

Annual Report of the Departments of Health and Human Services and Justice



Health Care Fraud and Abuse Control Program FY 2020

**The Department of Health and Human Services
and
The Department of Justice
Health Care Fraud and Abuse Control Program
Annual Report for Fiscal Year 2020**

July 2021

TABLE OF CONTENTS

I.	EXECUTIVE SUMMARY	1
II.	STATUTORY BACKGROUND	3
III.	Program Results and Accomplishments	5
	Monetary Results	5
	Expenditures	7
	Overall Recoveries	8
	Strike Force	8
	Opioid Fraud and Abuse Detection Unit	10
	Health Care Fraud Prevention and Enforcement Action Team (HEAT) Health Care Fraud Prevention Partnership (HFPP)	11
	COVID-19 Pandemic-Related Enforcement	12
	COVID-19 Pandemic-Related Enforcement	13
	Highlights of Significant Criminal and Civil Investigations	14
IV.	DEPARTMENT OF HEALTH AND HUMAN SERVICES	31
	Office of Inspector General	31
	Centers for Medicare & Medicaid Services	59
	Administration for Community Living	83
	Office of the General Counsel	87
	Food and Drug Administration Pharmaceutical Fraud Program	91
V.	DEPARTMENT OF JUSTICE	94
	United States Attorneys	94
	Civil Division	96
	Criminal Division	101
	Civil Rights Division	106
	Office of the Inspector General	110
VI.	APPENDIX	111
	Federal Bureau of Investigation	111
	Total Health Care Fraud and Abuse Control Resources	118
VII.	Glossary of Common Terms	119

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 24th 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) 2020, the Federal Government won or negotiated more than \$1.8 billion in health care fraud judgments and settlements,² in addition to other health care administrative impositions. Because of these efforts, as well as those of preceding years, almost \$3.1 billion was returned to the Federal Government or paid to private persons in FY 2020. Of this \$3.1 billion, the Medicare Trust Funds³ received transfers of approximately \$2.1 billion during this period, in addition to the \$128.2 million in Federal Medicaid money that was similarly transferred separately to the Treasury due to these efforts.

Enforcement Actions

In FY 2020, the Department of Justice (DOJ) opened 1,148 new criminal health care fraud investigations. Federal prosecutors filed criminal charges in 412 cases involving 679 defendants. A total of 440 defendants were convicted of health care fraud related crimes during the year. Also, in FY 2020, DOJ opened 1,079 new civil health care fraud investigations and had 1,498 civil health care fraud matters pending at the end of the fiscal year. Federal Bureau of Investigation (FBI) investigative efforts resulted in over 407 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 101 health care fraud criminal enterprises.

In FY 2020, investigations conducted by HHS's Office of Inspector General (HHS-OIG) resulted in 578 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid, and 781 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 2,148 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 (891) or to other health care programs (316), for patient abuse or neglect (230), and as

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.

a result of state health care licensure revocations (509). HHS-OIG also issued numerous audits and evaluations with recommendations that, when implemented, would correct program vulnerabilities and save Medicare and Medicaid funds.

Sequestration Impact

Due to the FY 2020 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.⁴ A total of \$11.0 million was sequestered from the HCFAC program in FY 2020, for a combined total of \$150.6 million in mandatory funds sequestered in the past eight years. Including funds sequestered from the FBI (\$70.0 million in the past eight years), \$220.6 million has been sequestered from mandatory HCFAC funds since FY 2013.

⁴ Section 3709 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Public Law (P.L.) 116-136) suspended Medicare sequestration from May 1, 2020 through December 31, 2020; the Consolidated Appropriations Act, 2021 (P. L. 116-260) extended this suspension to March 31, 2021; and an extension of the Medicare sequester moratorium until December 31, 2021 was signed by President Joe Biden in April 2021. This sequester adjustment was meant to provide an economic boost to Medicare providers treating patients during the COVID-19 public health emergency (PHE) and has resulted in additional funding for the HCFAC program. A pro-rated sequester suspension was applied to resources from which the sequester reduction is taken at the beginning of the fiscal year, so the FY 2020 sequester amount reflects the period from May 1, 2020 to September 30, 2020. The FY 2021 sequester amount will reflect the period from October 1, 2020 to December 31, 2021.

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 2020 is provided as required by Section 1817(k)(5) of the Social Security Act.

The Social Security Act Section 1128C(a), as established by HIPAA (P.L. 104-191, 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 portions 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 2010.⁵ 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 2020, the Secretary and the Attorney General certified \$308.7 million in mandatory funding to the Account after accounting for sequester reductions of \$11.0 million to the total appropriation. Additionally, Congress appropriated \$786.0 million in discretionary funding. A detailed breakdown of the allocation of these funds is set forth later in this report. HCFAC appropriations generally supplement the direct appropriations of HHS that are devoted to health care fraud enforcement and have supported almost three-fourths of DOJ’s health care fraud funding and over three-fourths of HHS-OIG’s appropriated budget in FY 2020. (Separately, the FBI, which is discussed in the Appendix, received \$145.1 million from HIPAA, after accounting for \$5.2 million in mandatory sequester reductions). Under the joint direction of the Attorney General and the Secretary, the Program’s goals are:

⁵ 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 (P.L.116-94, Further Consolidated Appropriations Act, 2020) 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 2020, about \$3.1 billion was deposited with the Department of the Treasury (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 2020	
Department of the Treasury	
Deposits to the Medicare Trust Fund, as required by HIPAA:	
Gifts and Bequests	\$50
Amount Equal to Criminal Fines	1,542,396
Civil Monetary Penalties	27,687,424
Asset Forfeiture	701,421,449
Penalties and Multiple Damages	836,940,628
Subtotal	\$1,567,591,948
Centers for Medicare and Medicaid Services	
HHS/OIG Audit Disallowances: Recovered–Medicare	31,668,839
Restitution/Compensatory Damages*	508,750,907
Subtotal	\$540,419,746
Total Transferred to the Medicare Trust Funds	\$2,108,011,694
Restitution/Compensatory Damages to Federal Agencies	
TRICARE	\$89,475,247
HHS/OIG	27,740,068
Office of Personnel Management	21,154,377
Veterans Benefits Administration	15,040,676
DOJ/Drug Enforcement Administration	1,965,122
Other Agencies	7,994,444
Subtotal	\$163,369,933
Centers for Medicare and Medicaid Services	
Federal Share of Medicaid	128,190,320
HHS/OIG Audit Disallowances: Recovered–Medicaid	280,549,727
Subtotal	\$408,740,047
Total	\$572,109,980
Relators' Payments**	\$395,713,010
GRAND TOTAL MONETARY RESULTS***	\$3,075,834,684

*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 24th year of operation, the Secretary and the Attorney General certified \$308.7 million in mandatory funding as necessary for the Program, after accounting for mandatory sequester reductions of \$11.0 million as required by law. Additionally, Congress appropriated \$786.0 million in discretionary funding. See allocation by recipient below:

FY 2020 ALLOCATION OF HCFAC APPROPRIATION				
Organization	Mandatory Allocation⁶	Discretionary Allocation	Funds Sequestered⁷	Total Allocation
Department of Health and Human Services				
Office of Inspector General	\$233,403,225	\$93,000,000	(7,300,773)	\$319,102,452
Office of the General Counsel	7,427,491	0	0	7,427,491
Administration for Community Living	0	18,000,000	0	18,000,000
Food and Drug Administration	6,067,333	0	0	6,067,333
Centers for Medicare & Medicaid Services	0	592,000,000	0	592,000,000
Assistant Secretary for Planning and Evaluation	5,000,000	0	0	5,000,000
Unallocated Funding	1,396,361	0	(1,396,361)	0
Subtotal	\$253,294,410	\$703,000,000	(\$8,697,134)	\$947,597,276
Department of Justice				
United States Attorneys	\$33,878,794	\$29,046,805	\$0	\$62,925,599
Civil Division ⁸	18,000,000	20,973,369	0	38,973,369
Criminal Division	9,189,872	19,064,598	0	28,254,470
Civil Rights Division	2,953,087	5,436,000	0	8,389,087
Justice Management Division	86,735	0	0	86,735
Federal Bureau of Investigation	0	7,729,228	0	7,729,228
Office of the Inspector General	0	750,000	0	750,000
Unallocated Funding	2,279,502	0	(2,279,502)	0
Subtotal	\$66,387,990	\$83,000,000	(\$2,279,502)	\$147,108,488
TOTAL	\$319,682,400	\$786,000,000	(\$10,976,636)	\$1,094,705,764

⁶ As of FY 2007, mandatory funds are available until expended. Discretionary funds are available for two years.

⁷ The sequester amounts reflect the post-sequester suspension because of the CARES Act.

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

Overall Recoveries

During the fiscal year, the Federal Government won or negotiated more than \$1.8 billion in judgments and settlements and attained additional administrative impositions in health care fraud cases and proceedings. Because of these efforts, as well as those of preceding years, almost \$3.1 billion was returned to the Federal Government or private persons. Of this \$3.1 billion, the Medicare Trust Funds received transfers of approximately \$2.1 billion during this period; another \$128.2 million in Federal Medicaid money was transferred to the Treasury separately due to these efforts.⁹

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

The return on investment (ROI) for the HCFAC program over the last three years (2018–2020) is \$4.30 returned for every \$1.00 expended. Because the annual ROI can vary from year to year depending on the number and type of cases that are settled or adjudicated during that year, DOJ and HHS use a three-year rolling average ROI for results contained in the report. Additional information on how the ROI is calculated may 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 relies on actual recoveries and collections, and 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.

Strike Force

Health Care Fraud Strike Force Teams (Strike Force) harness data analytics and the combined resources of Federal, State, and local law enforcement entities to prosecute complex health care fraud matters and cases involving the illegal prescription, distribution, and diversion of opioids. 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.

⁹ Note that some of the judgments, settlements, and administrative actions that occurred in FY 2020 will result in transfers in future years, just as some of the transfers in FY 2020 are attributable to actions from prior years.

First established in March 2007, Strike Force teams currently operate in 24 districts across the United States, including, but not limited to: 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 the National Rapid Response Strike Force (NRRSF) located in Washington, D.C.

In 2020, Acting Assistant Attorney General Brian Rabbitt announced the creation of the NRRSF, comprised of dedicated prosecutors who target large-scale and multi-jurisdictional schemes occurring across the country. This new Strike Force's cases have included an alleged \$1.4 billion billing fraud scheme perpetrated through a series of rural hospitals, brought in conjunction with the Middle District of Florida; prosecutions of laboratory owners and operators for kickback offenses, responsible for alleged losses in the hundreds of millions; and forms of fraud exploiting the coronavirus disease 2019 (COVID-19) pandemic. 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.

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 U.S. Attorneys' Offices (USAOs) to analyze data obtained from a wide variety of sources including CMS and bring cases in federal district court. During FY 2020, Strike Force accomplishments in the areas noted above, as well as USAO accomplishments included:¹⁰

- Filing 263 indictments, information, and complaints involving charges against 405 defendants who allegedly billed federal health care programs and private insurers more than \$4.7 billion;
- Obtaining 254 guilty pleas and trying 24 jury trials, with guilty verdicts against 30 defendants; and
- Securing imprisonment for 254 sentenced defendants, with an average of nearly 42 months of incarceration per sentenced defendant.

Since its inception, Strike Force prosecutors filed more than 2,100 cases charging more than 4,600 defendants who collectively billed federal health care programs and private insurers approximately \$23.0 billion; more than 3,000 defendants pleaded guilty and over 390 others were convicted in jury trials; and more than 2,800 defendants were sentenced to imprisonment for an average term of approximately 50 months. Medicare payment trends demonstrate the positive impact of Strike Force enforcement and prevention efforts.

In September 2020, the Criminal Division's Health Care Fraud Unit organized and led a historic national takedown, in collaboration with USAOs, HHS-OIG, FBI, the Drug Enforcement Administration (DEA), and other federal and state partners. On September 30, 2020, Acting

¹⁰ The summary statistics in this document exclude sealed cases.

Assistant Attorney General Brian Rabbitt announced this nationwide enforcement action, which involved 345 charged defendants across 51 federal districts, including more than 100 doctors, nurses, and other licensed medical professionals. These defendants were collectively charged with submitting more than \$6.0 billion in allegedly false and fraudulent claims to federal health care programs and private insurers, including more than \$4.5 billion connected to schemes that involved telemedicine fraud, more than \$845.0 million connected to substance abuse treatment facilities, or “sober homes,” and more than \$806.0 million connected to other health care fraud and illegal opioid distribution schemes across the country. This enforcement initiative included cases charged during an unprecedented national health emergency, from April 2020 to September 2020, with the majority (nearly two-thirds) being charged or unsealed after Labor Day (September 7, 2020).

In an initial April 2019 “Surge,” and a second takedown in September 2019, Trial Attorneys in the Fraud Section, in conjunction with Assistant United States Attorneys (AUSAs) in more than 10¹¹ federal districts, charged 73 individuals, including 64 medical professionals, with opioid-related crimes. Another 18 defendants were charged in FY 2020, including six medical professionals. As of September 30, 2020, 31 of the Appalachian Regional Opioid Strike Force (ARPO) defendants have entered guilty pleas, with more pleas scheduled. Two additional defendants have been convicted at trial, including one two-week trial in West Virginia that took place during the pandemic in 2020.¹² Sixteen ARPO defendants were sentenced in FY 2020.

Opioid Fraud and Abuse Detection Unit

On August 2, 2017, the Attorney General announced the formation of the Opioid Fraud and Abuse Detection Unit in the Criminal Division to use data from various health care databases to identify medical practitioners who are contributing to the prescription opioid epidemic. As a part of a related effort, the Department created 11 Opioid Fraud and Abuse Detection (OFAD) three-year-term positions for experienced AUSAs to focus solely on investigating and prosecuting offenses with a health-care-fraud nexus related to prescription opioids, including pill mill schemes and pharmacies that unlawfully divert or dispense prescription opioids for illegitimate purposes. The AUSAs work with FBI, DEA, HHS, local and state partners to target and prosecute doctors, pharmacies, and medical providers who are unlawfully furthering the opioid epidemic.

In June 2020, the Deputy Attorney General favorably assessed the performance of the OFAD AUSA program and extended the term positions for an additional two years. 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, Middle District of North Carolina, and Southern District of West Virginia.

¹¹ Two non-ARPO districts also participated in the Surge in 2019, bringing the district total to 12.

¹² A total of three ARPO jury trials have occurred. Two of the three cases resulted in guilty verdicts; one of the three cases resulted in a mistrial due to a hung jury, and the defendants pleaded guilty thereafter; and none of the cases were dismissed or resulted in acquittals.

In FY 2020, the OFAD AUSA program handled hundreds of investigations and prosecutions involving medical professionals. Defendants were charged with a range of crimes, including health care fraud, drug trafficking, and money laundering. Some representative efforts include:

- In the Eastern District of Michigan, the OFAD AUSA indicted a 19-defendant opioid distribution conspiracy case that included ten doctors, nurse practitioners, pharmacists, and pharmacy techs for prescribing and dispensing more than 1,951,148 dosage units of Schedule II controlled substances. The prescribed oxycodone and oxymorphone, alone, carried a conservative street value of more than \$41.0 million.
- The OFAD program in Middle District of Florida convicted multiple staffers of a medical clinic, a patient, a pharmacist and a pharmacy tech of conspiracy to commit tax evasion, tax evasion, money laundering, unlawful drug distribution, and drug conspiracy involving fraudulent opioid prescriptions.

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. DOJ and HHS-OIG established the Health Care Fraud Prevention and Enforcement Action Team (HEAT) in 2009 to build and strengthen existing programs combatting Medicare fraud, while investing new resources and technology to prevent and detect fraud and abuse. HEAT expanded the DOJ-HHS Health Care Fraud Strike Force program noted above, which targets emerging or migrating fraud schemes, to include fraud by criminals masquerading as health care providers or suppliers. The mission of HEAT is:

- **To marshal significant resources across government to prevent waste, fraud and abuse in the Medicare and Medicaid programs** and crack down on the fraud perpetrators who are abusing the system and costing 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. HEAT activities have also expanded to include significant involvement from

MFCUs, which play a critical role in the many fraud cases involving both Medicare and Medicaid. Finally, five MFCUs participated in the National Health Care Fraud Takedown in September 2020.

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 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.

Health Care Fraud Prevention Partnership (HFPP)

The HFPP is a voluntary public-private partnership among 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 172 public, private, and state partner organizations at the end of FY 2020. Collectively, these organizations represent more than 218 million covered lives, equivalent to more than three in four insured Americans. Forty of the current partners are actively submitting claim level data representing more than 104 million individuals, or more than one in three insured Americans.

The HFPP commenced or completed studies using multiple partners' data to address fraud, waste, and abuse in FY 2020, 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 the HFPP section in the CMS section for more information on HFPP activities.

COVID-19 Pandemic-Related Enforcement

Since the start of the Public Health Emergency (PHE) in March 2020, CMS has examined how the PHE – and more specifically, the waivers and flexibilities offered by the Agency – create new fraud risks to federal health programs. CMS has developed a robust fraud risk assessment process to identify potential risks and vulnerabilities associated with PHE and potential unintended consequences of the waivers and flexibilities. Fraud, waste, and abuse mitigation strategies include data analyses and studies, development of Fraud Prevention System (FPS) and National Correct Coding Initiative (NCCI) models and edits, and implementation of new policies. DOJ is working with CMS, HHS-OIG, and other law enforcement agency partners to investigate and prosecute frauds from identified risks and related schemes. Examples include:

- **Performing additional, unnecessary services:** Offering COVID-19 tests to Medicare beneficiaries in exchange for personal details, including Medicare information. However, the services are unapproved and illegitimate. In one fraud scheme, some labs are targeting retirement communities claiming to offer COVID-19 tests but are drawing blood and billing federal health care programs for medically unnecessary services. Fraudsters are targeting beneficiaries in a number of ways, including telemarketing calls, text messages, social media platforms, and door-to-door visits. These scammers exploit the pandemic to benefit themselves, and beneficiaries face potential harms. The personal information collected can be used to fraudulently bill federal health care programs and commit medical identity theft. If Medicare or Medicaid denies the claim for an unapproved test, the beneficiary could be responsible for the cost.
- **Additional unnecessary laboratory testing:** Requiring tests in addition to the COVID-19 test, such as expensive tests or services that do not test for COVID-19, e.g. medically unnecessary and expensive respiratory testing, allergy testing, and genetic testing. For example, providers are billing a COVID-19 test with other far more expensive tests such as the Respiratory Pathogen Panel (RPP) and antibiotic resistance tests. Other potentially unnecessary tests being billed along with a COVID-19 test include genetic testing and cardiac panels CPT codes. Providers are also billing respiratory, gastrointestinal, genitourinary, and dermatologic pathogen code sets with the not otherwise specified code CPT 87798.
- **Health care technology schemes:** False and fraudulent representations about COVID-19 testing, treatments, or cures that are used to defraud insurance carriers and to perpetrate fraud on the financial markets by defrauding investors.
- **Fraudulently obtaining COVID-19 health care relief funds:** Filing false claims and applications for federal relief funds, such as those provided under the Coronavirus Aid, Relief, and Economic Security (CARES) Act's Provider Relief Fund, the Paycheck Protection Program and Health Care Enhancement Act, or the Economic Impact Disaster Loan (EIDL) program.

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 June 2020, two owners of an ambulance and transportation services company located in Guam, were sentenced to serve 71 and 63 months, respectively, in federal prison in connection with their October 2019 guilty pleas to one count of conspiracy to commit health care fraud and one count of conspiracy to engage in monetary transactions with the proceeds of specified unlawful activity. They were also ordered to pay \$10.8 million in restitution. According to their admissions at the plea hearing, from approximately March 2010 to approximately March 2014, the defendants engaged in a conspiracy to defraud Medicare and TRICARE by submitting claims for reimbursement for medically unnecessary ambulance services that the company provided to patients with end-stage renal disease (ESRD). The defendants admitted they were aware that their company was transporting patients who did not qualify for ambulance transportation under applicable Medicare and TRICARE regulations and guidelines.

Clinics

(SF) In November 2019, at the conclusion of a two-week trial, the head of multiple New York medical clinics was found guilty of money laundering, kickback, and tax charges for his role in a vast fraud scheme with losses of approximately \$100.0 million in billed claims. The trial evidence showed that the clinic owner and his co-conspirators executed the alleged scheme by referring beneficiaries to a variety of medical professionals in exchange for kickbacks. The clinic owner and his co-conspirators then laundered a substantial portion of fraudulent proceeds through companies he controlled, including by cashing checks at several New York City check-cashing businesses. The clinic owner failed to report that cash income to the IRS. In August 2020, the clinic owner was sentenced to 13 years in prison for his part in leading this scheme.

(SF) In December 2019 and June 2020, defendants responsible for a multi-faceted criminal fraud and diversion scheme perpetrated at Abyssinia Love Knot (ALK) of Southfield, Michigan, and 1st Priority Physical Therapy (1st PRIORITY) of Detroit, Michigan, received 11-year prison sentences. While both clinics advertised that they provided legitimate physical therapy services, the clinics served as the largest pill mill operation in the Detroit-metro area from 2009 to 2016. The investigation revealed that ALK and 1ST PRIORITY owners worked with Detroit-area patient recruiters to bring patients to their physical therapy clinics, charging them between \$300 and \$1,000 cash per individual “slot” to see one of the many physicians they controlled. Additionally, the clinic owners charged the patients’ health insurance (Medicare or private insurance) for services that were never provided. In return for the cash payments and for billing the patients’ insurance, the physicians controlled by the clinic owners wrote medically unnecessary prescriptions for oxycodone, Xanax, and other controlled substances, which were sold on the street in the metro-Detroit area as well as out-of-state. From 2013 through 2016,

approximately 4.5 million opioid dosage units of various controlled substances were prescribed by physicians through ALK. From 2009 through 2016, ALK and 1ST PRIORITY billed approximately \$36.0 million dollars to Medicare. In addition, approximately \$5.5 million was billed to Blue Cross Blue Shield of Michigan for physical therapy services that were either medically unnecessary or never provided. On December 19, 2019, and on March 10, 2020, each of the two lead defendants (the clinic owners) were sentenced to 11 years in prison.

In January 2020, at the conclusion of a three-month trial, four defendants were found guilty in the Eastern District of Tennessee in connection with their roles in the operation of four separate pain clinics. The evidence showed that they operated the pain clinics as pill mills inviting abuse by providers, employees, customers, and drug traffickers with awareness that patients travelled long distances to illegally obtain controlled substances and requested prescriptions for large quantities of Schedule II Controlled Substances. A part owner of the clinics was found guilty of Racketeering Influenced Corrupt Organization (RICO) conspiracy, a drug conspiracy, money laundering, and maintaining drug-involved premises. Three nurses who worked at the clinics were convicted of maintaining a drug-involved premises. The drug conspiracy involved the distribution of over 11 million tablets of oxycodone, oxymorphone, and morphine that generated over \$21.0 million of clinic revenue, with a street value of \$360.0 million.

Drug Companies

In June 2020, Novartis Pharmaceuticals Corporation (Novartis), based in East Hanover, New Jersey, agreed to pay a total of over \$642.0 million to resolve civil FCA allegations in two separate settlements. In the first settlement, Novartis agreed to pay \$51.3 million to resolve allegations that it illegally used three foundations as conduits to pay the copayments of Medicare patients taking the Novartis drugs Gilenya and Afinitor. In the second settlement, Novartis agreed to pay over \$591.0 million to resolve claims that it paid kickbacks to doctors in the form of sham speaker payments, to induce the doctors to prescribe the Novartis drugs Lotrel, Valtorna, Starlix, Tekturna, Tekturna HCT, Tekamlo, Diovan, Diovan HCT, Exforge, and Exforge HCT. The government also alleged that Novartis sales representatives, on the instruction of their managers, selected high-volume prescribers to serve as the paid “speakers” at so-called speaker events to induce the prescribers to write Novartis prescriptions. The company also made extensive factual admissions in the settlement and agreed to strict limitations on any future speaker programs, including reductions to the amount it may spend on such programs. In addition to the civil FCA resolution, Novartis also agreed to a civil forfeiture of \$38.4 million. Separately, as part of the resolution, Novartis entered into a five-year Corporate Integrity Agreements (CIA) with HHS-OIG. In addition to the federal recovery, Novartis agreed to pay more than \$48.0 million to resolve state Medicaid claims.

