and severally in the amount of \$459,907 to resolve allegations made by the United States in the Eastern District of Pennsylvania that they made repeated false statements to state and federal officials. As part of the settlement, each defendant has also agreed to a term of exclusion of not less than five years from all federal health care programs. According to the allegations in the complaint filed in U.S. District Court, the defendants individually or collectively made repeated false statements, from September 2015 through August 2016, in order to avoid overpayment debts to the United States' Medicare program and to hide the fact that one of the owner's state paramedic license had previously been suspended because he had admitted to forging a physician's signature.

Clinics

In October 2018, Vascular Access Centers L.P., along with its 23 subsidiary and related corporations (collectively "VAC"), agreed to pay at least \$3.8 million and up to \$18.3 million over five years, to resolve civil FCA allegations that it billed Medicare for non-reimbursable vascular access procedures performed on End Stage Renal Disease (ESRD) beneficiaries and engaged in an alleged kickback scheme related to referrals for such procedures. The government alleged that VAC billed Medicare for vascular access surgical procedures performed on ESRD beneficiaries, including fistulagrams and percutaneous transluminal angioplasties, without all of the required medical documentation supporting the necessity of the procedures. The government also alleged that VAC submitted false claims to Medicare for services that resulted from referrals that VAC had induced through improper remuneration to physician investors and medical directors, in violation of the Anti-Kickback Statute. As part of the resolution, VAC entered into a five-year Corporate Integrity Agreement (CIA) with HHS-OIG.

In October 2018, three community mental health clinics and their two owners entered into a consent judgment in the Eastern District of Pennsylvania as part of a settlement resolving a

health care fraud lawsuit. One of the owners had been convicted of Medicaid fraud in 2000 by the Commonwealth of Pennsylvania. As a result, he was excluded from participating in all federally funded health care programs, including Medicaid and Medicare. The exclusion prohibited him from owning, managing, or receiving payments from any federally funded health care provider. The United States alleged in the lawsuit that in spite of his exclusion, the owner, assisted by his wife, continued to own and operate two clinics in Pennsylvania, and that he started a third clinic in North Carolina while his exclusion was ongoing in 2009.

In November 2018, the owner of a pain management clinic pleaded guilty to operating a pill mill that illegally distributed over 600,000 oxycodone pills. The defendant had twice previously surrendered his medical license, both times admitting to creating a substantial risk to public health by engaging in wrongful prescribing practices for opiates, including oxycodone, oxymorphone, hydrocodone, and hydromorphone. Upon surrendering his license in the second time, the defendant founded a clinic that operated out of the same office, had the same employees, and the same patients, as his former practice. The defendant admitted that between the clinic's 2013 founding and 2015, he caused the distribution of more than 600,000 pills containing oxycodone.

(SF) In November 2018, the owner of two clinics was sentenced to 160 months' imprisonment, followed by three years of supervised release, and was ordered to pay jointly and severally with her co-conspirators \$6.3 million in restitution and forfeiture. The defendant pleaded guilty to one count of conspiracy to commit health care fraud and one count of health care fraud. The individual submitted claims to Medicare for medically unnecessary services and for the payment of kickbacks. The defendant's three co-conspirators have been sentenced.

In December 2018, the owner and manager of 1st Class Sleep Diagnostic Center and 1st Class Medical in Virginia were convicted for conspiring to defraud Medicare, TRICARE, private insurance, and the Internal Revenue Services (IRS) of more than \$10 million. The owner formed the primary entities used to commit the crimes. The defendants directed their employees to solicit patients who were referred to the clinics for legitimate sleep studies for supplemental but medically unnecessary studies. To conceal the scheme, the owner, for example, instructed employees not to send study results to the patients' doctors, lied to patients about not having to pay copays or coinsurance, and cross-billed using different entities to get out-of-network payments for in-network services. The defendants also used the original referring doctors' names and identifying information on claims without their permission. The individuals were sentenced to a combined 9 years and 11 months in prison and were ordered to pay \$10.6 million in restitution, jointly and severally.

(SF) In April 2019, the owner of Sunshine Medical Care Group, a medical clinic in South Florida, was sentenced to 91 months in prison and ordered to pay \$2.5 million in restitution. The defendant submitted false and fraudulent claims to Medicare for medical services that were not provided or were not medically necessary. In addition, the defendant accepted kickbacks from several Miami-area home health agencies in exchange for providing prescriptions for Part A home health services that were not needed or were never provided.

(SF) In May 2019, a physician and co-owner of a pain management clinic was sentenced to 37 months in prison. The defendant fraudulently maximized reimbursements by billing Medicare and Blue Cross Blue Shield of Louisiana for office visits and minor surgical procedures actually provided in a single day, as if the services were provided on subsequent days, a practice commonly referred to as “unbundling.” To support the fraudulent billing, the physician, along with a billing manager, falsified the dates of minor surgical procedures in the treatment records.

In May 2019, CRC Health, LLC and Acadia Healthcare Corporation (its parent corporation) agreed to pay \$17 million to resolve civil FCA allegations of a billing scheme that defrauded Medicaid of \$8.5 million in West Virginia. The United States alleged that specified CRC outpatient drug treatment centers submitted claims to West Virginia Medicaid for moderate to high complexity urine drug tests as if they were performed by the CRC outpatient drug treatment centers when those centers did not have the proper laboratory certifications to perform that testing. The settlement represents the largest health care fraud settlement in the history of West Virginia. As part of the resolution, CRC and Acadia agreed to enter into a five-year CIA with HHS-OIG requiring that CRC and Acadia maintain a compliance program, implement a risk assessment, and hire an Independent Review Organization.

In July 2019, a part owner of several pain clinics pleaded guilty in the Eastern District of Tennessee to a Racketeering Influenced Corrupt Organization (RICO) conspiracy charge in connection with a large pill-mill prosecution involving illegal operation of pain clinics in Tennessee and Florida which prescribed vast quantities of opioids and generated revenues of over \$21 million. In pleading guilty, the defendant admitted that the pain clinics’ business model centered on providing opioid-based prescriptions to patients for profit by prescribing and/or dispensing powerful narcotics outside the scope of professional practice and not for a legitimate medical purpose. The defendant admitted that onsite clinic managers operated the clinics in such a way as to invite abuse by providers, employees, customers and drug traffickers and were aware that patients travelled long distances to illegally obtain controlled substances and requested prescriptions for large quantities of Schedule II Controlled Substances.

In August, 2019, a pain clinic owner and the medical director of the clinic were sentenced to 25 years and 21 years in prison, respectively, in the Eastern District of Kentucky. After a month-long trial earlier in 2019, a jury convicted the two men, along with another co-owner, of operating the clinic as a pill mill, and for money laundering related to proceeds from the clinic. The three men were responsible for the illicit distribution of more than 1.6 million oxycodone 30 mg pills, and hundreds of thousands of other narcotic pills and sedative pills, such as Xanax.

(SF) In August 2019, a doctor and clinic owner was sentenced to four years in prison in the Central District of California. The doctor was charged in 2015 with billing Medicare for medical equipment and services that were not medically necessary and often not provided. From January 2005 through May 2015, recruiters associated with the clinic traveled throughout the Southland looking for Medicare beneficiaries so that the doctor could write “medically unnecessary” prescriptions for medical supplies and home health services.

(SF) In September 2019, a defendant pled guilty to conspiracy to receive and pay health care kickbacks and conspiracy to defraud the IRS. In November 2019, one of his co-conspirators, the manager of the clinics, was convicted on all counts, following a two-week trial. These defendants were involved in a \$96 million money laundering and health care fraud kickback scheme, where doctors, physical and occupational therapists paid the defendant and his co-conspirators kickbacks via checks to shell companies. After laundering the funds, a portion of this cash was used to pay ambulance drivers/patient recruiters, who in turn paid kickbacks to beneficiaries to go to the clinics for purported treatment. The defendant and co-conspirators then filed false tax returns, omitting income from the checks written to their shell companies.

Dental

In November 2018, ImmediaDent of Indiana, LLC (ImmediaDent), which operates nine dental care practices in Indiana, and Kansas based Samson Dental Partners, LLC (SDP), which provides administrative support services to ImmediaDent, agreed to pay \$3.4 million to resolve civil FCA allegations that they improperly billed Indiana's Medicaid program for dental services. Both companies are alleged to have submitted false claims to Indiana's Medicaid program by (1) improperly billing simple tooth extractions as though they were surgical extractions and (2) improperly billing Scale and Root Planings (otherwise known as "deep cleanings") that were either not performed or not medically necessary. In addition to the federal recovery, ImmediaDent and SPD agreed to pay \$1.7 million to Indiana resolve their state Medicaid liability.

In April 2019, a defendant was sentenced to 24 months in prison in the Southern District of New York for committing health care fraud, conspiracy to commit health care fraud, and conspiracy to violate the anti-kickback statute. From in or around 2012 through at least November 2017, the defendant, who was not a licensed dentist, and others conspired and participated in a scheme to defraud insurance providers of more than \$2 million. The defendant and his coconspirators induced patients to be seen at a dental clinic on the Upper West Side of Manhattan by offering patients a \$25 cash kickback. Once the patients were in the door, the defendant and his coconspirators charged insurance companies for services that were never performed and for services performed by defendant that he was not licensed to perform.

In April 2019, a dentist agreed to pay \$75,000 in civil penalties to resolve allegations in the District of Minnesota that he issued illegitimate prescriptions for opioid medications and repeatedly failed to comply with the recordkeeping requirements of the Controlled Substances Act. According to the allegations in the complaint, the defendant unlawfully issued multiple prescriptions for Schedule II controlled substances, namely, oxycodone and hydrocodone, without a legitimate medical purpose. The complaint further alleges that the defendant failed to keep complete and accurate records regarding the receipt and dispensing of controlled substances used at his clinic. As a result of the defendant's alleged actions, hundreds of doses of controlled substances went unaccounted for and are presumed to have been diverted for illicit purposes.

In June 2019, a dentist was sentenced to 33 months in prison in the Middle District of Tennessee for operating a scheme to defraud health care benefit programs. The defendant owned and operated a dental practice with four locations. Between November 2013 and January 2018, the

defendant caused the submission of false and fraudulent claims to health care benefit programs, including Delta Dental, Cigna, TennCare and DentaQuest, TennCare's dental benefits program administrator. The fraudulent claims included billing for dental work that had not been completed or performed at all; falsifying dates of service to appear to comply with benefit programs' timeframe and preauthorization requirements; falsifying claims to appear that services had been rendered by a benefits program credentialed dentist; falsifying supporting documents and adding false narratives to support the upcoding of claims; and others, including continuing to submit false claims after being advised by insurance companies that audits had determined a pattern of false claims and that the Tennessee Bureau of Investigation was conducting a criminal investigation into the company's billing practices.

Device Companies

In November 2018, medical device manufacturer Covidien LP (Covidien) agreed to pay \$13 million to resolve civil FCA allegations that it paid kickbacks to induce the use of its Solitaire mechanical thrombectomy device. The government alleged that after receiving the U.S. Food and Drug Administration (FDA) clearance for the Solitaire device, Covidien launched a registry to pay hospitals and institutions to collect data about user experiences with the device. For about two years beginning in August 2014, Covidien paid a fee to hospitals and institutions that participated in a registry each time they used a new Solitaire device and reported certain clinical data about their practices for treating stroke patients to Covidien. Covidien solicited certain hospitals and institutions for the registry in order to convert their business from the competitor's product and/or persuade them to continue using Covidien products, and knowingly and willfully used the registry to increase device sales.

In December 2018, ev3 Inc., a device manufacturer based in Minnesota, agreed to plead guilty in the District of Massachusetts to charges related to the distribution of its neurovascular medical device, and pay \$17.9 million in fines and forfeiture. According to court documents, the device was approved by the FDA as a liquid embolization device that is surgically injected into blood vessels to block blood flow to arteriovenous malformations in the brain. The FDA has approved the device only for use inside the brain. Despite the FDA's limited approval of the device, from 2005 to 2009, sales representatives for the defendant encouraged surgeons to use the device in large quantities for unproven and potentially dangerous surgical uses outside the brain. The company's sales force continued to tout unapproved and potentially dangerous uses of the device even after FDA officials told ev3 executives in 2008 that they had specific safety concerns regarding uses of the device outside the brain.

In March 2019, medical device manufacturer Covidien LP (Covidien) agreed to pay \$17.5 million to resolve civil FCA allegations that it provided free or discounted practice development and market development support to physicians located in California and Florida to induce purchases of Covidien's vein ablation products in violation of the Anti-Kickback Statute. The government alleged that, from January 2011 through September 2014, Covidien provided customized marketing plans for specific vein practices; scheduled and conducted "lunch and learn" meetings and dinners with other physicians to drive referrals to specific vein practices; and provided substantial assistance to specific vein practices in connection with planning, promoting, and conducting vein screening events to cultivate new patients for those practices. In

addition to the federal recovery, Covidien agreed to pay an additional \$2.5 million to Florida and California to resolve state Medicaid liability.

In June 2019, ACell Inc. (ACell), a Maryland-based medical device manufacturer, pleaded guilty to a misdemeanor count of failure and refusal to report a medical removal, regarding its MicroMatrix powder wound dressing product in violation of the Food, Drug and Cosmetic Act (FDCA). Pursuant to a plea agreement, ACell admitted that it learned in January 2012 that more than 30,000 MicroMatrix devices were contaminated with endotoxin levels that posed a risk to patient health. Due to that health risk, ACell initiated a removal of certain sizes of MicroMatrix devices from the market which it did not report to the FDA. ACell also admitted that it concealed the reason for the product removal from doctors, hospitals, and the company's own sales force, and did not notify doctors who had already used MicroMatrix devices from the contaminated lots of the elevated endotoxin levels. Under the terms of the plea agreement, ACell agreed to pay a fine of \$3 million and abide by an agreement with the Department of Justice requiring ACell to enact extensive compliance reforms. ACell also agreed to pay \$12 million to resolve civil FCA allegations that it marketed MicroMatrix with false and misleading messages that MicroMatrix powder was safe and effective for both non-topical and internal use and paid kickbacks to induce prescribers to order ACell products.

In July 2019, a pain medicine doctor and his wife were indicted in the Eastern District of Missouri for purchasing non-FDA approved medical devices and smuggling them into the United States. The couple was also charged with health care fraud related to billing for the same devices, when they knew Medicare and Medicaid would not reimburse for the non-FDA approved devices. The doctor-defendant did not disclose to his patients that they were receiving treatment via a non-FDA approved device.

Diagnostic Services

In May 2019, two owners of diagnostic testing facilities each pleaded guilty in the Eastern District of New York to one count of health care fraud and one count of conspiracy to defraud the lawful functions of the IRS. The defendants, a married couple, were the co-owners of several diagnostic testing facilities. As part of their guilty pleas, the defendants admitted that they submitted fraudulent health care claims for diagnostic testing services. The defendants admitted that they paid approximately \$18.5 million in kickbacks for the referral of beneficiaries who submitted themselves to diagnostic testing and other purported medical services. The defendants falsely reported to the IRS that the illegal kickback payments were legitimate business expenses, which caused relevant tax forms to falsely under-report business income and claim deductions.

Drug Companies

In December 2018, Actelion Pharmaceuticals US, Inc. (Actelion), based in San Francisco, California, agreed to pay \$360 million to resolve civil FCA allegations that it illegally used a foundation, which claims 501(c)(3) status for tax purposes, as a conduit to pay the copays of thousands of Medicare patients taking Actelion's pulmonary arterial hypertension (PAH) drugs. From 2014 to 2015, Actelion donated to the foundation, which, in turn, used those donations to pay copays of patients prescribed the PAH drugs. The government alleged that Actelion

routinely obtained data from the foundation detailing how much the foundation had spent for patients on each drug; it then used this information to decide how much to donate to the foundation and to confirm that its contributions were sufficient to cover the copays of only patients taking Actelion's PAH drugs. The government also alleged that, meanwhile, Actelion had a policy of not permitting Medicare patients to participate in its free drug program, which was open to other financially needy patients, even if those Medicare patients could not afford their copays. Instead, to generate revenue from Medicare and induce purchases of the PAH drugs, the government alleged that Actelion referred such Medicare patients to the foundation, which allowed the patients copays to be paid and resulted in claims to Medicare for the remaining cost.

In April 2019, Astellas Pharma US Inc. (Astellas) agreed to pay \$100 million to resolve civil FCA allegations that it illegally used two foundations as conduits to pay the copays of thousands of Medicare patients taking Astellas's drug Xtandi, an androgen receptor inhibitor (ARI) used to treat certain prostate cancer. The government alleged that, in May 2013, Astellas asked two foundations about the creation of copay assistance funds to cover the copays for Medicare patients taking ARIs, but not for other types of prostate cancer drugs. In July 2013, both foundations opened ARI-only copay funds; Astellas was the sole donor to both funds. The government alleged that Astellas knew that Xtandi would likely account for the vast majority of utilization from each fund, and, in fact, Medicare patients taking Xtandi received nearly all of the copay assistance from the two ARI funds. As part of the resolution, Astellas entered into a five-year CIA that requires Astellas to implement measures, controls and monitoring designed to promote independence from any patient assistance program to which it donates.

In April 2019, three pharmaceutical companies in Massachusetts (Jazz Pharmaceuticals plc, Lundbeck LLC, and Alexion Pharmaceuticals Inc.) agreed to pay a total of \$122.6 million to resolve civil allegations that they each violated the FCA by illegally paying the Medicare or Civilian Health and Medical Program copays for their own products, through purportedly independent 501(c)(3) foundations that the companies used as mere conduits. The foundations operated funds that pay the copayments of certain patients, including Medicare patients. Jazz and Lundbeck each entered into a five-year CIAs in connection with its respective settlement.

In May 2019, the founder and four former executives of a pharmaceutical company were convicted in the District of Massachusetts in connection with bribing medical practitioners to prescribe a highly addictive sublingual fentanyl spray intended for cancer patients experiencing breakthrough pain, and for defrauding Medicare and private insurance carriers. Prior to the start of the trial, two other high-level executives with the company pleaded guilty and testified during the trial. From May 2012 to December 2015, the defendants conspired to bribe practitioners, many of whom operated pain clinics, in order to induce them to prescribe the company's fentanyl-based pain medication to patients often when medically unnecessary. The defendants used pharmacy data to identify practitioners who either prescribed unusually high volumes of rapid-onset opioids, or had demonstrated a capacity to do so, and bribed and provided kickbacks to the practitioners to increase the number of new prescriptions, and to increase the dosage and number of units of the medication. The defendants also measured the success of their criminal enterprise by comparing the net revenue earned from targeted practitioners with the total value of bribes and kickbacks paid. The defendants used this information to reduce or eliminate bribes

paid to practitioners who failed to meet satisfactory prescribing requirements, which they determined to be the net revenue equal to at least twice the amount of bribes paid to the practitioner.

In June 2019, Insys Therapeutics (Insys), based in Arizona, agreed to pay \$225 million to resolve criminal and civil liability relating to its marketing of the opioid drug Subsys. As part of the criminal resolution, Insys agreed to enter into a deferred prosecution agreement with the government, Insys's operating subsidiary agreed to plead guilty to five counts of mail fraud, and the company agreed to pay a \$2 million fine and \$28 million in forfeiture. Insys also agreed to pay \$195 million to settle civil FCA allegations that Insys paid kickbacks to induce physicians and nurse practitioners to prescribe Subsys for their patients. In addition to payments for sham speaker programs, the kickbacks also allegedly took the form of jobs for the prescribers' relatives and friends, and lavish meals and entertainment. The government also alleged that Insys improperly encouraged physicians to prescribe Subsys for patients who did not have cancer, and lied to insurers about patients' diagnoses in order to obtain reimbursement for Subsys prescriptions that had been written for Medicare and TRICARE beneficiaries. As part of the resolution, Insys entered into a five-year CIA and Conditional Exclusion Release with HHS-OIG that includes several novel provisions, such as enhanced material breach provisions.

In July 2019, Reckitt Benckiser Group plc (RB Group) agreed to pay \$1.4 billion to resolve criminal and civil liability related to the marketing of the opioid addiction treatment drug Suboxone, which is a formulation of buprenorphine. Until December 2014, RB Group's wholly owned subsidiary, Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals, Inc.), marketed and sold Suboxone throughout the United States. To resolve criminal allegations regarding Indivior's promotional conduct, RB Group executed a non-prosecution agreement that requires the company to forfeit \$647 million in proceeds and not to manufacture, market, or sell Schedule I, II, or III controlled substances in the United States for three years. RB Group also agreed to pay \$500 million to the United States to resolve civil FCA allegations that, from 2010 through 2014, RB Group directly or through its subsidiaries knowingly: (a) promoted the sale and use of Suboxone to physicians who were writing prescriptions without any counseling and for uses that were unsafe, ineffective, and medically unnecessary; (b) promoted Suboxone Film to physicians and state Medicaid agencies with false and misleading claims that it was less susceptible to diversion, abuse, and accidental pediatric exposure than other buprenorphine products; and (c) took steps to delay the entry of generic competition for Suboxone in order to improperly control pricing of Suboxone. In addition to the federal recovery, RB Group agreed to pay up to \$200 million to resolve state Medicaid liability and \$50 million to resolve claims that it engaged in unfair methods of competition in violation of the Federal Trade Commission Act.

In September 2019, Avanir Pharmaceuticals (Avanir), a pharmaceutical manufacturer based in Aliso Viejo, California, was charged for paying kickbacks to a physician to induce prescriptions of its drug Nuedexta. To resolve the one-count indictment, Avanir agreed to a deferred prosecution agreement, under which Avanir admits that it paid the doctor to induce him to not only maintain but increase his prescription volume. Under the agreement's terms, Avanir will pay a monetary penalty in the amount of \$7.8 million, and a forfeiture in the amount of \$5 million. The United States will defer prosecuting Avanir for a period of three years to allow the company to comply with the agreement's terms. Avanir also agreed to pay \$95.8 million to

resolve civil FCA allegations that it paid kickbacks to induce prescriptions and engaged in false and misleading marketing of Nuedexta to providers in long-term care facilities to induce them to prescribe it for behaviors commonly associated with dementia patients, which is not an approved use of the drug. In addition to the federal recovery, Avanir agreed to pay an additional \$7 million to resolve state Medicaid claims. As part of the resolution, Avanir entered into a five-year CIA that requires Avanir to implement additional controls around its interactions with physicians and conduct internal and external monitoring of promotional and other activities. It also increases individual accountability by requiring compliance-related certifications from its Board and key executives.

Drug Distributor

In January 2019, a medical company executive was sentenced in the Eastern District of Virginia to 26 months in prison for conspiring to smuggle misbranded pharmaceuticals into the United States and for the unlicensed wholesale distribution of prescription drugs. According to court documents, the defendant instructed subordinates to smuggle misbranded prescription drugs and devices into the United States, including oncology drugs, orthopedic injections, and cosmetic devices. These products were not approved by the FDA and did not contain the labels, warnings, and instructions required by the FDA. In order to smuggle these products into the United States, employees used false names and false customs forms, and broke large shipments into multiple smaller shipments. At the defendant's direction, co-conspirators in the United States stored the products in their private residences, often in violation of safety regulations requiring the pharmaceuticals to be stored at cool temperatures.

Durable Medical Equipment (DME)

In April 2019, the former CEO of a pain management company was found guilty for his role in an illegal kickback scheme involving approximately \$4 million in tainted DME claims to Medicare. According to evidence presented at trial, the defendant abused his position as CEO of the pain management company to arrange for referrals of Medicare DME orders to a co-conspirator. Evidence showed that the defendant operated a shell company, which he had registered in the name of his wife. Despite having no involvement with the shell company and performing no work, the shell company received over \$770,000 in illegal kickbacks. Together, the defendant and his co-conspirator pocketed over \$2.4 million dollars in improper reimbursement from Medicare. The defendant used funds from his company to pay bonuses to providers who ordered DME for Medicare beneficiaries and referred those orders to his co-conspirator.

(SF) In January 2019, a former owner and CEO of a Tennessee-based DME company, pled guilty for her role in a \$4.6 million kickback scheme. Charges stem from an agreement by which the defendant paid a physician 60 percent of all Medicare proceeds earned from billings of Medicare DME orders referred by providers from the physician's practice, a 12-state, 60-office pain management provider. The physician obstructed efforts from his Board and employees to obtain Medicare DME billing numbers for each office and instructed them that the defendant's DME company was the exclusive Medicare DME provider for the entire practice. In August 2019, the defendant was sentenced to 42 months in prison and ordered to forfeit approximately \$600,000.

In May 2019, the CEO of a string of DME companies based in Savannah, Georgia, was sentenced to 3 years and 4 months in prison for his role in a scheme that defrauded Medicare out of millions of dollars and was ordered to pay more than \$1.9 million in restitution. The CEO oversaw a multi-year scheme resulting in nearly \$10 million in billed Medicare claims. Working with others, the CEO operated a network that paid kickbacks to obtain patient information, specifically that of Medicare patients. Using a third-party biller, the CEO would then bill Part B and Part C plans for medically unnecessary medical equipment and orthotics, including a variety of back and knee braces that were not ordered as medically necessary by a physician. The CEO also billed for equipment not provided and utilized sales representatives to promote equipment to Medicare patients. Agents determined the CEO and his affiliates were linked to the larger nationwide scheme known as “Operation Brace Yourself” (described in more detail in the HHS-OIG section of this report.) The CEO is the first defendant sentenced under the ongoing investigation.