In August 2020, DUSA Pharmaceuticals, Inc. (DUSA), a subsidiary of Sun Pharmaceutical Industries, Inc. (Sun Pharma) agreed to pay \$20.8 million to resolve civil FCA allegations that DUSA caused physicians to submit false claims to Medicare and the Federal Employee Health Benefit Program (FEHBP). The government alleged that between January 2014 and December 2016, DUSA knowingly promoted an administration process for the drug Levulan Kerastick, a prescription topical solution, that contradicted the product instructions approved by the Food and

Drug Administration (FDA) and was unsupported by sufficient clinical evidence. As part of the settlement, DUSA and Sun Pharma agreed to enter into a CIA with HHS-OIG.

In September 2020, Gilead Sciences, Inc. (Gilead), based in Foster City, California, agreed to pay \$97.0 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 Gilead's pulmonary arterial hypertension (PAH) drug, Letairis, because Gilead knew that the price it set for Letairis could otherwise pose a barrier to such purchases. The government alleged that from 2007 to 2010, Gilead made payments to the foundation, which, in turn, used those funds to pay copays of patients prescribed Letairis. The government alleged that Gilead routinely obtained data from the foundation detailing how much the foundation had spent for patients on Letairis; it then used this information to decide how much to pay to the foundation to cover the copays of patients taking Letairis but not of patients taking other manufacturers' PAH drugs. The government also alleged that, to generate revenue from Medicare and induce purchases of Letairis, Gilead referred Medicare patients to the foundation, which resulted in claims to Medicare to cover the cost of Letairis.

Durable Medical Equipment (DME)

(SF) In October 2019, an owner and operator of two orthotic brace supplier companies in New York, New York, pleaded guilty to one count of conspiracy to defraud the United States and to pay and receive health care kickbacks. The charges resulted from a \$5.6 million conspiracy in which the defendant offered and paid kickbacks and bribes to several purported telemedicine companies in exchange for completed doctors' orders of medically unnecessary orthotic braces for Medicare beneficiaries. The defendant and her co-conspirators concealed the fraud by entering into sham contracts and producing false invoices characterizing the kickbacks and bribes as payments for "marketing." The defendant agreed to pay over \$3.0 million in restitution and to forfeit over \$3.0 million in proceeds of her crime.

(SF) In November 2019, a New Jersey physician and professor at Rutgers New Jersey Medical School pleaded guilty to a one-count information alleging he conspired to commit health care fraud. The defendant moonlighted for a purported telemedicine company for which he wrote medically unnecessary orders for orthotic braces for Medicare beneficiaries between July 2018 and April 2019 resulting in a \$6.0 million intended loss to Medicare. The defendant and his co-conspirators, among other things, created brace orders claiming that he had discussions or conversations regarding the benefits of the braces with beneficiaries or had conducted diagnostic testing for beneficiaries, however the defendant generally had not spoken to beneficiaries regarding the braces and had not conducted diagnostic testing on beneficiaries in connection with the ordering of orthotic braces. The defendant agreed to pay over \$3.0 million in restitution and to forfeit over \$34,000 in proceeds of his crime.

In December 2019, ResMed Corp., a DME manufacturer based in San Diego, California, agreed to pay more than \$37.5 million to resolve civil FCA allegations that it paid kickbacks to DME suppliers, sleep labs, and other health care providers. The settlement resolved allegations that ResMed provided DME companies with free patient outreach services that enabled these

companies to order resupplies for their patients with sleep apnea; provided sleep labs with free and below-cost positive airway pressure masks and diagnostic machines, as well as free installation of those machines; arranged for, and fully guaranteed the payments due on, interest-free loans that DME suppliers acquired from third-party financial institutions for the purchase of ResMed equipment; and provided non-sleep specialist physicians free home sleep testing devices. In connection with the settlement, ResMed entered into a CIA with HHS-OIG.

(SF) In January 2020, the owner of several durable medical equipment supplier companies in Florida, California, and Georgia, was convicted of charges resulting from his involvement in a scheme to defraud Medicare and TRICARE. According to court documents, from approximately November 2015 through March 2019, the owner and his co-defendants paid kickbacks and bribes in exchange for signed doctors' orders for orthotic braces that were not medically necessary. The combined billed amount for both Medicare and TRICARE was \$125.1 million and the combined paid amount was \$70.3 million. The owner pleaded guilty to conspiracy to commit health care fraud and was sentenced to six years and eight months in prison and ordered to pay restitution of \$70.3 million (which includes \$69.6 million to Medicare Part B and \$751,406 to TRICARE), joint and several with other co-conspirators. The owner was also ordered to forfeit \$35.1 million.

(SF) In July 2020, an owner of a South Florida telemedicine company was convicted of charges resulting from a scheme to generate and sell doctors' orders that were used to defraud Medicare. In connection with his guilty plea, the owner admitted that, from approximately January 2017 through approximately April 2019, the owner and his co-defendants sold doctors' orders for medically unnecessary orthotic braces in exchange for kickbacks. The owner told physicians not to speak with patients before prescribing braces, and he knew physicians often did not speak with patients at all. The owner then sold the doctor's orders to DME companies, which submitted claims to Medicare for the braces. The owner disguised the illegal kickbacks by entering into sham contracts that inaccurately described the services provided by the telemedicine company, and by procuring a fraudulent legal opinion letter that falsely described the telemedicine company's business model. Doctors' orders sold by the owner were used to fraudulently bill Medicare over \$39.0 million. The owner is awaiting sentencing. As part of his plea, he agreed that his Guidelines range is 188-235 months. The co-owner of the business pleaded guilty in November 2019 and was sentenced to 10 years in prison.

(SF) In September 2020, an operator of three DME supplier companies was convicted of charges resulting from his involvement in a scheme to defraud Medicare. The operator admitted that, from approximately April 2015 through approximately April 2019, the operator and his co-defendants paid kickbacks in exchange for signed doctors' orders for orthotic braces that were not medically necessary. To falsely make the sale of doctors' orders appear to be for legitimate "marketing" or "business process outsourcing" services, the operator and his co-conspirators executed sham contracts with purported marketing companies from which they purchased doctors' orders. The operator also hid the role of his co-conspirators in the DME company by lying about who the true owners of the DME companies were. The operator's DME companies collectively billed Medicare \$23.9 million. The operator is awaiting sentencing. As part of his plea, the operator has agreed that his Guidelines range is 78-97 months.

Electronic Health Records

In January 2020, Practice Fusion Inc. (Practice Fusion), a health information technology developer based in San Francisco, California, agreed to pay \$145.0 million to resolve criminal and civil liability relating to its electronic health records (EHR) software. As part of the criminal resolution, Practice Fusion executed a deferred prosecution agreement based on its solicitation and receipt of kickbacks from a major opioid company in exchange for implementing clinical decision support alerts in its EHR software that were designed to increase prescriptions for the drug company's products, and agreed to pay over \$26.0 million in criminal fines and forfeiture. This case marked the first ever kickback action against an EHR developer for receipt of remuneration from a pharmaceutical company. The resolution included extensive factual admissions, as well as robust compliance and oversight overhauls. In separate civil settlements, Practice Fusion agreed to pay approximately \$113.4 million to the federal government, and up to \$5.2 million to participating states, to resolve civil FCA allegations that it accepted kickbacks from the opioid company and other pharmaceutical companies and also caused its users to submit false claims for federal incentive payments by misrepresenting the capabilities of its EHR software.

Genetic Testing/RPP Testing Paired with COVID-19 Testing

(SF) In February 2020, an owner of a telemedicine company was convicted of charges resulting from a scheme to generate and sell doctors' orders that were used to defraud Medicare. The owner admitted that from approximately March 2018 through April 2019, the owner's co-conspirators targeted and recruited Medicare beneficiaries to receive the genetic testing through telemarketing campaigns. After the beneficiaries agreed to take the genetic tests, the co-conspirators paid the owner kickbacks in exchange for doctor's orders. After receiving the signed doctor's orders, the owner's co-conspirators sold the tests and doctor's orders to laboratories in exchange for illegal kickbacks. The laboratories billed Medicare more than \$12,000 per test. Doctor's orders sold by the owner were used to fraudulently bill Medicare for more than \$6.0 million. The owner is awaiting sentencing.

(SF) In September 2020, a broker between telemarketing companies and medical laboratories was charged via information on charges resulting from a scheme geared towards submitting cancer genetic tests ("CGX"), as well as COVID-19 and RPP tests that were not eligible for reimbursement to Medicare. The broker admitted that from approximately November 2018 through March 2020 the broker and her co-conspirators paid kickbacks to telemarketers who would obtain completed CGX tests from Medicare beneficiaries. The broker and her co-conspirators would also pay kickbacks to a telemedicine company in order to obtain doctor's orders authorizing the CGX tests. The broker and her co-conspirators would send the completed CGX test and the doctor's orders to a medical laboratory that would bill Medicare for the cancer genetic test, and then the broker received kickbacks from the laboratory in return. The laboratory broker also conspired with others to convince beneficiaries to agree to submit to genetic testing for COVID-19 tests. The broker was then going to sell the sample to laboratories, who would bundle the relatively inexpensive COVID-19 test with the more expensive RPP tests. RPP tests do not test for COVID-19. The Medicare reimbursement for RPP tests was

approximately four times higher than COVID-19 tests. The broker admitted that she caused the submission of more than \$3.0 million in fraudulent billing to the Medicare program for genetic testing. The recruiter is awaiting sentencing.

Home Health Providers

In December 2019, two owners of a network of health care entities in Florida were sentenced to prison for their roles in a \$38.0 million health care fraud and wire fraud scheme. According to court documents, the owners built a vast empire of fraud, consisting of at least six fraudulent home health agencies, three fraudulent therapy staffing companies, and two fraudulent pharmacies. Each of these entities purportedly provided home health services, therapy services, and prescription drugs, respectively, to qualified Medicare beneficiaries, though in fact they did not. From May 2010 through September 2016, the owners and their co-conspirators used this empire to submit more than \$38.0 million in fraudulent claims to Medicare, for which Medicare paid \$33.0 million. The owners were sentenced to a total of 23 years and eight months in prison and ordered to pay \$33.8 million in restitution, joint and several with a co-defendant. Four defendants involved in the scheme were previously sentenced to a combined 12 years and one month in prison and ordered to pay \$135,245 in restitution.

(SF) In March 2020, a medical doctor was convicted of charges resulting from a scheme to write prescriptions for home health services for Medicare beneficiaries he knew did not actually need home health services. In connection with his guilty plea, the doctor admitted that from October 2012 through June 2017, he knew the owners of home health agencies located in the Miami, Florida area used the prescriptions to submit more than \$3.4 million in false and fraudulent claims to Medicare for home health services that were not medically necessary.

In March 2020, after an eight-day trial, a Denver jury convicted an employee of the Department of Veterans Affairs (VA) for health care fraud, soliciting and receiving kickbacks, money laundering, and public corruption charges in connection with his scheme to defraud the VA's Spina Bifida Health Care Benefits Program of approximately \$20.0 million over the course of one year. The VA employee was a case management liaison for the VA program that provided health care benefits to children of war veterans born with spina bifida as a result of their parents' service in Korea and Vietnam. The employee devised a scheme in which he and his friends and family members opened sham home health companies that then "hired" beneficiary family members or others who were not medical providers to provide "home health" services to this vulnerable population. He encouraged his friends and family members to bill for up to 20 hours per day of "home health" services, even though the services were not made by legitimate health care providers and, in many cases, were not provided at all. The employee took payments from the "home health agencies" as bribes and kickbacks for patient referrals he made to the agencies. The defendant was sentenced to 192 months imprisonment and ordered to pay nearly \$19.0 million in restitution.

Hospice Care

In November 2019, the Louisiana Department of Health (LDH) agreed to pay \$13.5 million to resolve civil FCA allegations that LDH submitted false and inflated Medicaid claims for long-term nursing home and hospice care. The United States alleged that, in order to receive higher Federal share percentage rates for Louisiana's Medicaid payments, LDH fraudulently caused its healthcare contractor, Molina Medical Solutions, to prepare, submit, and pay claims for nursing home and hospice services in December 2010, March 2011, June 2011, and September 2013, before providers had submitted any claims for those services to Louisiana. In connection with this resolution, LDH entered into a State Agency Compliance Agreement with HHS-OIG.

Hospitals and Health Systems

In October 2019, Jewish Hospital & St. Mary's Healthcare, Inc., doing business as Pharmacy Plus and Pharmacy Plus Specialty (collectively, Jewish Hospital), of Louisville, Kentucky, agreed to pay more than \$10.1 million to resolve civil FCA allegations. The government alleged that Jewish Hospital submitted claims to Medicare for prescriptions drugs that did not meet Medicare coverage requirements, including the need for a detailed written order establishing medical necessity, to confirm that refills were reasonable and necessary, and to document that the medications were in fact delivered. The government also alleged that Jewish Hospital provided improper remuneration to Medicare beneficiaries in the form of free blood glucose testing supplies and waiver of copayments and deductibles for insulin, in violation of the Anti-Kickback Statute (AKS).

In October 2019, several hospitals owned and operated by Sutter Health (Sutter), a California-based health care services provider, and Sacramento Cardiovascular Surgeons Medical Group Inc. (Sac Cardio) agreed to pay the United States a total of approximately \$46.0 million to resolve civil FCA allegations. As part of the settlements, one of Sutter's hospitals, Sutter Memorial Center Sacramento (SMCS), agreed to pay \$30.5 million to resolve allegations that, from 2012 to 2014, it violated the Stark Law by billing Medicare for services referred by Sac Cardio physicians, to whom it paid amounts under compensation arrangements that exceeded the fair market value of the services provided. In addition, Sac Cardio agreed to pay \$506,000 to resolve allegations that it knowingly submitted duplicative bills to Medicare for services performed by physician assistants that it was leasing to SMCS under one of those compensation arrangements. Separately, Sutter agreed to pay \$15.1 million to resolve other conduct that it self-disclosed to the United States, principally concerning additional violations of the Stark Law by Sutter hospitals.

In July 2020, Oklahoma Center for Orthopedic and Multi-Specialty Surgery (OCOM), a specialty hospital in Oklahoma City, Oklahoma, its part-owner and management company, USP OKC, Inc. and USP OKC Manager, Inc. (collectively USP), Southwest Orthopedic Specialists, PLLC (SOS), an Oklahoma City-based physician group, and two SOS physicians, agreed to pay a total of \$72.3 million to resolve civil FCA allegations of improper relationships between OCOM and SOS that resulted in the submission of false claims to the Medicare, Medicaid, and TRICARE programs. The settlement resolved allegations that between 2006 and 2018, OCOM

and USP provided improper remuneration to SOS and certain of its physicians in exchange for patient referrals to OCOM in the form of: (1) free or below-fair market value office space, employees, and supplies, (2) compensation in excess of fair market value for the services provided by SOS and certain of its physicians, (3) equity buyback provisions and payments for certain SOS physicians that exceeded fair market value, and (4) preferential investment opportunities in connection with the provision of anesthesia services at OCOM. As a result of the settlement, USP agreed to pay \$60.9 million to the United States, \$5.0 million to the State of Oklahoma, and \$206,000 to the State of Texas; SOS and two of its physicians agreed to pay \$5.7 million to the United States, and \$495,619 to the State of Oklahoma. In connection with the settlement, OCOM and SOS each entered into a five-year CIA with HHS-OIG.

In September 2020, Wheeling Hospital, Inc., an acute care hospital in Wheeling, West Virginia, agreed to pay \$50.0 million to resolve civil FCA allegations that it knowingly submitted claims to Medicare that resulted from violations of the Stark Law and the Anti-Kickback Statute. The government alleged that, from 2007 to 2020, under the direction and control of its prior management, Wheeling Hospital systematically violated the Stark Law and AKS by knowingly and willfully paying improper compensation to referring physicians that was based on the volume or value of the physicians' referrals or was above fair market value.

Laboratories

In October 2019, UTC Laboratories Inc. (RenRX), headquartered in New Orleans, Louisiana, agreed to pay \$41.6 million, and its three principals agreed to pay \$1.0 million, to resolve civil FCA allegations that they paid kickbacks in exchange for laboratory referrals for pharmacogenetic testing and for furnishing and billing for tests that were not medically necessary. The government alleged that between 2013 and 2017, UTC and its principals offered and paid remuneration to physicians to induce the ordering of pharmacogenetic tests, purportedly in return for their participation in a clinical trial. The government also alleged that UTC and its principals offered and paid remuneration, including sales commissions, to entities and individuals as part of the scheme, and furnished and billed Medicare for pharmacogenetic tests that were not medically necessary. As part of the resolution, RenRX also agreed to a 25 year period of exclusion from participation in any federal health care program.

In November 2019, Boston Heart Diagnostics Corporation (Boston Heart), a laboratory in Framingham, Massachusetts, agreed to pay \$26.7 million to resolve civil FCA allegations involving payments for patient referrals in violation of the AKS and the Stark Law. The government alleged that from 2015 through 2017, Boston Heart conspired with others to pay doctors kickbacks disguised as investment returns, in return for referrals to Boston Heart and small Texas hospitals for laboratory tests performed by Boston Heart and then billed to federal health care programs. The government also alleged that, in order to receive higher reimbursements from federal health care programs, Boston Heart conspired with the Texas hospitals and others to submit claims for outpatient laboratory testing for patients who were not hospital outpatients. In addition, the settlement resolved allegations that Boston Heart directly or indirectly paid processing and handling fees, waived patient copayments and deductibles, and

provided physician practices with in-office dietitians in exchange for physician referrals for laboratory testing.

In December 2019, six defendants, including one doctor, were convicted of health care fraud in Miami for their role in a nation-wide scheme that defrauded TRICARE and Medicare out of more than \$9.6 million. In furtherance of the scheme, the defendants, through several corporate entities, solicited and misled TRICARE and Medicare beneficiaries into agreeing to order medically unnecessary compounded prescription medicines and cancer genetic tests. Defendants falsely claimed that the compound drugs were free and uniquely tailored to the beneficiaries' individual needs, when in fact they were designed to maximize profit and required mandatory copayments. Defendants also falsely marketed the genetic tests as a tool to predict a beneficiary's chances of developing cancer, when in fact the tests are intended to aid doctors in treating patients with a pre-existing cancer diagnosis. Defendants paid doctors to ratify pre-printed prescriptions for the expensive drugs and genetic tests, and then sold the fraudulent prescriptions to pharmacies and labs around the country in exchange for half the profits. In most cases the doctors had no existing relationship with, and often never consulted, the beneficiaries. The defendants were sentenced to a combined 32 years and six months in prison and were ordered to pay \$9.6 million in restitution.

(SF) In January 2020, a laboratory owner in Baton Rouge, Louisiana was convicted for his role in a conspiracy to defraud the United States and pay and receive health care kickbacks wherein he paid illegal remuneration to marketers for the referral of DNA specimens and attendant physicians' orders for medically unnecessary genetic testing, cancer screens, which were ultimately performed by the laboratory and billed to Medicare. Through sham contracts and invoices, the owner tried to conceal the payment to marketers of up to 50 percent of the reimbursements paid by Medicare for medically unnecessary genetic testing. Between March 2018 and July 2019, the owner submitted approximately \$127.0 million in false and fraudulent claims to Medicare for these medically unnecessary genetic tests and paid more than approximately \$23.0 million in kickbacks and bribes to marketers.

In April 2020, reference laboratory Logan Laboratories Inc. (Logan Labs) and pain clinic Tampa Pain Relief Centers Inc. (Tampa Pain), both located in Tampa, Florida, and two of their former executives agreed to pay a total of \$41.0 million to resolve civil FCA allegations for billing Medicare, Medicaid, TRICARE, and other federal health care programs for medically unnecessary Urine Drug Testing (UDT) between January 1, 2010 and December 31, 2017. The settlement resolved allegations by the United States that defendants developed and implemented a policy and practice of automatically ordering both presumptive and definitive UDT for all patients at every visit, without any physician making an individualized determination that either test was medically necessary for the particular patients for whom the tests were ordered. In connection with the settlement, Logan Labs entered into an Integrity Agreement and Tampa Pain entered into a CIA with HHS-OIG.

In April 2020, Genova Diagnostics Inc., a clinical laboratory services company based in Asheville, North Carolina, agreed to pay up to approximately \$43.0 million to resolve civil FCA allegations that it: (1) improperly submitted claims to Medicare, TRICARE, and the federal

employee health program for its IgG allergen, NutrEval, and GI Effects lab test profiles because the tests were not medically necessary, (2) engaged in improper billing techniques, and (3) paid compensation to three phlebotomy vendors that violated the Stark Law. Under the settlement, Genova agreed to pay approximately \$17.0 million through the surrender of claim funds held in suspension by Medicare and TRICARE, plus up to an additional \$26.0 million if certain financial contingencies occur within the next five years. In addition, as part of the resolution, Genova entered into a five-year CIA with HHS-OIG.

Medical Devices

In October 2019, hospital entities Sanford Health, Sanford Medical Center, and Sanford Clinic (collectively, Sanford), of Sioux Falls, South Dakota, agreed to pay \$20.3 million to resolve civil FCA allegations that Sanford knowingly submitted false claims to federal health care programs resulting from violations of the AKS and medically unnecessary spinal surgeries. The government alleged that Sanford knew that one of its top neurosurgeons was improperly receiving kickbacks from his use of implantable devices distributed by his physician-owned distributorship, but continued to employ the neurosurgeon, continued to allow him to profit from the devices he used in surgeries performed at Sanford, and continued to submit claims to federal health care programs for these surgeries, including procedures that were medically unnecessary. In connection with this resolution, Sanford entered into a five-year CIA with HHS-OIG.

Nursing Homes and Facilities

In October 2019, a health care company located in Nevada entered into a civil FCA settlement agreement with the United States. The company agreed to pay \$4.0 million to resolve allegations that it filed improperly coded claims for Inpatient Rehabilitation Facility (IRF) services provided at one of its locations. Specifically, the United States alleged that the company submitted false claims to Medicare because it had improperly assigned inaccurate and artificially low admission Functional Independence Measure scores on Patient Assessment Instrument forms (IRF- PAIs) for some of its patients, resulting in the company receiving greater reimbursement for its services for those patients than was warranted.

In February 2020, Guardian Elder Care Holdings Inc., and related companies Guardian LTC Management Inc., Guardian Elder Care Management Inc., Guardian Elder Care Management I Inc., and Guardian Rehabilitation Services Inc. (Guardian) agreed to pay more than \$15.0 million to resolve civil FCA allegations that they knowingly overbilled Medicare and the Federal Employees Health Benefits Program for medically unnecessary rehabilitation therapy services. The United States alleged that between January 2011 and December 2017, Guardian caused certain facilities in Pennsylvania, West Virginia, and Ohio to bill for patients at the highest level of Medicare reimbursement, when services at that level were not medically necessary and were influenced by financial considerations rather than resident needs. The settlement also resolved civil claims relating to conduct voluntarily disclosed by Guardian that it had employed two people who were excluded from federal health care programs, causing Guardian to inappropriately receive payment for ineligible services. In connection with the resolution, Guardian entered into a chain-wide, five-year CIA with HHS-OIG.

In February 2020, Diversicare Health Services Inc. (Diversicare), based in Brentwood, Tennessee, agreed to pay \$9.5 million to resolve civil FCA allegations that it submitted false claims to Medicare for rehabilitation therapy services provided in its skilled nursing facilities that were not reasonable, necessary, or skilled. The government alleged that from January 2010 through December 2015, Diversicare's corporate policies and practices were designed to place as many beneficiaries in the highest level of Medicare reimbursement irrespective of the individual clinical needs of the patients. The settlement also resolved allegations that Diversicare submitted forged pre-admission evaluations of patient need for skilled nursing services to TennCare, the State of Tennessee's Medicaid Program. As part of the settlement, Diversicare entered into a five-year CIA with HHS-OIG.

Occupational Therapy

In December 2019, a doctor located in New York was sentenced for his participation in a \$30.0 million scheme to defraud Medicare and the New York State Medicaid Program. Between 2007 and 2013, the doctor falsely posed as the owner of three medical clinics, which were actually owned by a corrupt businessman, and falsely claimed that he had examined and treated thousands of patients whom he had not in fact seen. The doctor was convicted on charges of health care fraud, wire fraud, mail fraud, conspiracy to commit those offenses, and conspiracy to make false statements in connection with a Federal health care program and was sentenced to four years in prison and ordered to pay \$16.3 million in restitution, joint and several. Nine co-defendants involved in the scheme were previously sentenced to a combined 26 years and eight months in prison.