Electronic Health Records

In February 2019, Greenway Health LLC (Greenway), a Tampa, Florida-based developer of electronic health records (EHR) software, agreed to pay \$57.2 million to resolve civil FCA allegations that Greenway caused its users to submit false claims to the government by misrepresenting the capabilities of its EHR product “Prime Suite” and providing unlawful remuneration to users to induce them to recommend Prime Suite. The government contended that Greenway falsely obtained a certification for Prime Suite when it concealed from its certifying entity that Prime Suite did not fully comply with the requirements for certification. Among other things, Greenway’s product did not incorporate the standardized clinical terminology necessary to ensure the reciprocal flow of information concerning patients and the accuracy of electronic prescriptions. The government further alleged that a version of Prime Suite caused users to falsely attest that they were eligible for EHR incentive payments when, in fact, they had not met all necessary use requirements. The government also alleged that Greenway violated the Anti-Kickback Statute by paying money and incentives to its client providers to recommend Prime Suite to prospective new customers. As part of the resolution, Greenway entered into a five-year CIA with HHS-OIG requiring, among other things, that Greenway retain an Independent Review Organization to assess Greenway’s compliance systems and to review arrangements with health care providers.

Home Health Providers

(SF) In October 2018, two home health agency (HHA) owners near Detroit, Michigan, were sentenced to a total of 16 years in prison for their roles in a Medicare fraud scheme by billing for home health services that were never provided. The owners were ordered to pay restitution of \$9.6 million and \$4.4 million, respectively, jointly and severally with their co-conspirators. The defendants each pleaded guilty to conspiracy to commit health care fraud and wire fraud and conspiracy to pay and receive health care kickbacks; they admitted that they paid illegal kickbacks in exchange for the referral of Medicare beneficiaries to HHAs that they owned. Between 2009 and 2017, they also submitted false Medicare claims for home health services that were never provided. The individuals were charged along with three other individuals. Two individuals pleaded guilty and are pending sentencing; one remains a fugitive.

(SF) In January 2019, the owner and operator of Amex Medical Clinic and a doctor in Texas were convicted of charges resulting from their involvement in a Medicare fraud scheme. From about December 2011 through about August 2015, the individuals conspired to defraud Medicare out of payments for medical services. The owner sold medical orders and other documents signed by the doctor to HHAs in and around Houston. In these medical orders, the doctor falsely certified information about the patient's medical condition and need for home health services. Co-conspirators at HHAs then used the false paperwork to bill to, and receive payment from, Medicare for services that were not medically necessary or not provided. The owner also caused Amex to bill Medicare for purported physician services that were actually provided by an unlicensed practitioner, if at all. The individuals were sentenced to a combined 55 years in prison and ordered to pay up to \$26.7 million in restitution, jointly and severally.

In April 2019, a former medical doctor and his business partner were each sentenced to 33 months in prison in the District of Nevada for their roles in a \$7.1 million Medicare health care fraud scheme that occurred at three Las Vegas hospice and home health care agencies. The defendants filed false enrollment documents with Medicare to enable the former doctor to operate hospice and home care agencies through nominees despite his prior exclusion from all federal health care programs. Furthermore, they submitted fraudulent hospice care claims for people who were not terminally ill and did not require hospice care.

(SF) In April 2019, the owner of two home health agencies, Exceptional Home Health and Mobility Home Health Care, was sentenced to 84 months in prison and ordered to pay \$8.3 million in restitution, following a May 2018 guilty plea. The charges stem from the defendant's role in a fraud scheme involving illegal kickbacks for Medicare beneficiary referrals and the provision of medically unnecessary services not eligible for reimbursement. Medicare paid approximately \$8.3 million for claims submitted by the defendant's home health agencies.

(SF) In April 2019, the former co-owner of Elder Care Home Health Care Services, a now-defunct home health company located in Garland, Texas, was sentenced to 188 months in prison after an October 2018 conviction. The charges stem from the defendant's involvement in an approximately \$3.5 million home health fraud scheme. Three co-defendants also were sentenced to 97, 85, and 60 months in prison.

(SF) In May 2019, a patient recruiter for multiple Houston-area home health agencies and owner of Circuit Wide, was sentenced to 188 months in prison, followed by three years of supervised release, and was ordered to pay \$12.9 million in restitution. The charges stem from a \$20 million scheme to pay illegal health care kickbacks to physicians and Medicare beneficiaries in order to fraudulently bill for medically unnecessary home health services, and to launder the proceeds. In April 2019, a nurse was sentenced to 120 months for her involvement in a related case.

(SF) In September 2019, the former owner Hexagon Home Healthcare, was sentenced to 36 months in prison, after her March 2019 convictions at trial on ten counts, including conspiracy to commit health care fraud, conspiracy to pay and receive kickbacks, and visa fraud. The defendant's company fraudulently billed Medicare approximately \$3 million.

Hospice Care

In October 2018, the owner and operator of a series of hospice organizations pled guilty to hospice fraud in the Northern District of Mississippi. The Defendant admitted that she fraudulently submitted claims to Medicare and Medicaid for hospice services that were not medically necessary or that were not provided to the hospice patients as claimed. She further admitted that she illegally recruited patients who were not hospice eligible. The Government alleged at the change of plea hearing that the defendant submitted more than \$11 million in fraudulent claims to Medicare and more than \$2 million in fraudulent claims to Medicaid.

In December 2018, SouthernCare, Inc. in Pennsylvania entered into a FCA settlement agreement to resolve allegations that, between January 2009 and December 2014, it submitted false claims to Medicare for certain patients at SouthernCare's Pennsylvania offices when the patients did not meet applicable Medicare eligibility requirements or documentation for the hospice benefit was not satisfied. SouthernCare agreed to pay over \$5.8 million to resolve its alleged liability.

Hospitals and Health Systems

In November 2018, a Health Management Associates, Inc. (HMA) subsidiary, Carlisle HMA, LLC pled guilty to conspiracy to commit health care fraud in Tennessee. Up until 2017, Carlisle operated an acute care hospital in Carlisle, Pennsylvania. In September 2018, HMA entered into a three-year Non-Prosecution Agreement (NPA) with the DOJ's Criminal Division 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 (ED) patient admissions regardless of the medical necessity. 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 NPA terms, HMA will pay a \$35 million monetary penalty and a criminal fine of \$2.5 million. Community Health Systems, Inc, HMA's parent company, also agreed to cooperate with the investigation, report allegations of evidence of violations of Federal health care offenses, and ensure that its compliance and ethics program satisfies the requirements of an amended and extended CIA between Commonwealth and HHS-OIG. This is part of a global resolution, including eight FCA cases filed against HMA, and included a civil resolution where HMA agreed to pay over \$261 million to resolve these matters.

In February 2019, Union General Hospital agreed to pay \$5 million to resolve civil FCA allegations in the Northern District of Georgia engaged in improper financial relationships with referring physicians. The settlement resolved allegations that the hospital engaged in several different improper financial relationships with physicians between 2012 and 2016, in violation of the Stark Law, which forbids hospitals from billing Medicare for certain services referred by physicians who have a financial relationship with the hospital unless the relationship falls within a defined exception. The United States alleged that the relationships the hospital had with certain physicians were prohibited because the hospital compensated the physicians in amounts that were above or inconsistent with fair market value or in a manner that took into account the volume or value of the physicians' referrals.

In February 2019, a hospital owner and a doctor were convicted of conspiracy to commit health care fraud, 17 counts of health care fraud, and three counts of money laundering. During trial, the jury heard evidence that the two defendants unlawfully enriched themselves by submitting false and fraudulent claims for medical tests that were not medically necessary, not provided or both and then billed at the hospital at a higher reimbursement rate. The hospital owner also instructed his employees to falsely bill the medical services at the hospital and other associated entities, when, in fact, the patients never received services from the hospital and the other entities.

In March 2019, MedStar Health Inc. (MedStar) in Columbia, Maryland, MedStar Union Memorial Hospital, and MedStar Franklin Square Medical Center agreed to pay \$35 million to resolve civil FCA allegations that MedStar paid kickbacks to MidAtlantic Cardiovascular Associates (MACVA), a cardiology group based in Pikesville, Maryland, in exchange for referrals, through a series of professional services contracts at Union Memorial and Franklin Square Hospitals in Baltimore. The government alleged that Medstar paid kickbacks to MACVA under the guise of professional services agreements, in return for MACVA's referrals to Union Memorial of lucrative cardiovascular procedures, including cardiac surgery and interventional cardiology procedures, from January 1, 2006, through July 31, 2011. The settlement also resolved allegations that MedStar received Medicare payments from Jan. 1, 2006, through December 28, 2012, for medically unnecessary stents performed by a doctor employed by MACVA who was later employed by MedStar.

In July 2019, Eagleville Hospital agreed to pay \$2.85 million to resolve civil FCA allegations in the Eastern District of Pennsylvania that, from January 2011 through December 2018, it had submitted claims to Medicare, Medicaid, and the Federal Employees Health Benefits Program ("FEHBP") for hospital-level detoxification treatment services when the patients were ineligible for admission to receive such services or lacked documentation to support the claims. In his qui tam complaint, the whistleblower alleged that the hospital admitted certain groups of its substance use disorder treatment patients for the higher-reimbursing hospital-level detoxification treatment, rather than the residential-level treatment, without satisfying the medical necessity requirements to do so. The whistleblower alleged that this practice resulted in false claims to Medicare, Medicaid, and FEHBP.

(SF) In September 2019, a hospital administrator at Atrium Medical Center and Pristine Healthcare, was sentenced to 120 months in prison and ordered to pay \$6.3 million in restitution, for his role in a \$16.9 million Medicare fraud scheme. The defendant and his co-conspirators paid and received kickbacks and bribes in exchange for the referral of Medicare beneficiaries, who did not meet the Medicare qualifications for or need partial hospitalization program (PHP) services. PHP is a form of intensive outpatient treatment for severe mental illness.

Identity Theft

In October 2018, a man pled guilty in the Southern District of Florida to one count of money laundering in connection with a fraud scheme that ran from 2013 through 2015. During this period, the defendant caused the cashing of checks that were the proceeds of fraudulent activity, including identity-theft tax refund fraud, health care fraud, and mortgage fraud. On numerous

occasions, the defendant cashed individual fraudulent Medicare checks exceeding \$200,000 and individual U.S. Treasury tax refund checks exceeding \$150,000. The defendant knew that the checks had been obtained from fraudulent activity and, on occasion, knowingly accepted fake identification documents.

In August 2019, a doctor pled guilty in the Northern District of New York to conspiring to distribute controlled substances, health care fraud, aggravated identity theft, and obstruction of justice. As part of her guilty plea, the defendant, an obstetrician-gynecologist, admitted that between 2015 and 2017, she wrote numerous prescriptions for oxycodone, morphine, and hydromorphone to third parties, for no legitimate medical purpose, and then instructed a co-conspirator to fill those prescriptions by impersonating the named patients at pharmacies, knowing that health care benefit programs would pay the cost of the drugs. In pleading guilty, the defendant also admitted that she attempted to obstruct the federal investigation into her activities by instructing a co-conspirator to falsely testify before a federal grand jury that she (the defendant) was the subject of extortion. As the defendant admitted in her guilty plea, she was not the subject of an extortionate scheme, and was a willing member of the conspiracy to distribute opioids for no legitimate medical purpose. The defendant further admitted that she had agreed to pay her co-conspirator for false testimony in the hope of minimizing her criminal exposure and keeping her medical license.

Laboratories

In December 2018, GenomeDx Biosciences Corp, a genetic testing company headquartered in Vancouver, British Columbia, agreed to pay just under \$2 million to resolve civil FCA allegations in the Southern District of California that it had submitted improper claims to Medicare for a post-operative genetic test for prostate cancer patients. The United States alleged that the company had knowingly submitted claims for the Decipher test to Medicare between September 2015 and June 2017 that were not medically reasonable and necessary because the prostate cancer patients did not have risk factors necessitating the test, including pathological stage T2 disease with a positive surgical margin, pathological stage T3 disease or rising Prostate-Specific Antigen (PSA”) levels after an initial PSA nadir.

In January 2019, pathology laboratory company Inform Diagnostics, formerly known as Miraca Life Sciences Inc., which is headquartered in Irving, Texas, agreed to pay \$63.5 million to resolve civil FCA allegations that it engaged in improper financial relationships with referring physicians. The government alleged that the company violated the Anti-Kickback Statute and the Stark Law by providing to referring physicians’ subsidies for electronic health records (EHR) systems and free or discounted technology consulting services. Although regulations adopted by HHS in 2006 included provisions that allowed laboratories to provide EHR donations to physicians under certain conditions, the United States alleged that the defendant violated those conditions. HHS withdrew those exemptions for laboratories in 2013.

In June 2019, a doctor agreed to pay more than \$900,000 to resolve civil FCA allegations in the Western District of Pennsylvania that he received improper payments for making referrals to a drug testing laboratory, and caused false claims to be submitted to Medicare for drug testing services. The United States alleged that the lab paid the doctor to refer patients to the lab for

drug tests; the lab then submitted claims to Medicare for the drug testing services. The United States alleged that the financial arrangement between the doctor and the lab violated the physician self-referral law, commonly known as the Stark Law, and the Anti-Kickback Statute.

In July 2019, the owner of two medical laboratories was sentenced to 30 months in prison in the Eastern District of Missouri for conspiracy to commit health care fraud and to pay illegal kickbacks for health care services. The defendant paid illegal kickbacks to “marketers” for urine and saliva specimens sent to the labs for testing. In some instances, doctors’ names were used on orders for the tests, although the doctors had never seen or evaluated the patients and did not know their names were being used on the orders. During the conspiracy, many disabled and elderly patients living in residential care facilities were repeatedly subjected to medically unnecessary testing. The defendant usually paid the marketers \$150–\$200 for each specimen that Medicare and Medicaid paid for testing.

Managed Care

In April 2019, Sutter Health LLC, a California-based health care services provider, and several affiliated entities, Sutter East Bay Medical Foundation, Sutter Pacific Medical Foundation, Sutter Gould Medical Foundation, and Sutter Medical Foundation (“Sutter”), agreed to pay \$30 million to resolve allegations that the affiliated entities submitted inaccurate information about the health status of beneficiaries enrolled in Medicare Advantage Organization (MAO) plans, which resulted in the plans and providers being overpaid. The government alleged that Sutter and its affiliates submitted unsupported diagnosis codes for certain patient encounters of beneficiaries under their care. These unsupported diagnosis scores inflated the risk scores of these beneficiaries, resulting in the MAO plans being overpaid.

In July 2019, Beaver Medical Group L.P. (Beaver), which is headquartered in Redlands, California, and one of its physicians agreed to pay \$5.1 million to resolve civil FCA allegations that they reported invalid diagnoses to Medicare Advantage plans and thereby caused those plans to receive inflated payments from Medicare.

Medical Devices

In October 2018, a doctor in Kentucky was found guilty of health care fraud and sentenced to three years and six months in prison and ordered to pay \$257,515 in restitution. The doctor defrauded Medicare, Medicaid, and other insurers by implanting medically unnecessary pacemakers in patients and causing unnecessary procedures and follow-up care to be billed to health insurance programs. Between 2007 and 2011, the doctor implanted approximately 234 pacemakers in patients at St. Joseph London hospital. Dozens of those patients’ pacemakers were medically unnecessary under well-established national guidelines and Medicare coverage rules. Several patients testified that the doctor pressured them into getting the procedures and told them misleading information about their health conditions.

Nursing Homes and Facilities

In January 2019, Conway Lakes NC, LLC, a skilled nursing facility in Orlando, Florida, a physician, and related providers agreed to pay \$1.5 million to resolve civil FCA allegations in

the Middle District of Florida that they engaged in a kickback scheme related to the referral of Medicare and TRICARE patients. The United States alleged that the skilled nursing facility and its managers conspired to pay the physician under a sham “medical director” agreement to induce him to illegally refer Medicare and TRICARE patients to the facility for rehabilitation services that were billed to the United States.

In February 2019, Vanguard Healthcare LLC, and related Vanguard companies (Vanguard) agreed to pay more than \$18 million in allowed claims to resolve a civil FCA lawsuit brought by the United States and the State of Tennessee for billing the Medicare and Medicaid programs for grossly substandard nursing home services. Vanguard’s CEO and former director of operations also agreed to pay \$250,000 to resolve allegations against them. The United States and Tennessee alleged that the five Vanguard nursing facilities failed to administer medications as prescribed; failed to provide standard infection control; failed to provide wound care as ordered; failed to take prophylactic measures to prevent pressure ulcers; used unnecessary physical restraints on residents; and failed to meet resident’s basic nutrition and hygiene requirements. The lawsuit further alleged that the defendants were responsible for the submission of hundreds of preadmission forms by these facilities to Tennessee’s Medicaid Program, which contained forged nurse or physician signatures. As part of the resolution, Vanguard agreed to enter into a five-year, chain-wide, quality of care CIA with HHS-OIG.

In February 2019, Tennessee Health Management, Inc., a skilled nursing facility management company, agreed to pay more than \$9.7 million to resolve civil FCA allegations in the Middle District of Tennessee that it submitted false claims for payment to TennCare, Tennessee’s Medicaid program, related to nursing facility services. TennCare requires that a placement evaluation be conducted and certified by a physician for each patient entering a nursing home. This settlement resolved allegations by the United States and the State of Tennessee that during the period of January 1, 2010 through December 31, 2017, the defendant submitted pre-admission evaluations with photocopied or pre-signed physician signatures on the required certifications for claims rendered to TennCare beneficiaries at its associated Tennessee skilled nursing and rehabilitation facilities.

(SF) In April 2019, an individual in Florida was convicted for his role in the largest health care fraud scheme ever charged by the DOJ, involving \$1.3 billion in fraudulent claims. The individual worked as a physician’s assistant at skilled nursing facilities (SNF) owned by his co-defendant. According to the investigation, the co-defendant led an extensive health care fraud conspiracy involving a network of assisted living facilities and SNFs that he owned. The co-defendant bribed physicians to admit patients into his facilities, and then cycled the patients through his facilities, where they often failed to receive appropriate medical services, or received medically unnecessary services, then billed to Medicare and Medicaid. Several witnesses testified that poor conditions in the facilities and the inadequate care patients received, which the co-defendant concealed from authorities by bribing an employee of a Florida State regulator for advance notice of surprise inspections scheduled to take place. The individual facilitated the fraud scheme by prescribing medically unnecessary prescriptions for treatment at SNFs. The individual pleaded guilty to conspiracy to commit health care fraud and wire fraud and was sentenced to six years and eight months in prison and ordered to pay \$12.5 million in restitution. Six defendants involved in the scheme were previously sentenced to a combined two years and

three months in prison and ordered to pay \$425,470. The co-defendant is awaiting sentencing. In June 2019, the United States announced that a Chicago-area physical therapy center, its owner, and four nursing facilities had resolved civil FCA allegations that they provided unnecessary services to increase Medicare payments for \$9.7 million. The settlements resolved allegations that skilled therapy service provider Quality Therapy & Consultation Inc. and its owner worked with four skilled nursing facilities—The Carlton at the Lake Inc., Ridgeview Rehab and Nursing Center, Lake Shore Healthcare and Rehabilitation Centre, LLC, and Balmoral Home Inc.—to increase Medicare reimbursements by upcoding their patients' Resource Utilization Group scores. The allegations also contend that the providers rendered skilled therapy to patients who did not need it or could not benefit from it, as part of an effort to bill the highest possible amount to Medicare. As part of the resolution, the owner of Quality Therapy & Consultation also agreed to be excluded from all participation as a provider in Medicare, Medicaid, and all federal health care programs for a period of five years.

Pharmacies

(SF) In November 2018, a pharmacist and marketer was sentenced to 16 months in prison, after pleading guilty for his involvement in a compounding prescription scheme to defraud government health care benefit programs, including TRICARE. To date, 11 people have been charged and 8 convicted for the largest health care fraud scheme ever investigated and prosecuted in the State of Mississippi.

(SF) In December 2018, a pharmacy owner was sentenced to seven years and three months in prison and ordered to pay \$8.4 million in restitution for engaging in an \$8.4 million Medicare fraud scheme in the Miami, Florida area. The individual owned A.R.A Medical Services Inc. pharmacy (which did business under the name Valles Pharmacy Discount). Between January 2011 and August 2017, the individual allegedly engaged in a conspiracy to defraud Medicare Part D. The individual paid illegal health care kickbacks to Medicare beneficiaries in exchange for a promise from the beneficiaries to fill their prescriptions at Valles, and to allow Valles to submit Medicare claims for prescription drugs that were not provided to the beneficiaries. During the course of the scheme, Valles submitted over \$32 million in Medicare claims for prescription drugs, of which approximately \$8.4 million was for medically unnecessary prescription drugs that Valles never purchased and were never provided to beneficiaries.

In January 2019, Walgreens Boots Alliance, Inc. (Walgreens) agreed to pay \$269.2 million to resolve civil FCA allegations in two matters. In the first, Walgreens agreed to pay \$168 million to resolve allegations that Walgreens routinely submitted false days-of-supply data to federal health care programs when it sought federal reimbursement for insulin pens it dispensed to federal beneficiaries who did not need them. Walgreens admitted that when a federal health program denied a claim from Walgreens because the reported days of supply for a full carton of five insulin pens exceeded the federal program's days-of-supply limit, it was Walgreens's practice to dispense and bill for the full carton and reduce the reported days of supply to conform to the program's days-of-supply limit; and Walgreens thus repeatedly reported days-of-supply data to federal health programs that were different from, and lower than, the days-of-supply calculated according to the standard pharmacy billing formula. In addition to the federal recovery, Walgreens agreed to pay up to \$41.2 million to resolve state Medicaid liability.

In the second settlement, Walgreens agreed to pay \$32 million to resolve civil FCA allegations that Walgreens operated a program called the Prescription Savings Club (the “PSC”) that resulted in overbilling Medicaid. Walgreens admitted that Medicaid regulations directed Walgreens to seek Medicaid reimbursement only at the lowest of certain drug price points, including the “usual and customary price” which is often defined as the price offered through discount programs like the PSC. Contrary to these requirements, Walgreens did not disclose to Medicaid the discount drug prices it offered customers through the PSC when it sought reimbursement from Medicaid, resulting in inflated reimbursements from Medicaid. In addition to the federal recovery, Walgreens agreed to pay up to \$28 million to resolve state Medicaid liability. As part of these resolutions, Walgreens entered into a five-year CIA with HHS-OIG.

In February 2019, a former pharmaceutical representative pleaded guilty in the Western District of Texas for her role in a scheme to defraud health care benefit programs by paying over \$400,000 in kickbacks and bribes to health care providers that prescribed compounded medications to individuals who did not need the medications. The Defendant and her co-conspirators attempted to disguise the kickbacks and bribes to health care professionals by writing fictitious and back-dated “consulting agreements.” In many instances, the Defendant and her co-conspirators submitted prescriptions to compounding pharmacies for patients that had never seen a medical professional. Moreover, the Defendant and her co-conspirators would occasionally forge the signature of a medical professional on prescriptions. The Defendant admitted that she conspired with two compounding pharmacies that would submit claims for reimbursement to health care benefit programs, including TRICARE, for compounded medications based on the prescriptions. In exchange for her role in the conspiracy, the two compounding pharmacies paid the Defendant approximately \$1.1 million. From approximately February 2013 through December 2014, health care benefit programs reimbursed the two compounding pharmacies approximately \$8.8 million based on the claims submitted in connection with the compounded medications.

(SF) In February 2019, the owner of California-based, Akhtamar Pharmacy, was sentenced to 48 months in prison. A federal jury found the defendant guilty for her role in a scheme in which the pharmacy submitted \$1.5 million in false claims to Medicare Part D plan sponsors for prescription drugs that the pharmacy never ordered from wholesalers and never dispensed to beneficiaries. The defendant attempted to cover up the scheme through the use of false wholesaler invoices.

(SF) In March 2019, the pharmacist of A to Z Pharmacy, in New Port Richey, Florida, was sentenced to 120 months in prison, followed by three years of supervised release, and was ordered to pay \$3.2 million in restitution, as well as \$1.4 million in forfeiture. The defendant was convicted on January 11, 2019, after a four-day trial on nine counts, for their role in a scheme to defraud Medicare, TRICARE, and private insurance companies through a compounding pharmacy scheme. The defendant and co-conspirators submitted false and fraudulent claims through A to Z Pharmacy for compound medications, primarily pain and scar creams, by paying kickbacks to doctors for prescriptions, billing for compound medications that were more expensive than what the pharmacy actually used, and waiving millions of dollars’

worth of copays. In total, the defendant and co-conspirators stole more than \$157 million through the scheme. All co-conspirators have pled guilty.

(SF) In August 2019, two pharmacy owners were convicted in the Central District of California for participating in a \$35 million health care fraud and money laundering scheme to bill Medicare for medications that were never provided and to launder the proceeds of the fraud. According to the evidence presented at trial, from 2012 to 2015, the defendants fraudulently billed Medicare and CIGNA for prescription medications that were not actually dispensed to beneficiaries by the pharmacy they owned. To hide the fraud, the defendants obtained fake invoices from a co-conspirator to make it appear as if their pharmacy had purchased the medicines it had billed Medicare for when it had not. The evidence further established that the defendants also used these fake invoices to launder the proceeds of the fraud through the co-conspirator.

In August 2019, a pharmacist was sentenced to 63 months in prison in the Central District of California for illegally distributing prescription opioids and money laundering. The defendant filled at least 345 fraudulent prescriptions for oxycodone during a one-year period that ended in July 2017. The prescriptions were written under the name and DEA registration number of a retired doctor. When she pleaded guilty, the pharmacist admitted knowing the prescriptions were fraudulent, outside the usual scope of professional practice, and without a legitimate medical purpose.