Pharmacies

In November 2019, Fagron Holding USA LLC (Fagron) agreed to pay \$22.1 million to resolve civil FCA allegations concerning the establishment of false and inflated Average Wholesale Prices (AWPs) by its wholly owned subsidiary Freedom Pharmaceuticals Inc. (Freedom) for active pharmaceutical ingredients used in compound prescriptions. The government alleged that Freedom's pricing scheme caused pharmacies that purchased Freedom's compound ingredients to submit false prescription claims to the Defense Health Agency, which administers the TRICARE Program for the Department of Defense and the Department of Labor's Office of Workers Compensation Programs (federal health care programs). The settlement also resolved allegations that Fagron's wholly owned pharmacy subsidiary, Pharmacy Services Inc. and its pharmacy affiliates, submitted fraudulent compound prescription claims to federal health care programs, used sham insurance programs to manipulate pricing, paid kickbacks to physicians for bogus consulting agreements, and illegally waived copays, as well as allegations against another Fagron subsidiary, B&B Pharmaceuticals Inc., for setting an inflated AWP for a compound ingredient.

In December 2019, a doctor, pharmacists, and marketers in a compounding pharmacy scheme were sentenced for conspiring to pay and receive health care kickbacks for prescriptions for compounded creams billed to TRICARE, Medicare, and private insurance. Between May and November 2014, the pharmacy billed health insurers more than \$12.4 million for compounded

cream prescriptions written by the doctor and marketed by the marketing firm. Even after the pharmacy closed and the doctor withdrew from the conspiracy, the marketing firm transferred the existing refills from the original doctor's prescriptions to a new pharmacy, which filled the prescriptions and billed TRICARE. In all, the marketing firm caused TRICARE to be billed more than \$50.0 million for compounded creams prescribed to patients that it had recruited. The five co-defendants involved in the scheme were sentenced to a combined five years, six months, and two days in prison and ordered to pay \$6.4 million in restitution.

(SF) In February 2020, two owners and operators of a Los Angeles pharmacy were both sentenced to 12 years in prison for their roles in a health care fraud scheme where Medicare and CIGNA were billed more than \$11.8 million in fraudulent claims for prescription drugs. From 2012 to 2015, the owners fraudulently billed Medicare and CIGNA for prescription medications that their pharmacy never purchased or dispensed to beneficiaries. In order to hide the fraud, the owners obtained fake drug invoices from co-conspirators to make it appear as if the pharmacy had purchased the medicines for which it had billed Medicare and CIGNA, when it actually had not. The owners also used these fake invoices to launder the proceeds of the fraud through a co-conspirator. The defendants were both ordered to pay restitution of \$11.8 million to Medicare and one of the defendants was also ordered to pay restitution of \$17.1 million to CIGNA.

(SF) In March 2020, a pharmacist and owner of a compounding pharmacy was convicted of one count of conspiracy to pay and receive kickbacks, 11 counts of health care fraud, three counts of wire fraud, and one count of conspiracy to commit money laundering as charged in a November 2018 superseding indictment. The defendant and his co-conspirator created a scheme to generate compounded pain cream prescriptions and bill, primarily, to health care programs for injured State and Federal employees, including Department of Labor Office of Workers Compensation Programs and Federal Employee's Compensation Act. As part of the scheme, the conspirators created a separate entity to receive government program money and launder the proceeds of their crimes. During the course of the conspiracy, the pharmacy billed the Department of Labor approximately \$21.8 million for compound gels and creams dispensed as a result of illegal kickback payments that were not medically necessary. In June 2020, the Defendant was sentenced to 10 years in prison and over \$12.0 million in restitution. The Defendant's wife and a pharmacy employee also pled guilty as part of the scheme.

(SF) In June and July 2020, two doctors and two nurses were sentenced for their roles in a compounding pharmacy scheme wherein they conspired to commit health care fraud by prescribing medically unnecessary compounded medications to Medicare and TRICARE beneficiaries as well as members of various private insurance programs in exchange for kickbacks and bribes. Between March 2014 and February 2015, the associated compounding pharmacy billed health insurers more than \$8.1 million for the dispensation of medically unnecessary compounded medications prescribed by the physicians and referred to the compounding pharmacy. In turn, the compounding pharmacy paid the prescribing doctor approximately 35 percent of the reimbursements paid by the various insurance companies, including Medicare and TRICARE. The four co-defendants were collectively sentenced to nine years' imprisonment and ordered to pay \$4.8 million in restitution.

(SF) In July 2020, two owners of a compounding pharmacy, a marketer, and a nurse practitioner were sentenced for their roles in a compounding pharmacy scheme wherein they conspired to commit health care fraud and launder monetary instruments. The owners created formulas to maximize reimbursements paid by health care providers and further paid remuneration to the nurse practitioner and marketer in exchange for prescribing and referring prescriptions for high adjudicating compounded medications, including medications reimbursed by TRICARE. Between April 2013 and January 2016, the compounding pharmacy billed health insurers more than \$189.0 million for the dispensation of medically unnecessary compounded medications. Thereafter, the owners laundered the proceeds of their fraud scheme for the purpose of evading taxes through purported offshore accounts. The owners were sentenced to 14 years' and 13 years' imprisonment, respectively, the marketer was sentenced to eight years' imprisonment, and the nurse practitioner was sentenced to 18 months, and the four co-defendants were ordered to pay \$189.0 million in restitution.

In July 2020, the owner of numerous compounding pharmacies pled guilty to defrauding private insurers and TRICARE of more than \$500 million. The guilty plea followed an investigation into coordinated fraudulent schemes related to prescription-compounded drugs that has resulted in more than 40 criminal convictions, significant custodial sentences, and the seizure, forfeiture, and restitution of hundreds of millions of dollars. The defendants' sophisticated scheme involved multi-level marketers who received kickbacks to recruit straw private and TRICARE insurance beneficiaries to sign up to receive unnecessary compounded drugs. Patients were sometimes fraudulently induced to receive the drugs, while others received kickbacks. The recruiters sent pre-filled prescriptions to co-conspirator medical clinics to be signed by doctors who were often "paid to sign their name." In most cases, automatically refilling prescriptions were written without corresponding doctor visits, medical histories, or contraindicated drug checks, resulting in hundreds of thousands of dollars of fraudulent reimbursements.

Physical Therapy

In March 2020, Saber Healthcare Group LLC, based in Bedford Heights, Ohio, and related entities (collectively, Saber) agreed to pay \$10.0 million to resolve civil FCA allegations that Saber caused nine of its skilled nursing facilities to submit false claims to Medicare for rehabilitation therapy services that were not reasonable, necessary, or skilled by engaging in a systematic effort to increase Medicare billings. The United States alleged that Saber improperly established general goals that all patients be provided with the highest level of rehabilitation therapy, regardless of the patients' individual therapeutic needs, and enforced that expectation by pressuring therapists to provide therapy at that level to each patient at those nine facilities. In connection with the settlement, Saber entered into a five-year CIA with HHS-OIG.

In March 2020, Longwood Management Corporation and 27 affiliated skilled nursing facilities (Longwood) located in California agreed to resolve civil FCA allegations that they submitted false claims to Medicare for rehabilitation therapy services that were not reasonable or necessary. The United States alleged that Longwood pressured therapists to increase the amount of therapy provided to patients to meet pre-planned targets for Medicare revenue, which were allegedly set without regard to patients' individual therapy needs. In connection with the

settlement, Longwood entered into a five-year CIA with HHS-OIG.

Physician and Other Practitioners

In October 2019, the physician owner of South Georgia Health Group and medical director of multiple nursing homes in Valdosta, Georgia, was convicted of defrauding Medicare and Georgia Medicaid of more than \$6 million. Over a period of four years, he directed his employees, including his co-defendant physician assistant, to bill for and falsify documentation for nursing home visits and medical services not provided to the vulnerable and elderly patient populations of four nursing homes. The physician instructed his non-physician employees to falsely document that he himself had seen and treated the patients on multiple dates when he was not present or even gambling in Las Vegas, and to always bill at the highest complexity levels to capture the highest payments from Medicare and Medicaid regardless of what services were documented. He also gave increasingly large billing quotas to his employees, culminating in billing for numerous “impossible days” of more than 24 hours of alleged services in a single day. The physician was sentenced to eight years and one month in prison after a jury found him guilty on all seven fraud counts after less than two hours of deliberations; his physician assistant pleaded guilty and was sentenced to two years in prison. Both were jointly and severally ordered to pay \$2.3 million in restitution.

(SF) In October 2019, a Los Angeles, California doctor was sentenced to 10 years in prison for his role in a \$33.0 million Medicare fraud scheme in which he and co-conspirators billed Medicare for physician clinic, home health, and hospice services, and DME that patients did not need or did not receive. Co-conspirator owners of a home health care company paid kickbacks to patient recruiters to recruit Medicare beneficiaries to the physician’s clinic, where the physician then billed Medicare for office services and tests that patients did not need or did not receive. The physician also referred the Medicare beneficiaries for a variety of services, including home health and hospice services, as well as ordered DME, which the patients did not need or did not receive. Based on referrals from the physician, the home health care company owned by the co-conspirators also billed Medicare for home health services that were not rendered or were not medically necessary. One of the co-conspirators worked as an office manager at the physician’s clinic and sold physician referrals to other home health and DM agencies. Together, the physician defendant and his co-conspirators submitted and caused to be submitted claims of approximately \$33.0 million, of which Medicare paid approximately \$22.0 million.

In January 2020, a physician and his ex-wife were sentenced for conspiring to defraud Medicare and Blue Cross Blue Shield of over \$8.0 million as owners and operators of Reliant Family Practice in Gainesville, Florida. Between January 2013 and July 2016, Reliant Family Practice submitted fraudulent claims for chemical peels and dermabrasions relating to false diagnoses of rosacea and actinic keratosis. The ex-wife was further convicted of money laundering charges for spending the fraudulently obtained proceeds on such things as paying off her home mortgage, a swimming pool, obtaining plastic surgery, purchasing commercial property, and funding an annuity for herself. The physician was sentenced to 42 months in prison, and his ex-wife was

sentenced to 90 months prison. The defendants were also jointly ordered to pay \$4.5 million in restitution.

Prescription Drugs and Opioids

In October 2019, a doctor in Virginia was convicted on 861 Federal counts of drug distribution, including distribution resulting in death, for operating a “pill mill.” Evidence presented at trial showed the doctor prescribed controlled substances to every patient in his practice, resulting in over 500,000 Schedule II controlled substances being distributed. The doctor caused West Virginia Medicaid to pay \$469,220 and Medicare Part D to pay \$775,479 in suspected fraudulent prescriptions. The doctor was found guilty of one count of maintaining a place for the purpose of illegally distributing controlled substances, one count of possession with the intent to distribute controlled substances, and 859 counts of illegally prescribing Schedule II controlled substances. The doctor was sentenced to 40 years in prison.

In December 2019, a federal jury convicted the president and co-owner of pharmaceutical marketing company group CMGRX of paying and receiving illegal kickbacks and conspiring to defraud TRICARE of over \$70.0 million. The evidence at trial showed that CMGRX hired marketers to recruit more than 2,300 patients, many of whom were on active duty at Fort Hood, and incentivized them to obtain costly pain and scar cream prescriptions with their TRICARE benefits in exchange for kickbacks of \$250 per prescription. The owners of CMGRX disguised these illegal kickbacks by claiming they were payments for participation in a bogus medical study and by funneling the money through the “Freedom from Pain Foundation,” a sham charity they funded, directed, and controlled. CMGRX also paid multiple doctors, who had no prior relationship with the patients, to write their prescriptions after brief telephone calls. The doctors sent the signed prescriptions back to CMGRX, so that the company could send the prescriptions to partner pharmacies. In exchange for those prescription referrals, the pharmacies billed TRICARE for the drugs and kicked back a percentage of the reimbursement to CMGRX. In July 2020, the court sentenced the defendant to 20 years in prison and ordered him to pay \$68.0 million in restitution. Seven other defendants, including the CEO and co-owner of CMGRX, have pled guilty in connection with the scheme. Five of the defendants are awaiting sentencing.

In February 2020, a physician was sentenced to 240 months of imprisonment for unlawful drug distribution and health care fraud, capping a coordinated parallel prosecution of a major pill mill network. The network led by the physician was responsible for distributing in excess of five million dosage units of controlled substances – frequently prescribed in dangerous cocktails – and were prescribed so prolifically that Medicare identified the physician as the #1 ranked physician in the country for certain drug combinations. To address this public health threat, the government initiated a comprehensive parallel criminal-civil investigation to prosecute not only the physicians at the core but also those pharmacists who willfully enabled the prolific distribution. These coordinated efforts resulted in five criminal convictions, including both physicians and pharmacists, as well as 12 civil judgments or settlements with pharmacies or pharmacists-in-charge totaling up to \$7.7 million. Administratively, DEA obtained a series of compliance agreements, an immediate suspension, and multiple voluntary surrenders of

registrations. Prescriptions for the physician’s “Cocktail,” including oxycodone, Xanax, carisoprodol, and Adderall, have dropped more than 50 percent in the targeted communities.

(SF) In February 2020, a federal jury in Memphis, Tennessee, convicted a psychiatrist on three counts of unlawful distribution of a controlled substance. The charges stemmed from the psychiatrist’s role in prescribing oxycodone without legitimate medical purpose and outside the usual course of professional practice. As trial evidence demonstrated, the psychiatrist’s conduct included trading prescriptions for sexual acts and female companionship. The psychiatrist was sentenced to 48 months in prison.

In May 2020, Omnicare, Inc., a subsidiary of CVS Health, agreed to pay \$15.3 million and adopt operational changes to resolve an investigation into violations of the Controlled Substances Act related to its handling of opioids and other controlled substances. Omnicare operates “closed door” pharmacies that provide controlled substances to long-term care facilities (LTCFs). Omnicare makes daily deliveries of prescription medications to residents of LTCFs, and it pre-positions limited stockpiles of controlled substances at LTCFs in “emergency kits,” which are to be dispensed to patients on an emergency basis. The investigation concluded that Omnicare violated the CSA in its handling of emergency prescriptions, its controls over the emergency kits, and its processing of written prescriptions that lacked required elements such as the prescriber’s signature or DEA number. Omnicare failed to control emergency kits by improperly permitting LTCFs to remove opioids and other controlled substances from emergency kits days before doctors provided a valid prescription.

(SF) On August 10, 2020, a federal jury in Huntington, West Virginia, convicted a physician on 17 counts of unlawfully distributing controlled substances. The physician unlawfully distributed controlled substances outside the usual course of professional practice and without a legitimate medical purpose, to among other patients, a patient in a parking lot, in hopes of obtaining sexual favors; and a patient to whom he prescribed four times the CDC-recommended volume for acceptable Morphine Milligram Equivalents. The physician’s Cadillac Escalade was also forfeited as part of the trial. Sentencing is currently set for January 6, 2021.

Psychiatric and Psychological Testing and Services

In July 2020, Universal Health Services, Inc., UHS of Delaware, Inc. (together, UHS), and UHS facility Turning Point Care Center, LLC (Turning Point) agreed to pay a combined total of \$122.0 million to resolve civil FCA allegations in two separate settlements. In the first settlement, UHS, headquartered in King of Prussia, Pennsylvania, and which owns and provides management and administrative services to inpatient psychiatric hospitals and residential psychiatric and behavioral treatment facilities nationwide, agreed to pay the United States and participating states a total of \$117.0 million to resolve allegations that UHS’s hospitals and facilities knowingly submitted false claims for payment to the Medicare, Medicaid, TRICARE, VA, and FEHBP for inpatient behavioral health services that were not reasonable or medically necessary and/or failed to provide adequate and appropriate services for adults and children admitted to UHS facilities. In a separate civil settlement, Turning Point, located in Moultrie, Georgia, agreed to pay the United States and the State of Georgia \$5.0 million to resolve

allegations that it provided free or discounted transportation services to induce Medicare and Medicaid beneficiaries to seek treatment at Turning Point's inpatient detoxification and rehabilitation program or intensive outpatient program. In addition, UHS has entered into a five-year CIA with HHS-OIG.

Substance Abuse Treatment Centers

In March 2020, after a six-week trial, the owner and CEO of Serenity Ranch Recovery, a substance abuse treatment center in Broward County, Florida, was convicted of health care fraud and money laundering offenses. Between 2016 and 2019, Serenity Ranch Recovery fraudulently billed commercial insurance companies more than \$36.0 million for addiction treatment services. As part of the scheme, Serenity Ranch offered unlawful kickbacks including free housing, vapes, manicures, cash, airline tickets, and copayment waivers, to attract patients between the ages of 18-26 on their parents' insurance plans. Serenity Ranch billed for addiction treatment services not rendered or not medically necessary and caused the ordering of expensive and medically unnecessary urine analysis testing three times a week for each patient. The Clinical Directors and Director of Operations pled guilty before trial and were sentenced to between 32 and 120 months' imprisonment, and collectively ordered to pay over \$8.0 million in restitution.

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 is focused 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 MFCUs. HHS-OIG is also strengthening oversight of managed care in the Medicare Advantage (MA), Medicaid managed care programs, new value-based models, and technology and cybersecurity.

Responding to the COVID-19 Pandemic

Continued efforts to respond to COVID-19 remains an unprecedented challenge for HHS and for the delivery of health care and human services to the American people. In response to the COVID-19 Emergency Declaration, HHS-OIG immediately coordinated numerous COVID-19 related investigations in conjunction with FBI, DEA, the Food and Drug Administration (FDA), the Federal Emergency Management Agency (FEMA), as well as various state agencies. Moreover, HHS-OIG issued the OIG Strategic Plan: Oversight of COVID-19 Response and Recovery. This plan sets forth the four goals that drive HHS-OIG's strategic planning and mission execution with respect to HHS's COVID-19 response and recovery. These goals are to: (1) protect people, (2) protect funds, (3) protect infrastructure, and (4) promote effectiveness of HHS programs—now and into the future. Finally, HHS-OIG is using risk assessment and data analytics to identify, monitor, and target potential fraud, waste, and abuse affecting HHS programs and beneficiaries and to promote the effectiveness of HHS's COVID-19 response and recovery programs, including Medicare and Medicaid programs and beneficiaries.

HHS-OIG Priority Outcomes

With a \$1.3 trillion portfolio to oversee, HHS-OIG sets priority outcomes to achieve the greatest impact across HHS's diverse programs. In the FY 2020 President's Budget, HHS-OIG 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
- 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

A certain portion of the funds appropriated under HIPAA are, by law, set aside for Medicare and Medicaid activities of HHS-OIG. In FY 2020, the Secretary and the Attorney General jointly allotted \$205.3 million to HHS-OIG after accounting for a sequester reduction of \$7.3 million. HHS-OIG was allocated an additional \$20.8 million in HCFAC mandatory funds from the Secretary. Additionally, Congress appropriated \$93.0 million in discretionary funding for HHS-OIG HCFAC activities.

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

Results

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

In FY 2020, HHS-OIG investigations resulted in 578 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid; and 781 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 2020, HHS-OIG excluded a total of 2,148 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. HHS-OIG makes recommendations to agency managers to address these vulnerabilities as required by the Inspector General Act. 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 2020, 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 \$2.4 billion—\$2.1 billion in Medicare savings and \$290.0 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 \$4.1 billion, which resulted in a ROI of about \$12.40 to \$1.00.¹⁴

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>.

Enforcement

HHS-OIG works with its law enforcement partners to conduct criminal and civil investigations involving the Medicare and Medicaid programs and participates in the settlement of False Claims Act cases, including through the negotiation of 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 CMPs for a variety of health care related offenses.

¹⁴ This ROI uses a 3-year average of expected recoveries, fines, penalties, and stolen and misspent funds relating to HHS-OIG's health care oversight and is compared with HHS-OIG's annual obligations. This ROI differs from the HCFAC ROI, which uses actual dollars returned to the government. 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.

Combatting the Opioid Epidemic

Fighting the opioid crisis and protecting beneficiaries from prescription drug abuse is among HHS-OIG's top priorities. Opioid-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, seven pharmacists, eight nurse practitioners, and seven 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 1,451 providers based on conduct related to opioid diversion and abuse.

Strike Force Operations

In FY 2020, 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 September 2020, the largest national takedown resulted in charges against 345 individuals for submitting more than \$6.0 billion false and fraudulent claims to federal health care programs and private insurers, including more than \$4.5 billion connected to telemedicine, more than \$845.0 million connected to substance abuse treatment facilities, or "sober homes," and illegal opioid distribution schemes across the country. 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 MFCUs 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 2020, HHS-OIG excluded a total of 2,148 individuals and entities. In addition to those mentioned in the Program Accomplishments section above, exclusion actions by HHS-OIG included:

- In January 2020, a massage therapist in Texas was excluded for a minimum period of 50 years based on his conviction for sexual assault. During a massage therapy session, this massage therapist touched the patient inappropriately to include sexually penetrating her while providing massage therapy services. The court sentenced this individual to serve 18 years of incarceration, and the Texas Department of Licensing and Regulation revoked his license as a massage therapist.
- In July 2020, an osteopathic physician in Virginia was excluded for a minimum period of 50 years based on his conviction for maintaining a place for the purpose of unlawfully distributing controlled substances, distributing Schedule II controlled substances without legitimate purpose and beyond the bounds of medical practice, and distributing Schedule II controlled substances without a legitimate medical purpose and beyond the bounds of medical practice which resulted in death. The osteopathic physician opened a medical office and, from about 2015 to about August 2017, prescribed controlled substances to every patient in his practice. This resulted in the distribution of over 500,000 Schedule II controlled substances. Drugs involved in the scheme included oxymorphone, oxycodone, and fentanyl. Most of the patients would travel hundreds of miles to receive the drugs. The osteopathic physician did not accept any insurance but took payment via cash or credit card for the prescriptions. One patient died as a result of this prescribing activity. The court sentenced the individual to 480 months of incarceration, and the Virginia Board of Medicine suspended his license to practice medicine.
- In August 2020, the owner of a home health agency in Michigan was excluded for a minimum period of 20 years based on his conviction of health care fraud conspiracy. From about October 2005 to about March 2013, the individual and his wife controlled and operated home health agencies that billed Medicare for services that were not medically necessary or were not provided. In addition, the individual created false physical therapy files and claimed that physical therapy services had been provided, when in fact, no such services had been provided. The court sentenced him to serve 32 months of incarceration and repay approximately \$12.1 million in restitution.
- In August 2020, the owner of a pharmacy in Mississippi was excluded for a minimum period of 75 years based on his conviction for conspiracy to commit health care fraud. From about December 2014 to about January 2016, this individual participated in a scheme to defraud TRICARE by formulating compounded medications that did not fit the individualized needs of patients but instead were formulated to obtain maximum reimbursement from TRICARE. In addition, this individual and his co-conspirators arranged for their employees to purchase prepaid debit cards to make copayments for beneficiaries. The court ordered this individual to pay approximately \$243.5 million in restitution and serve 120 months of incarceration. The Mississippi Board of Pharmacy also revoked his license to practice as a pharmacist.

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 2020, HHS-OIG concluded cases involving more than \$31.9 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 AKS 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 2020, HHS-OIG recovered more than \$8.2 million in false claims and kickback affirmative enforcement actions. HHS-OIG also excluded 19 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:

- December 2019, New York—A doctor and his practice entered into a \$191,210 CMPL settlement agreement with HHS-OIG. The settlement agreement resolves allegations that the doctor and his practice: (1) submitted claims for neuromuscular junction testing that were not performed; and (2) billed for 13 or more nerve conduction studies (NCS), when only 12 or fewer NCS were performed.
- March 2020, Colorado—Two doctors and a medical group, entered into a \$54,982 CMPL settlement agreement with HHS-OIG. The settlement agreement resolves allegations that the medical group solicited and received remuneration from laboratory companies, in the form of "process and handling" payments related to the collection of blood. HHS-OIG alleged that doctors and medical group received the remuneration from laboratories in exchange for the medical group and medical group's employees referring patients for laboratory testing services to laboratories, for which the Medicare program paid.
- May 2020, Texas—A drug manufacturer, entered into a \$45,000 CMPL settlement agreement with HHS-OIG. The settlement agreement resolves allegations that the manufacturer failed to submit timely certified monthly and quarterly Average Manufacturer's Price (AMP) data to the CMS for certain months and quarters in 2015, 2016, 2017, and 2018. The Medicaid Drug Rebate Program requires manufacturers to enter into and have in effect a national rebate agreement with the Secretary of Health and Human Services in order for Medicaid payments to be available for the manufacturer's

covered outpatient drugs. Companies with such rebate agreements are required to submit certain drug pricing information to CMS, including quarterly and monthly AMP data.

- July 2020, New York—A federally qualified health center (FQHC), entered into a \$100,000 CMPL settlement agreement and the first ever compliance agreement between HHS-OIG and an HHS grant recipient. The settlement and compliance agreements resolve allegations that the FQHC submitted false specified claims in the form of drawdowns from the HHS Payment Management System for Health Resources and Services Administration grant funds. HHS-OIG alleged the drawdowns were not supported by adequate documentation, timesheets, and a financial management and control system that ensured that HHS grant funds were used solely for authorized purposes in accordance with federal law and the terms of the awards. HHS-OIG also alleged that the FQHC falsely represented to HHS that it had in place: (1) safeguards to prohibit employees from using their positions for personal gain; and (2) a financial management and control system that ensured that HHS grant funds were used solely for authorized purposes in accordance with federal law.

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 Emergency Department with an emergency medical condition. In FY 2020, HHS-OIG recovered more than \$620,000 in cases under the EMTALA statute. Patient dumping examples include:

- April 2020, Georgia—DeKalb Medical Center, Inc. (DeKalb) entered into a \$260,000 settlement agreement with HHS-OIG. Based on HHS-OIG’s investigation, the settlement agreement resolves allegations that DeKalb violated the EMTALA statute when it failed to provide an adequate screening examination and stabilizing treatment for 21 individuals. The following is an example of such incidents: Patient N.R.A., a 25-year-old female, presented to DeKalb’s ED with complaints of acute gastric pain, nausea, and vomiting. The medical records also listed possible pregnancy as her chief complaint. N.R.A. had a prior history of peptic ulcer disease and gastric ulcers. The medical records indicated that N.R.A. was seen by a registered nurse and was triaged using an emergency severity level index at level four (indicating a non-urgent patient). The triage nurse recorded N.R.A.’s vital signs and marked "no" next to nine questions on a non-patient-specific checklist. Within six minutes of the nurse starting the triage process, N.R.A. was discharged from DeKalb’s ED. HHS-OIG determined that DeKalb’s ED was capable of providing an appropriate medical screening examination to determine whether the patients at issue had an emergency medical condition and providing stabilizing treatments in the event patients had such conditions, but HHS-OIG contends that DeKalb failed to do so.

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.

HHS-OIG collected \$21.9 million under the Protocol in FY 2020.

Self-disclosure examples include:

- April 2020, Alaska—After it self-disclosed conduct to HHS-OIG, the City and Borough of Sitka, formerly doing business as Sitka Community Hospital, a Department of the City and Borough of Sitka (Sitka) agreed to pay \$4.1 million for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks. HHS-OIG alleged that Sitka paid remuneration to providers in the form of: (1) excessive compensation under ED call coverage arrangements; and (2) excessive compensation under advance practice provider's arrangements.

Corporate Integrity Agreements 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. Providers under a CIA are required to disclose certain "Reportable Events" which may implicate OIG's Civil Monetary Penalties authorities. HHS-OIG may impose penalties on entities that fail to comply with the requirements of their CIAs, as shown. HHS-OIG collected more than \$2.5 million in CIA enforcement. CIA enforcement examples include:

- June 2020, Tennessee—On June 1, 2020, the Departmental Appeals Board (DAB) upheld HHS-OIG's demand that Friendship Home Health, Inc., et al. (Friendship Entities) pay \$1.3 million in stipulated penalties for breaches of their CIA. On November 19, 2018, HHS-OIG sent the Friendship Entities a demand for \$1.3 million in stipulated penalties for their failure to repay overpayments identified in their second and third annual reports. The Friendship Entities appealed this demand and requested a hearing with a DAB Administrative Law Judge (ALJ). On October 31, 2019, the ALJ upheld HHS-OIG's demand. The Friendship Entities then appealed to the DAB. In its decision, the DAB agreed with the ALJ's conclusions that the CIA's auditing and repayment provisions created independent obligations to repay overpayments to Medicare and Medicaid, and that each time the Friendship Entities violated those obligations to repay overpayments, it created a separate basis for HHS-OIG to demand stipulated penalties. The DAB also

agreed that the Friendship Entities were properly subject to stipulated penalties arising from those failures and further held that the CIA authorizes per-day stipulated penalties to run concurrently for each failure to make timely repayment.

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 2020, HHS-OIG issued 178 audit reports and 44 evaluations, resulting in 689 new recommendations issued to HHS operating divisions. HHS operating divisions also implemented 286 recommendations during FY 2020.

HHS-OIG's audit and evaluation findings in FY 2020 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

States Continued To Fall Short in Meeting Required Timeframes for Investigating Nursing Home Complaints: 2016-2018. Twenty-one states failed to meet required timeframes for investigating the second-most serious nursing home complaints and 10 of these states did not meet the threshold for eight consecutive years. Furthermore, four of the five states that fell short in the timely investigation of the most serious nursing home complaints, which require investigating within two days, from 2011 through 2015, continued to fall short from 2016 through 2018. Generally, HHS-OIG found that the states it communicated with face challenges with receiving a high volume of complaints, triaging complaints, and having adequate human resources to investigate complaints. HHS-OIG's findings raise questions about some states' ability to address serious nursing home complaints and about the effectiveness of the CMS's oversight of states. (OEI-01-19-00421)

CMS Should Pursue Strategies To Increase the Number of At-Risk Beneficiaries Acquiring Naloxone Through Medicaid. CMS and state Medicaid agencies can be encouraged by their progress to date in increasing access to naloxone—a drug that reverses opioid overdoses—while also continuing to look for ways to further expand naloxone availability under Medicaid. HHS-OIG's findings can help CMS pursue strategies to increase the number of at-risk beneficiaries acquiring community-use versions of naloxone (i.e., that versions that can be appropriately administered in emergency situations by those with minimal to no training) through Medicaid. (OEI-BL-18-00360)

National Background Check Program for Long-Term-Care Providers: Assessment of State Programs Concluded in 2019. States participating in the National Background Check Program for long-term care providers had varying degrees of state-level legal requirements and practical infrastructure for conducting background checks. This affected their ability to implement select Program requirements and to consistently report quality data. HHS-OIG's findings can help CMS identify ways to strengthen its support of the Program. (OEI-07-20-00180)

States Could Do More To Prevent Terminated Providers From Serving Medicaid Beneficiaries. Nearly 1,000 terminated providers—or 11 percent of all terminated providers—were inappropriately enrolled in state Medicaid programs or were associated with at least \$50.3 million in Medicaid payments. Despite legislative requirements in the 21st Century Cures Act designed to strengthen Medicaid program integrity, terminated providers continue to serve Medicaid beneficiaries. Some of these providers were terminated for criminal convictions, licensure issues, and provider misconduct, representing a risk to beneficiaries' safety and their quality of care. In addition, only eight states' managed care contracts all clearly included the provision—required by the Cures Act—that prohibits terminated providers from participating in Medicaid managed care networks. This vulnerability may allow terminated providers to serve Medicaid beneficiaries and reduce states' ability to limit these providers' participation in Medicaid managed care networks. (OEI-03-19-00070).

23 States Reported Allowing Unenrolled Providers To Serve Medicaid Beneficiaries. HHS-OIG found that 23 states had not enrolled all Medicaid providers. Of the 27 states that reported enrolling all providers, 16 reported lacking enrollment processes or enforcement controls to ensure ongoing compliance with federal provider enrollment requirements. When states do not enroll and screen providers, Medicaid beneficiaries are exposed to potentially harmful providers. (OEI-05-19-00060)

Medicare Part D Beneficiaries at Serious Risk of Opioid Misuse or Overdose: A Closer Look. Most Part D beneficiaries at serious risk of opioid misuse or overdose in 2017 received high amounts of opioids the following year, while 11 percent had an overdose or adverse effect from an opioid in 2017 or 2018, and about 48 percent have been diagnosed with opioid use disorder or other conditions related to the misuse of opioids. Only seven percent of those who were diagnosed with opioid use disorder received drugs for medication-assisted treatment (MAT drugs) through Part D, possibly because of challenges that beneficiaries have in accessing prescribers. Although opioids can be appropriate under certain circumstances, steps should be taken to mitigate the risk of misuse and overdose, especially when beneficiaries receive high amounts of opioids for long periods of time. (OEI-02-19-00130)

Opioid Use in Medicare Part D Continued To Decline in 2019, but Vigilance Is Needed as COVID-19 Raises New Concerns. Medicare Part D has seen a steady decline in opioid use over the past several years and an increased use of drugs for MAT. About one in four Part D beneficiaries received opioids in 2019, a decrease from the prior three years. At the same time, the number of beneficiaries receiving drugs for MAT for opioid use disorder increased to 209,000 in 2019. In addition, the number of beneficiaries receiving prescriptions for naloxone through Part D has continued to grow. Nearly 267,000 beneficiaries received high amounts of

opioids in 2019, with almost 34,000 beneficiaries at serious risk of opioid misuse or overdose. About 140 prescribers ordered opioids for large numbers beneficiaries at serious risk. The changes in recent years in opioid use and MAT show progress from the efforts of HHS and others to address the opioid crisis. Nonetheless, it is critical to remain vigilant. The COVID-19 pandemic poses additional danger for this population. (OEI-02-20-00320)

Registered Nurses Did Not Always Visit Medicare Beneficiaries' Homes at Least Once Every 14 Days To Assess the Quality of Care and Services Provided by Hospice Aides. Registered nurses did not always: (1) visit hospice beneficiaries' homes at least once every 14 days to assess the quality of care and services provided by hospice aides or (2) document the visits in accordance with federal requirements. Of the approximately 189,000 high-risk date-pairs (a date-pair consisted of two care visits that were made by a registered nurse to a beneficiary's home and that were more than 14 days apart) in our sample, HHS-OIG identified: (1) an estimated 99,000 instances in which the registered nurses did not make the required supervisory visits at least once every 14 days and (2) an estimated 5,000 instances in which supervisory visits were not documented in accordance with federal requirements. These deficiencies occurred because of hospices' lack of oversight, scheduling errors, employee turnover, and the registered nurses not being aware of the 14-day supervisory visit requirement. As a result, there was no assurance that beneficiaries admitted to those hospices received the appropriate care while in hospice care. (A-09-18-03022)

Some Nursing Homes' Reported Staffing Levels in 2018 Raise Concerns; Consumer Transparency Could Be Increased. Nursing homes' reported staffing levels often vary on a day-to-day basis, and seven percent fell below required federal staffing levels on at least 30 total days in 2018. CMS's Star Rating System ranks nursing homes on their average staffing levels each quarter; as a result, daily staffing variations are not transparent to consumers. This review, initiated before the COVID-19 pandemic emerged, focuses on staffing data from 2018. However, the 2020 pandemic reinforces the importance of adequate staffing for nursing homes, as inadequate staffing can make it more difficult for nursing homes to respond to infectious disease outbreaks like COVID-19. (OEI-04-18-00450)

Medicaid Data Can Be Used To Identify Instances of Potential Child Abuse or Neglect. HHS-OIG determined that Medicaid claims data can be used to identify incidents of potential child abuse or neglect. Using that data, HHS-OIG estimated that 29,260 of the 29,534 Medicaid beneficiaries in the sampling frame were involved with incidents of potential child abuse or neglect that were supported by Medicaid claims data and evidence contained in the medical records. HHS-OIG further estimated that, of the beneficiaries in the population associated with incidents of potential child abuse or neglect, 3,928 were involved with incidents that were not reported to child protective services. HHS-OIG determined that most incidents of potential child abuse or neglect identified in HHS-OIG's sample occurred in familiar settings by perpetrators known to the victims. CMS did not identify similar incidents of potential child abuse or neglect during the audit period or encourage the states to identify the incidents. (A-01-19-00001)

New Jersey Did Not Ensure That Incidents of Potential Abuse and Neglect of Medicaid Beneficiaries Residing in Nursing Facilities Were Always Properly Reported and Investigated.

New Jersey did not ensure that nursing facilities always investigated and reported incidents of potential abuse or neglect to the state in accordance with federal and state requirements. Of the 103 claims in the sample, 79 claims were not the result of potential abuse or neglect; therefore, nursing facilities were not required to report the incident to the state. Of the remaining 24 claims, ten claims were the result of potential abuse or neglect that should have been reported to the state. However, five of the ten claims were not properly investigated and reported to the state. For the other 14 claims, nursing facilities did not provide documentation, or their records did not contain sufficient documentation for state officials to determine whether the incident should have been investigated and reported. These deficiencies occurred because nursing facility staff did not follow requirements for investigating and reporting potential incidents of abuse or neglect. In addition, New Jersey did not have adequate survey procedures for ensuring that nursing facilities documented all such incidents. HHS-OIG estimated that 311 Medicaid hospital claims with selected diagnosis codes resulted from incidents of potential abuse or neglect at a nursing facility in New Jersey during calendar year 2016. Of this amount, HHS-OIG estimated that 220 claims were the result of potential abuse or neglect that the nursing facilities did not investigate and report to the state. In addition, HHS-OIG estimated that, for 616 claims, the associated beneficiary's nursing facility did not have records to sufficiently document the circumstances of the beneficiary's injuries or condition that led to the hospital transfer so that state officials could determine whether the incident was the result of potential abuse or neglect. (A-02-18-01006)

New York's Oversight of Medicaid Managed Care Organizations Did Not Ensure Providers Complied With Health and Safety Requirements at 18 of 20 Adult Day Care Facilities Reviewed. New York's oversight of Medicaid Managed Care Organizations (MCOs) did not ensure that 18 of the 20 adult day care services providers we audited complied with federal and state health and safety requirements. Specifically, HHS-OIG found 476 instances of noncompliance with requirements for staff training, physical environment and safety, emergency preparedness, and staff health status. The instances of noncompliance occurred because the MCOs did not adequately monitor their contracted providers to ensure compliance with health and safety requirements. These deficiencies could have significantly impacted the health and safety of vulnerable Medicaid beneficiaries. (A-02-18-01027)

Pennsylvania Did Not Fully Comply With Federal and State Requirements for Reporting and Monitoring Critical Incidents Involving Medicaid Beneficiaries With Developmental Disabilities. Pennsylvania did not fully comply with federal Medicaid waiver and state requirements for reporting and monitoring incidents involving Medicaid beneficiaries with developmental disabilities who resided in community-based settings. Specifically, Pennsylvania did not: (1) ensure that community-based providers reported thousands of 24-hour reportable incidents within required timeframes, (2) ensure that community-based providers and county and regional investigators analyzed and investigated all beneficiary deaths, and (3) ensure that community-based providers referred all suspicious deaths to law enforcement. Pennsylvania did not have adequate controls to detect unreported 24-hour reportable incidents and did not have controls in place to ensure that all beneficiary deaths were investigated and that all suspicious deaths were referred to law enforcement. Therefore, Pennsylvania did not fulfill participant safeguard assurances it gave to CMS to ensure the health, welfare, and safety of the 18,770 Medicaid

beneficiaries with developmental disabilities covered by the Medicaid waiver in HHS-OIG's audit. (A-03-17-00202)

North Carolina Did Not Ensure That Nursing Facilities Always Reported Allegations of Potential Abuse and Neglect of Medicaid Beneficiaries and Did Not Always Prioritize Allegations Timely. North Carolina did not ensure that nursing facilities always reported potential abuse or neglect of Medicaid beneficiaries transferred from nursing facilities to hospital emergency departments. In addition, it did not always fully comply with federal requirements for assigning a priority level to reported allegations of potential abuse and neglect or for correctly recording the associated dates. Finally, North Carolina's complaint and incident report program may not have been effective in promoting and protecting the health, safety, and welfare of residents, patients, and other clients receiving health care services. (A-04-17-04063)

Texas Did Not Fully Comply With Federal and State Requirements for Reporting and Monitoring Critical Incidents Involving Medicaid Beneficiaries With Developmental Disabilities Texas did not ensure that all beneficiary deaths were reported and reviewed; that all complaints not closed within 10 days were tracked; and that all allegations of abuse, neglect, and exploitation were entered into the Human Services Enterprise Administration Reporting and Tracking (HEART) system. Texas had a procedure to detect unreported deaths but was not following it, did not have a system in place to track complaints not closed within 10 days, and did not have procedures to ensure that allegations were entered into the HEART system. (A-06-17-04003)

Iowa Did Not Comply With Federal and State Requirements for Major Incidents Involving Medicaid Members With Developmental Disabilities. Iowa did not fully comply with federal and state requirements for reporting and monitoring major incidents involving Medicaid members with developmental disabilities. Specifically, Iowa did not ensure that community-based providers reported all major incidents to the state; ensure that community-based providers documented the resolution of reported major incidents to prevent or diminish the probability of future occurrences; review Critical Incident Reports to determine trends, problems, and issues in service delivery; ensure that community-based providers reported all member deaths to the state; and report all known major incidents to CMS. Therefore, Iowa did not fulfill participant safeguard assurances it gave to CMS to ensure the health, welfare, and safety of the 16,056 Medicaid beneficiaries with developmental disabilities covered by the Medicaid waiver in HHS-OIG's audit. (A-07-18-06081)

North Carolina Should Improve Its Oversight of Selected Nursing Homes' Compliance With Federal Requirements for Life Safety and Emergency Preparedness. North Carolina did not ensure that selected nursing homes that participated in the Medicare or Medicaid programs complied with CMS and state requirements for life safety and emergency preparedness. Of the 20 nursing homes that HHS-OIG visited, 18 had deficiencies in areas related to life safety or emergency preparedness. The instances of noncompliance occurred because nursing homes had inadequate management oversight and high staff turnover. In addition, North Carolina did not have a standard life safety-training program for all nursing home staff and generally performed life safety surveys no more frequently than once every eight to 15 months, even at these higher

risk nursing homes. (A-04-19-08070)

Illinois Should Improve Its Oversight of Selected Nursing Homes' Compliance With Federal Requirements for Life Safety and Emergency Preparedness. Illinois did not ensure that selected nursing homes in the state that participated in the Medicare or Medicaid programs complied with CMS requirements for life safety and emergency preparedness. During site visits, HHS-OIG identified deficiencies in areas related to life safety and emergency preparedness at all 15 nursing homes reviewed. As a result, residents at the 15 nursing homes were at increased risk of injury or death during a fire or other emergency. The identified deficiencies occurred because the existing life safety-training program for nursing home management could not educate all Illinois nursing home management in a timely manner, and the state did not offer an emergency preparedness-training program for nursing home management. (Currently, CMS requires neither of the two training programs.) Further, Illinois performed abbreviated surveys of emergency preparedness plans and had insufficient personnel for its workload. In addition, Illinois did not determine whether carbon monoxide alarms were installed in accordance with state law. (A-05-18-00037)

Oregon's Oversight Did Not Ensure That Four Coordinated-Care Organizations Complied With Selected Medicaid Requirements Related to Access to Care and Quality of Care. The four Coordinated-Care Organizations (CCOs) looked at by HHS-OIG generally complied with federal and state requirements related to time and distance standards and timely access standards, as well as requirements related to assignment of primary care providers (PCPs). However, the CCOs did not comply with requirements related to provider credentialing and beneficiary grievances and appeals. Specifically, CCOs: (1) did not ensure that services were provided within the scope of license of a provider with a restricted license or report providers with licensing board actions against them, (2) did not credential all provider types (e.g., mental health providers), and (3) did not perform or document all minimum required credentialing checks. In addition, CCOs did not resolve or review beneficiary grievances appropriately and did not adjudicate appeals in compliance with their contracts with Oregon. CCOs also submitted inaccurate or incomplete data on grievances and appeals, which Oregon used for oversight. These issues occurred because: (1) Oregon provided insufficient oversight of, and guidance to, the CCOs and (2) the CCOs provided insufficient oversight of, and guidance to, their subcontractors. Because not all providers were appropriately credentialed, there was an increased risk of poor quality of care. In addition, the mishandling of grievances and appeals may have reduced beneficiaries' access to care and the quality of care. (A-09-18-03035)

Safeguard Programs From Improper Payments and Fraud

Some Drug Manufacturers Reported Inaccurate Product Data to CMS. Manufacturers reported inaccurate drug product data for 14 percent of the national drug codes HHS-OIG reviewed that were associated with Medicare Part B-covered drugs. (Such drugs are generally those that are injected or infused in physicians' offices or hospital outpatient settings.) If manufacturer-reported product data is incorrect, Medicare may make inaccurate payments for drugs and Medicaid may collect inaccurate rebates from manufacturers. (OEI-03-19-00200)

Billions in Estimated Medicare Advantage Payments From Diagnoses Reported Only on Health Risk Assessments Raise Concerns. Billions of estimated MA risk-adjusted payments supported solely through health risk assessments (HRAs) raise concerns about the completeness of payment data submitted to CMS, the validity of diagnoses on HRAs, and the quality of care coordination for beneficiaries. Diagnoses that MA organizations reported only on HRAs—and on no other encounter records in 2016—resulted in an estimated \$2.6 billion in risk adjusted payments for 2017. In addition, in-home HRAs generated 80 percent of these estimated payments. Most in-home HRAs were conducted by companies that partner with or are hired by MA organizations to conduct these assessments—and therefore are not likely conducted by the beneficiary’s own primary care provider. 20 MA organizations generated millions in payments from in-home HRAs for beneficiaries for whom there was not a single record of any other service being provided in 2016. (OEI-03-17-00471).

Billions in Estimated Medicare Advantage Payments From Chart Reviews Raise Concerns. Billions of estimated MA risk-adjusted payments supported solely through chart reviews raise potential concerns about the completeness of payment data submitted to CMS, the validity of diagnoses on chart reviews, and the quality of care provided to beneficiaries. Diagnoses that MA organizations reported only on chart reviews—and not on any service records—resulted in an estimated \$6.7 billion in risk-adjusted payments for 2017. CMS based an estimated \$2.7 billion in risk-adjusted payments on chart review diagnoses that MA organizations did not link to a specific service provided to the beneficiary. Although limited to a small number of beneficiaries, almost half of MA organizations reviewed had payments from unlinked chart reviews where there was not a single record of a service being provided to the beneficiary in all of 2016. (OEI-03-17-00470)

Key Medicare Tools To Safeguard Against Pharmacy Fraud and Inappropriate Billing Do Not Apply to Part D. Part D does not have three key tools to protect against pharmacy fraud that are available in other parts of Medicare: pharmacy enrollment, revocation, and preclusion. These three tools apply to pharmacies only when they bill Parts B or C, not when they bill Part D. (OEI-02-15-00440).