In September 2019, Diabetic Care Rx LLC, also known as Patient Care America (PCA), two of its executives, and private equity firm Riordan, Lewis & Haden Inc. (RLH) agreed to pay \$21.4 million to resolve civil FCA allegations that they paid kickbacks to generate referrals of prescriptions for expensive pain creams, scar creams, and vitamins. The government alleged that: PCA paid kickbacks to outside “marketers” to target military members and their families for prescriptions for compounded creams and vitamins, which were formulated to ensure the highest possible reimbursement from TRICARE; marketers paid telemedicine doctors who prescribed the creams and vitamins without seeing the patients, or in some cases, even speaking to them; PCA and a marketer routinely jointly paid the copayments owed by patients referred by the marketer, without any verification of the patients’ financial needs, and then disguised the payments as coming from a sham charitable organization; and PCA continued to claim reimbursement for prescriptions referred by the marketers despite regularly receiving complaints from patients that prescriptions were being generated without patient consent or a valid patient-prescriber relationship. RLH, the private equity firm that managed PCA on behalf of its investors, allegedly knew of and agreed to the plan to pay outside marketers to generate the prescriptions and financed the kickback payments to the marketers.

Physical Therapy

In June 2019, Encompass Health Corporation (Encompass), formerly known as HealthSouth Corporation, agreed to pay \$48 million to resolve civil FCA allegations that some of its inpatient rehabilitation facilities (IRFs) provided inaccurate information to Medicare to maintain their status as an IRF and to earn a higher rate of reimbursement, and that some admissions to its IRFs were not medically necessary. The government alleged that beginning in 2007, to ensure compliance with Medicare’s rules regarding classification as an IRF, and to increase Medicare

reimbursement, some Encompass IRFs falsely diagnosed patients with what they referred to as “disuse myopathy” when there was no clinical evidence for this diagnosis. Additionally, Encompass IRFs allegedly admitted patients who were not eligible for admission to an IRF because they were too sick or disabled to participate in or benefit from intensive inpatient therapy.

In August 2019, Baldwin Bone & Joint, P.C., an orthopedic and physical therapy practice, agreed to pay \$1.2 million to resolve civil FCA allegations in the Southern District of Alabama that it billed Medicare and TRICARE for physical therapy services performed by unauthorized providers, including athletic trainers and an exercise physiologist, who are prohibited from billing these programs. The government also alleged that the practice’s direct compensation arrangements with its shareholder physicians violated the Stark Law because the compensation paid to its shareholder physicians directly or indirectly related to the volume of each shareholder physician’s referrals for designated health services such as physical therapy, X-rays, and MRI’s.

Physician and Other Practitioners

In October 2018, a doctor was sentenced in the District of Oregon to six months’ probation for illegally purchasing foreign-sourced Botox and Juvaderm on the internet and administering both to patients in her home. According to court documents, beginning in 2008, the defendant provided medical services from her home as a supplement to her full-time position with an outside medical practice. The doctor would purchase Botox and Juvaderm from websites that were manufactured for distribution in foreign countries, but not approved for use in the United States. She would then administer Botox and Juvaderm to clients from her home office.

In November 2018, a doctor was sentenced to two years’ probation in the Eastern District of Missouri, after previously pleading guilty to obstructing an investigation by the FBI regarding whether he billed the Medicare program and private insurers for face-to-face office visits performed on dates when he was actually traveling outside of Missouri, and sometimes traveling outside of the United States. The Court further imposed a fine of \$45,000 and restitution in favor of Medicare and several private insurance companies. According to his plea agreement, the defendant created medical records using a template which falsely recited patients’ symptoms and histories, and sometimes recorded vital signs (e.g., pulse rates) that did not change between patients’ visits. Moreover, from time to time, the defendant traveled to various destinations, including Punta Cana in the Dominican Republic and Florida. For these timeframes when the defendant was out of town, he created office notes with false entries reflecting that he had seen patients in his office, using his electronic signature. These medical records did not discuss the role of the other employees in his office during the out-of-town visits, or his absence from the office on the dates of service. The government served the defendant’s office with a subpoena requesting medical records regarding his office visits in late 2016. In response to the subpoena, the defendant produced medical records to the FBI in which he had made false entries about face-to-face office visits, in an effort to impede, obstruct, and influence the FBI’s billing investigation.

In December 2018, Coordinated Health Holding Company, LLC together with its direct and indirect subsidiaries, including but not limited to CHS Professional Practice, P.C. and CH

Hospital of Allentown, LLC (collectively, “Coordinated Health”) and its owner in Pennsylvania agreed to pay \$12.5 million to resolve civil FCA allegations. The government alleged that (1) from January 2007 through May 2014, Coordinated Health submitted claims to federal health care programs for orthopedic surgical procedures that were improperly unbundled using Modifier 59; and (2) from April 2009 through December 2009, the owner submitted claims to federal health care programs for orthopedic surgical procedures that were improperly unbundled using Modifier 59. As part of the resolution, Coordinated Health also entered into a five-year CIA with HHS-OIG.

In April 2019, National Spine and Pain Centers (NSPC), and Physical Medicine Associates (PMA), with pain management clinics in northern Virginia, Glen Allen and Fredericksburg, agreed to pay approximately \$3.3 million to settle civil FCA allegations. The government alleged that NSPC and PMA billed Medicare and other federal health care providers for medical services performed by physician assistants and nurse practitioners as if physicians had provided the services, submitted claims for urine drug tests in violation of the Stark Law and/or the Anti-Kickback Statute, and ordered medically unnecessary urine drug tests.

(SF) In June 2019, a federal jury found a physician and a marketer guilty of a total of thirteen and nine counts of conspiracy to commit health care fraud and health care fraud respectively. The charges stem from a fraud scheme in which the physician billed Medicare for clinic services that patients did not need or did not receive and referred Medicare beneficiaries for home health, hospice, and DME services that were unnecessary or were never rendered. The defendants were charged with two co-conspirators, an office manager and co-owners of a home health agency. Later in June, the co-conspirators were sentenced to 120 and 78 months in prison. Together, the defendants submitted and caused to be submitted claims of approximately \$33 million, of which Medicare paid approximately \$22 million.

In July 2019, a doctor pleaded guilty in the District of Alaska to one count of conspiracy to commit controlled substance fraud and one count of health care fraud. The defendant knowingly and intentionally distributed controlled substances outside the usual course of professional practice and without a legitimate medical purpose. According to court documents, from May 2015 to March 2018, the defendant issued 465 prescriptions of meperidine to 30 different recipients, totaling 32,109 meperidine pills, knowing that the recipients did not truly need the medication for a legitimate medical purpose. The investigation revealed that the defendant issued the meperidine prescriptions as part of a conspiracy in which the recipients filled the meperidine prescriptions and, then, distributed the meperidine to the defendant. In exchange for the recipients diverting the meperidine to the defendant, he provided prescriptions for controlled substances, including fentanyl and oxycodone, to the recipients. The investigation further revealed that the defendant failed to make and preserve accurate records regarding approximately 790 prescriptions for controlled substances, and failed to keep any medical records whatsoever regarding five patients to whom he wrote prescriptions for controlled substances. In a scheme to obtain money from Medicaid, the defendant caused claims to be submitted to Medicaid regarding these 790 prescriptions, resulting in Medicaid paying \$3,286 to his medical practice. Further, Medicaid paid \$3,601 to pharmacies for these 790 controlled substance prescriptions.

Prescription Drugs and Opioids

In December 2018, a physician assistant in California was found guilty of conducting a scheme to unlawfully distribute prescription drugs. The individual intentionally prescribed drugs to five different patients, knowing that the prescriptions were outside the usual course of professional practice and without a legitimate medical purpose. On two occasions, a patient asked the individual to double his prescriptions for powerful opioids so that the patient could sell the drugs. The individual doubled the prescriptions and discussed with the patient how to do it in a way to avoid scrutiny by pharmacies or law enforcement. The individual wrote false medical records of those visits to cover up what he was doing and falsified records of other patients, detailing exams and reviews of lab work that never took place. A jury found the individual guilty of 39 counts of unlawful distribution of controlled substances, and he was sentenced to 10 years in prison.

In March 2019, a marketer was sentenced to 51 months imprisonment for creating fraudulent prescriptions for oxycodone using a physician's stolen prescription template and then facilitating the sale of the oxycodone pills that resulted in the diversion of at least 10,000 30 mg pills of oxycodone on the black market in Orleans and Jefferson Parishes.

(SF) In March 2019, an individual was sentenced to 51 months in prison for conspiracy to obtain possession of oxycodone by fraud and to distribute oxycodone. The defendant created fraudulent prescriptions for oxycodone using a physician's stolen prescription template and facilitated the sale of the pills on the black market. The defendant's cooperation led to nine guilty pleas of co-conspirators.

In March 2019, a pharmacy marketer pled guilty in the Southern District of Texas in connection with her role in a multi-million dollar illegal kickback conspiracy involving a pharmacy in the Rio Grande Valley and doctors throughout Texas. The defendant admitted that as part of her role as a purported marketer, she recruited physicians to write prescriptions for expensive compound drugs to be filled by Pharmacy A and for which the pharmacy would bill federal health care programs. During an approximately two-year period starting in late 2014, the owner of Pharmacy A paid the defendant approximately \$7.5 million in return for compound drug prescriptions written by physicians the defendant recruited. In turn, the defendant paid a cut of the payments from Pharmacy A to the prescribing physicians.

In April 2019, a doctor in Michigan pleaded guilty to conspiracy to distribute and possess with intent to distribute controlled substances and was sentenced to 11 years and three months in prison. The doctor and his co-conspirators engaged in an \$18 million health care fraud scheme involving the illegal distribution of prescription drugs. The doctor wrote medically unnecessary and highly addictive controlled substance prescriptions (e.g., Hydrocodone-Acetaminophen, Oxycodone) in return for cash payments. The doctor prescribed more than 2,700,000 dosage units of Schedule II, III and IV controlled substances during the course of the conspiracy. The doctor used patient recruiters to bring fake patients to his office; recruiters paid cash to acquaintances to act as patients and paid the doctor cash at each office visit for the prescriptions provided. After a cursory examination or no examination at all, the doctor always prescribed the requested controlled substances. The patient recruiters ultimately took control of the controlled substances prescribed by the doctor for illegal distribution in Michigan and elsewhere. Six

defendants involved in the scheme were previously sentenced to a combined eight years and four months in prison.

(SF) In June 2019, a physician was sentenced to 60 months imprisonment for writing medically unnecessary oxycodone prescriptions in exchange for cash. The defendant prescribed more than 693,000 mg. of oxycodone in a 19-month period from the homes of his two co-defendants and other patient recruiters, who provided lists of patients and cash in exchange for receiving opioid prescriptions.

(SF) In June 2019, the owner of a pain clinic and a pharmacy in South Florida, was sentenced to 78 months in prison for his role in a \$2.2 million scheme involving medically unnecessary physician visits and prescriptions. The defendant allowed physicians employed at his clinic to continue prescribing at inappropriately high levels, even after learning of a physician-patient sexual relationship.

(SF) In August 2019, a doctor was sentenced to 48 months of imprisonment, followed by five years of supervised release, and was ordered to pay \$4.3 million in restitution. The defendant plead guilty in November 2017 to one count of conspiracy to distribute controlled substances charged in an information. Medicare was billed for physician office services, tests that were never performed, and durable medical equipment that was not medically necessary, resulting in \$8.6 million worth of false claims. The defendant's co-conspirators were convicted at trial.

Private Health Insurance Fraud

In May 2019, in the Eastern District of Louisiana, a corporation and two individuals, who operated a multiple employer welfare arrangement (MEWA), pleaded guilty to making and conspiring to make false statements in connection with the operation of the MEWA; money laundering conspiracy; and conspiracy to defraud the United States causing losses which may exceed \$48 million. The scheme involved defrauding participants in the enrollment and payment for health care coverage by falsely representing to employers and employees that their costs would be greatly reduced by a loan arrangement used to fund benefits. Defendants admitted that they never obtained a loan or health insurance policy and the contributions, loan and insurance policy were merely "paper transactions" to improperly reduce participants' taxable wages and employers' FICA payments without their knowledge of the impropriety. Participants were also exposed to adverse financial consequences of unpaid taxes, fees, and penalties; reduced Social Security payments; and ineligibility for certain government programs, such as unemployment benefits. Defendants agreed to forfeit approximately \$6.3 million and pay restitution for the loss which may total more than \$48 million. An accountant previously pleaded guilty to conspiracy to make false statements in the marketing of the health care arrangement.

Psychiatric and Psychological Testing and Services

In March 2019, a psychiatrist and his medical practice agreed to pay more than \$3.3 million to resolve civil FCA claims in the District of Connecticut. The government alleged that the psychiatrist submitted claims to Medicare for multiple units of urine drug screening tests, when they knew or should have known that only one unit of service could be billed per patient

encounter. By coding their claims using multiple units, instead of a single unit, the government alleged that the psychiatrist submitted false claims to the Medicare program and received payments that he and his practice were not entitled to receive. In addition, the government alleged that the psychiatrist submitted claims to Medicaid for alcohol tests conducted on patient urine samples that they know or should have known were a component of the urine drug screening test for which the psychiatrist and his practice were already being paid by Medicare. Finally, the government alleged that the psychiatrist defrauded the Connecticut Medicaid program by submitting claims for definitive urine drug tests (also known as “quantitative” or “confirmation” tests) that were not actually performed, and by improperly submitting claims to Medicaid for specimen validity testing of urine samples.

(SF) In May 2019, a clinic owner was sentenced to 360 months in prison for her involvement in a fraudulent Medicaid billing scheme. The defendant and her co-conspirator stole identities of licensed counselors and Medicaid recipients to submit false claims for psychotherapy services that were never provided. The defendant carried out this scheme while awaiting sentencing on a prior health care fraud conviction.

In August 2019, a psychologist agreed to plead guilty in the Northern District of Alabama to defrauding the Alabama Medicaid Agency by filing false claims for counseling services that were not provided. An investigation was initiated by the Program Integrity Division of the Alabama Medicaid Agency after an audit showed that the defendant’s billings to the Medicaid Agency had increased from \$99,000 in 2015 to more than \$2.2 million in 2017. The Program Integrity Division referred its findings to the Alabama Attorney General’s Medicaid Fraud Control Unit after the defendant submitted falsified records during the Program Integrity audit. A subsequent investigation was conducted by the Medicaid Fraud Control Unit and the Office of Investigations of HHS-OIG. This investigation determined that the majority of claims submitted by the defendant’s practice during 2016 through 2018 were fraudulent and that defendant submitted and directed her employees to submit claims for counseling services that never occurred, and in some instances for individuals—including family members and friends of employees—who never received services at all.

Transportation

In November 2018, the owner of Tonieann EMS and Rosenberg EMS in Texas was convicted of charges resulting from his involvement in a Medicare fraud scheme. The individual admitted to submitting false claims to Medicare for ambulance transport services that were not provided and not medically necessary. The individual submitted ambulance claims for Medicare beneficiaries transported by vans, not ambulances, to routine psychotherapy appointments and for at least one other beneficiary who did not require ambulance transportation. The individual also instructed a licensed emergency medical technician to create fake ambulance transport records, which included fake vital signs, patient narratives, and transport mileage. Additionally, more than 2,000 fake ambulance transport records contained the name of another technician who never worked for him. The individual pleaded guilty to conspiracy to commit health care fraud, was sentenced to four years in prison, and ordered to pay \$1.09 million in restitution.

In January 2019, Fort Bend entered into a settlement agreement with HHS-OIG wherein Fort Bend agreed to pay \$4.5 million to resolve allegations that Fort Bend knowingly presented to Medicare, TriCare, the Department of Veterans Affairs/Champus, and the Railroad Retirement Board claims for items or services that Fort Bend knew or should have known were not provided as claimed and were false or fraudulent. From October 2009 to January 2016, Fort Bend submitted claims for ambulance transportation services provided to beneficiaries, which were improper because it failed to obtain necessary beneficiary authorization for the transports. Fort Bend self-disclosed this conduct pursuant to HHS-OIG's Self-Disclosure Protocol.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

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 serve. 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. HHS-OIG's law enforcement component investigates fraud and abuse against HHS programs and holds wrongdoers accountable for their actions. In addition to safeguarding Federal funds, HHS-OIG takes oversight and enforcement action to promote the safety and quality of services delivered by HHS programs.

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 strives to be a flexible and efficient organization that adapts to the needs of the time. HHS-OIG deploys resources as optimally as possible to keep pace with the fast-changing nature of health care programs and the corresponding changes in fraud, waste, and abuse. To do so, 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. HHS-OIG also continues to modernize its infrastructure capacity to deliver high quality, timely, actionable data to produce these results. HHS-OIG's Chief Data Officer, the first in the Inspector General community, has focused the organization on developing data-driven key performance indicators and helped achieve results in priority areas and measures that further the goals of HHS-OIG's work.

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 also strengthening oversight of managed care in the Medicare Advantage, Medicaid managed care programs, new value-based models, and technology and cybersecurity.

A certain portion of the funds appropriated under HIPAA are, by law, set aside for Medicare and Medicaid activities of HHS-OIG. In FY 2019, the Secretary and the Attorney General jointly allotted \$195.8 million to HHS-OIG after accounting for a sequester reduction of \$12.9 million. HHS-OIG was allocated an additional \$14.6 million in HCFAC mandatory funds from the Secretary. Additionally, Congress appropriated \$87.2 million in discretionary funding for HHS-OIG HCFAC activities.

Results

HHS-OIG delivers financial savings to taxpayers while protecting beneficiaries and safeguarding programs from mismanagement and fraud.

In FY 2019, HHS-OIG investigations resulted in 747 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid; and 684 civil actions, which include false claims and unjust-enrichment lawsuits filed in federal district court, CMP settlements, and administrative recoveries related to provider self-disclosure matters. In addition, during FY 2019, HHS-OIG excluded a total of 2,640 individuals and entities, the details of which are below.

HHS-OIG's 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 2019, 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 \$27.5 billion—\$27.0 billion in Medicare savings and \$495 million in savings to the federal share of Medicaid. HHS-OIG's expected recoveries from its involvement in health care audits and investigations totaled over \$5.7 billion, which resulted in a ROI of about \$13 to \$1.¹²

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 <https://oig.hhs.gov>.

OIG Priority Outcomes

With a \$1.2 trillion portfolio to oversee, HHS-OIG sets priority outcomes to achieve the greatest impact across HHS's diverse programs. In the FY 2019 President's Budget, HHS-OIG

¹² This ROI uses a 3-year average of expected recoveries, fines, penalties, and stolen and misspent funds relating to HHS-OIG's health care oversight and is compared with HHS-OIG's annual obligations. This ROI differs from the HCFAC ROI, which uses actual dollars returned to the government. HHS-OIG expects the ROI to fluctuate over time due to factors including the type and size of settlements and identified disallowances, complexity of schemes that are the subject of HHS-OIG scrutiny in a given year, and heightened focus on high-value but lower-dollar work addressing patient safety and quality of care.

introduced its key performance indicators that align with HHS-OIG's priority outcomes. HHS-OIG's current priority outcome areas were selected based on 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 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 grants¹³

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

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 FCA 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. In addition to investigating criminal and civil matters, HHS-OIG imposes civil monetary penalties (CMPs) 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 April 2019, HHS-OIG and its Federal and State law enforcement partners led the first ARPO Strike Force Takedown. The takedown resulted in enforcement actions involving 60 charged defendants across 11 Federal districts, including 31 doctors, 7 pharmacists, 8 nurse practitioners, and 7 other licensed medical professionals, for their alleged participation in the illegal prescribing and distributing of opioids and other dangerous narcotics and for health care fraud schemes. Since June 2018, HHS-OIG has excluded more than 650 providers based on conduct related to opioid diversion and abuse.

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.¹⁴

¹³ HHS-OIG's work in this area is outside the scope of HCFAC work.

¹⁴ 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.

Strike Force Operations

In FY 2019, HHS-OIG continued to staff and support 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. For example, in April 2019, HHS-OIG and its law enforcement partners announced their efforts in dismantling one of the largest health care fraud schemes ever investigated, in terms of amount billed to Medicare. Twenty-four defendants in 17 Federal districts were charged for allegedly participating in the scheme, in which fraudsters submitted over \$1.7 billion in Medicare claims and were paid \$900 million. In the alleged scheme, medical professionals working with fraudulent telemedicine companies received illegal kickbacks and bribes from medical equipment companies. In exchange, the medical equipment companies obtained prescriptions for medically unnecessary orthotic braces and used them to fraudulently bill Medicare. The continued support of Strike Force operations is a top priority for HHS-OIG.

Program Exclusions

One important mechanism for safeguarding program beneficiaries and helping ensure the quality of care provided to them is through exclusion of providers and suppliers who have engaged in crimes related to Medicare or Medicaid, patient abuse or neglect, financial misconduct, 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 2019, HHS-OIG excluded a total of 2,640 individuals and entities. In addition to those mentioned in the Program Accomplishments section above, exclusion actions by HHS-OIG included:

- In November 2018, the owner of a pain management clinic in Maryland was excluded for a minimum of 50 years for conspiracy to distribute controlled substances, violation of the drug kingpin statute, and conspiracy to keep a common nuisance. The owner and his co-conspirators ran a pill mill, dispensing controlled substances without a legitimate medical purpose. From about January 2013 to about April 2017, the owner was responsible for issuing prescriptions signed by a co-conspirator for oxycodone, morphine, and Tramadol

that were not medically necessary. Patients would pay the owner cash to receive these prescriptions. The owner was sentenced to 20 years in prison based on his conviction.

- In December 2018, a certified nursing assistant in Kansas was excluded for a minimum of 20 years based for attempted aggravated criminal sodomy and mistreatment of a dependent adult. While working in a skilled nursing home, the individual sexually abused patients in the facility. The individual was sentenced to seven years and seven months in prison.
- In June 2019, an employee of several testing facilities in Texas was excluded for a minimum period of 50 years for conspiracy to commit health care fraud and conspiracy to commit money laundering. The individual conspired with others to defraud Medicare and Medicaid by submitting claims for services that had not been performed or were not medically necessary. As part of the scheme, the individual rented offices for testing facilities but kept the actual spaces empty. No patients were seen, and no testing was performed at the offices. To further deceive Medicare and Medicaid, the individual hired people to pose as patients to sit in the empty offices and answer the phones as though the facility was open and operational. The court sentenced the individual to 20 years in prison and ordered her to pay approximately \$15.2 million in restitution.
- In July 2019, a pediatrician in Pennsylvania was excluded for a minimum period of 75 years for indecent assault, corruption of minors, endangering the welfare of children, unlawful contact with minors and aggravated indecent assault. The pediatrician sexually assaulted 31 minor victims, most of them patients. The court sentenced the pediatrician to serve 79 to 158 years in prison. The Pennsylvania State Board of Medicine also suspended the pediatrician's license to practice as a medical doctor.

Civil Monetary Penalties

HHS-OIG has the authority to seek CMPs, assessments, and exclusion under the Civil Monetary Penalties Law (CMPL) against an individual or entity based on a wide variety of prohibited conduct. OIG brings cases under the CMPL in order to emphasize HHS-OIG guidance, enhance HHS-OIG work such as audits and evaluations, fill enforcement gaps, and level the playing field for compliant providers. HHS-OIG uses these authorities in three common ways: false claims and kickback affirmative enforcement, Emergency Medical Treatment and Labor Act (EMTALA) enforcement, and the Self-Disclosure Protocol. In FY 2019, HHS-OIG concluded cases involving more than \$68.3 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. In FY 2019, HHS-OIG recovered more than \$11.5 million in false claims and kickback affirmative

enforcement actions. HHS-OIG also excluded 31 individuals and entities from participation in Federal health care programs based on conduct at issues in these health care fraud cases.

Affirmative litigation examples include:

- In October 2018, the Miami Urogynecology Center in South Miami, Florida, entered into about a \$173,768 settlement agreement with HHS-OIG to resolve its liability under the CMPL for submitting claims to Medicare for items or services that it knew or should have known were not provided as claimed and were false or fraudulent. The center allegedly submitted claims for (1) diagnostic electromyography services using CPT code 51784 when therapeutic services, not diagnostic services, had been provided; (2) pelvic floor physical therapy services using CPT codes 97032 and 97110 when those services were provided by an unqualified individual; and (3) evaluation and management services using CPT codes 99213 and 99214 that were billed in conjunction with pelvic floor therapy procedures when no separate and identifiable services were provided.
- In December 2018, a doctor and his practice entity, the Center for Pain and Rehabilitation Medicine, in San Jose, California, agreed to pay \$60,406 to resolve HHS-OIG's contentions that the doctor submitted claims for Healthcare Common Procedure Coding System codes where he did not perform the pathology consultations represented by the code (i.e., no consultation request had been made, no written narrative report by a consultant pathologist was produced, and no exercise of medical judgment by a consultant pathologist was required).
- In June 2019, Ethos Laboratory in Kentucky entered into about a \$1.3 million CMPL settlement agreement with HHS-OIG. The settlement agreement resolves allegations that Ethos submitted claims to Medicare for specimen validity testing, a non-covered service.
- In June 2019, Midland Medical, Inc., and its subsidiary, Midland Medical-Broward, Inc., (collectively, "Midland") entered into a \$102,204 CMPL settlement agreement with HHS-OIG in Florida. The settlement agreement resolves allegations that Midland received remuneration from laboratory companies Health Diagnostic Laboratory, Inc. (HDL) and Singulex, Inc., in the form of "process and handling" payments related to the collection of blood. Midland allegedly received the remuneration from HDL and Singulex in exchange for employees referring patients for laboratory testing services to HDL and Singulex, for which the Medicare program paid.

Patient Dumping

HHS-OIG may also seek a CMP against any hospital that negligently violates its obligations under 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 ED with an emergency medical condition. In FY 2019, HHS-OIG recovered more than \$380,000 in cases under the EMTALA statute.