Medicaid Fraud Control Units Fiscal Year 2019 Annual Report. The annual report highlights statistics on the accomplishments of the 52 MFCUs in operation during FY 2019. HHS-OIG found that the number of convictions in FY 2019 (1,527) remained consistent with previous years. Of the 1,111 MFCU fraud convictions, 44 percent involved personal care services attendants and agencies. Fraud cases accounted for 73 percent of the MFCU convictions, while 27 percent involved patient abuse or neglect. MFCUs were responsible for 658 civil settlements and judgments, 25 percent of which involved pharmaceutical manufacturers. MFCUs reported \$1.9 billion in criminal and civil recoveries. (OEI-09-20-00110)

Medicare Improperly Paid Acute-Care Hospitals \$54.4 Million for Inpatient Claims Subject to the Post-Acute-Care Transfer Policy. Medicare improperly paid acute-care hospitals \$54.4 million for 18,647 claims subject to Medicare’s post-acute-care transfer policy. These hospitals improperly billed the claims by using incorrect patient discharge status codes. Specifically, they coded these claims as discharges to home or to certain types of health care institutions, such as

facilities that provide custodial care, rather than as transfers to post-acute care. Medicare makes the full Medicare Severity Diagnosis-Related Group (MS DRG) payment to an acute-care hospital that discharges an inpatient to home or certain types of health care institutions. In contrast, Medicare pays an acute-care hospital that transfers a beneficiary to post-acute care a per diem rate for each day of the beneficiary's stay in the hospital. The total overpayment of \$54.4 million represented the difference between the amount of the full MS DRG payments and the amount that would have been paid if the per diem rates had been applied. (A-09-19-03007)

CMS Made an Estimated \$93.6 Million in Incorrect Medicare Electronic Health Record Incentive Payments to Acute-Care Hospitals, or Less Than One Percent of \$10.8 Billion in Total Incentive Payments. CMS did not always make Medicare EHR incentive payments to acute-care hospitals in accordance with federal requirements. The incorrect net incentive payments occurred because: (1) the Medicare administrative contractors (MACs) did not review the supporting documentation for all hospitals to identify errors in the hospitals' cost-report numbers used to calculate the incentive payments, and (2) CMS did not include labor and delivery services in the incentive payment calculations, which resulted in hospitals receiving inflated incentive payments. Based on HHS-OIG's sample results, HHS-OIG estimates that CMS made incorrect net incentive payments of \$93.6 million, or less than one percent of the \$10.8 billion in total incentive payments for our audit period. (A-09-18-03020)

CMS's Controls Over Assigning Medicare Beneficiary Identifiers and Mailing New Medicare Cards Were Generally Effective but Could Be Improved in Some Areas. CMS's controls were generally effective in ensuring that: (1) beneficiaries were properly assigned Medicare Beneficiary Identifiers (MBIs), (2) deceased beneficiaries were not mailed new Medicare cards, and (3) payments were not made on behalf of deceased beneficiaries. However, in a small percentage of cases, CMS's controls did not prevent multiple MBIs from being assigned to beneficiaries or prevent mailing of new Medicare cards to deceased beneficiaries. In addition, CMS made improper payments of \$2.3 million on claims for deceased beneficiaries. HHS-OIG found the CMS assigned 2 or more MBIs associated with multiple enrollment records that contained the same SSN and date of birth to 22,662 beneficiaries. In addition, CMS mailed 58,420 new Medicare cards after the beneficiaries' dates of death. Finally, CMS made improper payments for claims with dates of service after the beneficiaries' dates of death. By improving its controls, CMS can limit unintended consequences, such as claim processing errors and inappropriate release of personally identifiable information. (A-09-19-03003)

Hospitals Received Millions in Excessive Outlier Payments Because CMS Limits the Reconciliation Process. From FYs 2011 through 2014, CMS paid 60 hospitals that had received \$3.5 billion in outlier payments a net of \$502.0 million more than the hospitals would have been paid if their outlier payments had been reconciled. (HHS-OIG refers to this net amount as excessive outlier payments.) CMS did not detect or recover these excessive outlier payments because the 236 associated cost reports did not meet the 10-percentage-point threshold for reconciliation. The cost reports did not meet CMS's 10-percentage-point threshold because when hospitals increased their charges at a rate higher than that of cost increases, this usually resulted in only a small percentage-point change in their cost-to-charge ratios. CMS set the 10-percentage-point threshold because it believed that the threshold would appropriately capture

those hospitals whose outlier payments would be substantially inaccurate when the hospital uses the ratio from the contemporaneous cost-reporting period. Based on the estimated time and costs that we received from seven MAC's, we estimate that the administrative burden on the MACs to reconcile the 236 cost reports that did not meet the ten-percentage-point threshold would be a minimum of \$11,800 and a maximum of \$425,000 per year. (A-05-16-00060)

Inadequate Edits and Oversight Caused Medicare To Overpay More Than \$267 Million for Hospital Inpatient Claims With Post-Acute-Care Transfers to Home Health Services. Medicare improperly paid most inpatient claims subject to the transfer policy when beneficiaries resumed home health services within three days of discharge but the hospitals failed to code the inpatient claim as a discharge to home with home health services or when the hospitals applied condition codes 42 (home health not related to inpatient stay) or 43 (home health not within three days of discharge). Of the 150 inpatient claims in our sample, Medicare properly paid three; however, it improperly paid 147 with \$722,288 in overpayments. Medicare should have paid these inpatient claims using a graduated per diem rate rather than the full payment. Based on HHS-OIG's sample results, HHS-OIG estimated that Medicare improperly paid \$267.0 million during a two-year period for hospital services that should have been paid a graduated per diem payment. (A-04-18-04067)

CMS Could Have Saved \$192 Million by Targeting Home Health Claims for Review With Visits Slightly Above the Threshold That Triggers a Higher Medicare Payment. Not all payments to home health agencies (HHAs) for home health services with five to seven visits in a payment episode complied with Medicare requirements. Of the 120 sampled claims we reviewed, 91 complied with requirements, and four claims lacked the documentation available to make a compliance determination. However, the remaining 25 claims did not comply with requirements. As a result, Medicare improperly paid HHAs for a portion of the payment episode (14 claims) and for the full payment episode (11 claims), totaling \$41,613. These improper payments occurred because the MACs did not analyze claim data or perform risk assessments to target those claims with visits slightly above the Low Utilization Payment Adjustment threshold of four visits for additional review. On the basis of sample results, HHS-OIG estimated that Medicare overpaid HHAs nation-wide \$191.8 million for our audit period. (A-09-18-03031)

Hospitals Overbilled Medicare \$1 Billion by Incorrectly Assigning Severe Malnutrition Diagnosis Codes to Inpatient Hospital Claims. Hospitals correctly billed Medicare for severe malnutrition diagnosis codes for 27 of the 200 claims that we reviewed. However, hospitals did not correctly bill Medicare for the remaining 173 claims. For nine of these claims, the medical record documentation supported a secondary diagnosis code other than a severe malnutrition diagnosis code, but the error did not change the diagnosis-related group or payment. For the remaining 164 claims, hospitals used severe malnutrition diagnosis codes when they should have used codes for other forms of malnutrition or no malnutrition diagnosis code at all, resulting in net overpayments of \$914,128. On the basis of sample results, HHS-OIG estimated that hospitals received overpayments of \$1.0 billion for FYs 2016 and 2017. (A-03-17-00010)

Medicare Made \$11.7 Million in Overpayments for Nonphysician Outpatient Services Provided Shortly Before or During Inpatient Stays. Medicare made incorrect payments to outpatient

providers for 40,984 nonphysician outpatient services provided nation-wide within three days before the date of admission, on the date of admission, or during inpatient prospective payment system stays (excluding date of discharge) that we reviewed. These incorrect payments occurred because the Common Working File edits were not designed to accurately identify all potentially incorrect claims. As a result, Medicare made \$11.7 million in incorrect payments to hospital outpatient providers during Calendar Years (CYs) 2016 and 2017. This includes claims beyond the four-year reopening period. In addition, beneficiaries incurred \$2.7 million in coinsurance and deductible liabilities related to these incorrect payments. (A-01-17-00508)

CMS's Encounter Data Lacks Essential Information That Medicare Advantage Organizations Have the Ability to Collect. Medicare Advantage (MA) encounter data continue to lack National Provider Identifiers (NPIs) for providers who order and/or refer durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); clinical laboratory services; imaging services; and home health services. However, almost all MA organizations have data systems that are able to receive and store these NPIs when providers submit them. In addition, a substantial portion of MA organizations reported that providers already are submitting the ordering provider NPIs on claims or encounter records for DMEPOS, laboratory services, and imaging services. Further, a majority of MA organizations require NPIs to be submitted for their other lines of business. Finally, almost half of MA organizations believe that using NPIs for ordering providers is critical for combating fraud. (OEI-03-19-00430)

New Jersey Improperly Claimed Tens of Millions for Medicaid School-Based Administrative Costs Based on Random Moment Sampling That Did Not Meet Federal Requirements. The random moment sampling methodology New Jersey used to claim Medicaid school-based administrative costs did not meet federal requirements. Specifically, it did not comply with statistical sampling requirements and was not adequately supported. Also, the methodology did not comply with New Jersey's approved cost allocation plan. New Jersey's coding of what school employees were doing during random moments was mostly incorrect or unsupported. HHS-OIG determined that New Jersey claimed \$63.8 million in unallowable federal Medicaid reimbursement. (A-02-17-01006)

New Jersey Did Not Ensure That Its Managed Care Organizations Adequately Assessed and Covered Medicaid Beneficiaries' Needs for Long-Term Services and Supports. New Jersey did not ensure that its MCOs complied with certain federal and state requirements for beneficiaries enrolled in its Medicaid managed long-term services and supports program. For 68 of the 100 monthly capitation payments in our random sample, MCOs did not comply with the requirements to adequately assess and cover the associated beneficiaries' needs for long-term services and supports. Specifically, MCOs did not comply with requirements for: (1) providing adequate service planning and care management to the beneficiaries, and (2) conducting and documenting assessments as well as developing, reviewing, and updating beneficiaries' care plans. These deficiencies occurred because New Jersey did not adequately monitor MCOs for compliance with certain federal and state requirements. MCOs' failure to meet contract requirements for adequately assessing and covering beneficiaries' needs for long-term services and supports could have resulted in beneficiaries not getting the services that they needed and may have put their health and safety at risk. HHS-OIG estimated that New Jersey made monthly

payments totaling approximately \$386.0 million (federal share) to MCOs that did not comply with certain federal and state requirements. (A-02-17-01018)

More Than One-Third of New Jersey's Federal Medicaid Reimbursement for Providing Community-Based Treatment Services Was Unallowable. New Jersey did not ensure payments for Programs of Assertive Community Treatment (PACT) services submitted for federal Medicaid reimbursement complied with federal and state requirements. Specifically, of the 100 sampled claims, 50 complied with federal and state requirements and 50 did not. HHS-OIG also identified potential quality-of-care issues related to PACT services. Specifically, PACT team psychiatrists associated with 33 of the sample claims did not provide the minimum amount of face-to-face psychiatric time required for their caseload. Also, despite defining the PACT program as rehabilitative, New Jersey did not require periodic reauthorizations or reevaluations of beneficiaries' program eligibility. The deficiencies occurred because New Jersey did not inform PACT providers of all federal and state requirements for providing PACT services and did not adequately monitor or have procedures in place to ensure that providers claimed PACT services in accordance with these requirements. Based on HHS-OIG's sample results, HHS-OIG estimated that New Jersey improperly claimed at least \$14.9 million in federal Medicaid reimbursement. (A-02-17-01020)

New York Claimed Tens of Millions of Dollars for Opioid Treatment Program Services That Did Not Comply With Medicaid Requirements Intended To Ensure the Quality of Care Provided to Beneficiaries. New York claimed federal Medicaid reimbursement for opioid treatment programs (OTP) services that did not comply with federal and state requirements. Of the 150 claims in HHS-OIG's random sample, 115 claims complied with Medicaid requirements, but 35 claims did not. In addition, of the 598 claims in a non-statistical sample, 299 claims were billed in error. Based on HHS-OIG's sample results, HHS-OIG estimated that New York improperly claimed at least \$39.3 million in federal Medicaid reimbursement for OTP services during our audit period. These improper claims occurred because providers: (1) failed to maintain or provide documentation of OTP services, (2) did not ensure that OTP services were provided in accordance with beneficiaries' treatment plans, and (3) did not maintain signatures for OTP services. Although New York inspects providers to verify compliance with federal and state Medicaid requirements, it did not ensure that its oversight prevented the errors identified by our audit. (A-02-17-01021)

New York Made Unallowable Payments Totaling More Than \$10 Million for Managed Care Beneficiaries Assigned Multiple Medicaid Identification Numbers. New York improperly claimed federal Medicaid reimbursement for Medicaid beneficiaries who were assigned more than one Medicaid identification (ID) number. Specifically, for 102 of the 103 beneficiary-matches in HHS-OIG's sample, New York made managed care payments to different managed care organizations for the same beneficiary for the same month under different Medicaid ID numbers. These errors occurred because: (1) New York's procedures for identifying whether a Medicaid applicant had already been assigned a Medicaid ID number were not always followed, (2) system queries were not adequate to ensure that all individuals with existing Medicaid ID numbers were identified, and (3) staff did not use all available resources to ensure that qualified applicants were not issued multiple Medicaid ID numbers. HHS-OIG estimated that New York improperly claimed \$11.5 million in federal Medicaid reimbursement for payments made on behalf of beneficiaries assigned more than one Medicaid ID number. HHS-OIG reduced this estimate to \$11.3 million because New York recovered some managed care payments after the start of our audit. (A-02-18-01020)

North Carolina Received \$30 Million in Excess Federal Funds Related to Improperly Claimed Health Home Expenditures. North Carolina did not claim federal Medicaid reimbursement for health home expenditures in accordance with federal and state requirements. Instead, it improperly claimed \$124.6 million in Primary Care Case Management (PCCM) expenditures, which should have been reimbursed at the regular federal medical assistance percentage (FMAP) (\$81.5 million federal share), as health home expenditures, which were reimbursed at the enhanced FMAP (\$112.2 million federal share). North Carolina did not claim any health home expenditures before or after the enhanced FMAP period for federal fiscal years 2012 and 2013. Of the 2,999 payments associated with 100 beneficiaries in HHS-OIG's stratified random sample, none met all of the requirements for payment identified in North Carolina's approved state plan amendment for health home services. North Carolina claimed PCCM expenditures as health home expenditures because it did not take certain steps to ensure implementation of the health home option and did not implement the internal controls needed to ensure compliance. As a result, North Carolina received \$30.7 million in excess federal funds. (A-04-18-00120)

The New York State Medicaid Agency Made Capitation Payments to Managed Care Organizations After Beneficiaries' Deaths. HHS-OIG estimated that New York made unallowable capitation payments totaling at least \$23.3 million (\$13.7 million federal share) to managed care entities after beneficiaries' deaths during the audit period. Of the 100 capitation payments in HHS-OIG's stratified random sample, New York made 84 unallowable payments totaling \$269,473 (\$143,643 federal share). In addition, New York adjusted 12 capitation payments before our audit. Based on New York and Social Security Administration data available to HHS-OIG, HHS-OIG could not fully confirm that two beneficiaries associated with four of the 100 capitation payments were deceased. The unallowable payments occurred because New York did not: (1) have system edits to identify errors in the automated process that terminates beneficiaries' eligibility after dates of death were identified; (2) update the eligibility and payment systems with correct dates of death; (3) identify deceased and disenroll beneficiaries that had a date of death in one of its death data sources; or (4) use additional

sources of death information and alternative procedures similar to those that we used in our audit to identify, verify, or determine dates of death. (A-04-19-06223)

Michigan Made Capitation Payments to Managed Care Entities After Beneficiaries' Deaths. HHS-OIG estimated that Michigan made unallowable capitation payments totaling at least \$39.9 million (\$27.5 million federal share) to managed care entities on behalf of deceased beneficiaries during the audit period. Of the 100 capitation payments in HHS-OIG's stratified random sample, Michigan made 99 unallowable payments totaling \$117,746 (\$79,348 federal share). The unallowable payments occurred because Michigan did not always identify and process Medicaid beneficiaries' death information. Although Michigan's Medicaid Management Information System (MMIS) and eligibility systems interfaced with state and federal death files that identify dates of death, Michigan did not always identify those dates of death in its MMIS system, and the MMIS system and eligibility system did not share dates of death information with each other. Michigan also did not recover payments caused by dates of death not promptly identified in its MMIS system. (A-05-17-00048)

Texas Did Not Ensure That Its Managed-Care Organizations Complied With Requirements Prohibiting Medicaid Payments for Services Related to Provider-Preventable Conditions. Texas did not ensure that its Medicaid MCOs complied with federal and state requirements prohibiting payments to providers for inpatient hospital services related to treating certain provider-preventable conditions (PPCs). HHS-OIG identified Medicaid claims totaling \$29.4 million that contained PPCs for five MCOs. Of this amount, HHS-OIG determined that claims totaling \$12.7 million were in compliance with federal and state regulations regarding nonpayment of PPCs. However, claims totaling \$16.7 million were not in compliance. Texas' internal controls were not adequate to ensure that its MCOs complied with federal and state requirements. Specifically, Texas: (1) did not have policies and procedures to determine whether its MCOs complied with federal and state requirements and provisions of the managed-care contract relating to the nonpayment of PPCs and (2) did not ensure that the MCOs' payment rates were based only on services that were covered in the state plan. (A-06-16-01001)

Most of the Non-Newly Eligible Beneficiaries for Whom Colorado Made Medicaid Payments Met Federal and State Requirements, but Documentation Supporting That All Eligibility Requirements Were Verified Properly Was Not Always in Place. Most of the Medicaid payments that Colorado made during the audit period were on behalf of non-newly eligible beneficiaries who met federal and state eligibility requirements. However, Colorado made Medicaid payments on behalf of some non-newly eligible beneficiaries who may not have met federal and state eligibility requirements. Colorado correctly determined eligibility and, therefore, correctly claimed federal Medicaid reimbursement, on behalf of 135 of the 140 beneficiaries in HHS-OIG's statistical sample. For the remaining five beneficiaries, Colorado had no documentation (specifically, that it had performed annual verifications of resources) to support that all eligibility requirements were verified properly during redeterminations as required by federal and state regulations, and by Colorado's state Medicaid plan. Although Colorado had policies and procedures in place, it did not always follow them to ensure that redeterminations were properly documented. HHS-OIG estimated that Colorado made Medicaid payments of at least \$46.7 million (\$23.8 million federal share) on behalf of at least 3,603 potentially ineligible

beneficiaries. (A-07-18-02812)

Iowa Inadequately Monitored Its Medicaid Health Home Providers, Resulting in Tens of Millions in Improperly Claimed Reimbursement. For 62 of the 130 payments, Iowa improperly claimed federal Medicaid reimbursement for payments made to health home providers that did not comply with federal and state requirements. Specifically, Iowa's health home providers did not document core services, integrated health home outreach services, diagnoses, and enrollment with providers. In addition, Iowa's providers did not maintain documentation to support higher payments for intense integrated health home services and did not ensure that beneficiaries had full Medicaid benefits. The improper payments occurred because Iowa did not adequately monitor providers for compliance with certain federal and state requirements. HHS-OIG estimated that Iowa improperly claimed at least \$37.1 million in Federal Medicaid reimbursement for payments made to health home providers. (A-07-18-04109)

CMS Could Take Actions To Help States Comply With Federal Requirements Prohibiting Medicaid Payments for Inpatient Hospital Services Related to Provider-Preventable Conditions. In 2011, CMS issued federal regulations prohibiting federal Medicaid payments for services related to provider-preventable conditions (PPCs). The goal of the regulations is to improve quality of care by prohibiting payments for medical errors. Prior HHS-OIG audits of nine states found that none of them fully complied with federal requirements. This audit found that CMS could take actions to: (1) verify that all state plans fully comply with federal requirements prohibiting Medicaid payments for inpatient hospital services related to treating PPCs and (2) issue clarifying guidance to address specific areas in which states did not comply with those requirements. If CMS does not verify that state plans fully comply with federal requirements and provide clear guidance on these requirements, states may continue to struggle to prevent unallowable payments for PPCs and may not take measures to improve the quality of inpatient hospital services through the prevention of medical errors. (A-09-18-02004)

Loophole in Drug Payment Rule Continues to Cost Medicare and Beneficiaries Hundreds of Millions of Dollars. As of December 2019, CMS continued to include noncovered, self-administered versions when calculating Part B payment amounts for Orencia and Cimzia, the same two drugs identified in HHS-OIG's November 2017 report. Based on HHS-OIG's analysis, these were the only two drugs for which noncovered, self-administered versions were used to set Part B payment amounts in 2017 or 2018. Closing the payment loophole for self-administered drugs would have saved Medicare and its beneficiaries nearly half a billion dollars on Orencia and Cimzia in 2017 and 2018. Further, HHS-OIG found that physicians almost never administered the self-injected versions of Orencia to patients in their offices, and that the payment loophole may give physicians substantial incentives to administer Orencia and Cimzia instead of other drugs for the same conditions. (OEI-BL-20-00100)

Medicare Market Shares of Diabetes Test Strips From April Through June 2019. Non-mail-order claims composed 85 percent of the total Medicare market for diabetes test strips (DTS) during the time period we reviewed. The suppliers in HHS-OIG's sample provided 25 types of DTS to Medicare beneficiaries via non-mail-order and 21 types of DTS via mail order. The suppliers in our samples provided eight types of DTS to Medicare beneficiaries both via non-

mail-order and mail order. The Medicare Improvements for Patients and Providers Act of 2008 prohibits CMS from awarding contracts in the National Mail-Order Program to a supplier of DTS if the supplier's bid does not cover at least 50 percent, by volume, of all types of DTS provided to Medicare beneficiaries. HHS-OIG's analysis assists CMS in determining whether bidding suppliers meet this 50-percent rule. (OEI-04-19-00481)

Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2020. HHS-OIG found that overall, the rate at which Part D plan formularies include the drugs commonly used by dual eligibles (i.e., individuals who are eligible for both Medicare and Medicaid) is high, with some variation. The 448 unique formularies used by the 4,610 Part D plans include 97 percent of the 195 drugs most commonly used by dual eligibles and covered by Part D. In addition, 75 percent of the commonly used drugs are included by all Part D plan formularies. On average, formularies applied utilization management tools to 29 percent of the unique drugs we reviewed in 2020. Because some variation exists in formularies' inclusion of these drugs and in their application of utilization management tools to the drugs, some dual eligibles may need to use alternative methods to access the drugs they take. (OEI-05-20-00190)

Medicare Lab Test Expenditures Increased in 2018, Despite New Rate Reductions. Total Medicare Part B spending for lab tests increased to \$7.6 billion in 2018, despite lower payment rates for most laboratory (lab) tests. The \$459.0 million spending increase was driven by: (1) increased spending on genetic tests; (2) ending the discount for certain chemistry tests; and (3) the move to a single national fee schedule. Congress mandated that the Office of Inspector General monitor Medicare payments for lab tests and the implementation and effect of the new payment system for those tests. This report also provides the fifth annual analysis of the top 25 lab tests by Medicare spending. (OEI-09-19-00100)

Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2018 Average Sales Prices. Based on 2018 data, CMS lowered Medicare Part B reimbursement for 16 drugs, saving Medicare and its beneficiaries \$4.4 million over one year. This finding highlights the success of OIG's mandated quarterly comparisons of average sales prices (ASPs) with average manufacturer prices (AMPs) and implementation of CMS's current price-substitution policy. If OIG finds that the ASP for a drug exceeds the AMP by a certain percentage—currently, five percent—the ASP based payment amount is substituted with a lower calculated rate. This serves as a mechanism for monitoring market prices and limiting potentially excessive payment amounts. (OEI-03-20-00130)

The Majority of Providers Reviewed Used Medicare Part D Eligibility Verification Transactions for Potentially Inappropriate Purposes. The majority of providers reviewed (25 of 30) used Medicare Part D eligibility verification transactions (E1 transactions) for some purpose other than to bill for a prescription or determine drug coverage billing order. On average, 98 percent of these 25 providers' E1 transactions were not associated with a prescription. HHS-OIG did not contact 10 providers because they were closed, under investigation, or both. 15 providers submitted or hired other entities to submit E1 transactions for inappropriate purposes, which involved using a beneficiary's protected health information. After HHS-OIG's audit period,

CMS took additional steps to monitor use of the eligibility verification system and take appropriate enforcement action when abuse is identified. (A-05-17-00020)

Medicare Allowable Amounts for Certain Orthotic Devices Are Not Comparable With Payments Made by Select Non-Medicare Payers. Medicare allowable amounts for certain orthotic devices are not comparable with payments made by select non-Medicare payers. For CYs 2012 through 2015, HHS-OIG estimated that Medicare and beneficiaries paid \$341.7 million more than select non-Medicare payers on 142 Healthcare Common Procedure Coding System (HCPCS) codes and \$4.2 million less than select non-Medicare payers on 19 HCPCS codes. Generally, Medicare allowable amounts are more than select non-Medicare payer payments because CMS does not routinely evaluate pricing trends for orthotic devices or payments made by select non-Medicare payers. Instead, CMS uses statutorily mandated fee schedule payments that have an economic update factor applied to them annually. (A-05-17-00033)

Medicare Made Hundreds of Thousands of Dollars in Overpayments for Chronic Care Management Services. Physician and outpatient payments made by CMS for chronic care management (CCM) services provided during CYs 2015 and 2016 did not always comply with federal requirements, resulting in \$640,452 in overpayments associated with 20,165 claims. For these 20,165 claims, beneficiaries were overcharged a total of up to \$173,495 in cost sharing. Further, we identified 37,124 claims totaling \$1.2 million in potential overpayments for instances in which a CCM service was billed by an outpatient facility, but a corresponding claim was not submitted by a physician. HHS-OIG set aside these potential overpayments for review and determination by CMS. For these 37,124 claims, beneficiaries may have been overcharged a total of up to \$373,726 in cost sharing. These errors occurred because CMS did not have adequate controls in place, including claim system edits, to identify and prevent overpayments. (A-07-17-05101)