Patient dumping examples include:

- In December 2018, Hartford Hospital in Hartford, Connecticut, entered into a \$50,000 settlement agreement with HHS-OIG to resolve allegations that it violated EMTALA. The hospital failed to provide an appropriate medical screening examination to a 21-year-old woman who was 23.5 weeks pregnant who presented to Hartford's ED with symptoms of preeclampsia, an emergency medical condition.
- In December 2018, Mobile Infirmary Medical Center in Mobile, Alabama, agreed to pay \$80,000 to resolve its potential liability under EMTALA. Mobile failed to provide an appropriate medical screening examination and stabilizing treatment for two patients. In the first instance, a 24-year old male presented to Mobile's ED by ambulance, complaining of weakness and altered mental status. The patient was purportedly noncompliant with staff directions, which led to him leaving the ED, where he collapsed on the way out and a security officer wheeled him off hospital property. Approximately four hours later, the patient was found cold and unresponsive where the security officer had left him. The patient was then taken to another hospital where he later died. In the second instance, a 35-year old male arrived at Mobile's ED complaining of shortness of breath and chest pain. After allegedly becoming verbally abusive to staff, the patient was escorted out of the ED. Shortly thereafter, he was brought back to the ED, reportedly having suffered a seizure. Mobile staff refused to help the patient out of the vehicle, and the patient and driver were asked to leave the property. The patient was then driven to another hospital and pronounced dead within 20 minutes of his arrival.
- In May 2019, Park Royal Hospital in Florida entered into a \$52,414 settlement agreement with HHS-OIG to resolve allegations that Park Royal violated the EMTALA. The hospital, which has specialized psychiatric capabilities, failed to accept a transfer of a patient with an unstabilized emergency medical condition from another hospital's ED. The patient was presented to the ED following a suicide attempt and was diagnosed with lacerations to the wrist and an emergency psychiatric condition. Park Royal refused to accept the transfer because the patient's insurance was out of network, despite having the specialized capabilities to stabilize the patient and the capacity at the time of transfer.
- In June 2019, Transylvania Regional Hospital (TRH), MH Transylvania Regional Hospital, LLLP, and Transylvania Community Hospital, Inc., entered into a \$25,000 settlement agreement with HHS-OIG in North Carolina to resolve allegations that TRH violated the EMTALA. The patient presented to TRH's ED complaining of abdominal pain and pain radiating bilaterally to his lower extremities and had an elevated blood pressure and respiratory rate. TRH discharged the patient without providing an adequate medical screening examination or stabilizing treatment. The patient returned to TRH's ED later the same day via ambulance, complaining of paralysis of the lower extremities, leg pain, and leg swelling. TRH ultimately transferred the patient to another hospital.

Self-Disclosure

HHS-OIG maintains the Self-Disclosure Protocol (Protocol) whereby providers may voluntarily identify, disclose, and resolve instances of potential fraud involving Federal health care programs

for resolution under the CMPL. The Protocol incentivizes providers to detect and prevent fraud internally and to bring potential fraud to HHS-OIG's attention. Under the Protocol, HHS-OIG provides these entities and individuals with speedy resolutions, reduced CMPs, and other benefits as compared to affirmative cases brought by HHS-OIG or DOJ for similar conduct. In FY 2019, HHS-OIG collected \$61.3 million under the Protocol.

Self-disclosure examples include:

- In December 2018, after self-disclosing conduct to HHS-OIG, the Cancer Treatment Centers of America, headquartered in Florida, agreed to pay more than \$8.2 million to resolve its alleged liability under the CMPL. The organization paid improper remuneration in the form of "Treatment Rate Bonuses" to certain physicians.
- In December 2018, after self-disclosing conduct to HHS-OIG, WellDyneRx, LLC, and HillCour, Inc., in Florida, both mail order pharmacies and pharmacy benefit managers, agreed to pay more than \$7 million to resolve potential anti-kickback liability under a prior arrangement when WellDyneRx was privately-owned and controlled by WellDyne, Inc. (now known as HillCour, Inc.). The disclosing parties and Express Meds Rx, LLC, d/b/a Reliance Meds had a set of improper arrangements, addenda, and amendments to provide a variety of pharmacy services to Prestige Health Choice, a Florida managed care plan. The pharmacies paid remuneration to Reliance under these arrangements, including a percentage of compensation received from Prestige, although Reliance did not perform some or all of the services assigned under the arrangements.
- In April 2019, after self-disclosing conduct to HHS-OIG, Great River Health System, Inc. (GRHS), Great River Foundation (GRF), Riverview System, Inc., (RSI) Great River Medical Center (GRMC), and Great River Physicians and Clinics, Inc., (GRPC) agreed to pay over \$3.0 million⁰ for allegedly violating the CMPL including provisions applicable to kickbacks in Iowa. GRHS, GRF, RSI, and GRPC paid remuneration to a physician in the form of excessive compensation in exchange for referrals. In addition, GRHS, GRMC, and GRPC submitted or caused to be submitted false claims to Medicare, Medicaid, and TRICARE, for medically unnecessary and improperly coded hyperbaric oxygen therapy and wound care services provided by the physician.

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 November 2018, HHS-OIG discovered while onsite that OSD Management, LLC, located in Texas, failed to screen its Covered Persons as required by the CIA. HHS-OIG issued a Demand Letter for Stipulated Penalties, and OSD paid Stipulated Penalties of \$35,000 for failure to screen its covered Persons in accordance with the requirements of the CIA. In October 2014, OSD, its owner, the One Step Independent Diagnostic Testing Facilities (IDTFs), and the One Step holding companies agreed to pay \$1.2 million and entered into a CIA to resolve One Step's alleged FCA liability for entering into personal services arrangements with physicians and chiropractors in the form of medical directorships and consulting agreements as incentives to induce patient referrals to the IDTFs. Additionally, the owner allegedly paid the physicians/chiropractors well above fair market value to perform quality reviews for images produced at the IDTFs.
- In November 2018, HHS-OIG excluded Tri-County Ambulance in Indiana, for a period of five years based on a material breach of its CIA. HHS-OIG issued a letter demanding stipulated penalties of \$25,000 based on Tri-County's failure to submit its Annual Report. After Tri-County failed to pay the stipulated penalties and cure the breach or request a hearing by an HHS Administrative Law Judge, HHS-OIG issued a notice of material breach and intent to exclude in January 2019. Under the terms of the CIA, Tri-County had 25 days to request a hearing with an Administrative Law Judge. Tri-County did not request a hearing. HHS-OIG excluded Tri-County effective April 3, 2019.
- In June 2019, North Broward Hospital District in Florida paid a stipulated penalty of \$690,000 for failing to comply with certain CIA requirements. Specifically, Broward Health failed to: (1) develop and implement written policies designed to promote compliance with the Anti-Kickback Statute and the Stark Law; (2) provide all employees with general compliance training; (3) implement and comply with all of the arrangements procedures and arrangements requirements of the CIA; and (4) comply with certain disclosure program requirements. Effective August 31, 2015, Broward Health entered into a CIA with HHS-OIG to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs.

Audits and Evaluations

HHS-OIG promotes the economy, effectiveness, and efficiency of HHS programs through audits and evaluations. HHS-OIG uses a dynamic, data-driven 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's work is informed by mandatory requirements set forth in laws, regulations, or other directives; requests made or concerns raised by Congress, HHS management, or the Office of Management and Budget; or alignment with strategic goals, etc. With respect to Medicare and Medicaid, HHS-OIG assesses relative risks to identify the areas most in need of attention and, accordingly, to set priorities for the sequence and proportion of resources to be allocated.

Throughout FY 2019, HHS-OIG issued 163 audit reports and 46 evaluations, resulting in 582 new recommendations issued to HHS operating divisions. HHS operating divisions also implemented 341 recommendations during FY 2019.

HHS-OIG's audit and evaluation findings in FY 2019 are listed below and organized by HHS-OIG's two broad priority outcomes to: 1) minimize risks to beneficiaries, and 2) safeguard programs from improper payments and fraud.

Minimize Risks to Beneficiaries

Oversight of Opioid Prescribing and Monitoring of Opioid Use: States Have Taken Action To Address the Opioid Epidemic. HHS-OIG identified actions that eight selected States (Nebraska, Nevada, New Hampshire, Tennessee, Texas, Utah, Washington State, and West Virginia) that took action related to their oversight of opioid prescribing and their monitoring of opioid use. The States have created policies and procedures and passed laws and regulations related to opioids and are using opioid-related data to perform data analytics, as well as performing outreach to providers and patients. The States have implemented a number of opioid-related prevention, detection, and treatment programs and have taken many other actions to address the opioid epidemic. (A-09-18-01005)

National Review of Opioid Prescribing in Medicaid Is Not Yet Possible. Thirty-two States were missing data for variables needed to review opioid prescribing in Medicaid. Limitations of data from the Transformed Medicaid Statistical Information System, the national Medicaid claims database, impede identification of individual beneficiaries for national opioid analysis. Until data are complete in all States and limitations across States are addressed, it will not be possible to conduct a national evaluation of Medicaid beneficiaries at risk of opioid misuse or overdose. (OEI-05-18-00480)

Concerns About Opioid Use in Medicare Part D in the Appalachian Region. Thirty-six percent of beneficiaries in five States in the Appalachian region (Alabama, Kentucky, Ohio, Tennessee, and West Virginia) received a prescription opioid through Medicare Part D in 2017. Almost 49,000 beneficiaries in these States received high amounts of opioids, far exceeding levels CDC says to avoid. Of these, nearly 6,000 beneficiaries were at serious risk of opioid misuse or overdose and received extreme amounts of opioids or appeared to be doctor shopping. 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-02-18-00224)

Opioid Use Decreased in Medicare Part D, While Medication-Assisted Treatment Increased. Nearly 3 in 10 Medicare Part D beneficiaries received opioids in 2018, a decrease from the previous 2 years. At the same time, the number of beneficiaries receiving drugs for medication-assisted treatment for opioid use disorder steadily increased and reached almost 174,000 in 2018. The number of beneficiaries receiving naloxone, a drug that can reverse the effects of an opioid overdose- through Part D more than doubled from 2017 to 2018. Nearly 354,000 beneficiaries received high amounts of opioids in 2018, with about 49,000 of them at serious risk of opioid misuse or overdose. About 200 prescribers had questionable opioid prescribing for the beneficiaries at serious risk. (OEI-02-19-00390)

Opioid Use in Medicare Part D in Missouri. One-third of beneficiaries in Missouri received an opioid through Part D in 2018, which is higher than the national rate. In addition, almost 10,000 beneficiaries in Missouri received high amounts of opioids. About 1,400 beneficiaries in

Missouri are at serious risk of opioid misuse or overdose. The severity of the national opioid crisis makes it imperative that States, including Missouri, take effective steps to address the epidemic. HHS-OIG supports State and Federal efforts to combat the opioid crisis, such as efforts to implement and enforce strong prescription drug monitoring programs that require prescribers and pharmacies to check a database before prescribing and dispensing opioids. (OEI-02-19-00391)

Hospice Deficiencies Pose Risks to Medicare Beneficiaries. Over 80 percent of hospices had at least one deficiency. The most common types of deficiencies involved poor care planning, mismanagement of aide services, and inadequate assessments of beneficiaries. Further, one-third of hospices had complaints filed against them. Over 300 hospices were poor performers in that each had at least one serious deficiency or at least one substantiated severe complaint in 2016. (OEI-02-17-00020)

Safeguards Must Be Strengthened To Protect Medicare Hospice Beneficiaries From Harm. Some beneficiaries have been seriously harmed when hospices provided poor care or failed to take action in cases of abuse. These cases reveal vulnerabilities in beneficiary protections that CMS must address, including strengthening reporting requirements, to better ensure that beneficiary harm is identified, reported, addressed, and, ultimately, prevented. (OEI-02-17-00021)

CMS Guidance to State Survey Agencies on Verifying Correction of Deficiencies Needs To Be Improved To Help Ensure the Health and Safety of Nursing Home Residents. In a series of audits, HHS-OIG found that seven of nine State agencies did not always verify that nursing homes corrected deficiencies, as required. These State agencies did not obtain evidence of nursing homes' correction of deficiencies or maintain sufficient evidence that they had verified deficiency correction for 326 of the 700 sampled deficiencies. For less serious deficiencies, six of the seven State agencies accept a nursing home's correction plan as confirmation of substantial compliance with Federal participation requirements without obtaining evidence of correction from the nursing home. Further, three of the seven State agencies had technical issues with maintaining supporting documentation; as a result, they did not have sufficient evidence of deficiency correction. As a result, the health and safety of nursing home residents may be placed at risk. (A-09-18-02000)

Data Brief: Trends in Deficiencies at Nursing Homes Show That Improvements Are Needed To Ensure the Health and Safety of Residents. HHS-OIG's analysis of nursing home deficiencies identified by State survey agencies found that: (1) the number of nursing home surveys and deficiencies slightly increased each year from 2013 through 2016, then slightly decreased in 2017; (2) 94 percent of deficiencies had "less serious" ratings while 6 percent had "more serious" ratings; (3) approximately 31 percent of nursing homes had a deficiency type that was cited at least five times during the review period; and (4) 10 States accounted for half of the deficiencies identified; the top 10 of 340 deficiency types accounted for more than forty percent of deficiencies. Analysis results do not clearly indicate whether the quality of care and safety of nursing home residents improved during its review period. (A-09-18-02010)

New York Should Improve Its Oversight of Selected Nursing Homes' Compliance With Federal Requirements for Life Safety And Emergency Preparedness. New York did not ensure that selected State nursing homes that participated in the Medicare or Medicaid programs complied with CMS life safety and emergency preparedness requirements. Deficiencies were identified in areas related to life safety and emergency preparedness at the 20 nursing homes that it inspected onsite. Specifically, 205 areas of noncompliance were identified with life safety requirements (e.g., building exits and fire barriers, fire detection and suppression systems, etc.) and 219 areas of noncompliance were identified with emergency preparedness requirements (e.g., written emergency plans, emergency supplies and power, etc.). As a result, nursing home residents were at increased risk of injury or death during a fire or other emergency. (A-02-17-01027)

Adverse Events in Long-Term-Care Hospitals: National Incidence Among Medicare Beneficiaries. Twenty-one percent of Medicare patients in long-term-care hospitals experienced adverse events as a result of medical care; an additional 25 percent of patients experienced temporary harm events. This rate of patient harm is higher than in other settings and may be due, in part, to longer stays and high patient acuity. Nevertheless, these events endanger patient health and reviewers determined over half to be preventable. (OEI-06-14-00530)

Four States Did Not Comply With Federal Waiver and State Requirements in Overseeing Adult Day Care Centers and Foster Care Homes. Previous HHS-OIG reviews found violations of health and safety and administrative requirements at 96 of the 100 centers and homes reviewed in Minnesota, Illinois, Wisconsin, and Mississippi. About 1,141 instances of noncompliance were identified with health, safety, and administrative requirements. (A-05-19-00005)

Kentucky Did Not Comply With Federal Waiver and State Requirements at 14 of 20 Adult Day Health Care Facilities Reviewed. Kentucky did not fully comply with Federal waiver and State requirements in overseeing providers that serve vulnerable adults receiving adult day health care services through the program. Of the 20 providers reviewed, 12 did not comply with 1 or more health and safety requirements, and 10 did not comply with 1 or more administrative requirements. (A-04-18-00123)

California Needs To Improve Oversight of Community-Based Adult Services Providers' Compliance With Health and Safety and Administrative Requirements. California's oversight did not ensure that providers serving vulnerable adults who received services through its Community-Based Adult Services Program complied with Federal waiver and State requirements. All 24 providers HHS-OIG reviewed did not comply with 1 or more health and safety or administrative requirements. Each of the 24 providers reviewed had from 1 to 21 instances of noncompliance. In total, HHS-OIG found 290 instances of noncompliance with health and safety and administrative requirements. (A-09-18-02002)

CMS Could Use Medicare Data To Identify Instances of Potential Abuse or Neglect. HHS-OIG identified 34,664 Medicare claims that contained diagnosis codes indicating the treatment of injuries potentially caused by abuse or neglect of Medicare beneficiaries during its audit period. An estimated 30,754 of these claims were supported by medical records that contained evidence of potential abuse or neglect. Additionally, of the claims associated with incidents of potential abuse or neglect, 2,574 were allegedly perpetrated by a health care worker; 3,330 occurred in a

medical facility; and 9,294 were not reported to law enforcement. CMS did not identify similar incidents of potential abuse or neglect during the review period, but it took some corrective actions in response to HHS-OIG's Early Alert sent to CMS. According to CMS officials, it did not identify the claims because it did not extract data consisting of Medicare claims containing the 17 diagnosis codes related to abuse or neglect. The lack of a data extract impeded CMS or public or patient safety organizations' ability to pursue appropriate remedies to ensure the safety, health, and rights of Medicare beneficiaries. (A-01-17-00513)

Incidents of Potential Abuse and Neglect at SNFs Were Not Always Reported and Investigated. An estimated one in five high-risk hospital ER Medicare claims for treatment provided in CY 2016 were the result of potential abuse or neglect, including injury of unknown source, of beneficiaries residing in a SNF. SNFs failed to report many of these incidents to the Survey Agencies in accordance with applicable Federal requirements. Several Survey Agencies failed to report some findings of substantiated abuse to local law enforcement. Lastly, CMS does not require all incidents of potential abuse or neglect and related referrals made to law enforcement and other agencies to be recorded and tracked in the Automated Survey Processing Environment Complaints/Incidents Tracking System. (A-01-16-00509)

Provider Shortages and Limited Availability of Behavioral Health Services in New Mexico's Medicaid Managed Care. New Mexico's Medicaid managed care program has limited availability of behavioral health services for its enrollees, including few behavioral health providers and difficulty arranging services. The challenges faced by New Mexico—including provider shortages and limited availability of behavioral health services—are likely shared by other States and will require both State and national attention. (OEI-02-17-00490)

Princeton Place Did Not Always Comply With Care Plans for Residents Who Were Diagnosed With Urinary Tract Infections. Based on HHS-OIG's medical record review of a sample of Medicaid-eligible residents assessed with urinary tract infections from January 5, 2014, through October 21, 2015, Princeton Place did not always provide services to Medicaid-eligible residents diagnosed with the infections in accordance with their care plans, as required by Federal regulations. Specifically, staff did not always document that they monitored the residents' urine appearance at the frequencies specified in their care plans. It also did not have policies and procedures to ensure that its staff provided services in accordance with its residents' care plans. As a result, residents were at increased risk for contracting the infections and incurring complications, including requiring hospitalization. (A-06-17-02002)

Alaska Did Not Fully Comply With Federal and State Requirements for Critical Incidents Involving Medicaid Beneficiaries With Developmental Disabilities. Alaska did not fully comply with Federal Medicaid waiver and State requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities residing in community-based settings. Specifically, Alaska did not ensure that community-based providers reported all critical incidents to the State. For the 303 judgmentally selected claims, 68 percent (205 claims) were not reported to Alaska as critical incidents. (A-09-17-02006)

Many Medicaid-Enrolled Children Who Were Treated for Attention Deficit Hyperactivity Disorder (ADHD) Did Not Receive Recommended Follow-up Care. HHS-OIG's review of

Medicaid claims data from all States and the District of Columbia found over 500,000 Medicaid-enrolled children newly prescribed an ADHD medication did not receive followup care within the timeframes outlined in the national quality measures. Follow-up care is an important part of treatment for ADHD, as the disorder can affect all aspects of a child's academic and health outcomes. (OEI-07-17-00170)

Safeguard Programs from Improper Payments and Fraud

Midwood Ambulance & Oxygen Service, Inc. Billed for Nonemergency Ambulance Transport Services That Did Not Comply With Medicare Requirements. Midwood did not comply with Medicare requirements for billing nonemergency ambulance transport services for 89 of the 100 claims HHS-OIG reviewed. Midwood incorrectly billed Medicare for beneficiaries whose conditions did not meet medical necessity requirements and billed for services that did not meet documentation requirements. These errors occurred because Midwood did not have adequate controls to prevent the incorrect billing of nonemergency ambulance transport claims. Midwood received estimated overpayments of at least \$19.2 million for the audit period, including claims with payment dates outside of the Medicare 4-year claim-reopening period. (A-02-16-01021)

Medicare Payments to Providers for Polysomnography Services Did Not Always Meet Medicare Billing Requirements. Medicare made payments to providers for polysomnography services that met Medicare billing requirements for 117 beneficiaries with 276 corresponding lines of service out of 200 randomly selected beneficiaries. However, Medicare made payments for the remaining 83 beneficiaries with 150 corresponding lines of service that did not meet requirements, resulting in \$56,668 in net overpayments. Medicare made overpayments of \$269 million for polysomnography services during the audit period. These errors occurred because CMS oversight was insufficient to ensure that providers complied with Medicare requirements or prevent payment of claims that did not meet those requirements. Without periodic reviews of claims for these services, Medicare Administrative Contractors (MAC) were unable to determine whether providers had received payments for claims that did not meet requirements or to take remedial action. (A-04-17-07069)

Accountable Care Organizations' Strategies for Transitioning to Value-Based Care: Lessons from the Medicare Shared Savings Program. As part of their transition to value-based care, Medicare Shared Savings Program accountable care organizations reported a number of successful strategies in reducing Medicare spending and improving quality of care for patients. These strategies should inform CMS's broader efforts to transform the health care system from fee-for-service to value-based care. (OEI-02-15-00451)

Significant Vulnerabilities Exist in the Wage Index System for Medicare Payments. Significant vulnerabilities exist in the wage index system, including: (1) absent misrepresentation or falsification, CMS lacks the authority to penalize hospitals that submit inaccurate or incomplete wage data; (2) MAC limited reviews do not always identify inaccurate wage data; (3) the rural floor decreases wage index accuracy; and (4) hold-harmless provisions in Federal law and CMS policy pertaining to geographically reclassified hospitals' wage data decrease wage index accuracy. As a result, wage indexes may not always accurately reflect local labor prices and, therefore, Medicare payments to hospitals and other providers may not be appropriately adjusted to reflect local labor prices. (A-01-17-00500)

Medicare Could Have Saved Millions of Dollars in Payments for Three-Dimensional Conformal Radiation Therapy Planning Services. From CYs 2008 through 2017, Medicare made \$576.9 million in payments to 1,454 hospitals for development of Three-dimensional conformal radiation therapy (3D-CRT) treatment plans. Medicare could have saved \$125.4 million by implementing billing requirements and system edits to prevent additional payments for separately billed 3D-CRT planning services. These services were primarily billed on a different date of service from the procedure code for development of a treatment plan. (A-09-18-03026)

Payments Made by Novitas Solutions, Inc., to Hospitals for Certain Advanced Radiation Therapy Services Did Not Fully Comply With Medicare Requirements; Payments Made by National Government Services, Inc., to Hospitals for Certain Advanced Radiation Therapy Services Did Not Fully Comply With Medicare Requirements. Novitas Solutions, Inc., the MAC responsible for processing Medicare payments for outpatient services in Jurisdictions H and L, and National Government Services, Inc., the MAC responsible for processing payments in Jurisdictions 6 and K, incorrectly paid hospitals for IMRT services provided to nearly all of the beneficiaries associated with HHS-OIG's review. For unallowable IMRT services, hospitals in Jurisdictions H and L received Medicare overpayments of at least an estimated \$7.2 million and hospitals in Jurisdictions 6 and K received at least \$5.7 million. (A-02-16-01006); (A-02-16-01007)

CMS Did Not Always Ensure Hospitals Complied With Medicare Reimbursement Requirements for Graduate Medical Education. In seven of HHS-OIG's eight audits teaching hospitals did not always comply with Federal requirements when claiming Medicare graduate medical education reimbursement for residents. Specifically, hospitals in the six reviewed MAC jurisdictions claimed reimbursement for residents who were claimed by more than one hospital for the same period and whose total full-time equivalent (FTE) count exceeded one, totaling almost \$4 million in excess reimbursement. This occurred because CMS did not have adequate procedures to ensure that hospitals do not count residents as more than one FTE. For example, CMS did not review hospital resident data to detect whether a resident had overlapping rotational assignments or require the MACs to perform this work. (A-02-17-01017)

Medicare Improperly Paid Suppliers for DME, Prosthetics, Orthotics, and Supplies Provided to Beneficiaries During Inpatient Stays. From the January 2015 through December 2017 audit period, Medicare should not have paid suppliers for any of the \$34 million for DME, prosthetics, orthotics, and supplies provided during inpatient stays. Beneficiaries were also held responsible for unnecessary deductibles and coinsurance of \$8.7 million paid to the suppliers for these items. Medicare overpaid the suppliers because of inadequate system edits that should have prevented or detected the overpayments. If system edits had been designed properly since 2008, Medicare could have saved \$223.1 million, and beneficiaries could have saved \$56.3 million in deductibles and coinsurance that may have been incorrectly collected. (A-09-17-03035)

First Coast Service Options, Inc., Paid Providers for Hyperbaric Oxygen Therapy (HBO) Services That Did Not Comply With Medicare Requirements. Of the 120 sampled outpatient claims totaling \$415,513, First Coast Service Options, Inc., made payments for HBO therapy that did not comply with Medicare requirements for 110 claims (92 percent), resulting in overpayments for HBO totaling \$351,970 during the audit period. First Coast 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. First Coast overpaid providers in Jurisdiction N an estimated \$39.7 million for HBO therapy that did not comply with Medicare requirements. (A-04-16-06196)

Medicare Paid Twice for Ambulance Services Subject to SNF Consolidated Billing Requirements. Medicare made Part B payments to ambulance suppliers for transportation services that were also included in Part A SNF payments as part of consolidated billing requirements. Medicare made Part B payments that were incorrect for 78 of 100 beneficiary days HHS-OIG sampled with dates of service from July 2014 to June 2016. Medicare overpaid the ambulance suppliers because the Common Working File edits were not designed to prevent or detect Part B overpayments for all transportation subject to consolidated billing. Ambulance suppliers also did not have the necessary controls to prevent incorrect billing. Medicare made a total of \$19.9 million in Part B overpayments to ambulance suppliers for transportation services for beneficiaries in Part A SNF stays. Beneficiaries also incurred an estimated \$5.2 million in coinsurance and deductible liabilities related to these payments. (A-01-17-00506)

Medicare's Oversight of Ambulatory Surgical Centers (ASC). CMS has made progress in strengthening oversight of ASCs and addressing vulnerabilities that we previously identified, and more can be done. Most ASCs—known as nondeemed ASCs—undergo a State agency survey to demonstrate they meet Medicare requirements; others—known as deemed ASCs—undergo a survey from an approved accreditor. States largely met Medicare's requirement to survey 25 percent of nondeemed ASCs in FY 2017, and nearly half met its requirement to have surveyed all ASCs within the prior 6 years. However, infection control deficiencies found in State surveys continue to be a concern. From FYs 2013 to 2017, States received complaints for fewer than 4 percent of all ASCs (deemed and nondeemed) each year, but the share of those complaints requiring an onsite survey more than tripled. (OEI-01-15-00400)

CMS Improperly Paid Millions of Dollars for SNF Services When the Medicare 3-Day Inpatient Hospital Stay Requirement Was Not Met. To be eligible for coverage of posthospital extended care services, a Medicare beneficiary must be an inpatient in a hospital for not less than 3 consecutive calendar days (3-day rule) before being discharged from the hospital. CMS improperly paid 65 of the 99 SNF claims HHS-OIG sampled when the 3-day rule was not met. Improper payments associated with these claims totaled \$481,034. CMS improperly paid \$84 million for SNF services that did not meet the 3-day rule from 2013 through 2015. These problems will not be corrected until CMS requires a consistent documentation standard for SNFs that provides verifiable evidence of a qualifying hospital stay, which it can use to certify allowable reimbursements or detect and recover improper reimbursements. (A-05-16-00043)

Medicare Part D Is Still Paying Millions for Drugs Already Paid for Under the Part A Hospice Benefit. Medicare Part D paid for drugs during 2016 that hospices should have paid for under the Part A hospice benefit. On the basis of sample results, the Part D total cost was \$160.8 million for drugs that hospice organizations should have paid for under the Part A benefit. Although hospices stated they should not have paid for the drugs associated with the remaining \$261.9 million of the \$422.7 million total cost, a review of CMS communications with hospices and sponsors between 2012 and 2016 indicates otherwise. Hospice organizations or beneficiaries—not Part D—likely should have paid for many of these drugs. (A-06-17-08004)

Vulnerabilities Exist in State Agencies' Use of Random Moment Sampling To Allocate Costs for Medicaid School-Based Administrative and Health Services Expenditures. Ten State agencies claimed a total of \$435.4 million in school district administrative claiming (SDAC) and school-based health services (SBHS) costs that were not in accordance with Federal requirements and guidance. Of the 10 State agencies, 5 claimed unallowable SDAC and SBHS costs, 3 claimed SDAC costs without having properly submitted cost allocation plans that described their random moment time studies methodologies, and all 10 did not correctly develop the methodologies used to allocate costs. In addition, some annual cost settlements performed by three State agencies did not take all interim payments into account and three State agencies could not provide medical record documentation to support the responses provided by study participants. HHS-OIG could not determine whether services for which the State agencies had claimed SBHS costs had actually been performed, nor which portions of an additional \$325.1 million of SDAC and SBHS costs were allowable in two States whose methodologies used sample universes that were or may have been inaccurate. (A-07-18-04107)

Medicaid Fraud Control Units Fiscal Year 2018 Annual Report. The number of convictions in FY 2018 resulting from MFCU cases remained similar to those in recent years. Forty-five percent of the 1,109 MFCU fraud convictions involved personal care services attendants and agencies. Fraud cases accounted for 74 percent of the MFCU convictions, while 26 percent involved patient abuse or neglect. MFCUs were responsible for 810 civil settlements and judgments, 27 percent of which involved pharmaceutical manufacturers. MFCUs reported \$859 million in criminal and civil recoveries. (OEI-09-19-00230)

Problems Remain for Ensuring All High Risk Medicaid Providers Undergo Criminal Background Checks. Thirteen States had not implemented fingerprint-based criminal background checks for their high-risk Medicaid providers as of January 1, 2019. Unscrupulous providers could exploit loopholes in the provider enrollment process to enroll in Medicaid without undergoing these checks. If not all high-risk providers undergo criminal background checks, the Federal and State governments are vulnerable to unscrupulous providers' intent on defrauding the Medicaid program. (OEI-05-18-00070)

Several States Did Not Comply with Federal and State Requirements Prohibiting Medicaid Payments for Inpatient Hospital Services Related to Provider-Preventable Conditions. HHS-OIG conducted a series of reviews to determine compliance with Federal and State requirements prohibiting Medicaid payments for inpatient hospital services related to treating certain provider-preventable conditions (PPCs). PPCs are reasonably preventable conditions caused by medical accidents or errors in a health care setting. New York's State Medicaid agency did not provide sufficient evidence that it properly identified claims containing PPCs or determined whether the payments for the related services should have been reduced. In four other States (Louisiana, Rhode Island, Massachusetts, and Pennsylvania), the Medicaid agencies did not comply or ensure compliance with Federal and State requirements prohibiting Medicaid payments for inpatient hospital services related to treating certain provider-preventable conditions. (A-02-16-01022, A-06-16-02003, A-01-17-00004, A-01-17-00003, A-01-17-00003, A-03-16-00205)

Medicaid Could Save Hundreds of Millions by Excluding Authorized Generic Drug Transactions from Brand Name Drugs' Average Manufacturer Price (AMP) Calculations. By including authorized generic drug transactions to secondary manufacturers in the brand name drug's AMP calculations, Medicaid received 46 percent less in rebates than it otherwise would have for the nine brand name drugs HHS-OIG reviewed, amounting to \$595 million for CY 2017. (A-06-18-04002)

Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2017 Average Sales Prices (ASP). On the basis of 2017 data, CMS lowered Medicare Part B reimbursement for 14 drugs, saving Medicare and its beneficiaries \$7 million over 1 year. This finding highlights the success of HHS-OIG's mandated quarterly comparisons of ASPs with AMPs and implementation of CMS's current price-substitution policy. (OEI-03-19-00260)

Reasonable Assumptions in Manufacturer Reporting of AMPs and Best Prices. Under current practices, CMS never assesses the majority of the "reasonable assumptions" that it allows manufacturers to make when calculating AMP and best price. Historically, CMS has provided little formalized oversight of the reasonable assumptions process, specifically instructing manufacturers not to submit their reasonable assumptions to CMS. Ensuring the accuracy of manufacturer-reported AMPs and best prices is vital given that these prices are the primary benchmarks that the Federal Government uses to calculate the rebates and discounts available to Medicaid and certain safety-net providers. (OEI-12-17-00130)

New York Claimed Federal Reimbursement for Some Assertive Community Treatment Services That Did Not Meet Medicaid Requirements. New York claimed Federal reimbursement for some Assertive Community Treatment (ACT) services that did not comply with certain Medicaid requirements. These deficiencies occurred because providers did not always ensure ACT services were provided in accordance with a beneficiary's treatment plan nor verify that the required number of contacts needed to claim the ACT full payment rate was provided. Further, certain providers failed to maintain or provide documentation to support ACT services claims. New York improperly claimed at least an estimated \$4.4 million in Federal Medicaid reimbursement for ACT services from April 2011 through March 2016. (A-02-17-01008)

CMS Had Not Recovered More Than a Billion Dollars in Medicaid Overpayments Identified by OIG Audits. CMS did not collect \$1.6 billion in overpayments identified in 77 current period HHS-OIG audits and \$188.6 million in overpayments identified in 7 prior HHS-OIG audits. CMS is in discussions with State officials regarding 26 reports and 51 outstanding overpayments that continue to be in the disallowance process. CMS also did not ensure that States correctly reported Medicaid overpayments on the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program Form CMS-64. Finally, HHS-OIG could not verify the accuracy of \$2.7 million that CMS stated was reported by States because CMS disposed of documents supporting that overpayments were recovered. (A-05-17-00013)

California Made Medicaid Payments on Behalf of Non-Newly Eligible Beneficiaries Who Did Not Meet Federal and State Requirements. California made Medicaid payments of an estimated \$959.3 million (\$536 million Federal share) on behalf of 802,742 ineligible beneficiaries and \$4.5 billion (\$2.6 billion Federal share) on behalf of 3.1 million potentially ineligible

beneficiaries. 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-09-17-02002)

Wisconsin Did Not Report and Refund the Full Federal Share of Medicaid-Related Settlements and a Judgment. Wisconsin did not report and return \$27.6 million (Federal share) of Medicaid-related settlements and a judgment from October 2008 through September 2016. Wisconsin did not properly report the settlements and a judgment because it lacked policies that addressed the reporting of recoveries from State actions taken because of harm to its Medicaid program and it did not have procedures to help ensure it reported recoveries on Form CMS-64. (A-05-17-00041)

Virginia Received Millions in Unallowable Bonus Payments. Some of the Children's Health Insurance Program Reauthorization Act of 2009 bonus payments that Virginia received for FYs 2011 through 2013 were not allowable in accordance with Federal requirements. Most of the data used in Virginia's bonus payment calculations were in accordance with Federal requirements. However, Virginia overstated its current enrollments in its bonus requests to CMS because it improperly inflated its current enrollment by a fixed percentage estimate to account for potential retroactive enrollment, instead of using actual enrollment and the adjustment process to account for actual retroactive enrollment. CMS guidance instructed Virginia to calculate current enrollment based on actual enrollment. As a result of the overstated numbers, CMS overpaid Virginia approximately \$13.8 million in bonus payments. (A-04-17-08060)

New Mexico Did Not Always Appropriately Refund the Federal Share of Recoveries from Managed Care Organizations (MCO). New Mexico appropriately made recoveries when Medicaid MCOs profits exceeded contract-established limits. However, for CYs 2014 and 2015 it incorrectly calculated the Federal share of recoveries and underreported the Federal share by \$4.4 million. It also did not perform reconciliations of capitation payments for community based long-term care services as required under its contracts with MCOs. (A-06-18-09001)

Missouri Claimed Some Unallowable Medicaid Payments for Targeted Case Management Services. Missouri claimed Federal Medicaid reimbursement of almost \$3.8 million for unallowable targeted case management services' payments which it made during FYs 2014 and 2015. Missouri's policies and procedures did not ensure providers complied with Federal and State requirements for documenting case managers' qualifications and for documenting and claiming these services. In addition, it did not have policies and procedures to ensure that it correctly reported recouped payments to the Federal government. (A-07-17-03219)

New Jersey Did Not Provide Adequate Oversight of Its Medicaid Delivery System Reform Incentive Payment (DSRIP) Program. DSRIP programs allow States to receive Medicaid reimbursement for incentive payments made to providers for meeting performance goals. In an audit of the New Jersey DSRIP program, HHS-OIG could not determine what portion of pay-for-performance incentive payments, totaling approximately \$51 million (\$25 million Federal share) was appropriate. Specifically, no documentation was found to support the achievement of Medicaid claims-related performance goals, and that hospitals had reported information inconsistent with performance measurement criteria. (A-02-17-01007)

Medicaid MCOs Received Capitation Payments After Beneficiaries' Deaths. HHS-OIG conducted several State audits as part of its ongoing work to identify unrecovered managed care payments for services after beneficiary death. States made payments after beneficiaries died and did not recover the payments. The estimated Federal share of these unallowable payments included over \$38 million in Ohio, and over \$53 million in California. (A-05-17-00008, A-04-18-06220, A-05-18-00026, A-04-15-06183)

Medicare Part D Rebates for Prescriptions Filled at 340B Contract Pharmacies. If the Part D prescriptions for the sponsors in HHS-OIG's review had been filled at non-340B pharmacies, sponsors calculated that manufacturers would have paid rebates of up to over \$74.7 million for 554,549 claims in 2014. Manufacturers did not pay these rebates because, as sponsors reported, rebate agreements did not require manufacturers to pay rebates for Part D drugs filled at a 340B pharmacy. Because 340B identifiers are not on claims and prescription drug event records, sponsors do not have the data to distinguish whether prescriptions dispensed at a 340B pharmacy were filled using 340B drugs. Therefore, the possible up to \$74.7 million additional rebate amount is for both 340B and non-340B drugs filled at 340B pharmacies. Part D costs could potentially be reduced if sponsors were to collect rebates for claims for drugs dispensed by 340B pharmacies but not purchased under the 340B Program. (A-03-16-00002)

Some Medicare Part D Beneficiaries Face Avoidable Extra Steps that Can Delay or Prevent Access to Prescribed Drugs. In 2017, Part D insurance companies rejected millions of prescriptions that beneficiaries tried to fill at pharmacies and overturned a large number of drug-coverage denials when beneficiaries appealed. Some rejections and denials were avoidable or inappropriate, creating unnecessary extra steps for beneficiaries to obtain needed medications. Extra steps can delay or deter beneficiaries' access to medications if those beneficiaries are unable or unwilling to spend time navigating the approval process. (OEI-09-16-00411)

Rebates for Brand-Name Drugs in Part D Substantially Reduced the Growth in Spending from 2011 to 2015. Overall, increases in rebates substantially reduced the percentage increase in reimbursement for brand-name drugs in Part D from 2011 to 2015. Although rebates reduced the growth of total Part D spending, they did not prevent increased overall Part D spending for brand-name drugs from 2011 to 2015, as Medicare still spent \$2 billion more for brand-name drugs with rebates in 2015 than in 2011. At a drug-by-drug level, unit rebates did not always increase as unit reimbursement increased for brand-name drugs reviewed. In fact, while unit reimbursement increased for nearly all drugs, rebates declined as unit reimbursement grew for 39 percent of drugs reviewed. (OEI-03-19-00010)

New York Did Not Correctly Determine Medicaid Eligibility for Some Non-Newly Enrolled Beneficiaries. New York did not consider all available, relevant information or failed to comply with its Medicaid State plan or verification plan when determining Medicaid eligibility. Additionally, New York's enrollment system did not always query all electronic data sources to ensure individuals were reporting all sources of countable income when applying for Medicaid. Lastly, New York did not always maintain documentation to support eligibility determinations. New York made estimated Federal Medicaid payments of \$520.3 million on behalf of 383,893 ineligible beneficiaries and \$1.3 billion on behalf of 618,057 potentially ineligible beneficiaries during HHS-OIG's 6-month audit period. (A-02-16-01005)

New York Claimed Federal Reimbursement for Some Payments to Health Home Providers That Did Not Meet Medicaid Requirements. New York's health home providers did not provide services according to a comprehensive individualized patient-centered care plan, ensure that beneficiaries participated in the development and execution of their care plan, maintain documentation to support services billed, bill correctly for services, and bill only for services actually provided. New York also claimed reimbursement for services that duplicated similar ones provided under a different Medicaid-funded program New York improperly claimed at least an estimated \$65.5 million in Federal Medicaid reimbursement for payments made to health home providers. (A-02-17-01004)

New York Incorrectly Claimed Enhanced Federal Medicaid Reimbursement for Some Beneficiaries. New York incorrectly enrolled beneficiaries in eligibility categories for which services were reimbursed at an enhanced Federal Medical Assistance Percentage rate despite case file documentation indicating that they should have been enrolled in a group for which services qualified under the standard rate or were not eligible for reimbursement. For these beneficiaries, New York failed to correctly apply Federal and State requirements or consider all available, relevant information when enrolling beneficiaries in the new adult group. Staff also did not comply with the State's approved verification plan when verifying Medicaid eligibility and did not maintain documentation to support its determinations of beneficiary eligibility for enhanced Medicaid reimbursement. The State incorrectly claimed enhanced Federal Medicaid reimbursement of an estimated \$116.9 million on behalf of 184,590 Medicaid beneficiaries enrolled in the new adult group during HHS-OIG's 6-month audit period. (A-02-15-01023)

Some Diagnosis Codes That Essence Healthcare, Inc., Submitted to CMS Did Not Comply With Federal Requirements. Some of the diagnosis codes that Essence submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 75 of the 218 enrollee-years, the diagnosis codes (48 acute stroke and 27 major depressive disorder) that Essence submitted to CMS either were not supported in the medical records (70) or could not be supported because Essence could not locate the medical records (5). These errors occurred because Essence's policies and procedures to detect and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, were not always effective. As a result, Essence received \$158,904 of overpayments for the 75 enrollee-years. (A-07-17-01170)

Ohio Made Medicaid Capitation Payments That Were Duplicative or Were Improper Based on Beneficiary Eligibility Status or Demographics. Ohio did not always make capitation payments for its Medicaid managed care program in accordance with Federal and State requirements. HHS-OIG reviewed a sample of capitation payments and estimated that Ohio made improper payments totaling at least \$10.6 million (\$6.7 million Federal share) for the audit period from July 2014 through June 2015. (A-05-16-00061)

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 to better target OIG's resources for overseeing the Medicare and Medicaid programs. HHS-OIG has developed analytic tools to largely 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, calculate analytic metrics for services rendered and ordered, as well as other assessments "on demand." When united with the expertise of HEAT and other partners, HHS-OIG's data analysis supports a highly effective combination of cutting-edge technologies, analytic approaches, and traditional skills to fight against fraud, waste, and abuse.

HHS-OIG data analysis has supported several health care cases and initiatives. For instance:

HHS-OIG analysts examined Medicare and Medicaid claims to identify the full scope of a South Florida health care facility owner's activities in orchestrating a decades-long scheme to pay kickbacks and launder money in connection with fraudulent claims to Medicare and Medicaid for services deemed medically unnecessary. Following an eight-week jury trial, an individual was found guilty in April 2019 of conspiracy to defraud the United States, of receipt of kickbacks in connection with a Federal health care program, of making payment of kickbacks in connection with a Federal health care program, conspiracy to commit money laundering, money laundering, conspiracy to commit Federal program bribery and obstruction of justice. In September 2019, a Federal district judge sentenced the individual to 20 years in prison and 3 years of supervised release. Forfeiture and restitution hearings remain pending.

HHS-OIG data analytics supported or helped to initiate several criminal cases across the nation that involved individual prescribers of Subsys for patients who lacked cancer diagnoses, and other opioid prescribing cases. In December 2018, a physician's assistant was sentenced to 10 years in prison after a jury in the Northern District of California found the individual guilty on 39 counts of unlawful distribution of controlled substances, after a two-week trial. An HHS-OIG data analytics staff member testified at trial to support analysis that showed, among physicians who prescribed opioids to 50 or more Medicare patients, the defendant was the highest prescriber of opioids in California in 2015 and 2016.

Additionally, HHS-OIG's data analytics work has helped to inform cases filed as part of the Appalachian Regional Opioid Strike Force efforts.

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 2019, HHS-OIG, in consultation with DOJ, issued 8 advisory opinions. A total of 374 advisory opinions and 21 modifications to advisory opinions have been issued, four opinions have been terminated, and one opinion has been rescinded during the 23 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 stakeholders to seek insight on how to promote compliance, while encouraging innovation in the health care industry. For instance, HHS-OIG published a Request for Information seeking to identify ways that it could modify or add safe harbors to the Federal anti-kickback statute and exceptions related to the CMP for beneficiary inducements to foster arrangements that would promote care coordination and value-based care, while also protecting against harms caused by fraud and abuse.¹⁵

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 2019, CMS received an allocation of \$8.5 million by HHS and was appropriated \$599.4 million in discretionary funds by Congress to support its comprehensive program integrity strategy for Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and the Health Insurance Exchanges. In FY 2019, Congress required HHS to fund the Administration for Community Living's (ACL) Senior Medicare Patrol (SMP) Program; therefore, \$18.0 million of CMS's \$599.4 million in discretionary funding was allocated to ACL to support the program. More information on the SMP Program activities and accomplishments are discussed in ACL section of this report on page 85. With the HCFAC funds, CMS works to ensure that accurate payments are made to legitimate individuals and entities for allowable services or supplies provided to 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. This includes activities such as Medicare fee-for-service (FFS) improper payment rate

¹⁵ HHS-OIG, Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP, 83 Fed. Reg. 43,607 (Aug. 27, 2018).

measurement and program integrity activities such as the Recovery Audit Program, prior authorization, medical review, and provider outreach and education. These activities are discussed at length in the annual Medicare and Medicaid Integrity Programs Report to Congress, which can be found on the CMS website¹⁶.

Address the Full Spectrum of Fraud, Waste, and Abuse

CMS defines program integrity very simply: “pay it right.” Program integrity focuses on paying the right amount, to legitimate providers and suppliers, for covered, reasonable and necessary services provided to eligible beneficiaries while taking aggressive actions to eliminate fraud, waste and abuse. Federal health programs are quickly evolving; therefore, CMS’s program integrity strategy must keep pace to address emerging challenges.

CMS has developed a five-pillar program integrity strategy to modernize the Agency’s approach and protect its programs for future generations:

- **Stop Bad Actors.** CMS works with law enforcement agencies to identify and take action on those who defraud federal health programs. This collaboration allows CMS to maximize efforts to identify, investigate, and pursue providers and suppliers who might otherwise endanger program beneficiaries or commit fraud on Federal programs.
- **Prevent Fraud.** CMS continues to focus on moving away from an expensive and inefficient “pay and chase” model to preventing fraud, waste and abuse on the front end. This includes making system changes to avoid similar fraudulent activities in the future, as well as developing policies, regulations, and processes to prevent vulnerabilities from being exploited before claims are paid.
- **Mitigate Emerging Programmatic Risks.** CMS recognizes the need to be vigilant in monitoring new and emerging areas of risk, and developing methods to address these risks. This includes maintaining flexibility to respond to future data and trends and tailor strategies accordingly, and to use new approaches for high vulnerability services. CMS is also exploring ways to identify and reduce program integrity risks related to value-based payment programs by looking to experts in the health care community for lessons learned and best practices.
- **Reduce Provider Burden.** While CMS strengthens program integrity, the agency is also taking steps to ensure that these efforts do not create unnecessary time and cost burden on providers and suppliers. Efforts in this area include targeted medical review with individualized education to assist rather than punish providers who make good faith claim errors. CMS is working to make access to our coverage and payment rules more easily accessible to providers and suppliers, as well as streamlining and reducing documentation requirements that are duplicative or unnecessary. CMS is also exploring ways to centralize provider screening and provider monitoring across Medicare and Medicaid
- **Leverage New Technology.** CMS is looking to leverage new, innovative strategies and technologies, perhaps involving artificial intelligence and/or machine learning, to modernize and automate our program integrity efforts. This new technology could allow the Medicare program to review compliance on more claims with less burden on

¹⁶ <https://www.cms.gov/About-CMS/Components/CPI/CPIReportsGuidance>

providers and less cost to taxpayers. These innovations could be used in both our current payment models, as well as in new payment models.

This section describes the wide range of program integrity activities funded by the HCFAC account 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 Contractors (UPICs)

One way CMS investigates instances of suspected fraud, waste, and abuse in Medicare, as well as Medicaid, is through the activities of the UPICs. The UPICs develop investigations and take actions to prevent inappropriate payments from being made to Medicare providers and suppliers. UPICs undertake activities including provider and beneficiary interviews and site visits, initiating appropriate administrative actions (e.g., prepayment edits, payment suspensions, revocations), and performing program integrity reviews of medical records and documentation. While a variety of other contractors also perform medical review, UPIC reviews are uniquely focused on fraud detection and investigation. For example, the UPICs look for possible falsification of documents that may be associated with an attempt to defraud the Medicare program. Various UPIC administrative actions result in Medicare savings, including automated edit claim denials, non-automated review claim denials, provider revocations and deactivations, overpayment recoveries, and law enforcement referrals. Currently, the UPICs are carrying out program integrity activities in all five geographic 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 2010.¹⁷ FPS analyzes FFS claims using sophisticated algorithms to 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.

During FY 2019, the FPS generated leads that resulted in 766 new investigations and augmented information for 575 existing investigations. The UPICs reported initiating FPS-attributable actions against 509 providers in FY 2019.

National Correct Coding Initiative (NCCI)

The National Correct Coding Initiative (NCCI) consists of edits designed to reduce improper payments in Medicare Part B and Medicaid. NCCI Procedure-to-Procedure 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, while NCCI Medically Unlikely Edits 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. Estimated savings from Medicare NCCI

¹⁷ Public Law 111-240.

edits are published in the annual Report to Congress on the Medicare and Medicaid Integrity Programs.

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

Integrated Data Repository and the One Program Integrity (One PI) Portal

The Integrated Data Repository (IDR) contains Medicare Part A, Part B (including DME), MA (encounter), Part D prescription drug events, beneficiary, and provider data. This robust data warehouse supports program integrity analytics, such as the development of FPS models. CMS uses the IDR to provide broader and easier access to data and enhanced data integration while strengthening and supporting CMS's analytical capabilities.

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 augments the data available in the IDR to provide a comprehensive view of Medicare and Medicaid data including claims, beneficiary data, and prescription drug information. CMS has added Shared Systems location data for pre-adjudicated claims, claims submitter, and medical review utilization data.

CMS uses the One PI web-based portal in conjunction with the IDR to provide access to robust business intelligence analytical tools and to facilitate data sharing with program integrity contractors and law enforcement. One PI provides a single access point to the data within the IDR, as well as tools to conduct data analysis.

The Command Center and Coordinated Program Integrity Activities

The CMS Command Center opened in July 2012 and provides an opportunity for Medicare and Medicaid policy experts, law enforcement officials from HHS-OIG and the DOJ, including FBI, state law enforcement officials, clinicians, and CMS staff and program integrity contractors to collaborate in real time before, during, and after the development of fraud leads. These collaborative activities enable CMS to more quickly and efficiently take administrative actions such as revocations of Medicare billing privileges and payment suspensions.