Medicare Improperly Paid Suppliers an Estimated \$92.5 Million for Inhalation Drugs. Not all suppliers complied with Medicare requirements when billing for inhalation drugs. Suppliers complied with the requirements for 81 of the 120 sampled claim lines; however, of the remaining 39 claim lines, 22 suppliers did not comply with documentation requirements. HHS-OIG found the following documentation-related deficiencies: incomplete, invalid, or missing detailed written orders (28 claim lines); incomplete proof of delivery (six claim lines); incomplete refill requests (six claim lines); and medical records not provided (one claim line). (The total exceeds 39 because two claim lines had two deficiencies.) Based on sample results, HHS-OIG estimated that approximately \$92.5 million paid to suppliers for inhalation drugs was unallowable for Medicare reimbursement. Medicare contractor oversight was not sufficient to ensure that suppliers complied with documentation requirements. (A-09-18-03018)

Medicare Contractors Were Not Consistent in How They Reviewed Extrapolated Overpayments in the Provider Appeals Process. Although MACs and qualified independent contractors (QIC) generally reviewed appealed extrapolated overpayments in a manner that conforms with existing CMS requirements, CMS did not always provide sufficient guidance and oversight to ensure that these reviews were performed in a consistent manner. The most significant inconsistency we identified involved the use of a type of simulation testing that was only performed by a subset of

contractors. The test was associated with at least \$42.0 million in extrapolated overpayments that were overturned in FYs 2017 and 2018. These extrapolations should not have been overturned if CMS did not intend for the contractors to use this procedure. Conversely, if CMS intended that contractors use this procedure, it is possible that other extrapolations should have been overturned but were not. In addition, CMS's ability to provide oversight over the extrapolation review process was limited because of data reliability issues in the Medicare Appeals System (MAS). Of the 39 appeals cases HHS-OIG reviewed that were listed in the MAS as involving extrapolation, 19 cases did not actually involve statistical sampling. Improving the accuracy of the information in the MAS would potentially assist CMS with ensuring that extrapolated overpayments are reviewed by the MACs and QICs in a consistent manner. (A-05-18-00024)

CMS Could Improve Its Processes for Evaluating and Reporting Payment Recovery Savings Associated With the Fraud Prevention System. The FPS's adjusted savings for overpayment determinations and law enforcement referrals were approximately 10 percent of the identified savings for its second and third implementation years because: (1) the MACs' opportunities to collect FPS-identified overpayments were often limited by both the time it took to get referrals from the Zone Program Integrity Contractors and Program Safeguard Contractors (Contractors) and by unique challenges in attempting to recover overpayments from providers, and (2) CMS has not established a standard process for the Program Integrity Contractors to estimate the value of law enforcement referrals. CMS's reported FPS savings and return on investment (ROI) after the third implementation year gave stakeholders an incomplete picture of the FPS's value because CMS has continued to rely primarily on identified savings for its reporting. Historically, the overwhelming majority of the identified savings from payment recovery administrative actions have not been recovered. Reporting adjusted savings and the corresponding adjusted ROI in addition to identified savings would provide a more complete picture of the value of the FPS. (A-01-15-00510)

CMS Generally Met Requirements for the DMEPOS Competitive Bidding Program Round 1 Recompete. HHS-OIG reviewed the process CMS used to conduct the competitive bidding and subsequent pricing determinations that are the basis for bid amounts and single-payment amounts (SPAs) of the DMEPOS Competitive Bidding Program Round 1 Recompete (the DMEPOS Program). CMS consistently followed its established DMEPOS Program procedures and applicable federal requirements for 219 of the 225 winning suppliers associated with the sampled SPAs reviewed. Although the overall effect on Medicare payments to suppliers was relatively small, CMS did not consistently follow its established procedures and applicable federal requirements for selecting suppliers during the bid process for six of the 225 winning suppliers. Additionally, CMS did not monitor suppliers in accordance with established procedures and federal requirements for another seven suppliers for the first six months of 2014. Based on HHS-OIG's sample, HHS-OIG estimated that CMS paid suppliers \$24,054 more than they would have received without any errors, or less than 0.03 percent of the \$73.0 million paid under the Round 1 Recompete during the first six months of 2014. (A-05-16-00051)

Medicare-Allowed Charges for Noninvasive Ventilators Are Substantially Higher Than Payment Rates of Select Non-Medicare Payers. For CYs 2016 through 2018, we estimated that Medicare and beneficiaries could have saved \$86.6 million if Medicare-allowed charges were comparable with payment rates of select non-Medicare payers on HCPCS code E0466. Of this payment difference, we estimated that Medicare paid \$69.3 million and Medicare beneficiaries paid \$17.3 million. Generally, Medicare-allowed charges are higher than select non-Medicare payer payment rates because CMS does not routinely evaluate pricing trends for noninvasive ventilators or payment rates of select non-Medicare payers. Rather, CMS uses statutorily mandated fee schedule payments that have an economic update factor applied to them annually. In 2016, CMS was required to adjust certain fee schedule amounts for durable medical equipment, prosthetics, orthotics, and supplies using information from the competitive bidding program. But this change did not affect the noninvasive ventilator HCPCS code reviewed for this report. (A-05-20-00008)

CMS's Monitoring Activities for Ensuring That Medicare Accountable Care Organizations Report Complete and Accurate Data on Quality Measures Were Generally Effective, but There Were Weaknesses That Could Be Improved. CMS's monitoring activities were generally effective for ensuring that Accountable Care Organizations (ACOs) report complete and accurate data on quality measures through claims and administrative data and the CMS web portal. (For example, ACOs report data through the web portal on whether beneficiaries received preventive care, such as depression screenings.) However, we identified weaknesses in CMS's monitoring activities that could lead to ACOs reporting incomplete or inaccurate data through the patient survey. Specifically, CMS did not ensure that its contractor: (1) verified survey vendors' correction of identified issues even though the issues were directly related to the collection or reporting of data and (2) provided feedback reports in time for survey vendors to include in their Quality Assurance Plans (QAPs) all of the changes implemented to address identified issues. (A QAP describes a survey vendor's process for performing the patient survey and complying with the CMS Quality Assurance Guidelines.) In addition, CMS did not ensure that its contractor reviewed survey instruments (e.g., mail survey packages) translated into other languages. As a result of these weaknesses, ACOs may not report complete and accurate data on quality measures, which could affect the ACOs' overall quality performance scores and ultimately the shared savings payments. (A-09-18-03033)

To address the concerns identified by the OIG, CMS finalized a no cost extension modification to the current Statement of Work and the Schedule of Deliverables effective 11/23/2020. The OIG's recommendations are reflected in the respective tasks of the modified SOW. CMS is continually monitoring the contractor's adherence to these requirements. CMS will maintain these requirements in all future procurements.

Incorrect Acute Stroke Diagnosis Codes Submitted by Traditional Medicare Providers Resulted in Millions of Dollars in Increased Payments to Medicare Advantage Organizations. Our objective was to determine whether selected acute stroke diagnosis codes submitted by physicians under traditional Medicare that CMS later used to make payments to MA organizations on behalf of transferred enrollees complied with federal requirements. We reviewed 582 of 8,437 transferred enrollees (that we selected with a stratified random sample)

who received one instance of a high-risk acute stroke diagnosis code during 2014 or 2015. For almost all of the transferred enrollees in our sample, the medical records did not support the acute stroke diagnosis codes. Thus, the Ischemic or Unspecified Stroke Hierarchical Condition Categories (HCCs) were not validated. As a result, we estimated that CMS made inaccurate payments of just over \$14.4 million to MA organizations. (A-07-17-01176)

CMS's Implementation of a 2014 Policy Change Resulted in Improvements in the Reporting of Coverage Gap Discounts Under Medicare Part D. The Coverage Gap Discount Program made manufacturer discounts equal to 50 percent of the negotiated price of applicable, covered Part D drugs available to Medicare Part D beneficiaries during CYs 2011 through 2018. Although CMS generally ensured that Part D sponsors accurately reported Coverage Gap discounts, we identified instances in which sponsors should have reported these discounts but did not. Specifically, for CYs 2013 and 2014, we identified \$1.1 million in Coverage Gap discounts that should have been invoiced to manufacturers but were not because the discounts were not reflected in the prescription drug event (PDE) records submitted by sponsors. These discrepancies occurred because CMS did not always have the sponsor information it needed. For that reason, CMS was not always able to accurately, and in a timely manner, identify beneficiaries who were in the Coverage Gap. Effective January 1, 2014, a policy change enabled CMS to more easily identify PDEs that should have reflected Coverage Gap discounts. After implementation of the policy change, Employer Group Waiver Plans more accurately reported Coverage Gap discounts. (A-07-16-06067)

New York Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs. New York did not always comply with federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Specifically, New York did not invoice manufacturers for rebates associated with \$3.3 million (federal share) in single-source and top-20 multiple-source physician-administered drugs. Although New York's policies and procedures require the collection of utilization data necessary to invoice for rebates on all claims, its internal controls did not always ensure that the data were used to invoice manufacturers to secure rebates. (A-02-18-01011)

Michigan Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations. Michigan did not fully comply with federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to MCO enrollees. Michigan did not bill for and collect manufacturers' rebates that we calculated to be at least \$31.5 million (federal share). Michigan did not always bill for and collect manufacturers' rebates because Michigan and its contractor did not identify all of the rebate-eligible drugs in the utilization data submitted by the MCOs. (A-05-17-00017)

Maine Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs. Maine did not always comply with federal Medicaid requirements for invoicing manufacturers. Maine did not invoice for, and collect from manufacturers, rebates associated with \$4.3 million (federal share) in physician-administered drugs as required. Maine could have invoiced manufacturers for rebates totaling \$10.8 million (federal share) that were associated with physician-administered drugs dispensed at non-Critical Access Hospitals. (A-07-18-06079)

Other HHS-OIG Fraud and Abuse Prevention Activities

Data Analytics

HCFA funding supports HHS-OIG's advanced data analytics initiatives to expand our tools, models, and customized analytics with artificial intelligence (AI), and cloud computing to: (1) proactively monitor and target our oversight of high-risk HHS programs and health care providers, (2) identify trends, outliers, and potential investigative or audit targets, (3) enhance decision making, and (4) optimize HHS-OIG processes. HHS-OIG's team of highly trained data analysts, data scientists, and statisticians partner with HHS-OIG investigators, auditors, attorneys, and evaluators to identify HHS's most significant risks and better target fraud, waste, and abuse. HHS-OIG applies predictive and geospatial analytics, and leverage dashboards, machine learning, and AI capabilities including neural networks and text mining to high-value health care, grants, law enforcement, and operational data to identify and support the prosecution of sophisticated fraud schemes and potential audit and evaluation findings.

HHS-OIG's ability to use data proactively has become even more important during the COVID-19 pandemic. HHS-OIG analytics staff quickly pivoted to monitor COVID-19 testing, treatment, and billings other services, such as DME, allergy, genetic, respiratory, and other testing to detect patterns of inappropriate bundling of services and billing for services not rendered. HHS-OIG also monitored changes in services delivered through telemedicine to identify inappropriate billing schemes. HHS-OIG analytics supported agency investigative actions that led to criminal charges filed in U.S. courts involving at least 67 of the more than 100 doctors, nurses and other licensed medical professionals included in the nationwide health care fraud enforcement actions announced by DOJ and HHS on September 30, 2020. Furthermore, HHS-OIG's data analytics continue to identify and support cases filed as part of the Appalachian Regional Prescription Opioid Strike Force efforts.

Our data and technical experts are also partnering with HHS-OIG auditors and evaluators to provide custom data and analytics support focused on pandemic related work. To date, OIG analytics staff are supporting 27 audits and evaluations launched since the onset of the COVID-19 pandemic across the Medicare and Medicaid portfolio and dozens of COVID-19 related projects and exploratory work.

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 on the application of the federal AKS and other OIG administrative enforcement authorities to existing or proposed health care business transactions.

During FY 2020, HHS-OIG, in consultation with DOJ, issued six advisory opinions. A total of 380 advisory opinions and 21 modifications to advisory opinions have been issued, four opinions

have been terminated, and one opinion has been rescinded during the 24 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 AKS 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 2020, CMS was appropriated \$610.0 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 2020, Congress required HHS to fund the Administration for Community Living's (ACL) Senior Medicare Patrol (SMP) Program; therefore, \$18.0 million of CMS's \$610.0 million in discretionary funding was allocated to ACL to support the program. More information on the SMP Program activities and accomplishments are discussed in the ACL section of this report on page 83. 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.

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).

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 the Recovery Audit Program and Medicare Secondary Payer. CMS' program integrity activities are discussed at length in the annual Medicare and Medicaid Integrity Programs Report to Congress, which can be found on the CMS website.¹⁶

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 developed a five-pillar program integrity strategy intended to modernize the agency's approach and protect its programs for future generations. In FY 2020, CMS's strategy focused on:

- **Stopping Bad Actors.** CMS worked with law enforcement agencies to identify and take action on those who defraud federal health programs. This collaboration allowed CMS to maximize efforts to identify, investigate, and pursue providers and suppliers who might otherwise endanger program beneficiaries or commit fraud on Federal programs.
- **Preventing Fraud.** CMS continued 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 included 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.
- **Mitigating Emerging Programmatic Risks.** CMS recognized 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.

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

- **Reducing Provider Burden.** While CMS strengthened program integrity, the agency is also taking steps to ensure that these efforts did not create unnecessary time and cost burden on providers and suppliers. Efforts in this area included targeted medical review with individualized education to assist rather than punish providers who make good faith claim errors. CMS worked to make access to our coverage and payment rules more easily accessible to providers and suppliers, as well as streamlined and reduced documentation requirements that were duplicative or unnecessary. CMS also explored ways to centralize provider screening and provider monitoring across Medicare and Medicaid.
- **Leveraging New Technology.** CMS looked 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 providers and less cost to taxpayers. These innovations could be used in both our current payment systems, 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 and 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.

CMS also contracts with the UPICs to review the actions of Medicaid providers. The UPICs work closely with states to perform numerous functions to detect, prevent, and deter specific risks and broader vulnerabilities to the integrity of the Medicaid program, including conducting provider investigations and audits, which can result in the identification of overpayments, fraud referrals to law enforcement, and other referrals for state administrative action. Currently, the UPICs are carrying out program integrity activities in all five geographic jurisdictions: Midwest, Northeast, West, Southeast and Southwest.

Fraud Prevention System

FPS is the predictive analytics technology required under the Small Business Jobs Act of 2010.¹⁷ FPS analyzes fee-for-service (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 2020, the FPS generated alerts that resulted in 1,032 new leads for program integrity contractors (PICs) and augmented information for 413 existing PIC leads or investigations. The PICs reported initiating FPS-attributable actions against 599 providers in FY 2020.

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 edits are published in the Annual Report to Congress on the Medicare and Medicaid Integrity Programs.¹⁸

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.

¹⁷ Public Law 111-240.

¹⁸ <https://www.cms.gov/About-CMS/Components/CPI/CPIReportsGuidance>.

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, and CMS. 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 nearly 2,200 MCC reviews and 1,750 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 2020, CMS conducted over 1,100 MCC reviews and 800 referrals to law enforcement partners.

An example of the ways in which CMS has provided support to the OIG and DOJ throughout fiscal year 2020 includes:

In September 2020, DOJ announced a historic nationwide enforcement action involving 345 charged defendants across 51 federal districts, including more than 100 doctors, nurses and other licensed medical professionals. The largest amount of alleged fraud loss charged in connection with those cases relate to schemes involving telemedicine: the use of telecommunications technology to provide health care services remotely. In addition to the criminal charges announced related to the enforcement action, CMS' Center for Program Integrity (CPI) separately announced that it has taken a record-breaking number of administrative actions related to telemedicine fraud, revoking the Medicare billing privileges of 256 additional medical professionals for their involvement in telemedicine schemes. This represents the largest number of adverse administrative actions resulting from a single administrative health care fraud investigative initiative.

Durable Medical Equipment Prosthetics, Orthotics, and Supplies Initiatives

DME suppliers pose a high risk of fraud to the Medicare program and CMS has undertaken an aggressive strategy to address this risk. In FY 2020, our activities included DME investigations,

which included reviews of suppliers and physicians identified as potentially suspicious or high risk. CPI implemented a national investigative strategy and took administrative actions against referring providers associated with the DOJ's 2019 national DME takedown known as Operation Brace Yourself (OBY).¹⁹

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 2020, CMS denied approximately 471 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 2020, APS resulted in more than 6.5 million screenings. These screenings generated more than 43,000 potential licensure alerts, and more than 3,200 criminal alerts for potentially fraudulent providers and suppliers for further review by CMS. APS review resulted in approximately 93 criminal revocations and over 220 licensure revocations.

Site visits are a screening mechanism used to identify providers and suppliers that are not in compliance with program requirements and likely to pose a risk to the Medicare program, preventing them from enrolling or maintaining enrollment. CMS-authorized site-visit contractors validate that the provider or supplier complies with Medicare enrollment requirements during these visits. In FY 2020, the initiative resulted in 23,562 site visits conducted by the National Site Visit Contractor (NSVC), which conducts site visits for most

¹⁹ <https://www.justice.gov/opa/pr/federal-indictments-and-law-enforcement-actions-one-largest-health-care-fraud-schemes>.

Medicare FFS providers and suppliers, and 23,269 conducted by the National Supplier Clearinghouse (NSC), which conducts site visits for Medicare DME suppliers. This work resulted in about 217 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 2020, CMS deactivated 111,884 enrollments and revoked 2,827 enrollments. Site visits, revalidation, and other initiatives have contributed to the deactivation²⁰ and revocation²¹ 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 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 is used along with the APS, as a data source by the FPS and by many other program integrity partners including the UPICs, Recovery Audit Program, 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 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 streamlining and consistency in user workflows, as well as to standardize interfaces with systems internal and external to CMS.

²⁰ 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.

²¹ Revocation means the provider's or supplier's billing privileges are terminated. See 42 CFR 424.535.

In FY 2020, CMS made significant changes to PECOS to simplify access, improve the usability and enhance the security of the system, including the following changes:

- Added additional features necessary to facilitate the future implementation of Multi-Factor Authentication;
- Implemented Opioid Treatment Program supplier type and necessary extract changes related to the supplier type;
- Updated PECOS to support pay.gov web service migration from Open Collection Interface Interactive (OCI-I) service to Hosted Collection Pages (HCP);
- Implemented necessary changes to support provider enrollment using waivers and flexibilities during Public Health Emergency(PHE);
- 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;” and
- 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 CMS’s Medicare screening results for dually-enrolling providers, 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 2020, 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 States’ page in January 2017, and included provider enrollment information such as Medicare enrollment status, site visit information, fingerprint results, ownership information, reassignments, Medicare risk

levels, and more. Since May 2016, CMS has offered the data compare service that more easily enables 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). In FY 2018, CMS launched the Data Exchange (DEX) system, which is used to share data among CMS and the separate Medicaid programs of every state. The new system stores all state-submitted terminations as well as all Medicare revocations, and HHS-OIG exclusion data, and enhances collaboration, improves reporting, and creates transparency through this process. Lastly, in FY 2020, CMS continued the Medicaid screening pilot process, that began with Iowa and Missouri, to screen Medicaid providers through its APS system on behalf of states. CMS believes centralizing this process will improve efficiency and coordination across Medicare and Medicaid, reduce state and provider burden, and address one of the biggest sources of error as measured by the Payment Error Rate Measurement (PERM) program today. MO and IA are currently evaluating the screening results. In 2020, CMS began expanding the pilot to other states. Currently, Oklahoma and Nevada have agreed to participate in the pilot and CMS continues to reach out to other states to gauge their interest. CMS will continue to evaluate the overall effectiveness of the pilot as we move through Phase II, which includes expanding the pilot to additional states and increasing the volume of providers being placed in CMS' screening system.

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 continues to publish updates to the Medicaid Provider Enrollment Compendium (MPEC), which is sub-regulatory guidance designed to assist states in applying certain regulatory requirements. The latest update focused 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 the Medicare and Medicare Medical Review Contractors (MRCs). MRCs include the MACs, UPICs, and the Supplemental Medical Review Contractor (SMRC). In 2020, the MRAC also assisted with measuring the accuracy of medical review conducted by the RACs while a procurement for the RAC Validation Contractor (RVC) was underway. The MRAC helps CMS by measuring the accuracy rate for each contractor, to ensure the contractors are consistent in their medical review decisions, and feeds information into the Award Fee Component for the MACs to 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 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 (PMD) demonstration into the national program.

In FY 2019, CMS selected 12 additional DMEPOS items for required prior authorization: nationwide, beginning on July 22, 2019, 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.

In FY 2020, CMS selected six additional DMEPOS items to be subject to prior authorization. Beginning on September 1, 2020, prior authorization of certain lower limb prosthetic codes was required in California, Michigan, Pennsylvania, and Texas. Prior authorization for these codes expanded nationwide on December 1, 2020.²² 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.

In FY 2020, CMS finalized a regulation through the Calendar Year 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS-1717-FC) establishing a nationwide prior authorization process and requirements for certain hospital outpatient services that demonstrate significant increases in volume. Beginning July 1, 2020, CMS required prior authorization for the following services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation. This process serves as a method for controlling unnecessary increases in the volume of these services. The MACs review requests for prior authorization for the noted services, communicate decisions to providers, 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 Fund. 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's 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

²² Prior authorization for these lower limb prosthetic codes was originally scheduled to begin in California, Indiana, New Jersey, and North Carolina on May 11, 2020, and nationwide on October 8, 2020; however, CMS temporarily delayed implementation due to the COVID-19 public health emergency.

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 outlier providers per topic based on data analysis for a defined period of time. Topics are based on Government Accountability Office (GAO) and OIG reports, Comprehensive Error Rate Testing program findings, and 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 HCFAC program discretionary funds and other funding sources to develop and implement enterprise systems that support Medicaid. In particular, the Medicaid and CHIP Business Information Solution (MACBIS) initiative will improve CMS and states' 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. HCFAC funding also supports the preparation and dissemination of educational toolkits for states to use to enhance awareness of Medicaid fraud, waste, and abuse among providers, beneficiaries, managed care organizations, and others. States participate in and receive 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 UPICs
- Desk reviews of state processes and procedures

CMS also identifies areas of improvement and works with 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 is in the process of analyzing all statewide Home and Community-Based Services (HCBS) data available for all states to identify states to receive onsite or virtual reviews. As of September 2020, nine onsite reviews were conducted, including

Ohio, Massachusetts, Maryland, Oregon, the District of Columbia, California, Nebraska, West Virginia, and Montana. Due to COVID-19 restrictions, onsite reviews were placed on hold in late March of 2020. In order to continue reviews, the project was modified and the H&W SRT developed a virtual review standard operating procedure that is currently being finalized. The H&W SRT is anticipating the first virtual reviews will take place in Maine and Alaska and will continue until onsite reviews can be re-instated. During the last year, the H&W SRT also developed three trainings entitled “*Key Ingredients of an Effective 1915(c) Home and Community-Based Services Waiver Program Mortality Review Process*,” “*Effective Incident Investigations and Management in 1915(c) Home and Community-Based Services Waiver Programs*,” and “*Health & Welfare Special Reviews Team: Observations and State Considerations*.” A data tracker tool that will house all of the state findings, including promising practices, was developed and is currently being utilized by CMS. The H&W SRT will continue to conduct analyses, onsite and/or virtual visits, and trainings to help CMS identify, prevent, and address any systemic problems in the states’ implementation of, and compliance with, health and safety oversight systems within these settings.

State Audit Compliance and Financial Management Oversight

The State Audit Compliance and Financial Management Oversight projects began in September 2020. The purpose of these projects is to acquire contractor assistance for two separate efforts. The first is to perform data analysis, collection, and evaluation, including the use of statistical sampling techniques, to review data provided by states related to payments to health care providers to determine if Medicaid claims submitted by states for federal financial participation (FFP) are allowable under federal guidelines. As a whole, this work supports the overall responsibility of CMS to ensure that all claimed expenditures meet statutory and regulatory requirements and are appropriate for the Medicaid program to provide efficient review of activities relating to the performance of Financial Management Reviews (FMRs). The second effort will develop, implement, and align measures that improve CMS’ approach to the annual OMB single state agency (SSA) audit and identify opportunities to optimize the compliance supplement that guides single state auditors as they review state Medicaid and CHIP programs. This project will also improve the analysis of the findings resulting from SSA and HHS OIG audits of state Medicaid / CHIP programs to assist CMS in better identifying high risk policy areas.

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 regulation²³ and guidance, including the Medicaid Information Technology Architecture (MITA) framework, several standards and conditions,²⁴ and certification criteria. Adhering to these

²³ 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>)

²⁴ <https://www.medicaid.gov/medicaid/data-and-systems/mita/index.html>

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, an enterprise-wide initiative to empower states and the federal government to perform monitoring and oversight, inspect program integrity, evaluate 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 appropriately to implement the policy requirements (e.g., for provider enrollment or for eligibility and enrollment, etc.). Certain state systems also undergo a certification review conducted by CMS as an additional step in ensuring proper operation.