In FY 2018, CMS began a Major Case Coordination (MCC) initiative that includes representation from the HHS-OIG, DOJ, CMSS. This initiative provides an opportunity for Medicare and Medicaid policy experts, law enforcement officials, clinicians, and fraud investigators to collaborate before, during, and after the development of fraud leads. This level of collaboration has contributed to several successful coordinated law enforcement actions and helped CMS to better identify national fraud trends and program vulnerabilities.

As a result of the MCC, there has been a marked increase in the number and quality of law enforcement referrals from CMS. Since implementation of the MCC, there have been over 1,400 MCC reviews and 800 law enforcement referrals. CMS program integrity activities and

investigations will continue to contribute to law enforcement investigations, CMS administrative actions and CMS initiatives. In FY 2019, CMS conducted 42 MCC meetings in the Command Center that included participants from CMS and law enforcement partners.

Other examples of ways in which CMS has provided support to the OIG and DOJ throughout Fiscal Year 2019 include:

- In April 2019, CMS implemented over 130 administrative actions simultaneously with HHS-OIG and DOJ's "Operation Brace Yourself." CMS implemented payment suspensions on 130 DME suppliers. As of August 2019, CMS suspended payments of approximately \$74 million and revoked five suppliers from Medicare, a direct result of the takedown.
- In connection to the April 2019 coordinated law enforcement actions of the Appalachian Regional Opioid Strike Force (ARPO), CMS suspended payments for eight enrolled providers and revoked the Medicare enrollment of two providers.
- In September 2019, CMS took administrative action in connection with federal law enforcement actions involving five federal districts against 35 defendants associated with dozens of telemedicine companies and cancer genetic testing laboratories.
- In addition to the administrative actions CMS implemented, the Agency also developed new edits to claims systems to prevent future improper payments, and worked to update regulations to help minimize fraud, waste and abuse.

Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) Initiatives

DME suppliers pose a high risk of fraud to the Medicare program and CMS has undertaken an aggressive strategy to address this risk. UPICs have continued to conduct site visits and interviews of DME suppliers, providers, and beneficiaries receiving DME products in high billing areas for DME supplies and products. In FY 2019, these additional funds supported DME investigations consisting of site visits to, and interviews of, suppliers, doctors, and patients identified as potentially suspicious or high risk.

Electronic Visit Verification

Section 12006(a) of the 21st Century Cures Act, signed into law on December 13, 2016, added section 1903(l) to the Social Security Act, which mandates that states require electronic visit verification (EVV) use for Medicaid-funded personal care services (PCS) and home health care services (HHCS) for in-home visits by a provider. Specifically, states must use an EVV system to substantiate the type of service performed, the individual receiving the service, the date of the service, the location of service delivery, the individual providing the service, and the time the service begins and ends. The Congressional Budget Office estimates that EVV will save states \$290 million over a 10-year period.

States were required to implement EVV for PCS by January 1, 2020 and for HHCS by January 1, 2023. Otherwise, the state is subject to incremental reductions in Federal Medical Assistance Percentage (FMAP) matching of PCS and HHCS expenditures, which eventually reaches one percent. There is a limited exception for the first year of the requirement if the state had both made a "good faith effort" to comply with the EVV requirements and encountered unavoidable delays in implementation of an EVV system. States with approved "good faith effort" exceptions will not have their FMAP matching reduced for the first calendar year. All states except for

Tennessee had approved “good faith effort” requests by December 2019, meaning they will implement EVV for PCS by January 1, 2021. Implementation of EVV applies to PCS provided under the state plan or a waiver of the plan, including under sections 1905(a)(24), 1915(c), 1915(i), 1915(j), 1915(k), and 1115 of the Social Security Act, and HHCS provided under section 1905(a)(7) of the Social Security Act or under a waiver or demonstration project (e.g., section 1915(c) or 1115 of the Social Security Act).

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 regulations establish 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. In FY 2019, CMS denied approximately 769 enrollments and revoked 11 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 2019, APS resulted in more than 1.6 million screenings. These screenings generated more than 46,198 potential licensure alerts, and more than 3,000 criminal alerts for potentially fraudulent providers and suppliers for further review by CMS. APS review resulted in approximately 85 criminal revocations and over 77 licensure revocations.

Site visits are a screening mechanism used to prevent questionable providers and suppliers from enrolling or maintaining enrollment in the Medicare program. CMS-authorized site-visit contractors validate that the provider or supplier complies with Medicare enrollment requirements during these visits. In FY 2019, the initiative resulted in 30,668 site visits conducted by the National Site Visit Contractor (NSVC), which conducts site visits for most Medicare FFS providers and suppliers, and 26,438 conducted by the National Supplier Clearinghouse (NSC), which conducts site visits for Medicare DME suppliers. This work

resulted in about 232 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 and suppliers from the program. In FY 2019, CMS deactivated 146,638 enrollments, and revoked 2,253 enrollments. Site visits, revalidation, and other initiatives have contributed to the deactivation¹⁸ and revocation¹⁹ of more than one million enrollment records since FY 2012, when CMS started implementing these screening and enrollment requirements.

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 for the Merit-Based Incentive Payment System (MIPS), demonstrations and model tests, and DMEPOS competitive bidding, providing direct access to information on the relationships between individuals and organizations stored in enrollment records. PECOS is a critical part of CMS's program integrity strategy and it is the base data used by the Fraud Prevention System (FPS) as well as many program integrity partners including the Unified Program Integrity Contractors (UPICs), Recovery Audit Contractors (RACs), the HHS-OIG, and state program integrity 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 Integrated Data Repository (IDR). State Medicaid programs also rely on data-sharing efforts to support requirements for screening providers and suppliers. CMS is focused on transitioning PECOS to a modernized, enterprise resource that is a platform for all provider/supplier enrollments across Medicare, Medicaid, and other CMS 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.

In FY 2019, CMS made significant changes to PECOS to simplify access, improve the usability and enhance the security of the system, including the following changes:

¹⁸ 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.

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

- Added initial features necessary to facilitate the future implementation of Multi-Factor Authentication
- Implemented the enhancements necessary to ensure all enrollment data that flows to the claims system comes directly from PECOS
- Continued enhancing and streamlining the process that expedites the enrollment processing for users by allowing digital upload of the signature pages
- Implemented enhancements to the provider enrollment Process to support the implementation of the final rule CMS-6058 titled “Program Integrity Enhancements to the Provider Enrollment Process”
- Implemented a Medicare ID Search tool in the provider interface to ease the process of finding the Medicare billing numbers to assist the provider community with any inquiries

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 screening and enrollment. SMAs can comply with federally required Medicaid screening and enrollment requirements by using CMSs’ 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 as required for Medicare’s screening and enrollment process.

During FY 2019, 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 its actively enrolled provider population 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 2019, 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 (state visits and targeted technical assistance) to states on federal requirements for Medicaid screening and enrollment requirements. In addition, CMS published updates to the MPEC in FY 2018, which is sub-regulatory guidance designed to assist states in applying certain regulatory requirements. The FY 2018 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 claim determinations made by Medicare and Medicaid Medical Review Contractors (MRCs). MRCs include the MACs, UPICs, and the Supplemental Medical Review Contractor (SMRC). The MRAC helps CMS by measuring the accuracy rate for each contractor, ensures the contractors are consistent in their medical review decisions, feeds information into the Award Fee Component for the MACs and determine where policy/issues/medical review inconsistencies may be present. 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 Prosthetics, Orthotics, and 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. In FY 2018, CMS transitioned the Power Mobility Device demonstration into the national program.

In FY 2019, CMS selected 12 additional DMEPOS items for required prior authorization. Beginning on July 22, 2019, nationwide, seven additional PMD codes required prior authorization. Also beginning on this date, five codes for pressure reducing support surfaces required prior authorization in California, Indiana, New Jersey, and North Carolina. Prior authorization for these codes expanded nationwide on October 21, 2019. The DME MACs review requests for prior authorization for the noted items, communicate decisions with suppliers and physicians, and provide ongoing education and customer service.

- Comparative Billing Reports

Comparative Billing Reports (CBRs) are educational tools providers can use to support efforts to protect the Medicare Trust Funds. These reports compare an individual provider or supplier's billing and/or prescribing practices for a specific billing code, policy group, or service with the billing and/or prescribing practices of that provider or supplier's peers

in the same state and/or specialty, and national averages. CBRs inform providers about Medicare coding, billing, and coverage guidelines and strategies for implementing self-audit processes into their practices, where appropriate. Currently, CBRs are available for download by the provider or supplier on a secure electronic portal as well as mailed in full via postal mail. Since 2011, CBRs have been issued on topics such as physical therapy, opioids, and orthoses claims. Typically, CBRs are sent to approximately 5,000 outliers providers per topic based on data analysis for a defined period of time. Topics are based on GAO/OIG reports, Comprehensive Error Rate Testing program findings and through agency and contractor data analysis. A CBR does not necessarily indicate improper billing and/or prescribing by the provider and only in select instances are providers and suppliers referred for additional review or education.

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 HCFA 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. MACBIS is a CMS enterprise-wide initiative to modernize and transform the information and data exchanges with states and other key stakeholders. The MACBIS initiative is comprised of four key areas of improvement to help prevent fraud, waste, and abuse; program data (such as T-MSIS), operational data, quality data, and business process performance data. HCFA 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 support and technical assistance and education from CMS through:

- Medicaid Technical Advisory Groups
- Voluntary state assistance site visits
- Webinars
- Medicaid Integrity Institute (MII)
- 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 began to analyze all statewide HCBS data available for 15 states to identify states to receive the initial onsite reviews. Five states that would benefit from onsite reviews were identified based on the potential to generate promising practices, expectations of a waiver renewal submission in the near term, or awareness of potential areas needing improvement. Through the end of FY 2019, onsite reviews were conducted in Ohio, Massachusetts, Maryland, Oregon, and the District of Columbia. The H&W SRT also developed and presented two trainings entitled “Risk Assessment & Mitigation Strategies” and “Balancing Choice & Risk” and supported CMS in presenting an introductory training for states on the H&W SRT. A data tracker tool that will house all of the state findings including promising practices was developed. The H&W SRT will continue to conduct analyses, onsite visits and trainings to help CMS identify, prevent and address 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 regulation²⁰ and guidance, including the Medicaid Information Technology Architecture (MITA) framework, several standards and conditions²¹, 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. As noted above, CMS is working closely with states to support the delivery of comprehensive digital service products for MACBIS. MACBIS is an enterprise-wide initiative to empower Medicaid states and federal government users to perform monitoring and oversight, inspect program integrity, evaluation demonstrations, perform actuarial and quality of care analysis, negotiate waivers, and enable the sharing of comprehensive program data with states, stakeholders, and the research community.

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.

²⁰ 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>)

²¹ <https://www.medicaid.gov/medicaid/data-and-systems/mita/index.html>

Moving forward, CMS is focused on increasing accountability and state flexibility by creating an outcomes based oversight model for 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 agency is taking to reduce improper payments. The Medicaid program and CHIP have been identified as being 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 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.

As described in the PERM final rule (82 FR 31158, July 5, 2017), CMS resumed the eligibility component measurement for the first cycle of 17 states and reported an updated national eligibility improper payment estimate for FY 2019. Between FY 2015 and FY 2018, CMS did not conduct the eligibility measurement component of PERM; refer to page 72 of the Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2018 for additional information.²² The PERM final rule also sets forth the standard provisions for a revised Medicaid Eligibility Quality Control (MEQC) program, which operates during off-cycle PERM years. The MEQC program provides states additional opportunities to review eligibility determinations to allow for continuous oversight and helps states determine corrective actions for eligibility determinations that are not reviewed in the PERM program, such as denials and terminations.

In the HHS FY 2019 Agency Financial Report (AFR)²³, CMS reported the national Medicaid improper payment rate based on measurements conducted in FYs 2017, 2018, and 2019.²⁴ The FY 2019 national Medicaid improper payment rate was 14.90 percent, representing \$57.36 billion in gross federal improper payments. The FY 2019 national improper payment rates by component are 16.30 percent for Medicaid FFS, 0.12 percent for Medicaid managed care, and 8.36 percent for Medicaid eligibility. The Medicaid improper payment rate increased from 9.79 percent in FY 2018, but the Medicaid improper payment rates between FY 2018 and

²² <https://oig.hhs.gov/publications/docs/hcfac/FY2018-hcfac.pdf>

²³ <https://www.hhs.gov/about/agencies/asfr/finance/financial-policy-library/agency-financial-reports/index.html>

²⁴ The national eligibility improper payment rate still includes a proxy estimate for the remaining 34 states that have not yet been measured since the reintegration of the PERM eligibility component.

FY 2019 are not comparable as the measurement has changed dramatically because of the reintegration of the PERM eligibility component for FY 2019.

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. Most improper payments cited on claims are those where a newly 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 7.21 percent in FY 2018 to 6.28 percent in FY 2019.

While the screening errors described above are for newly enrolled providers, states must also revalidate the enrollment and rescreen all providers at least every five years. States were required to complete the revalidation process of all existing providers by September 25, 2016. In FY 2019, CMS measured the second 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.

Another area driving the FY 2019 Medicaid improper payment estimate is the reintegration of the PERM eligibility component, mentioned above. This is the first time in the history of the program that the eligibility component measurement has been conducted by a federal contractor; previously states conducted the measurement and self-reported results to CMS for reporting the national rate. This allows for consistent insight into the accuracy of Medicaid eligibility determinations and increases the oversight of identified vulnerabilities. Based on the measurement of the first cycle of states, eligibility errors are mostly due to insufficient documentation to verify eligibility or noncompliance with eligibility redetermination requirements. The majority of the insufficient documentation errors represent both situations where the required verification was not done at all and where there is indication that the verification was initiated but there was no documentation to validate the verification process was completed. These insufficient documentation situations are related primarily to income or resource verification. CMS will complete the measurement of all states under the new eligibility component and establish a baseline in FY 2021.

CMS also reported in the FY 2019 AFR the national CHIP improper payment rate that is based on measurements conducted in FYs 2017, 2018, and 2019. The FY 2019 national CHIP improper payment rate was 15.83 percent, representing \$2.74 billion in gross federal improper payments. The national improper payment rates by component are 13.25 percent for CHIP FFS, 1.25 percent for CHIP managed care, and 11.78 percent for CHIP eligibility. The CHIP improper payment rate increased from 8.57 percent in FY 2018, but the CHIP improper payment rates between FY 2018 and FY 2019 are not comparable as the measurement has changed dramatically because of the reintegration of the PERM eligibility component for FY 2019.

One area driving the FY 2019 CHIP improper payment estimate is the FY 2019 reintegration of the PERM eligibility component, mentioned above. This is the first time in the history of the

program that the eligibility component measurement has been conducted by a federal contractor; previously states conducted the measurement and self-reported results to CMS for reporting the national rate. This allows for consistent insight into the accuracy of CHIP eligibility determinations and increases the oversight of identified vulnerabilities. Based on the measurement of the first cycle of states, eligibility errors are mostly due to insufficient documentation to verify eligibility or noncompliance with eligibility redetermination requirements. The majority of the insufficient documentation errors represent both situations where the required verification was not done at all and where there is indication that the verification was initiated but there was no documentation to validate the verification process was completed. These insufficient documentation situations are related primarily to income verification. The CHIP improper payment rate was also driven by claims where the beneficiary was ineligible for CHIP, but was eligible for Medicaid, again, mostly related to beneficiary income. HHS will complete the measurement of all states under the new eligibility component and establish a baseline in FY 2021.

Additionally, since FY 2014, improper payments cited on claims where a newly enrolled provider or a provider due for revalidation had not been appropriately enrolled and screened by the state or a provider did not have the required NPI on the claim have also driven the CHIP rate. Although these errors remain a driver of the CHIP rate, state compliance with the newly enrolled provider requirements has improved as the CHIP FFS improper payment rate for these errors decreased from 7.73 percent in FY 2018 to 6.02 percent in FY 2019.

Medicaid 1115 Financial Oversight

The Medicaid section 1115 demonstration is an increasingly important vehicle for state innovation in Medicaid program development, expansion and financing. Three quarters of states operate at least one 1115 demonstration, and there are approximately 70 active demonstrations representing estimated federal outlays in the amount of \$150.9 billion in FY 2018. 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 2019 included the rollout to states of the information in the FY 2018 State Medicaid Director Letter documenting CMS's approach to various aspects of Medicaid 1115 budget neutrality calculations.²⁵ This included 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 continues 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 the budget neutrality workbook that was rolled out to states throughout

²⁵ <https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/smd18009.pdf>

FY2019 to standardize budget neutrality reporting and to improve level of review of that data. The budget neutrality workbook resides in the Performance Metrics Database and Analytics (PMDA) system that supports Section 1115 demonstration workflows and is accessible to states.

CMS continues to build performance measurement sets for high priority demonstrations such as for substance use disorders, severe mental illness 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 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 sixth version of this system was released in June 2019.

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

From September 30, 2018 to September 29, 2019, CMS completed 119 reviews of HCBS waivers for 36 states and compiled reports with findings pertaining to the waivers' fiscal and quality components for each. A survey of states' incident management systems for HCBS waivers was also completed during FY 2019. Findings from fiscal and quality reviews are aggregated in an annual report each year which helps inform technical assistance activities and guide program improvements. Since 2016, 25 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. Thirty-two PACE reviews spanning 26 states were also conducted during this time.

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 (NBI) Medicare Drug Integrity Contractor (NBI MEDIC) and Investigations MEDIC (I-MEDIC)

CMS split its Medicare Parts C and D program integrity initiatives between two contractors: The National Benefit Integrity (NBI) Medicare Integrity Contractor (NBI MEDIC) and Investigations MEDIC (I-MEDIC). The NBI MEDIC has a national focus related to plan oversight pertaining to the following Part C and Part D program integrity initiatives: identification of program vulnerabilities, data analysis, health plan audits, outreach/education and law enforcement support which includes requests for information (RFI). As a result of the NBI MEDIC's data analysis projects including Part D plan sponsor self-audits, HHS recovered \$3.8 million in the first nine months of FY 2019 from Part D sponsors.

The primary purpose of the I-MEDIC is to detect, prevent, and proactively deter fraud, waste, and abuse for high risk prescribers/pharmacies in Medicare Parts C and D by focusing primarily on complaint intake and response, data analysis, investigative activities, referrals to law enforcement partners, and law enforcement support which includes RFIs.

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 Medicare Advantage Plans, Part D Prescription Drug Plans (PDPs), Section 1876 Cost Plans, and Medicare-Medicaid Plans (MMPs) that fail to send timely ANOC documents 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 2019, CMS issued a total of twenty-three (23) notices of non-compliance (NONCs) to nineteen (19) parent organizations as part of a timeliness review. Thirteen (13) NONCs were issued to plans that failed to enter dates that their ANOCs or EOCs were mailed, three (3) NONCs were issued for incorrect coding of ANOC or EOC materials, and six (6) were issued for failing to send timely ANOCs to enrollees, and one (1) was issued for sending an incorrect ANOC.

CMS issued twenty-three (23) NONCs to twenty-three (23) parent organizations and one (1) warning letter (WL) to one (1) parent organization during the accuracy review. The NONCs and WL were based on substantive inaccuracies (e.g., benefits, cost-sharing) contained in ANOC or EOC documents issued to Medicare enrollees.

Program Audits

CMS conducts program audits of Parts C and D plan sponsors (including organizations offering Medicare-Medicaid Plans) and Programs of All-Inclusive Care for the Elderly (PACE) organizations 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, scheduled program audits in 2019, 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 or CMS is conducting a focused audit. Each sponsor that has deficiencies cited in its audit report is required to correct all of the deficiencies and undergo a validation audit to ensure the issues have been corrected before the program audit can be closed.

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

CMS has greatly increased the level of transparency with respect to audit materials, the performance of audits, and the results of those audits, including any enforcement actions that may result. CMS believes that program audits and consequences of possible enforcement actions are continuing to drive improvements in the industry and are increasing sponsor's compliance with core program functions in the Medicare Parts C and D and PACE programs.

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 5,600 Part C plans submitted plan benefit packages on June 3, 2019 and project to cover more than 24.0 million beneficiaries in contract year 2020. 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 almost 4.5 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 from reliance on diagnoses to encounter data in payment. In calendar year 2019, CMS increased 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 2019 (the latest year for which CMS has data, which is based on the 2017 payment year) was 7.87 percent or \$16.73 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. Payment recovery for the pilot audits has been completed, totaling \$13.7 million. After completing the pilots, contract-level RADV audits of payment years 2011 through 2013 were completed and recovery efforts are pending based on CMS finalizing its draft RADV rule. CMS launched the payment year 2014 RADV audit in April 2019.
- **Overpayment Recoveries Related to Regulatory Provisions:** As required by the Social Security Act, Part C organizations are required to report and return identified overpayments. HHS believes that this requirement will reduce improper payments by encouraging Part C organizations to submit accurate payment information. In FY 2019, Part C organizations reported and returned approximately \$44.66 million in self-reported overpayments.
- **Training:** Historically, CMS has conducted fraud, waste, and abuse in-person and webinar training sessions for Medicare Part C and DMA plans. In FY 2019, CMS conducted two small in-person Medicare Part C & D Fraud, Waste and Abuse Collaboration Missions (October 2018 and March 2019), a large in-person fraud, waste, and abuse training (July 2019) and two opioid missions (April 2019 and August 2019) three in-person missions (one in October 2017 and two in April 2018) and a large in-person fraud, waste, and abuse conference in July 2018. The missions included multi-disciplinary teams of experts and decision makers from HHS and its partners, and allowed them to undertake collaborative efforts to protect the Medicare Part C and D programs.

The Part D gross improper payment estimate reported for FY 2019 (based on CY 2017) the latest year for which CMS has data, was 0.75 percent or \$607.94 million, 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 Medicare Part C and Part D sponsors. In FY 2019 CMS conducted two small in-person Medicare Part C & D Fraud, Waste and Abuse Collaboration Missions (October 2018 and March 2019), a large in-person fraud, waste, and abuse training (July 2019), two opioid missions (April 2019 and August 2019), 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 missions included multi-disciplinary teams of experts and decision makers from HHS and its partners, and allowed them to undertake collaborative efforts to protect the Medicare Part C and D programs.
- **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 Statutory Provisions:** As required by the Social Security Act, HHS requires Part D sponsors report and return all identified overpayments. HHS believes that this overpayment statute contributed to increased attention to data accuracy by Part D sponsors. In FY 2019, Part D sponsors self-reported and returned approximately \$1.5 million in overpayments.

Central Data Abstraction Tool

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

The Federally-facilitated Exchanges (FFE) and the State-based Exchanges (SBEs) have increased their focus on program integrity. In FY 2019, CMS triaged thousands of consumer complaints, worked with health insurance issuers to cancel fraudulent policies, performed data analysis and license verifications to identify potentially noncompliant insurance agents and

brokers, conducted investigations, and referred egregious cases to the HHS-OIG. CMS also reviewed cases of agent and broker misconduct and taking administrative actions including terminating CMS's agreements with agents and brokers and imposing civil monetary penalties on those agents and brokers who were found to have engaged in misconduct. CMS and its program integrity contractors continuously analyze plan enrollment and other types of data to identify early warning signs of fraud. CMS hosts meetings with SBEs every other month to share best practices for identifying and deterring fraud and coordinate with states' Departments of Insurance (DOIs) to understand agent and broker licensing requirements and report noncompliance. Lastly, CMS supports ongoing OIG and DOI investigations by fulfilling requests for records regarding consumer enrollments and financial assistance, complaints, and results of CMS investigations.

Provide Greater Transparency into Program Integrity Issues within Medicare and Medicaid

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

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.

CMS continues to work with providers, states, and others to protect CMS programs from fraud, waste and abuse schemes. CMS is focused on safeguarding programs and protecting beneficiaries from fraud, waste and abuse, while also working to minimize unnecessary provider burden. Providing education and training opportunities that are responsive to stakeholder needs will continue to protect the financial security of CMS' 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 continues to provide needed information that is responsive to the realities of clinical practice.

In FY 2019, CMS continued to enhance its digital presence with the addition of the Medicaid Program Integrity Strategy webpage. This webpage focuses on strengthening the fight against Medicaid fraud with new and enhanced initiatives. To learn more, please visit <https://www.cms.gov/About-CMS/Components/CPI/Medicaid-PI-Strategy>. The Medicaid Program Integrity Strategy includes stronger audits and oversight functions, increased data

sharing and partnerships, and additional education, technical assistance, and collaboration (to learn more: <https://www.cms.gov/About-CMS/Components/CPI/Medicaid-PI-Strategy>).

The Medicaid Program Integrity Strategy includes stronger audits and oversight functions, increased data sharing and partnerships, and additional education, technical assistance, and collaboration.). CMS also coordinated multiple training events focusing on 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.

Additionally, in an effort to increase transparency and seek input into innovative program integrity solutions to meet the challenges of the new Medicare landscape, CMS held Request for Information (RFI) listening sessions related to two RFIs: the Future of Program Integrity and Using Advanced Technology in Program Integrity.²⁶

Healthcare Fraud Prevention Partnership (HFPP)

In July 2012, the Secretary of HHS and the U.S. Attorney General announced a groundbreaking 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 2019, the HFPP reached a total membership level of 144 partner organizations, comprised of 12 federal agencies, 13 associations, 71 private payers, and 48 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 and institutional claims and is planning to expand to collect pharmacy and dental claims in the future.

²⁶ <https://www.cms.gov/blog/future-medicare-program-integrity>.

Over 9.9 billion professional claim lines were submitted by partners through FY 2019 for the purpose of conducting cross-payer analyses, and by the end of FY 2019, the HFPP has commenced or completed more than 25 studies since program inception.

Examples of studies initiated in FY 2019 include the identification of:

- Potentially problematic sleep study providers
- 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 2019 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.

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. As of September 2018, New Hampshire has collaborated with CMS to develop and implement performance indicators, advanced analytics, and private-public partnerships to identify potential opioid overprescribing and misuse, and to enable data-driven interventions. This pilot project will give CMS a deeper understanding of state data, privacy and data sharing policy, and policy, and 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. The public can search, download, and evaluate the reported data.

For Program Year 2018, CMS published information regarding \$9.2 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 11.4 million total records attributable to 627,000 physicians and 1,180 teaching hospitals.

Payments in the three major reporting categories included:

- \$3.0 billion in general (i.e., non-research related) payments
- \$4.9 billion in research payments
- \$1.3 billion of ownership or investment interests held by physicians or their immediate family members.

Since the program's inception, CMS has published 64.8 million records, accounting for \$43 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 2019, HHS allocated \$18 million in HCFAC appropriations, plus an additional \$63,877 in carryover funding from FY 2018 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 2019, 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 \$15.5 million in funding to 54 SMPs nationwide, including eight new SMP grantees. In FY 2019, ACL provided continuation awards to the 54 grantees totaling \$15.5 million. 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.

Genetic Testing Fraud Schemes

Genetic testing fraud has become a widespread issue nationally with company representatives approaching seniors and other Medicare beneficiaries to solicit genetic tests at senior and community centers, health/senior fairs, other community events, and senior housing complexes. The SMP grantees have received reports of company representatives going door-to-door in the

community and within housing complexes in addition to extensive advertising on Facebook and other social media platforms.

ACL first became aware of these schemes in early 2019 through reports from the SMP grantees, and were the first to alert our partners at the OIG and CMS of the emerging trends. ACL has led HHS's outreach and education effort to warn the public and protect beneficiaries from becoming victims of these schemes. This outreach includes national social media campaigns conducted by the SMP grantee network to get the word out to the public as quickly as possible. The SMP National Resource Center has also developed sample press releases, outreach materials, and an infographic on the topic that can be used by partners and SMP state grantees to conduct outreach on the local level.

In addition to the outreach efforts being conducted nationally, ACL worked closely with CMS and the OIG to provide cases and complaints directly to investigators upon receipt to ensure the cases are getting in the right hands as quickly as possible. These efforts led to a federal law enforcement action involving dozens of companies and cancer genetic testing laboratories in September. The September 27, 2019, takedown resulted in charges against 35 individuals for their alleged participation in health care fraud schemes involving \$2.1 billion in losses. The coordinated federal investigation targeted an alleged scheme involving the payment of illegal kickbacks and bribes by cancer genetic testing laboratories in exchange for the referral of Medicare beneficiaries by medical professionals working with fraudulent companies for expensive cancer genetic tests that were medically unnecessary.

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 2018, the SMP projects had a total of 6,935 active team members who conducted 26,932 group outreach and education events, reaching an estimated 1.7 million people. In addition, the projects had 278,761 individual interactions with, or on behalf of, a Medicare beneficiary. For 2018, the SMP projects reported \$15,136 in expected Medicare recoveries and \$5,734 in expected Medicaid recoveries. Cost avoidance totaled \$602,063, while savings to beneficiaries and others totaled \$27,689. Further, additional Medicare expected recoveries totaled \$11.9 million. These recoveries came from three projects that validated information for existing cases regarding two home health fraud schemes and one individual physician who provided unnecessary services and falsified records.

Since SMP's inception, the program has educated almost 40.2 million beneficiaries through 414,247 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 2019 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.

SMP Infrastructure and Program Support

SMP Resource Center

During FY 2019, ACL awarded year three 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 2019, 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 2019, ACL implemented the second year of 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 from the first two years of the project are positive and include the following findings:

- 97 percent of participants were satisfied with the SMP group education session they attended;
- 97 percent of participants felt the presentation provided them with useful information;

- and
- 96 percent of participants would recommend the presentation to others.

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

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 2019, HHS allocated the Office of the General Counsel (OGC) \$7.3 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 2019 helped the Government establish over \$1.6 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 2019, OGC worked collaboratively with DOJ and OIG on numerous FCA matters regarding a variety of issues such as: kickbacks and other unlawful marketing practices in connection with the marketing of an addictive opioid painkiller; kickbacks related to medically unnecessary stent procedures; material misrepresentations made by an IT subcontractor during a state health benefits exchange contract award process; and the submission of inaccurate information about health status of Medicare Advantage beneficiaries. OGC efforts on these and other FCA matters in FY 2019 helped the Federal Government recover approximately \$1.5 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 long-term care facility for failure to satisfy the quality of care requirements under 42 C.F.R. § 483.25. In this instance, the facility had failed for eight consecutive months to arrange for one of its residents to receive a necessary procedure to extract the resident's teeth, all of which had rotted and decayed.

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 2019, OGC worked with CMS to prevail on an enrollment denial decision to a physician who had pled guilty to soliciting \$1.3 million in bribes from contractors in Afghanistan and to participating in a conspiracy to traffic heroin.

Part C and Part D Compliance

During FY 2019, 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. Attorneys' Offices, the Secret Service, U.S. Postal Service, and the U.S. Marshal's Service in filing petitions for remission directed to recover over \$282,067 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 2019, OGC petitioned these agencies to recover funds in matters in which Medicare was a victim of fraud.

Regulatory Review and Programmatic Advice

In FY 2019, 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 Medicare Shared Saving Program (MSSP), including advice regarding a final rule, program integrity screenings for applicants to the program, and appeals of application denials.
- OGC reviewed a proposed rule that would allow CMS to use extrapolation in Part C risk adjustment data validation (RADV) audits and which noted that CMS finds it is unnecessary to apply a fee-for-service adjuster to contract level RADV audits. OGC also reviewed several Federal Register Notices, which extended the comment period on these proposed provisions and addressed the release of the underlying data.
- OGC reviewed a final rule that made several changes to CMS’s “preclusion list” regulations, which prohibit certain suspect providers and prescribers from receiving reimbursement under Medicare Part C or having their prescriptions covered under Medicare Part D. The new regulations revised and clarified several requirements regarding placement on the preclusion list, the effect of preclusion, notice, and appeals.
- 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 2019, OGC provided extensive counsel to CMS related to the issuance of its proposed rule, Modernizing and Clarifying the Physician Self-Referral Regulations (CMS-1720-P), a rule intended to help providers embrace innovative care delivery by modernizing and clarifying regulations that interpret the Stark Law. The proposed rule intends to simplify compliance for health care providers across the industry, and would open additional avenues for physicians and other health care providers to coordinate the care of the patients they serve to ensure patients receive the highest quality of care. 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 2019, 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 2019, 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 2019, OGC negotiated stipulations for the transfer of the Medicare Part D Coverage Gap Discount Program and Medicaid Drug Rebate Agreements from a debtor pharmaceutical company to the new owners who acquired debtor's assets and agreements.

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 secured a favorable decision against the state of Maine involving disallowances of \$72.1 million in Federal Financial Participation for Disproportionate Share Hospital (DSH) payments and traditional Medicaid payments for services.

In summary, OGC's efforts in FY 2019 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 2019, \$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 (FDCA), 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 264 criminal HCFAC investigations. In FY 2019, FDA's tenth fiscal year of HCFAC Program activity, OCI, through its PFP, opened 26 criminal investigations, including investigations involving drug compounders, clinical trials, and foreign and domestic medical-product manufacturers.

The investigations opened in FY 2019 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 or test drugs, devices or biologics. Application fraud investigations opened in FY 2019 involve drug manufacturers and medical device manufacturers.
- Questionable manufacturing practices, involving the distribution of foreign-manufactured active pharmaceutical ingredients (APIs), drug compounding pharmacies, and biologic tissue products.
- Clinical trial fraud, involving possible falsification of study documents and/or fraudulent study subject enrollments. The investigations consist in part of individuals suspected of falsifying and/or manipulating clinical trial data or conducting clinical trials without FDA oversight.
- Fraudulent marketing schemes, involving the promotion of products through false or misleading claims, including opioid pain medications and stem cell biologic products.

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 December 2018, in the District of Massachusetts, the co-owner and four former employees of a compounding pharmacy were convicted by a jury, in connection with a nationwide fungal meningitis outbreak that killed 64 and caused infections in over 750 patients. Two former pharmacists were convicted of racketeering and mail fraud. Another pharmacist was convicted of misdemeanor misbranding violations, for helping to fill prescriptions using fake patient

names. In May 2019, one of the pharmacists was sentenced to 30 months in prison; one pharmacist was sentenced to 24 months of probation; and another was sentenced to 12 months of probation. On this same case, two additional pharmacists were convicted by a jury in May 2019, on felony misbranding violations. Another defendant in this case, a former hospital pharmacy buyer, was sentenced in January 2019 to 12 months of probation and ordered to forfeit \$40,000. 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 December 2018, in the District of New Jersey, a foreign multinational company that manufactured medical devices pled guilty to an information charging three misdemeanor counts of misbranding medical devices, in violation of the FDCA. The company was sentenced to pay an \$80 million criminal fine and another \$5 million in criminal forfeiture. The company's former Division Manager for Quality Assurance also pled guilty to one misdemeanor count of misbranding; and was subsequently sentenced to 12 months of probation as well as ordered to pay a \$5,000 fine. The case resulted from a failure by the defendants to file required Medical Device Reports (MDRs) with the FDA. MDR reports are one of the post-market surveillance tools used by the FDA to detect potential device-related safety issues.

In February 2019, in the Eastern District of Pennsylvania, an Allentown pharmaceutical company agreed to a \$4 million civil settlement to resolve False Claims Act liability, in connection with an alleged scheme to avoid paying fees associated with new drug applications filed with the FDA. Knowing it was ineligible for a fee waiver, the pharmaceutical company allegedly developed a scheme with two other companies to avoid paying the new drug application fees. The arrangement made between the defendant and these other two companies was never disclosed to the government, despite the government's request for such information.

In April 2019, in the Southern District of Indiana, the former CEO and owner of an Indiana compounding pharmacy was convicted in a jury trial of conspiracy to defraud the FDA and nine counts of adulterating drugs. The defendant's conviction resulted from distributing over- and under-potent drugs to hospitals and lying to the FDA inspectors to conceal out-of-specification drug potency test results. The former CEO was sentenced in September 2019 to 33 months in prison, plus one year of probation, and ordered to pay a \$25,000 fine. Another defendant in this case, a former compliance director, was sentenced in April 2019 to five months incarceration, plus three years of probation, after pleading guilty to adulterating drugs and conspiracy to defraud the FDA.

In May 2019, in the Central District of California, the owner of a Glendora medical marketing business pled guilty to health care fraud and subscribing to a false federal income tax return, in connection with a scheme to defraud a public health care benefit program. The scheme involved soliciting and paying health insurance beneficiaries to participate in a purported clinical trial. The defendant and others then submitted fraudulent claims for reimbursement for medications on behalf of the beneficiaries.

In June 2019, in the District of Maryland, a medical device manufacturer pleaded guilty to one misdemeanor count of failure and refusal to report a medical device removal from the market, in

violation of the Federal FDCA. The manufacturer removed its device from its point of use after learning that more than 30,000 devices were contaminated with endotoxin levels that posed a risk to patient health. The market removal of the device was never reported to the FDA and the reason for the product removal was concealed from doctors, hospitals, and the company's own sales force. To resolve both criminal and civil liability, the defendant agreed to pay a \$3 million criminal fine, plus \$12 million to settle civil liability for causing false claims to be submitted to government health care programs. This investigation is being conducted jointly with the HHS-OIG, the FBI, and the Department of Defense Criminal Investigative Service.

Furthermore, the 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 possibly pose a risk to the public's health and safety.

Finally, the 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 March 2019, the FDA conducted a one-day training session for supervisory criminal investigators. This training covered health care fraud and PFP-related topics, including case-related fraud schemes. On another occasion, in March 2019, the FDA conducted a one-day training session for newly hired criminal investigators. This training also covered health care fraud and PFP-related topics, including case-related fraud schemes.

In May 2019, the FDA conducted a one-day training session for criminal investigators in the Miami Field Office. This training covered health care fraud control and clinical trial fraud cases.

In July 2019, the FDA sent criminal investigators to a week-long the FDA sponsored Clinical Bioresearch Monitoring training, to train alongside consumer safety officers who conduct regulatory inspections at clinical trial study sites. This training covered PFP-related topics, such as identifying evidence of fraud and data falsifications.

In August 2019, the FDA sent criminal investigators to participate in a three-day training program sponsored by the National Health Care Anti-Fraud Association (NHCAA), entitled "Schemes for the Health Care Fraud Investigators & Analyst." FDA criminal investigators trained with other law enforcement and private partners involved in health care anti-fraud efforts.

In September 2019, the FDA conducted a one-day training session for criminal investigators in the Chicago Field Office. This training covered health care fraud and PFP-related topics. On another occasion, in September 2019, the FDA presented on the PFP to other law enforcement and insurance investigators at the National Insurance Crime Bureau in Melville, New York

DEPARTMENT OF JUSTICE

United States Attorneys

In FY 2019, the United States Attorneys' Offices (USAOs) were allocated \$56.9 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.

In addition, in October 2018, the Department announced the formation of the Appalachian Regional Opioid Strike Force (ARPO Strike Force), a joint law enforcement effort that brings together the resources and expertise of the Health Care Fraud Unit in the Criminal Division's Fraud Section (HCF Unit), the USAOs for nine federal districts in five states,²⁷ as well as law enforcement partners at the FBI, U.S. Department of Health and Human Services Office of the Inspector General (HHS-OIG) and DEA. The mission of the ARPO Strike Force is to identify and investigate health care fraud schemes in the Appalachian region and surrounding areas, and to effectively and efficiently prosecute medical professionals and others involved in the illegal prescription and distribution of opioids.

²⁷ The USAOs are the Northern District of Alabama, Eastern District of Kentucky, the Western District of Kentucky, the Southern District of Ohio, the Eastern District of Tennessee, the Middle District of Tennessee, the Western District of Tennessee, the Northern District of West Virginia, and the Southern District of West Virginia,

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 2019, the Office of Legal Education (OLE) offered a course entitled “Emerging Issues in Health Care Fraud” at the National Advocacy Center which was attended by approximately 90 Assistant United States Attorneys and which provided training on a variety of topics related to health care fraud. In addition, the Executive Office for United States Attorneys (EOUSA) presented multiple webinars during FY 2019 focusing on health care fraud issues. Many AUSAs, analysts, auditors, investigators, and paralegals participated in other federal, state, and private health care fraud seminars.

EOUSA also launched its SIRIS Resource Center in FY 2019, which gives USAO personnel access to the National Health Care Anti-Fraud Association’s (NHCAA) Special Investigation Resource and Intelligence System (SIRIS) database. The SIRIS database contains data contributed by NHCAA members (which include private insurers as well as federal and state law enforcement and regulatory officials with jurisdiction over health care fraud). Using the SIRIS Resource Center, USAO personnel can conduct inquiries as to particular providers or schemes to determine whether other NHCAA members have contributed relevant information to the database.

Criminal Prosecutions²⁸

In FY 2019, the USAOs opened 1,060 new criminal health care fraud investigations and filed criminal charges in 485 cases involving 814 defendants. During that same time period, 528 defendants were convicted of health care fraud-related crimes.

Civil Matters and Cases²⁹

In FY 2019, the USAOs opened 1,112 new civil health care fraud investigations and had 1,343 civil health care fraud matters pending at the end of the fiscal year.

Civil Division

In FY 2019, the Civil Division received approximately \$41 million in FY 2019 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. In FY 2019, the Fraud Section and the United States Attorneys’ Office won or negotiated more than \$2.6 billion under the FCA.

²⁸ FY 2019 numbers are actual data through the end of September 2019. This data includes records classified either with the primary or tertiary 03G – Health Care Fraud program code.

²⁹ FY 2019 numbers are actual data through the end of September 2019. This data includes those records classified under with the FRHC – Health Care Fraud civil code.

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 other law enforcement partners to pursue allegations of health care fraud.

The Fraud Section investigates and resolves matters involving a wide array of health care providers and suppliers. First and foremost, the Fraud Section takes seriously matters which raise the potential for patient harm, particularly in our vulnerable elderly population. For example, the Vanguard Health case resolved allegations that five Vanguard nursing facilities failed to administer medications as prescribed; failed to provide standard infection control, which led to infections; failed to provide wound care as ordered; failed to take prophylactic measures to prevent pressure ulcers, such as turning and repositioning; used unnecessary physical restraints on residents; and failed to meet basic nutrition and hygiene requirements of residents. Similarly, the Avanir case discussed above resolved allegations that Avanir targeted false and misleading marketing to long-term care facilities to induce prescriptions of its drug for unapproved uses.

The Fraud Section continues to pursue opioid-related fraud schemes, such as the Reckitt Benckiser Group (RB Group) matter, which resolved allegations that RB Group and its subsidiaries promoted its opioid product, Suboxone, using false and misleading claims that Suboxone Film was less susceptible to diversion and abuse than other buprenorphine products and that Suboxone Film was less susceptible to accidental pediatric exposure than tablets. In another example, the Fraud Section resolved allegations that Insys used sham speaker programs, jobs for the prescribers' relatives and friends, and lavish meals and entertainment to encourage physicians to prescribe Insys's opioid product, Subsys, notwithstanding the drug's high risk of abuse.

The Fraud Section continues to vigorously pursue pharmaceutical manufacturers who engage in illegal practices that contribute to soaring drug pricing. The Fraud Section has resolved a number of cases, including the Actelion and Astellas matters discussed above, alleging that pharmaceutical manufacturers are illegally using foundations, which claim 501(c)(3) status for tax purposes, as conduits to pay the copays of Medicare patients. Under these arrangements, which violate the Anti-Kickback Statute (AKS), the manufacturers funnel money to the foundation to be used specifically to pay the copays for Medicare patients and Medicare is billed for the remaining cost.

The Fraud Section has pursued other schemes that violate the AKS, which 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. AKS violations are pernicious because of their potential to subvert medical decision-making. For example, the Fraud Section resolved allegations that Patient Care America, a compounding pharmacy, paid kickbacks to generate referrals of prescriptions of expensive pain creams, scar creams, and vitamins, which were reimbursed by TRICARE, the federal health care program for military members and their

families. Other matters relating to AKS violations involved medical device manufacturers (Covidien and ACell), hospitals (MedStar Health), and laboratories (Inform Diagnostics).

Electronic health record (EHR) systems are a growing segment of the health care industry, and EHR related fraud schemes remain a focus of the Fraud Section's work. This year, the Fraud Section resolved matters alleging that EHR companies had caused its users to submit false claims to the government by misrepresenting the capabilities of its EHR product (Greenway) and had paid kickbacks to induce use of its products (Greenway and Inform Diagnostics).

As in years past, the Fraud Section also resolved a number of matters in which providers billed federal health care programs for medically unnecessary services or services not rendered as billed. Such matters involved allegations that providers, including hospices, inpatient rehabilitation facilities, pediatric dental providers, and cardiac clinics billed for services that the patients did not need (such as the SouthernCare, Encompass Health Corporation, ImmediaDent, and matters discussed earlier)). 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. Representative of these efforts, a number of corporate settlements required individuals, particularly senior executives or owners, to pay a portion of the settlement amount (such as the Patient Care America, Quality Therapy & Consultation, and Vanguard Health, matters discussed above).

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 enforces consumer protection laws to end dangerous practices that harm America's most vulnerable populations, such as the sick and elderly. The Branch aggressively pursues cases against those who market unsafe pharmaceuticals, medical devices, and dietary supplements that endanger the health and safety of patients. The Branch works closely with the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), and other law enforcement agencies to investigate a wide range of health care fraud cases, including those involving opioids and the promotion and distribution of unapproved and adulterated drugs and medical devices. It also collaborates with U.S. Attorneys' Offices and the Commercial Litigation Branch's Fraud Section on major health care fraud cases. Under the Department's regulations, the Branch is the primary component charged with enforcement of the Food, Drug, and Cosmetic Act (FDCA) in the federal court system.

The Consumer Protection Branch is advancing a number of Department priorities to combat the nation's opioid crisis, pursuing wrongdoers throughout the entire opioid distribution chain, including pharmaceutical manufacturers, wholesale distributors, pharmacies, and health care providers. The Branch is a leading member of the Department's Prescription Interdiction and Litigation (PIL) Task Force established in February 2018 to combat the opioid crisis at every level of the distribution system. The Branch is actively working on numerous criminal and civil investigations and litigation related to opioid manufacturers. For example, in April 2019, the Branch and the U.S. Attorney's Office for the Western District of Virginia indicted Indivior Inc., a wholly owned subsidiary of Reckitt Benckiser Group, for health care fraud and other offenses relating to its marketing of Suboxone. In addition, in July 2019, together with the Frauds Section and the U.S. Attorney's Office for the Western District of Virginia, the Branch reached a

landmark resolution with Reckitt Benckiser Group, which agreed to pay \$1.4 billion to resolve its potential criminal and civil liability related to its marketing of Suboxone. Reckitt Benckiser Group executed a non-prosecution agreement that required it to forfeit \$647 million of proceeds it received from Indivior and it entered into civil and administrative settlements totaling \$750 million. The company also agreed not to manufacture, market, or sell Schedule I, II, or III controlled substances in the United States for three years and to cooperate fully with all Suboxone investigations and prosecutions by the Department. The resolution was the largest recovery by the United States in an opioid drug case.

Using a variety of data sets and advanced analytics, the Consumer Protection Branch is advancing an effort to take all appropriate action against pharmacies, pharmacists, and health care providers fueling the diversion of prescription opioids. The Branch has brought a number of civil injunctive and penalty actions under the CSA to stop dangerous dispensing and prescribing conduct in advance of potential criminal prosecutions. Recent actions include a case filed against two doctors in the Northern District of Texas and a case against two rural pharmacies, their owner, and three pharmacists in the Middle District of Tennessee. The Branch also is advising numerous USAOs on techniques and theories for initiating and conducting their own investigations.

In addition to its opioid enforcement efforts, the Consumer Protection Branch prosecutes pharmaceutical and medical device manufacturers and their executives when they violate the FDCA in the manufacture and marketing of their products – conduct that often puts patient safety at risk. For instance, in FY 2019, the Branch played a leading role in the prosecution of three major medical device manufacturers. In one matter, medical device manufacturer ev3, Inc. pleaded guilty and was sentenced to pay a criminal fine and forfeiture of \$17.9 million related to Onyx, a liquid agent designed to solidify in malformed blood vessels that was used in minimally invasive brain surgeries to correct a potentially fatal vascular condition. Following FDA’s approval of Onyx for use in the brain, ev3 sales representatives trained, encouraged, and guided surgeons to use Onyx in larger doses in other parts of the body without FDA approval or appropriate clinical trials. As part of the plea agreement, Medtronic, which acquired ev3 subsequent to the course of criminal conduct, also agreed to prospective compliance measures to prevent future misconduct.

In December 2018, together with the U.S. Attorney’s Office for the District of New Jersey, the Branch prosecuted foreign multinational medical device manufacturer Olympus Medical Systems Corp. and its former top regulatory official, for failing to file required adverse event reports involving infections connected to the company’s duodenoscope device. The company pled guilty to an information charging three counts of misbranding and the former top regulatory official also pled guilty in connection with the case. The convictions stemmed from a series of incidents in which multiple patients at hospitals in Europe and the United States experienced serious infections after being treated with the company’s medical device.

Together with the U.S. Attorney’s Office for the District of Maryland, the Branch prosecuted medical device manufacturer ACell for its failure and refusal to report the removal of its MicroMatrix powder wound dressing product from the market in violation of the FDCA. Pursuant to a plea agreement, ACell admitted that it learned in January 2012 that more than 30,000 MicroMatrix devices were contaminated with endotoxin levels that posed a risk to patient

health. The company never reported the removal of its medical device to FDA and it concealed the reason for the product removal from doctors, hospitals, and the company's own sales force. Moreover, it did not notify doctors who had already used MicroMatrix devices from the contaminated lots of the elevated endotoxin levels. In addition to paying a \$3 million fine, under the terms of the plea agreement, ACell agreed to enact extensive compliance reforms. ACell also agreed to pay \$12 million to resolve civil FCA allegations that it marketed MicroMatrix with false and misleading messages that it was safe for internal use and paid kickbacks to induce prescribers to order ACell products.

In another case that put patients at risk, the Branch partnered with the U.S. Attorney's Office in the Southern District of Indiana to prosecute the former CEO and owner of an Indiana compounding pharmacy who was ultimately convicted by a jury of conspiracy to defraud the FDA and adulterating drugs. 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. Another defendant in this case, a former compliance director, was sentenced in April 2019 to five months incarceration, plus three years of probation, after pleading guilty to adulterating drugs and conspiracy to defraud FDA.

As the Department of Justice component charged with enforcing laws that ensure the integrity of Americans' food and drug supply, the Consumer Protection Branch is advancing an initiative to bring civil and criminal enforcement actions against dietary supplement manufacturers and importers who bring illicit ingredients and unregulated synthetic chemicals from China and elsewhere into the country for inclusion in misbranded supplements. The Consumer Protection Branch's civil actions aim to bring swift action to stop those entities and individuals who make or distribute dietary supplements as unapproved new drugs and/or fail to comply with current good manufacturing practice (CGMP) requirements imposed by FDA regulations. The Branch in these cases typically pursues civil injunctions that require the individuals and entities to cease operating until they have established their compliance with the law. Many cases involve firms that make unsupported claims that their dietary supplements can treat or prevent a host of serious conditions, such as cancer or heart disease. Cases may also assert that defendants failed to ensure their products meet CGMP specifications for identity, purity, strength, and composition. The Branch brought numerous civil actions against dietary supplement makers and distributors this past year.