Federal and state governments have invested heavily in the development and operations of Medicaid claims processing and information retrieval systems that engage in high volume transactions. In 2016, CMS released an update to the MMIS Certification process in the form of MECT 2.0 to ensure a more comprehensive analysis of CMS funded state systems functionality. Moving forward, CMS is focused on increasing accountability and state flexibility by creating an outcomes-based oversight model 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 Payment Integrity Information Act of 2019 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 and CHIP programs have been identified as being at risk for significant improper payments. CMS estimates improper payment rates in Medicaid and CHIP through the 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. States are required to submit corrective action plans to CMS to address root causes of errors and deficiencies in an effort to reduce improper payments.

In the HHS FY 2020 Agency Financial Report (AFR),²⁵ CMS reported the national Medicaid improper payment rate based on measurements conducted in FYs 2018, 2019, and 2020.²⁶ The FY 2020 national Medicaid improper payment rate was 21.36 percent, representing \$86.49 billion in gross federal improper payments. The FY 2020 national improper payment rates by component are 16.84 percent for Medicaid FFS, 0.06 percent for Medicaid managed care, and 14.94 percent for Medicaid eligibility. The FY 2020 national CHIP improper payment rate was 27.00 percent, representing \$4.78 billion in gross federal improper payments. The national improper payment rates by component are 14.15 percent for CHIP FFS, 0.49 percent for CHIP managed care, and 23.53 percent for CHIP eligibility.

The majority of Medicaid and CHIP improper payments are a result of eligibility errors discovered through the reintegration of the PERM eligibility component. A federal contractor²⁷ conducts the eligibility measurement, allowing for consistent insight into the accuracy of Medicaid and CHIP eligibility determinations and increased oversight of identified vulnerabilities. Based on the measurement of the first two cycles of states, eligibility errors are mostly due to insufficient documentation to verify eligibility or non-compliance with eligibility redetermination requirements. The majority of the insufficient documentation errors represent both situations where:

- The required verification was not done at all, and
- There is indication that the eligibility 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 inappropriately deemed eligible for CHIP, but was eligible for Medicaid, mostly related to beneficiary income, third party insurance, or household composition/tax filer status. Additionally, state non-compliance with provider screening, enrollment, and NPI requirements is a major contributor to the Medicaid and CHIP improper payment rates.

CMS works closely with states to develop state-specific corrective action plans to reduce improper payments. All states are responsible for implementing, monitoring, and evaluating the effectiveness of their plans, with assistance and oversight from CMS.

Additional information on the Medicaid and CHIP improper payments can be found in the FY 2020 Agency Financial Report²⁸ and CMS websites.²⁹

²⁵ <https://www.hhs.gov/about/agencies/asfr/finance/financial-policy-library/agency-financial-reports/index.html>

²⁶ The national eligibility improper payment rate still includes a proxy estimate for the remaining 17 states that have not yet been measured since the reintegration of the PERM eligibility component.

²⁷ Prior to FY 2014, the eligibility component was reviewed and self-reported by the states to CMS for national improper payment reporting.

²⁸ <https://www.hhs.gov/about/agencies/asfr/finance/financial-policy-library/agency-financial-reports/index.html>

²⁹ <https://www.cms.gov/ImproperPayments>

Medicaid Beneficiary Eligibility Reviews

HHS conducted beneficiary eligibility reviews to confirm whether states' Medicaid and CHIP beneficiary eligibility determinations were appropriate and the Federal match was assessed correctly. In FY 2020, HHS released reports³⁰ for New York, Kentucky, and Louisiana that (1) compared previous findings in similar reviews conducted by the HHS-OIG to ensure those findings have been appropriately addressed; (2) identified and assessed the impact of any changes to Medicaid eligibility policy due to the Affordable Care Act (ACA); and (3) determined whether non-expansion enrollment categories were impacted by the expansion enrollment process. HHS conducted a risk-based analysis to select additional states for review in FY 2021.

Medical Loss Ratio Examinations

HHS is conducting examinations of Medicaid managed care plans' financial reporting in selected states, focused on Medical Loss Ratio (MLR) and rate setting. In June 2020, CMS released its first MLR audit report that included a comprehensive examination of California's 22 Medicaid managed care plans' MLR reporting for the ACA Medicaid adult expansion population.³¹ HHS conducted a risk-based analysis to select additional states for review in FY 2021.

Medicaid 1115 Financial Oversight

Medicaid section 1115 demonstrations are an increasingly important vehicle for state innovation in Medicaid program development, expansion and financing. Forty-seven states and the District of Columbia operate at least one 1115 demonstration, and there are 78 active demonstrations representing estimated federal outlays of \$195 billion in FY 2019. The Medicaid section 1115 demonstration portfolio 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 monitor and oversee these demonstrations.

Related to demonstration fiscal integrity, CMS activities in FY 2020 included the continued phase-in of the revised budget neutrality policy represented in the FY 2018 State Medicaid Director Letter documenting CMS's approach to various aspects of Medicaid 1115 budget neutrality calculations.³² In addition, to strengthen the review of state-submitted quarterly budget neutrality performance reports, CMS has developed and implemented a standardized budget neutrality reporting tool for states. This tool will facilitate improved consistency in state reporting and CMS tracking of spending under section 1115 demonstrations. Further, the section 1115 IT reporting system, Performance Metrics Database and Analytics (PMDA), has been updated to support this revised workflow and the documentation of findings from the budget neutrality reviews. Most recently, CMS launched an internal initiative to more thoroughly document and train staff on the underlying principles, assumptions and data to be used in the formulation of the budget neutrality parameters reflected in the demonstration approval documents.

³⁰ The national eligibility improper payment rate still includes a proxy estimate for the remaining 17 states that have not yet been measured since the reintegration of the PERM eligibility component.

³¹ <https://www.cms.gov/About-CMS/Components/CPI/CPIReportsGuidance>

³² <https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/smd18009.pdf>

Beyond budget neutrality, CMS has also expanded and made more robust its oversight of the integrity of demonstration implementations. This has included the development of standard operating procedures and extensive training, as well as further updates and refinements of PMDA to strengthen internal controls and development of standardized reports that permit more efficient and meaningful review of demonstration performance relative to expectations established in the demonstration special terms and conditions. Relatedly, CMS is providing technical assistance to states to assure they understand and implement these more robust monitoring standards.

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 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; and
- 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, 2019 to September 30, 2020, CMS completed 126 reviews of HCBS waivers for 37 states and compiled reports with findings pertaining to the waivers' fiscal and quality components for each. Findings from fiscal and quality reviews are aggregated in an annual report each year, which helps inform technical assistance activities and guide program improvements. 20 PACE reviews, spanning 19 states, were also conducted during this period.

Since 2016, 28 presentations have been completed and made available to state staff via technical assistance calls and web posting. They covered topics such as findings from the CMS survey of states' incident management systems for HCBS waivers, using electronic visit verification to improve HCBS quality monitoring and oversight, preventing unallowable costs in HCBS programs, financial accountability of HCBS, rate sufficiency, and HCBS rate development.

Extend Work in Medicare Parts C and D

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

National Benefit Integrity (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 NBI MEDIC³³ and 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 \$6.5 million in the first nine months of FY 2020 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) documents and takes compliance action against Part C Plans, also known as MAOs, Part D Prescription Drug Plans (PDPs), Section 1876 Cost Plans, and Medicare-Medicaid Plans (MMPs) that fail to send timely and accurate ANOC documents to Medicare enrollees. The ANOC provides Medicare enrollees with vital information that can affect their ability to make informed choices concerning their Medicare health care and prescription drug options.

In FY 2020, CMS issued one notice of non-compliance (NONC) to one parent organization as part of the annual timeliness review. CMS issued 14 NONCs to 21 parent organizations during the accuracy review. The NONCs were based on substantive inaccuracies (e.g., benefits, cost-sharing) contained in ANOC or evidence of coverage 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 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 Parts C and D program audits in 2020, as well as in prior years, occur at the parent organization level, though PACE audits are conducted at the contract level.

CMS audits all program audit areas for sponsors and PACE organizations unless an area is not applicable to the entity's operation, or, CMS is conducting a focused audit. Each sponsor or PACE organization that has deficiencies cited in its audit report is required to correct all of the deficiencies and undergo a validation audit or monitoring to ensure the issues have been corrected before the audit can be closed.

³³ In FY 2020, a new NBI MEDIC contract was awarded and is now known as the Plan Program Integrity MEDIC.

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:

- CMPs;
- Intermediate sanctions (i.e., suspension of marketing, enrollment, payment); and
- 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; and
- 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. MAOs submitted to CMS more than 6,300 Part C plan benefit packages on June 1, 2020 and project to cover more than 26.8 million enrollees in contract year 2021. 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 that 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 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 helps 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.

CMS carefully conducts all of these reviews to ensure that plans make all necessary changes to their bids and plan benefit packages. These reviews are conducted between early June and August, and, as necessary, involve communications with Part C organizations to correct issues and resubmit their bids and plan benefit packages. Following bid and plan benefit approval, Part C organizations must complete the contracting process with CMS and may market to beneficiaries beginning October 1 of each year. Part C benefits requirements and review processes are intended to protect beneficiaries from discrimination and to ensure that Part C plans provide value to enrollees.

Encounter Data Processing System Contract

In the FY 2009 inpatient prospective payment system (IPPS) final rule, CMS revised regulations to require MA organizations to submit encounter data for each item and service provided to MA plan enrollees. Consistent with such regulations, as of January 3, 2012, CMS requires MA organizations to submit encounter data for dates of service beginning January 3, 2012. MA organizations are required to submit data for all institutional, professional, and DME services provided to MA plan enrollees on or after that date. CMS established and maintains the Encounter Data System (EDS), which to date, has collected over 5.9 billion encounter data records (EDRs).

The encounter data detail each item and service provided to enrollees of MA organizations. These records are comparable in format and detail to claims FFS providers submit to the MACs. The encounter data collected by the EDS will allow CMS to make more accurate payments reflecting the patterns of care and the predicted costs of diseases for MA enrollees. CMS is also

able to use the information to evaluate service utilization, assess quality of care, and assess the performance of MA organizations.

Beginning in CY 2015, CMS began to use encounter data as an additional source of diagnoses to risk adjust payments to MAOs. 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 percent and encounter data-based risk scores weighted at 10 percent. In CY 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. In CY 2020, CMS continued the transition to using encounter data for risk adjustment and increased the weighting of encounter data-based risk scores to 50 percent and reduced the weighting of RAPS-based risk scores to 50 percent. CMS finalized a new blend of 75 percent encounter data-based risk scores and 25 percent RAPS-based risk scores for 2021. 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 MA data collected by CMS. This plan aligns 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 MA organizations' 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 Payment Integrity Information Act of 2019.

The Part C gross improper payment estimate reported for FY 2020 (based on the 2018 payment year data) was 6.78 percent or \$16.27 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 Part C Improper Payment process, where CMS identifies unsupported diagnoses and calculates corrected risk scores. The Part C Improper Payment Measurement calculates the beneficiary-level payment error for the sample and extrapolates the sample payment error to the population subject to risk adjustment, resulting in a Part C gross payment error amount.

In an effort to improve the Part C improper payment rate, CMS has implemented the following specific corrective actions:

- Contract-level Risk Adjustment Data Validation (RADV) audits are CMS's primary corrective action to recoup overpayments. RADV uses medical record review to verify the accuracy of enrollee diagnoses submitted by MA organizations for risk adjusted payment. CMS expects payment recovery will have a sentinel effect on risk adjustment data quality submitted by plans for payment because contract-level RADV audits increase the incentive for MA organizations to submit valid and accurate diagnosis information. Contract-level RADV audits also encourage MA organizations to self-identify, report, and return overpayments. In September 2019, CMS launched the payment year 2015 RADV audit. On January 9, 2020, CMS held a contract-level RADV training session for the 2015 payment year audit that included an overview of RADV enrollee data, guidance on preparing and submitting medical records and demonstration of the Central Data Abstraction Tool (CDAT). Due to the COVID-19 PHE, CMS suspended the 2015 audit in March 2020 and resumed it in September 2020. On September 10, 2020, CMS provided a refresher training regarding the payment year 2015 RADV audit that also included updates on enrollee data and how to access systems to submit medical records. The payment year 2014 RADV audit medical record submission phase is complete, and the audit is expected to conclude in FY 2021. CMS expects to start contract-level RADV audits for payment years 2016 and 2017 by fall 2021.
- Training: Historically, CMS has conducted fraud, waste, and abuse in-person and webinar training sessions for Medicare Parts C and D 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, enabling them to undertake collaborative efforts to protect the Medicare Part C and D programs.

The Part D gross improper payment estimate reported for FY 2020 (based on the 2018 payment year) was 1.15 percent or \$927.50 million, which represents payment error related to PDE data. For the Part D Improper Payment Measurement, 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. A representative sample of beneficiaries undergoes a simulation to determine the Part D improper payment estimate.

To improve the Part D error rate, CMS has implemented the following key specific corrective actions:

- Training: CMS continued national training sessions on payment and data submission with detailed instructions as part of the improper payment estimation process for Part D sponsors. CMS also conducted in-person training sessions for Medicare Part C and Part D sponsors on program integrity initiatives, investigations, data analysis, and potential

fraud schemes. In FY 2020, CMS conducted two MAOs and Prescription Drug Plan fraud, waste, and abuse training webinars in January 2020 and July 2020; a Fraud, Waste, and Abuse COVID-19 webinar in April 2020; and two Opioid Education Missions in October 2019 and March 2020. The missions included multi-disciplinary teams of experts and decision makers from CMS and its partners and supported collaborative efforts to protect the Medicare Part C and D programs.

- Outreach: HHS continued formal outreach to plan sponsors for invalid or incomplete documentation. HHS distributed Final Findings Reports to all Part D sponsors participating in the PDE review process. This report provided feedback on their submission and validation results against an aggregate of all participating plan sponsors.

Additional information on the Medicare Part C and D improper payments can be found in the FY 2020 Agency Financial Report³⁴ and CMS website.³⁵

Central Data Abstraction Tool

CMS uses diagnosis information submitted by MA 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 MA organizations. 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 2020, 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 took administrative actions including terminating CMS's agreements with agents and brokers and imposing CMPs 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.

³⁴ <https://www.hhs.gov/about/agencies/asfr/finance/financial-policy-library/agency-financial-reports/index.html>

³⁵ <https://www.cms.gov/ImproperPayments>

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 suppliers 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 & suppliers, 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 2020, CMS coordinated multiple training events focusing on current Medicare Parts C and D fraud schemes, fraud prevention techniques, and anti-fraud, waste, and abuse activities. These sessions integrated group discussions, information-sharing exercises, presentations and panel discussions that focused on the latest fraud, waste, and abuse issues.

Healthcare Fraud Prevention Partnership

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; and
- 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 2020, the HFPP reached a total membership level of 172 partner organizations, comprised of five federal agencies, 32 law enforcement agencies, 13 associations, 80 private payers, and 42 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, and consistent with all applicable privacy requirements, 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.

Over 20 billion professional claim lines were submitted by partners through FY 2020 for the purpose of conducting cross-payer analyses, and the HFPP has commenced 11 studies during FY 2020.

Examples of studies initiated in FY 2020 include the identification of problematic billing in the following areas:

- Ambulance services;
- Deactivated rendering providers;
- Radiation oncology;
- Transitional care management;
- Mohs micrographic surgery; and
- Genetic testing.

The HFPP also continued its efforts to foster collaboration among partners in FY 2020 by hosting five 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.

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, where the reported data can be searched, downloaded, and evaluated.

For Program Year 2019, CMS published information regarding over \$10 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 approximately 11 million total records attributable to 614,910 physicians and 1,196 teaching hospitals. Payments in the three major reporting categories included:

- \$3.6 billion in general (i.e., non-research related) payments;
- \$5.2 billion in research payments; and
- \$1.2 billion of ownership or investment interests held by physicians or their immediate family members.

Since the program's inception, CMS has published 76.3 million records, accounting for \$53.1 billion in payments and ownership and investment interests.

Administration for Community Living

The mission of the 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 2020, HHS allocated \$18.0 million in HCFAC appropriations, plus an additional \$98,804 in carryover funding from FY 2019 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 \$17.6 million, still from CMS discretionary HCFAC appropriations. In FY 2020, the Secretary allocated \$18.0 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 2020, ACL provided continuation awards to the 54 grantees totaling \$15.6 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 use this funding to educate and empower Medicare beneficiaries to prevent, detect, and report Medicare fraud, errors, and abuse.

COVID-19 Fraud Schemes

Fraud schemes relating to COVID-19 became prevalent beginning in March 2020. The majority of complaints received by the SMP grantees related to COVID treatments, testing, vaccines, and cures, followed by COVID-related medical services. Other schemes reported included those related to general COVID-linked medical services or pandemic supplies and equipment. Most reported COVID fraud or schemes occurred via text or telephone, followed by in-person and internet attempts. Though grantees' education and outreach activities were limited to virtual methods during this period as opposed to typical face-to-face means, SMPs responded quickly to COVID-19 fraud attempts. Throughout this crisis, ACL has carefully recorded and analyzed complaint details nationally and prepared sanitized summary reports that are shared regularly with the SMP grantees, HHS-OIG, and CMS.

In addition, ACL, the HHS-OIG, and the SMP National Resource Center worked together on national level media campaigns to get the word out on COVID-19 related fraud schemes. In July, ACL and the HHS-OIG collaborated to conduct a Facebook Live event hosted on the OIG's Facebook page to highlight coronavirus fraud schemes occurring nationally to warn Medicare beneficiaries and their families to be careful. Similarly, the SMP National Resource Center developed and released a consumer fraud alert on this topic, which advised beneficiaries to be suspicious of strangers who offer unsolicited COVID-linked items, services, or testing. It also advised beneficiaries to be wary of scare tactics used to pressure them into taking action, and to be cautious about sharing their personal information, including their Medicare identification number, and warned that this information could be used to fraudulently bill Medicare and Medicaid.

Genetic Testing Fraud Schemes

Genetic testing fraud continued to be a widespread issue nationally in FY 2020 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 and the SMP grantees continued to conduct public education and outreach efforts on this topic during this period along with the HHS-OIG.

Annual SMP OIG Report

Each year, the HHS-OIG completes an annual performance report on the SMP projects. In CY 2019, the SMP projects had a total of 6,875 active team members who conducted 28,146 group outreach and education events, reaching an estimated 1.6 million people. In addition, the projects had 320,590 individual interactions with, or on behalf of, a Medicare beneficiary. For 2019, the SMP projects reported \$2.4 million in expected Medicare recoveries. Cost avoidance totaled \$60,971, while savings to beneficiaries and others totaled \$20,150. Almost all of these recoveries came from one project that uncovered a fraud scheme that encouraged low-income

senior citizens to submit DNA samples for medically unnecessary genetic testing. Three defendants were sentenced and ordered to pay a total of \$2.3 million in restitution and forfeitures.

Since SMP's inception, the program has received more than 3.3 million inquiries from Medicare beneficiaries about preventing, detecting, and reporting billing errors, potential fraud, or other discrepancies. SMP projects have also educated more than 41.7 million people through group presentations and community outreach events. The primary focus of these sessions is on education, prevention, and teaching beneficiaries how to protect themselves and avoid fraud in the first place. This is the true value of the SMP program. However, the impact of these education and prevention activities is extremely difficult to quantify in dollars and cents. As HHS-OIG indicated in their 2020 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 \$129.2 million in savings attributable to the SMP program since its inception in 1997.

SMP Infrastructure and Program Support

SMP Resource Center

During FY 2020, ACL competed and selected the Northeast Iowa Area Agency on Aging for a new five-year grant to serve as the SMP National Resource Center (the Center). The 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. Highlights of the SMP National Resource Center's planned work during the next five-year period include maintaining a new national SMP-focused telephone application, producing additional in-depth grantee resources and SMP Consumer Alerts as need arises, and acting as a clearinghouse for ACL on complex case data and referral information in SMP emerging fraud trends.

SMP Information and Reporting System

Since FY 2016, ACL has supported a national SMP information and 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 2020, ACL continued to work 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 2020, ACL implemented the third 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 original OMB approval in August 2017. Survey implementation began in early FY 2018 and continued over a three-year period. One-third of the SMP projects were surveyed during each year of the project.

At the conclusion of the project, the national and state-level survey results are overwhelmingly positive. The average national ratings were as follows (1 = Strongly Disagree; 5 = Strongly Agree):

- 4.65 - "Respondents were provided with useful information."
- 4.63 - "Overall, respondents were satisfied."
- 4.51 - "Respondents would contact SHIP/SMP aging for assistance."
- 4.64 - "Respondents would recommend SHIP/SMP to others."

The overall evaluation results were consistent across States and Territories. There was a strong correlation between the usefulness of information respondents received and the beneficiary's overall satisfaction with the service provided by the SMP.

In FY 2020 ACL developed a request for proposals to award a new expanded Beneficiary Satisfaction Survey contract. This new contract will build on the work completed with the original activities describe above by continuing to gauge satisfaction with the SMP public outreach events and adding a new survey to evaluate beneficiary satisfaction with the one-on-one assistance provided by the SMP grantees. Under this new contract, ACL will receive two national SMP reports annually providing satisfaction results for both the one-on-one assistance and group outreach activities conducted by the program grantees.

National Media Training and Materials

Given the high-profile nature of recent fraud schemes identified by the SMP network, in FY 2020 ACL funded the development and dissemination of detailed training to assist SMP grantees in working with the media. The virtual training developed provided detailed information and tips on using traditional media tools as well as social media to advance program messaging and information. The training also provided a detailed overview for the best ways to communicate and work with the wide array of media outlets available across the country.

ACL also developed two national level promotional videos that provide a clear overview of the

SMP program while also highlighting the standard program messaging to protect Medicare beneficiaries from fraud. These videos will be available for ACL and SMP grantees to use as appropriate in future media activities, trainings, and outreach.

Office of the General Counsel

In FY 2020, HHS allocated the Office of the General Counsel (OGC) \$7.4 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 2020 helped the Government establish over \$1.3 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 2020, OGC worked collaboratively with DOJ and OIG on numerous FCA matters regarding a variety of issues such as: physician self-referral, supplier billing of medically unnecessary laboratory tests, the submission of inaccurate information about health status of MA beneficiaries, failure to report discounted prescription drug prices, misrepresentations under the Medicare Electronic Health Records incentive programs, kickbacks and other unlawful marketing practices in connection with the marketing of an addictive opioid painkiller, and kickbacks related to medically unnecessary stent procedures. OGC efforts on these and other FCA matters in FY 2020 helped the Federal Government recover approximately \$1.2 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' commitment to policing this area.

OGC obtained several favorable outcomes regarding the imposition of CMPs during FY 2020. For example, OGC assisted CMS in obtaining a CMP recovery against a skilled nursing facility for its failure to timely and accurately administer medication to 46 nursing home residents causing harm, including, in some cases, hospitalization of the resident. OGC has also worked with CMS on nursing home enforcement actions involving infection control, including cases associated with COVID-19. OGC has advised CMS on numerous actions related to facilities' responses to the outbreak of infection.

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 2020, OGC defended CMS revocations based on the newly promulgated 42 C.F.R. § 424.535(a)(14), improper prescribing practices. In one case, OGC demonstrated that the revocation was proper because the physician engaged in a pattern or practice of prescribing drugs in a manner that failed to meet Medicare requirements, including by prescribing fentanyl at dangerously high dosages, and in combination with other prescriptions that put patients' lives at risk, to 10 patients who did not have the required indication of pain as a result of a cancer diagnosis to appropriately receive fentanyl.

Part C and Part D Compliance

During FY 2020, 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 were noncompliant or violated program rules. OGC defends CMS' imposition of CMPs in administrative hearings, and, in conjunction with DOJ, in federal court. OGC also continued its review of compliance-related correspondence that CMS issues to Part D sponsors and Part C plans, which include warning letters, imposition of corrective action plan letters, intermediate sanctions, CMP notices, and non-renewal or termination notices.