The Consumer Protection Branch's criminal actions seek to hold those companies and executives who knowingly distribute dangerously tainted products or sell products made with undisclosed illicit ingredients smuggled into the United States. In March 2019, for example, the Branch brought criminal charges against six individuals and two companies that sold hundreds of thousands of illegal products, including anabolic steroids, fraudulently representing that those products were high-quality, legal dietary supplements. Earlier in November 2018, the Branch charged two California residents in connection with a long-running scheme to smuggle illicit dietary supplement ingredients into the United States from China. And in March 2019, culminating years of investigation and litigation, multiple defendants pleaded guilty in Dallas to felony charges in connection with a massive fraudulent scheme to sell popular workout supplements known as Jack3d and OxyElite Pro. The indictment alleged that the defendants misrepresented the nature and origin of the active ingredients in their products. OxyElite Pro was recalled in 2013 after the FDA linked it to a deadly outbreak of serious liver injuries. The

individual defendants, together with the companies, agreed to pay criminal fines and forfeitures totaling about \$60 million.

Finally, the Consumer Protection Branch has long pursued fraudsters who prey on servicemembers and veterans. This work, conducted in partnership with the Defense Criminal Investigative Service (“DCIS”) and other military and law enforcement entities, involves, among other things, the theft of servicemembers’ identity, websites that deceptively pose as military recruitment sites, and other forms of fraud and criminal conduct including health care benefits fraud. As an example of this work, in August, an indictment was unsealed in San Antonio, Texas, charging five individuals with coordinating an identity theft and fraud scheme targeting servicemembers and veterans. The charged defendants, who were based both in the Philippines and the United States, are alleged to have used the stolen personal identifying information (PII) of thousands of military members to access Department of Defense and Veterans Affairs benefits sites and steal millions of dollars.

Criminal Division

In FY 2019, the Criminal Division was allocated \$32.1 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 instead defraud Medicare and other government health care programs. In FY 2019, the HCF Unit’s Strike Force program provided attorney staffing, litigation support, and leadership and management to the Health Care Fraud and Prescription Opioid Strike Forces operating in 24 federal judicial districts across the United States. The current strike forces include Miami and Tampa/Orlando, Florida; Nashville, Tennessee; Ft. Mitchell, Kentucky; Los Angeles, California; Detroit, Michigan; Houston, San Antonio and Dallas, Texas; Brooklyn, New York; Baton Rouge and New Orleans, Louisiana;

Chicago, Illinois; Newark, New Jersey/Philadelphia, Pennsylvania, along with a Corporate Strike Force located in Washington, D.C.

The Strike Forces in Nashville and Fort Mitchell were added this fiscal year as part of the Appalachian Regional Prescription Opioid (ARPO) Strike Force, announced by Assistant Attorney General Brian Benczkowski on October 25, 2018, as a joint effort between DOJ, HHS-OIG, FBI, DEA, and local law enforcement partners to combat health care fraud and the opioid epidemic in 9 federal districts. Following the ARPO Takedown on April 17, 2019, ARPO was expanded to include the Western District of Virginia. FY 2020 will see a Strike Force expansion to the Rio Grande Valley, including parts of the Southern and Western District of Texas, such as San Antonio, Texas. Since the inception of the Strike Force program in 2007, the HCF Unit and its Strike Force partners have charged over 4,200 defendants who have collectively billed the Medicare program approximately \$19.2 billion.

In FY 2019 alone, the HCF Unit achieved the following results:

- Filed 170 indictments, criminal informations and complaints involving charges against 344 defendants who allegedly collectively billed federal health care programs approximately \$4.1 billion;
- Obtained 157 guilty pleas and litigated 20 jury trials, with guilty verdicts against 23 defendants; and
- Sentenced 163 defendants, with an average sentence of over 60 months.

Each year, the HCF Unit coordinates large-scale, law enforcement actions with its partners. In FY 2019, the HCF Unit successfully completed 11 coordinated law enforcement actions.

- On April 9, 2019, the investigation called “Operational Brace Yourself” culminated in charges against 24 defendants, including the CEOs, COOs and others associated with five telemedicine companies, the owners of dozens of durable medical equipment (DME) companies and three licensed medical professionals, engaged in a Telemedicine and DME scheme involving over \$1.2 billion in losses. In conjunction with this effort, the Centers for Medicare & Medicaid Services, Center for the Program Integrity (CMS/CPI), announced it took adverse administrative action against more than 130 DME companies.
- On April 17, 2019, Attorney General William P. Barr and Department of Health and Human Services (HHS) Secretary Alex M. Azar II, announced the results of the first Takedown for the ARPO Strike Force. This Takedown resulted in charges against 60 defendants, including 53 licensed medical professionals across 11 federal districts. This effort also marked the first time the DOJ, DEA, HHS-OIG, HHS’ Substance Abuse and Mental Health Services Administration (SAMHSA), Centers for Disease Control and Prevention (CDC), and all impacted State Departments of Health deployed a coordinated public health response to address patient harm and insure continuity of care following a law enforcement action.

- On September 27, 2019, charges involving fraudulent genetic cancer testing were brought against 35 individuals responsible for over \$2.1 billion in losses in one of the largest health care fraud schemes ever charged. The scheme involved the payment of illegal kickbacks and bribes by cancer genetic testing laboratories in exchange for the referral of Medicare beneficiaries by medical professional working with fraudulent telemedicine companies for medically unnecessary cancer genetic tests. Among those charged were 10 medical professionals, including nine doctors. In conjunction with this effort, the Centers for Medicare & Medicaid Services, Center for Program Integrity (CMS/CPI), announced it took adverse administrative action against cancer genetic testing companies and medical professionals.
- From August 28 to September 27, 2019, eight regional takedowns were carried out. These regional takedowns resulted in charges against over 345 individuals who allegedly billed federal health care programs for more than \$1 billion and allegedly prescribed/dispensed approximately 50 million controlled substance pills in Houston, across Texas, the West Coast, the Gulf Coast, the Northeast, Florida and Georgia, and the Midwest. Charges include those against 105 defendants for opioid-related offenses.

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 tools to combat health care fraud. Throughout FY 2019, 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.

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 2019. 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. Attorneys' 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. Attorneys' 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. In addition, numerous 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 federal health care benefit programs.

Based on the Criminal Division, Fraud Section's prosecutions in FY 2019, 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 2019 continued defrauding the Medicare program, this would have resulted in an additional \$4.5 billion loss after 5 years, and \$7.1 billion loss after 10 years. The Impact of Investment shows that over 10 years, every dollar spent on the Criminal Division, Fraud Section in FY 2019, resulted in \$209 in savings to the Medicare program.

Time Frame	Monies Saved	Impact of Investment
1-year	\$1.117 billion	\$33 saved/ \$1 spent
3-year	\$3.009 billion	\$88 saved/ \$1 spent
5-year	\$4.520 billion	\$133 saved/\$1 spent
8-year	\$6.236 billion	\$183 saved/\$1 spent
10-year	\$7.097 billion	\$209 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. 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 2019, five OCGS attorneys conducted health care fraud prosecutions and investigations.

In Knoxville, two OCGS attorneys worked with the United States Attorney's Office for the Eastern District of Tennessee on an opioid pill-mill prosecution of seven individuals including

two leaders in Italy, for illegally operating pain clinics in Tennessee and Florida, which prescribed vast quantities of opioids. In July 2019, one defendant pleaded guilty to RICO conspiracy. Four individuals went to trial in October 2019 on charges including RICO conspiracy and drug trafficking conspiracy to distribute and dispense oxycodone, oxymorphone and morphine outside the scope of professional practice, not for a legitimate medical purpose and resulting in death. All four defendants are charged under enhanced penalty provisions for distribution of oxycodone or oxymorphone resulting in overdose deaths, which carries a sentence of 20 years to life. The indictment alleges that approximately 700 clinic patients have died and a significant portion of those deaths resulted directly or indirectly from overdosing on narcotics prescribed by the enterprise. This partnership between OCGS and the Eastern District of Tennessee has resulted in the investigation and prosecution of over 140 individuals. This case is summarized above in the Highlights of Significant Criminal and Civil Investigations.

In Washington, D.C., two OCGS attorneys handled the prosecution of a former union official and an outside lobbyist for health care fraud conspiracy and health care fraud. The union official allegedly 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. Thereafter the lobbyist allegedly obtained more than \$66,000 in medical insurance reimbursements to which she was not entitled. Trial is scheduled in FY 2020.

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) including fraud schemes by corrupt entities that sell unlicensed group health insurance. 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 appeal. For example, an OCGS attorney provided assistance to the complex investigation and prosecution in the Eastern District of Louisiana of two individuals and a corporation operating a multiple employer welfare arrangement (MEWA) who were indicted on charges of fraud and false statements in the marketing and sale of employee group health care coverage causing losses exceeding \$41 million. The operators of the MEWA, an accountant and the corporation have pleaded guilty. As part of their guilty pleas, the defendants agreed to forfeit approximately \$6.3 million in assets and to pay restitution for the amount of loss. This case is summarized above in the Highlights of Significant Criminal and Civil Investigations.

OCGS attorneys 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 MEWAs. 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 2019 the Civil Rights Division was allocated \$4.5 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), and the Supreme Court's ruling in *Olmstead v. L.C.*, 527 U.S. 581 (1999), the Division also works to prevent the unnecessary segregation of individuals who require health care supports and services.

The Division plays a critical role in the HCFAC Program. The Special Litigation Section of the Civil Rights Division is the sole DOJ component responsible for 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. Both the Disability Rights Section and the Special Litigation Section enforce the ADA's prohibition on unnecessary segregation.

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

FY 2019 Accomplishments

Key litigation and enforcement accomplishments in FY 2019 of the Civil Rights Division are:

- Number of matters in active enforcement: 15;
- Cumulative estimate of individuals with disabilities affected: 59,090; and
- Number of institutional facilities affected: 2,094.

Special Litigation Section

In Fiscal Year 2019, the Special Litigation Section litigated two large cases involving the alleged unlawful institutionalization of, and denial of community-based services to, individuals with disabilities, continued monitoring compliance with five statewide settlement agreements, and began monitoring a sixth statewide agreement. During FY 2019, the Section's active enforcement efforts affected more than 1,400 health care facilities in seven states.

In September, 2019, the Section obtained a key victory following a month-long bench trial in Mississippi. *United States v. Mississippi*, No. 3:16-CV-622-CWR-FKB, 2019 WL 4179997 (S.D. Miss. Sept. 3, 2019). The court ruled that Mississippi violates the ADA by institutionalizing thousands of persons with serious mental illness in State psychiatric hospitals when they could be served in integrated settings in the community. Litigation regarding a remedial order is ongoing.

In May, 2019, the Section entered into an agreement with West Virginia to address allegations that the State violates the ADA by failing to serve children with mental health conditions in the most integrated setting appropriate to their needs. The agreement is expected to affect more than 1,000 children statewide.

In October and November, 2018, the Section conducted a five-week bench trial regarding our claim that Texas violates the ADA by unnecessarily institutionalizing thousands of people with intellectual and developmental disabilities in nursing facilities. Post-trial briefing was completed in January 2019. The case is under submission with the Court.

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

The Section continued to work toward a resolution of the Division's investigative conclusion that South Dakota fails to serve older adults and people with disabilities in the most integrated setting appropriate to their needs.

Disability Rights Section

In FY 2019, 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. As of June 30, 2019, 3,038 individuals had been diverted or moved from large adult care homes to permanent supported housing since the agreement went into effect in 2012. One thousand two hundred twenty-eight 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 1,670 individuals moved out of adult care homes into the community. Of the 3,038 individuals who have moved into permanent supported housing, 2,114 (or 70 percent) continue to receive services in the community. In addition, 5,626 individuals were receiving ACT services and 2,222 individuals in the agreement's target population had received supported employment services over the course of the agreement.

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. On September 26, 2019, the District Court dismissed the case against the City of Providence early in response to a joint request from the Department and City. A year ahead of schedule, the Court Monitor found that the City was in substantial compliance with all provisions. The City now provides transitional services and supports to students with IDD at Mount Pleasant High School, including community experiences, to enable those students to prepare for and obtain competitive jobs in businesses in the community. The State has also made significant progress, including meeting or exceeding two of three Supported Employment placement targets ahead of schedule. Thus far, 838 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 850 former adult home residents are living and receiving services in the community, and more than 2,000 additional adult home residents have expressed interest in doing so.

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 2019, it had reduced the census of segregated sheltered workshop settings to 296 and the total number of hours worked in such settings to 13,233. The State has also reported that through the end of June 2019, it had provided supported employment services and related employment services so that 914 individuals receiving sheltered workshop services have newly obtained competitive integrated employment, 3,712 transition-aged youths have received at least one new employment service, and 3,239 of those youths received an Individual Plan for Employment.

In 2013, the Section commenced litigation against the State of Florida, alleging among other things, that the State 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 September 20, 2016, U.S. District Court for the Southern District of Florida issued an order dismissing the United States' claims. The United States filed a notice of appeal with the U.S. Court of Appeals for the Eleventh Circuit, which on September 17, 2019, issued an opinion reversing the District Court's order of dismissal and remanding the case to the District Court. *C.V. v. Dudek*, 209 F. Supp. 3d 1279 (S.D. Fla. 2016), reversed and remanded sub nomine *United States v. Fla.*, 938 F.3d 1221 (11th Cir. 2019), petition for rehearing filed.

Educational Opportunities Section

The Educational Opportunities Section (EOS) has participated in the HCFAC Program for the past five 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 2019, the Office of the Inspector General (OIG) was allocated \$0.5 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. The OIG's Investigation Division has one full time special agent, one part-time special agent, two analysts, and two supervisors to assist in identifying and investigating health care fraud. Additionally, the OIG's Office of Data Analytics has the equivalent of three personnel that collect, clean, validate, analyze, and store health care claims data related to DOJ programs to identify health care fraud issues for audit or

investigation. These efforts have resulted in the initiation of eleven cases for the Investigations Division and also a Procedural Reform Recommendation to the Bureau of Prisons (BOP) that they move toward electronic billing for health care data at all their facilities.

Given the DOJ's critical role in combating health care fraud, the OIG has also prioritized detecting health care claim fraud within DOJ operations. The OIG has used HCFAC funding to support the salary costs of staff performing analytics on the health care claims data, investigating potential leads, and cover health care fraud training. The OIG has also stood up a separate enclave to store sensitive data received from components and private entities and collaborated with other inspector general offices in health care working groups.

The OIG's efforts to combat health care fraud has primarily focused on identifying fraud schemes through data-driven proactive analysis. The Office of Data Analytics began regularly collecting biweekly feeds of the DOJ workers' compensation claims in FY2019 and referred leads to agents based on data-driven tests. The OIG also increased the oversight of BOP inmate health care spending in FY 2019 by obtaining additional data directly from the private companies and hospitals providing health care services to inmates under BOP Comprehensive Medical Services contracts. The Investigations Division has opened multiple BOP related cases as a result of fraud analytics. Through data-driven testing, the OIG has also identified investigative leads and audit risk from analyzing the USMS health care claims data. The OIG plans to expand its data-driven testing by collecting additional data, expand tripwire testing, and increase the number of data analytic tools available to agents and analysts.

APPENDIX

Federal Bureau of Investigation

In FY 2019, the FBI was allocated \$138.3 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 addition, the FBI received \$4.4 million of the DOJ HCFAC funding.

In FY 2019, the FBI initiated 677 new Health Care Fraud (HCF) investigations and had 2,174 pending investigations. Investigative efforts produced 612 criminal HCF convictions and 771 indictments and informations. In addition, investigative efforts resulted in over 558 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 151 HCF criminal enterprises.

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

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

As part of our collaboration efforts, the FBI maintains investigative and intelligence sharing partnerships with government agencies such as other DOJ components, HHS-OIG, state Medicaid Fraud Control Units, and other enforcement and regulatory agencies. The FBI conducts significant information sharing and coordination efforts with private insurance partners, such as the National Health Care Anti-Fraud Association, the National Insurance Crime Bureau, and private insurance investigative units. The FBI is also actively involved in the Health care Fraud Prevention Partnership, an effort to exchange facts and information between the public and private sectors in order to reduce the prevalence of HCF.

As a result of the collaboration and review process, the FBI has designated criminal enterprises and other crime groups, corporate-level fraud and abuse, and public safety issues – to include the rising prescription drug abuse epidemic, as the priority HCF threat areas of focus. Each field office conducts a similar analysis to determine their areas of focus and the actions they will take to mitigate the associated threats. For example, a FBI case from the Knoxville Field Office had 130 indictments to include RICO charges on multiple subjects for their roles in a conspiracy to

distribute and dispense oxycodone, oxymorphone, and morphine outside the scope of professional practice and not for a legitimate medical purpose; maintenance of drug-involved premises; distribution of oxycodone resulting in death; and money laundering. All are accused of being responsible for the distribution of a quantity of oxycodone, oxymorphone, and morphine sufficient to generate clinic revenue of at least \$17.5 million. Nine deaths were charged in the case and over \$2 million was seized.

FBI field offices throughout the U.S. address the HCF threat through joint investigative efforts; intelligence collection, sharing, and analysis; and the utilization of advanced and sophisticated investigative techniques. FBI field offices participate in HCF Task Forces and/or working groups with partners including local US Attorney's Office, HHS-OIG, DEA, IRS, FDA, other federal, state, and local law enforcement agencies, and private insurance personnel. Based on information sharing and coordination, additional cases are vetted and identified for investigation. These activities seek to identify and pursue investigations against the most egregious offenders involved in health care fraud and abuse.

The FBI's Health Care Fraud Unit (HCFU) oversees program efforts, including providing guidance to 56 field offices to mitigate the health care fraud threat. In support of joint agency activities and general threat mitigation efforts, the HCFU developed and supports four initiatives, including the Health Care Fraud Prevention and Enforcement Action Team (HEAT), Large Scale Conspiracies, Major Provider Fraud, and the Prescription Drug Initiative.

HEAT is a DOJ, FBI and HHS Cabinet-level commitment to prevent and prosecute HCF. HEAT, which is jointly led by the Deputy Attorney General and HHS Deputy Secretary, is comprised of top-level law enforcement agents, prosecutors, attorneys, auditors, evaluators, and other staff from DOJ, FBI and HHS and their operating divisions, and is dedicated to joint efforts across government to both prevent fraud and enforce current anti-fraud laws around the country. The Medicare Fraud Strike Force (Strike Force) teams are a key component of HEAT. As part of the HEAT Initiative, the FBI coordinates with the DOJ and HHS-OIG on funding, resource allocation, Strike Force expansion, target identification, training, and operations. The FBI supports eleven Strike Forces located in Miami, Detroit, Houston (also includes McAllen, Texas), New York City (Brooklyn), Tampa, Los Angeles, Chicago, Dallas, Philadelphia, Newark, and Southern Louisiana (Baton Rouge and New Orleans). 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. In FY19, the FBI participated in ten DOJ regional HCF takedowns charging 268 subjects, including 101 doctors, nurses and other licensed medical professionals, for their alleged participation in HCF schemes involving approximately \$2.6 billion in false billings. The continued support of Strike Force operations is a top priority for the FBI. Additionally, the FBI coordinates and shares intelligence with HHS and DOJ components on other prevention and enforcement activities, to include efforts associated with the Large Scale Conspiracies, Major Provider Fraud, and Prescription Drug Initiatives.

In October 2018, the U.S. Attorney General's Office announced the creation of the Appalachian Regional Prescription Opioid (ARPO) Strike Force. The ARPO Strike Force operates in Cincinnati, Louisville, Pittsburgh, Knoxville, Memphis, and Birmingham to investigate illegal opioid prescriptions in the surrounding areas. ARPO is an extension of the Strike Force, which investigates and prosecutes Medicare fraud nationwide in partnership with the FBI, HHS-OIG, and the DEA. 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. On April 17, 2019, the FBI and DOJ announced criminal charges against 60 defendants, including 53 doctors, pharmacists, nurse practitioners, and other medical professionals who allegedly gave thousands of opioid prescriptions to addicted patients. The effort was the largest law enforcement action to date against illegal opioid prescribers. The arrests and charges were among the first cases brought against medical providers as part of the ARPO Strike Force.

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 include support for undercover operations, source identification and support, and funding of investigative costs. An example of these types of cases includes the FBI-led investigation of a call center operating out of the Philippines by a US Citizen. The call center fraudulently produced and sold durable medical equipment (DME) orders to over 200 DME companies operating around the U.S. The majority of fraudulent DME prescriptions were obtained through tele-doctors. Approximately 18,000 DME orders were being submitted per week to Medicare for an approximate \$16 million weekly reimbursement. Conspirators billed Medicare for \$2.3 billion since 2015 and Medicare paid \$1.2 billion based on these claims.

In April 2019, twenty FBI field offices participated in a national takedown where 37 individuals were indicted, 130 DMEs across the nation were shut down, 83 search warrants were executed, and over 180 seizure warrants were served. In Virginia, an individual operating a fraudulent sleep study clinic was convicted of Conspiracy to Commit Health Care Fraud, Health Care Fraud, and False Tax Returns for submitting over \$83 million in claims to Medicare and private insurers. The defendant was sentenced to 84 months imprisonment and \$21 million in restitution was ordered by the court.

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 is the FBI-led investigation of Insys Therapeutics (Insys) alleging Insys

systematically and illegally promoted its prescription drug Subsys for off-label usage. Subsys is a fast acting drug approved by the FDA for the management of cancer pain in patients who are opioid tolerant. Additionally, the Insys sales force offered financial inducements, such as excessive speaker's fees, to physicians to prescribe Subsys in violation of the False Claims Act and the Federal Anti-Kickback Act. The total amount paid to eight physicians was approximately \$1.2 million. The case resulted in a \$225 million global resolution of criminal and civil investigations. In addition, Insys Pharma, a subsidiary of Insys was sentenced to a fine of \$2 million, and asset forfeiture of \$28 million. The FBI coordinated efforts in this case with HHS-OIG, FDA, DEA, OPM-OIG, the Office of Personnel Management, Veterans Affairs, DCIS, the Postal Inspection Service, USPIS-OIG, and the Department of Labor.

The Prescription Drug Initiative identifies and targets criminal enterprises and other groups or individuals engaged in prescription drug schemes, and prosecutes improper prescribing and dispensing practices of controlled substances. These schemes are a significant crime problem and impact public health and safety. Examples include a Birmingham physician who was convicted of various counts of unlawful distribution of controlled substances, health care fraud, and money laundering. In Houston, over 30 individuals related to the health care industry were arrested and over 20 searches were executed regarding a medical clinic that was involved in illegal prescription and diversion of controlled substances. With the Attorney General's allocation of funds to the FBI as part of the Opioid Fraud and Abuse Detection Unit, the FBI is dedicated to prioritizing prescription drug scheme investigations, particularly in at-risk federal judicial districts, with enhanced support from the Prescription Drug Initiative.

The FBI actively provides training and guidance on HCF matters. The FBI has teamed with the DOJ, HHS, and private insurance organizations to provide training in the priority threat areas of HCF. Funded training has included innovative methods of employing advanced investigative techniques; basic HCF training for FBI Special Agents and professional staff newly assigned to investigate HCF; and sessions on new and current HCF trends and issues. FBI personnel training opportunities included sessions offered by the FBI, other government agencies and the private sector. In FY 2019, more than 300 FBI HCF investigators and analysts received training. FBI personnel also conducted a wide range of training for external audiences, including private insurance and regulatory personnel.

Funding received by the FBI is used to pay direct and indirect personnel-related costs associated with the 814 funded positions. Funds not used directly for personnel matters, are used to provide operational support for HCF investigations, national initiatives, training, specialized equipment, expert witness testimony, and Strike Force operations.

Return on Investment Calculation

- The return on investment (ROI) for the HCFAC program is calculated by dividing the total monetary results to the Federal government (not including relator payments) by the annual appropriation for the HCFAC Account in a given year (not including portions of CMS funding dedicated to the Medicare Integrity Program listed in the table on page 5).
- 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 2019, including sequester reductions. The FBI also receives a stipulated amount of HIPAA funding for use in support of the Fraud and Abuse Control Program, which is shown below. Separately, CMS receives additional Mandatory Resources under the Medicare Integrity Program (section 1817(k)(4) of the Social Security Act). The inclusion of the activities supported with these funds is not required in this report, and this information is included for informational purposes. Since 2009, Congress has also appropriated annual amounts to help carry out health care fraud and abuse control activities within DOJ and HHS. Those amounts are set forth as Discretionary Resources in the table below and the results of the efforts supported with these funds are contained within this report.

Mandatory Resources¹	Fiscal Year 2019
Office of Inspector General	\$195,754,924
Health and Human Services Wedge ²	37,440,473
Medicare Integrity Program ³	897,714,523
<i>MIP/Medicare (non-add)</i>	828,659,560
<i>Medi-Medi (non-add)</i>	69,054,963
Department of Justice Wedge ²	61,120,076
Federal Bureau of Investigation ⁴	138,343,622
Subtotal, Mandatory HCFAC	1,330,373,618
Discretionary Resources	
Office of Inspector General	\$87,230,000
CMS Program Integrity	599,389,000
<i>Senior Medicare Patrols (ACL Non-Add)⁵</i>	18,000,000
Department of Justice	78,381,000
Subtotal, Discretionary HCFAC	765,000,000
Grand Total, HCFAC	\$2,095,373,618

¹ All mandatory resources are post-sequester.

² The HHS and DOJ Wedge funds are divided among multiple agencies within HHS and DOJ. Page 7 of this report includes the allocations of the HHS and DOJ Wedge by agency or activity.

³ Mandatory Medicare Integrity Program (MIP) and Medicaid Integrity Program fund fraud prevention and detection activities within Medicare and Medicaid, and are not part of this report to Congress. A separate report to Congress addresses MIP activities.

⁴ The FBI receives funding annually to conduct anti-fraud activities authorized by HIPAA. This funding is included in the HCFAC ROI calculation for this report.

⁵ The Department of Defense and Labor, Health and Human Services, and Education Appropriations Act of 2019 and Continuing Appropriations Act of 2019 requires that the Secretary provide not less than \$17,621,000 for the Senior Medicare Patrol program using 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

FFS—Fee-for-Service

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