Regulatory Review and Programmatic Advice

In FY 2020, 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:

- To support CMS' response to the presidential emergency declarations and the HHS Secretary's declaration of a Public Health Emergency to address the COVID-19 pandemic, OGC has provided counsel on a wide variety of topics in the context of Medicare, Medicaid, and CHIP. OGC has advised on issues related to section 1135 waivers, adjustments to permissible sites of care, telehealth rules, Emergency Medical Treatment and Labor Act requirements, survey and certification processes, provider/supplier enrollment, accelerated and advanced payments, debt recovery requirements, adjustments to audits of Medicare Part C and D organizations, improper payment measurement processes, Medicaid third party liability/coordination of benefits and cost avoidance, and waivers of the Stark Law and other fraud and abuse requirements. OGC has provided exceptionally expeditious responses to support the urgent enactment of new statutes and clearance of emergency rules, including three interim final rules with comment period.

- OGC continues to spend extensive time on various opioid-related issues, primarily related to potential CMS monetary recoveries stemming from other parties' settlements, judgments, and bankruptcy actions.
- OGC continues to counsel the CMS Quality, Safety, and Oversight Group (QSOG), formerly known as the Survey & Certification Group, which provides oversight and enforcement of certified institutional providers with program health and safety requirements intended to assure basic levels of quality and safety. OGC advises QSOG regarding the development of enforcement policies, authorities regarding various enforcement remedies such as CMPs and program termination, rulemaking, reviewing interpretive guidance, and administrative litigation issues.
- OGC reviewed several rules designed to improve Medicare program integrity. These included promulgated final rules that: made significant revisions to regulations governing DMEPOS face-to-face, physician order, and prior authorization requirements; established new regulations governing the enrollment of Opioid Treatment Program providers; and created a new prior authorization program for certain outpatient hospital services. OGC also reviewed a Medicare Secondary Payer proposed rule and a proposed rule that would codify and clarify a number of policies pertaining to Rewards and Incentives Programs for Medicare Part C enrollees.
- OGC continues 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, identifying and developing safeguards against fraud and abuse posed by the novel payment and care delivery theories, fraud and abuse waivers, the imposition of corrective action plans, participant screening, and recovery of funds for such models. OGC recently advised the Innovation Center on program integrity considerations in a final rule that will implement two new models.

Physician Self-Referral (Stark Law)

In FY 2020, OGC provided extensive counsel to CMS in its ongoing implementation of the Medicare Physician Self-Referral Disclosure Protocol, which was created to enable Medicare providers to self-disclose technical violations of the Stark law's physician self-referral prohibition. OGC continued to have a significant role in advising CMS on its Stark reform efforts under HHS's Regulatory Sprint to Coordinated Care (Regulatory Sprint), an effort aimed at removing existing regulatory obstacles to coordinated care. OGC has provided extensive assistance on CMS' October 17, 2019 Notice of Proposed Rulemaking (NPRM) that proposed to update and clarify the Stark regulations. The comment period closed in December 2019, and OGC continued to assist CMS with its efforts to draft a final rule, which was published in the last quarter of calendar year 2020. 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

OGC's efforts to recover Medicare's conditional payments for which other payers bear primary payment responsibility 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 2020, 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, supplier, and beneficiary education, use of claim sampling techniques, and rigorous scrutiny of claims with increased medical review. In FY 2020, OGC continued to play a major role in advising CMS regarding the development and implementation of these types of program integrity measures and in defending 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 2020, the United States sued the owners of twelve skilled nursing facilities to preserve collateral for \$169.0 million in Government-backed loans. Once defendants were placed in receivership, OGC negotiated Operations Transfer Agreement and sale order provisions to better protect non-party CMS rights, including CMS' right to assert successor liability.

State Medicaid Disallowances

Over the past several years, upon identifying an increasing number of questionable state financing schemes 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.

As a result of OGC's advocacy, CMS has prevailed in numerous matters in FY 2020 that have upheld millions of dollars in disallowances. For example, OGC successfully moved to dismiss an appeal filed by the Alaska State Medicaid agency against CMS concerning the date of CMS' certification of the State's Medicaid Management Information System.

In summary, OGC's efforts in FY 2020 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, Medicaid, and CHIP programs.

Food and Drug Administration Pharmaceutical Fraud Program

In FY 2020, over \$6 million in HCFAC funding was made available for the FDA Pharmaceutical Fraud Program (PFP). The PFP was instituted to enhance the health care fraud-related activities of FDA's Office of Criminal Investigations (OCI) and the Office of the General Counsel Food and Drug Division (OGC-FDD). OCI, with the support of OGC-FDD, investigates criminal violations of the Federal Food, Drug, and Cosmetic Act (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, 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 297 criminal HCFAC investigations. In FY 2020, OCI, through its PFP, opened 20 criminal investigations, including investigations involving drug compounders, clinical trials, and foreign and domestic medical-product manufacturers.

The investigations opened in FY 2020 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 2020 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 for medical indications and stem cell biologic products.

As noted in previous reports, 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 2019, in the District of Massachusetts, two additional pharmacists of a compounding pharmacy were sentenced, in connection with a nationwide fungal meningitis outbreak that killed more than 100 patients and caused infections in 793 patients. The pharmacists dispensed drugs in bulk without valid prescriptions and with the intent to defraud and mislead state and federal regulators. One defendant was sentenced to one year of probation and the other was sentenced to two years of probation. This investigation was 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 March 2020, in the Eastern District of Tennessee, five defendants were convicted for health care conspiracy, wire fraud, mail fraud, and payment of illegal remuneration, in connection with a scheme involving the marketing of sham prescriptions for compounded topical creams and medications. The scheme involved health care provider signatures for exorbitantly priced topical creams and medications with some prescriptions issued without seeing a physician or others that were not medically necessary. The five defendants were sentenced in July of 2020. The first of these defendants was sentenced to 24 months of incarceration and ordered to pay a money judgment of \$100,000. The second defendant was sentenced to 51 months of incarceration and ordered to pay a money judgment of \$150,000. The third defendant was sentenced to 108 months of incarceration and ordered to pay restitution in the amount of \$2.0 million. The fourth defendant was sentenced to 30 months incarceration and ordered to pay a money judgment of \$135,000. The fifth defendant was sentenced to 165 months of incarceration and ordered to pay restitution in the amount of \$2.0 million.

In April 2020, in the District of New Jersey, a Montvale medical device company agreed as part of a deferred prosecution agreement to pay a \$40.0 million fine and to forfeit \$3.0 million to resolve violations of the FDCA, in connection with the distribution of misbranded medical devices in interstate commerce. The company sold endoscopes without revised FDA-cleared instructions for cleaning during an 18-month period. The company also failed to file timely reports of two adverse events associated with its endoscopes.

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 January 2020, FDA conducted a one-day in-person training session for criminal investigators in the Los Angeles Field Office. This training covered health care fraud control, clinical trial fraud cases, and case studies. Because of the COVID-19 pandemic, FDA moved to a virtual training model to adapt to the needs of its workforce. In August 2020, FDA conducted a one-day virtual training session for newly hired criminal investigators. This training covered health care fraud and PFP-related topics, including case-related fraud schemes.

On another occasion in August 2020, FDA criminal investigators participated in a three-day virtual training program sponsored by the National Health Care Anti-Fraud Association (NHCAA), called "Managing and Navigating Complex Investigations." This training allowed FDA criminal investigators to enhance their skills and strategies for managing complex investigations, analyzing negotiation techniques, and interpreting data.

DEPARTMENT OF JUSTICE

United States Attorneys

In FY 2020, the United States Attorneys were allocated \$62.9 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 and false claims.

Criminal Prosecutions³⁶

In FY 2020, the USAOs opened 1,148 new criminal health care fraud investigations and filed criminal charges in 412 cases involving 679 defendants. During that same time period, 440 defendants were convicted of health care fraud-related crimes.

Civil Matters and Cases³⁷

In FY 2020, the USAOs opened 1,079 new civil health care fraud investigations and had 1,498 civil health care fraud matters pending at the end of the fiscal year.

The USAOs litigate the full spectrum of health care fraud matters, both independently and in partnership with the Civil and Criminal Divisions. USAOs receive many health care fraud referrals directly from investigative agencies and increasingly are developing cases in-house through data analytics. They also receive referrals through the filing of qui tam (or whistleblower) complaints. USAOs coordinate closely both internally, with AUSAs developing parallel cases with their civil or criminal colleagues, and with other USAOs, collaborating on investigations that sprawl across district borders.

Qui tam cases and other civil cases either are handled jointly with trial attorneys in the Civil Fraud Section, or independently. USAOs handle most criminal cases independently, but 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.

³⁶ FY 2020 numbers are actual data through the end of September 2020. This data includes records classified with the primary 03G – Health Care Fraud program code.

³⁷ FY 2020 numbers are actual data through the end of September 2020. This data includes those records classified with the primary FRHC – Health Care Fraud civil code.

Since 2018, the USAOs for ten federal districts in six states³⁸ have joined the Health Care Fraud the FBI, HHS-OIG and DEA, to form the ARPO Strike Force, a joint law enforcement effort 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.

In addition, USAOs partner with the Civil and Criminal Divisions on major initiatives. In FY 2020, as part of the National Nursing Home Initiative, USAOs have opened numerous civil and criminal investigations of nursing homes for gross failure of care. USAOs also take an active part in the nationwide Healthcare Fraud Takedowns.

Since March 2020, USAOs have been actively pursuing pandemic-related fraud, including using civil injunctions to shut down fraudsters hawking phony cures, criminally-prosecuting COVID-19-related scams, investigating failure of care at nursing facilities impacted by COVID-19, and investigating False Claims Act matters alleging fraud on Medicare and Medicaid related to the pandemic or stimulus health care funding.

Examples of successful health care fraud cases are discussed above, but notably include:

- The Medicine Shoppe/Advantage Pharmacy investigations, in which four Districts coordinated a large investigation of compounded drug fraud, resulting in 40 convictions to date;
- A parallel civil and criminal investigation of a pill mill that resulted in five criminal convictions, including both physicians and pharmacists, as well as 12 civil judgments or settlements with pharmacies or pharmacists-in-charge;
- The Practice Fusion EHR case, which resulted in a \$145.0 million payment to resolve criminal and civil liability. The investigation arose from evidence discovered by a USAO and is the first case involving kickbacks paid by a pharmaceutical manufacturer to an EHR company; and
- Several large pharmaceutical pricing cases brought under the FCA and AKS based on allegations of price-fixing and market allocation in the generic pharmaceutical industry.

In addition to funding attorneys, auditors, paralegals and investigators, the Executive Office of the U.S. Attorneys (EOUSA) provides critical litigation support for complex health care fraud investigations and litigation. EOUSA supports data analytics consultants and forensic investigators, which have been indispensable to the USAOs' success in complex cases. FY 2020 also saw the roll-out of EOUSA's Healthcare Fraud Nurse Consulting program, which allows USAOs to obtain medical record reviews and consulting without the need for individual, district-

³⁸ 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, the Southern District of West Virginia, and the Western District of Virginia.

level contracting. EOUSA partners with the Civil Division to provide support for other initiatives, such as nursing home consultants to assist on the Nursing Home Initiative. EOUSA provides other tools to the field, including the Special Investigation Resource and Intelligence System (SIRIS) Resource Center, which gives USAO personnel access to the NHCAA's SIRIS database. In addition to national-level support, EOUSA provides case-specific funding for litigation support for extraordinary needs. In FY 2020, HCFAC money funded more than 150 such requests from USAOs.

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 host working group and/or task force meetings within their districts, attended by federal investigative agencies, state MFCUs, private sector representatives and others. Coordinators also conducted training and outreach to a variety of audiences, including medical and hospital associations, the defense and relators' bar, and Medicare beneficiaries.

EOUSA also organizes extensive training for AUSAs, as well as paralegals, investigators, and auditors on a wide variety of health care fraud enforcement matters. Although some training was canceled due to the pandemic, EOUSA presented numerous webinars during FY 2020 focusing on health care fraud issues.

Civil Division

In FY 2020, the Civil Division received approximately \$39.0 million in FY 2020 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 2020, the Fraud Section and the USAOs won or negotiated more than \$1.8 billion in settlements and judgments under the FCA.

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 VA, and the FEHBP. The Fraud Section works closely with the USAOs 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. The Fraud Section continues to pursue opioid-related fraud schemes, such as the Practice Fusion Inc. (Practice Fusion) matter, which resolved allegations that Practice Fusion, a health information technology developer, accepted kickbacks from a major opioid company and other pharmaceutical companies in exchange for implementing clinical decision support alerts in its EHR software that were designed to increase prescriptions for the drug companies' products, and caused its users to submit false claims for federal incentive payments by misrepresenting the capabilities of its EHR software. In addition, the Practice Fusion matter reflects that complex EHR-related fraud schemes remain a focus of the Fraud Section's work.

The Fraud Section also continues to pursue vigorously pharmaceutical manufacturers who engage in illegal practices that contribute to soaring drug pricing. The Fraud Section has resolved a number of cases, including the Novartis and Gilead 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 AKS, the manufacturers paid money to the foundations 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 Novartis also paid kickbacks to doctors in the form of sham speaker payments, to induce the doctors to prescribe certain Novartis drugs. Other matters relating to AKS violations involved DME (ResMed), hospitals (OCOM and Wheeling Hospital), and laboratories (RenRX and Boston Heart).

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 a psychiatric service provider, laboratories, skilled nursing facilities, and hospitals billed for services that the patients did not need (such as the UHS, Genova, Sanford, Logan Labs, and Longwood matters discussed earlier). In addition, the Fraud Section continues to have a significant focus on other fraud in nursing facilities, which provides care to a particularly vulnerable population (such as the Guardian and Diversicare matters discussed earlier).

Further, the Fraud Section 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 Logan Labs, RenRX, and OCOM 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 coordinates 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-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 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.

In March 2020, the Department launched its National Nursing Home Initiative, which coordinates and enhances civil and criminal efforts to pursue nursing homes that provide grossly substandard care to their residents and focuses on some of the most problematic nursing homes around the country. The National Nursing Home Initiative is coordinated by the Elder Justice Initiative, in conjunction with the USAOs, and reflects the Department's commitment to protecting our nation's seniors.

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 USAOs, state MFCUs, state and local prosecutors' offices, the HHS, state Adult Protective Services agencies, Long-Term Care Ombudsman programs, and law enforcement. The ten districts are the Northern District of California, Northern District of Georgia, District of Kansas, Western District of Kentucky, Northern District of Iowa, District of Maryland, Southern District of Ohio, Eastern District of Pennsylvania, Middle District of Tennessee, and the Western District of Washington.

The Consumer Protection Branch

The Consumer Protection Branch (CPB or the 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 FDA, the 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 USAOs 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 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.

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 successes include achieving a consent decree in the Eastern District of North Carolina with a pharmacy under which the pharmacy and its owner paid a \$600,000 monetary penalty and are prohibited from ever again distributing controlled substances. 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 CPB 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. Not least among these are a substantial series of cases brought against companies purporting to provide fraudulent treatments for COVID-19. For example, in July 2020, Branch attorneys obtained judgment against the “Genesis II Church of Health and Healing,” along with two of the non-religious entity's four principals who were located in the United States. The permanent injunction prohibits the defendants from distributing “Miracle Mineral Solution,” an industrial bleach product the defendants touted as a cure for COVID-19 and a plethora of other serious diseases. As part of the permanent injunction, the district court also ordered refunds to consumers. In another matter, in April 2020, Branch attorneys secured the arrest of a Georgia resident who was attempting to defraud the VA out of millions of dollars of upfront payments in exchange for the purported sale of non-existent ventilators, face masks, and other personal protective equipment. In addition, the Branch, working in conjunction with a number of USAOs, stopped the efforts of a company purporting to sell health and safety items such as hand sanitizer and disinfecting wipes, but which had no intention of fulfilling the orders for which it was paid, and has obtained injunctive relief against numerous entities forcing them to cease the sales of ingestible silver products and other false cures for COVID-19.

In another matter involving misbranded medical products, the Branch obtained a trial verdict ordering Innovative BioDefense, Inc., along with its CEO and distributor, to cease distributing “Zylast” hand sanitizer products until the company removes disease-specific claims from product labeling or obtains FDA approval. In the complaint, the United States alleged that the defendants distributed Zylast products, in violation of the FDCA, as being effective against infection by pathogens such as norovirus, rhinovirus, rotavirus, the flu virus, Methicillin-Resistant Staphylococcus Aureus bacteria and Ebola, despite a lack of proof regarding the products' safety and effectiveness for such uses.

In April 2020, Branch attorneys along with the U.S. Attorney's Office for the District of New Jersey achieved a deferred prosecution agreement with Pentax Medical Company. Pentax was charged in a criminal complaint with failing to file timely reports of two hospital infection outbreaks associated with its duodenoscope and with shipping four other types of endoscopes for 18 months without FDA-approved instructions for use. Under the deferred prosecution agreement, Pentax agreed to pay \$43.0 million in criminal fines and forfeiture for violating the FDCA and, among other actions, to conduct a thorough audit of its current instructions for use for endoscopic devices and medical device reporting procedures to determine their compliance with FDA requirements and report to the FDA in writing.

Response to COVID-19 Pandemic

DOJ's Civil Division has undertaken efforts to protect consumers and federal programs from fraud schemes arising from the COVID-19 pandemic. Within days of the coronavirus being declared a pandemic, DOJ's Consumer Protection Branch began coordinating a multi-agency, multi-component data team to review complaints and leads related to coronavirus consumer fraud. That team of investigators, analysts, and attorneys has reviewed tens of thousands of consumer complaints and thousands of Suspicious Activity Reports, referring information and leads to federal agencies and USAOs. CPB maintains a deconfliction portal for the entire federal government, which has successfully prevented law enforcement from wasting time on competing investigations of the same targets. Along with referring leads, CPB attorneys also work closely with AUSAs to advance ongoing civil and criminal enforcement actions.

CPB attorneys have filed numerous civil injunctive and criminal actions to combat coronavirus fraud schemes. These actions included stopping the sale of a potentially dangerous bleach product touted as a COVID-19 treatment, an injunction against purveyors of a so-called ozone treatment, a successful action against defendants offering a colloidal silver product, a case against a fraudster peddling an herb treatment he claimed would save COVID-19 victims, and the prosecution of a scammer who attempted to defraud the Department of Veterans' Affairs out of hundreds of millions of dollars for nonexistent personal protective equipment (PPE).

CPB is also working closely with the Criminal Division's Computer Crimes and Intellectual Property Section and the FBI to collect information about websites involved in COVID-related fraud, malware, and phishing campaigns. These efforts have disrupted hundreds of internet domains used to exploit the pandemic and cause consumers' health-related harms. CPB also continues to support FDA efforts to issue warning letters to firms offering unapproved purported COVID-19 treatments to the public, and many recipients of such letters have dropped their unlawful campaigns without the need for costly court cases.

In addition, the Civil Division's Commercial Litigation Branch (Fraud Section) is investigating potential FCA violations in connection with fraudulent schemes arising from the COVID-19 pandemic that defraud government programs. This includes investigating whistleblower actions filed under the *qui tam* provisions of the FCA that involve allegations of fraudulent conduct related to the pandemic. In investigating these potential FCA violations, the Fraud Section is closely coordinating with HHS-OIG and CMS. The Fraud Section is also coordinating with non-

federal entities, including state Attorneys General and state MFCUs, regarding potential Medicaid fraud schemes arising from the pandemic.

Criminal Division

In FY 2020, the Criminal Division was allocated \$28.3 million in HCFAC funding to support criminal health care fraud litigation and interagency coordination, which is carried out primarily by the Fraud Section's Health Care Fraud Unit and, to a lesser extent, the Organized Crime and Gang Section.

The Fraud Section

The Fraud Section's Health Care Fraud Unit ("HCF Unit") employs criminal prosecutors who focus exclusively on investigating and prosecuting health care fraud matters and cases involving the illegal prescription, distribution, and diversion of opioids. In sum, the HCF Unit's core mission is to: (1) protect the public fisc from fraud, waste, and abuse; and (2) detect, limit, and deter fraud and illegal prescription, distribution, and diversion offenses resulting in patient harm. The HCF Unit also supports the USAO community by providing legal, investigative and data analytics support, guidance and training on criminal health care fraud and opioid-related 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 Health Care 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 operations in cities including, but not limited to, 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 the NRRSF located in Washington, D.C.

On October 25, 2018, Assistant Attorney General Brian Benczkowski announced the creation of ARPO, a joint effort between DOJ, HHS-OIG, FBI, DEA, and local law enforcement partners to combat health care fraud and the opioid epidemic in nine federal districts. Following the ARPO Takedown on April 17, 2019, ARPO was expanded to include the Western District of Virginia.

As of September 30, 2020, ARPO has charged 84 defendants. These efforts have resulted in 31 guilty pleas and two trial convictions. FY 2021 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.

In FY 2020, the HCF Unit achieved the following results:

- Filed 115 indictments, criminal informations and complaints involving charges against 187 defendants who allegedly collectively billed federal health care programs and private insurers approximately \$3.8 billion;
- Obtained 150 guilty pleas and litigated 15 jury trials, with guilty verdicts against 18 defendants; and
- Securing imprisonment for 98 defendants sentenced, with an average sentence of over 47 months.

Since its inception, Strike Force prosecutors filed more than 2,100 cases charging more than 4,600 defendants who collectively billed federal health care programs and private insurers approximately \$23.0 billion, more than 3,000 defendants pleaded guilty and over 390 others were convicted in jury trials, and more than 2,800 defendants were sentenced to imprisonment for an average term of approximately 50 months. Medicare payment trends demonstrate the positive impact of Strike Force enforcement and prevention efforts. Each year, the HCF Unit coordinates large-scale, law enforcement actions with its partners.

The nature and scope of health care fraud has evolved rapidly over the past few years with the advent of new technologies that have broadened the reach of health care and, consequently, health care fraud. As a result, the Fraud Section recently developed and launched the National Rapid Response Strike Force: a way to respond quickly to multi-jurisdictional health care fraud cases and priorities, without diverting attorneys from district-specific Strike Forces. NRRSF prosecutors, who are based in Washington, D.C. (and, where appropriate, based in certain existing Strike Force locations), are dedicated exclusively to the immediate and decisive response to new and emerging health care fraud trends. Like the other Strike Forces, the NRRSF coordinates with USAOs and federal and state law enforcement partners prosecute these significant multi-jurisdictional and corporate fraud cases. Examples of the types of matters under this Strike Force's purview include a large-scale rural hospitals billing fraud matter indicted in the Middle District of Florida, charges against former NFL players for their alleged roles in a nationwide fraud scheme that targeted a plan that provided tax-free reimbursement of out-of-pocket medical care expenses that were not covered by insurance, the recent sprawling telemedicine cases involving billions of dollars in alleged fraud loss, and prosecutions of those seeking to criminally exploit the COVID-19 pandemic through health care fraud and related financial fraud schemes.

In September 2020, the Criminal Division announced the Sober Homes Initiative, the first coordinated enforcement action in DOJ history focused on fraud schemes in the substance abuse treatment industry. Led by the HCF Unit's National Rapid Response, Los Angeles and Miami Strike Forces, with the participation of the U.S. Attorney's Offices for the Central District of California and the Southern District of Florida, the initiative focuses on schemes intended to exploit patients suffering from addiction. As part of this initiative, more than \$845.0 million in alleged loss connected to substance abuse treatment facilities was charged during the 2020 National Health Care Fraud and Opioid Takedown, including a scheme involving a physician in South Florida who submitted or caused the submission of more than \$746.0 million in alleged

loss to private insurance plans. This scheme lasted almost a decade and is the largest addiction treatment fraud case ever charged by the Department of Justice.

Since 2019, the HCF Unit has led nationwide efforts to combat telemedicine fraud and ensure that needed access to care that is provided by this new technology is not compromised by wrongdoers. In September 2020, the telemedicine component of the 2020 National Health Care Fraud and Opioid Takedown involved more than 80 defendants and more than \$4.0 billion in false and fraudulent claims. The focus on telemedicine fraud was an outgrowth of the 2019 Operation Brace Yourself Takedown, which involved a \$1.2 billion telemedicine and DME scheme. In these schemes, telemedicine executives allegedly paid doctors and nurse practitioners to order unnecessary DME, genetic and other diagnostic testing, and pain medications, either without any patient interaction or with only a brief telephonic conversation with patients they had never met or seen. Often, patients were lured into the scheme by a telemarketing network and the DME, test results, or medications were not provided to the beneficiaries or were unnecessary. Proceeds of the fraudulent schemes were allegedly laundered through shell corporations and foreign banks.

The HCF Unit chairs an interagency COVID-19 fraud working group with federal law enforcement and public health agencies to identify and combat health care fraud trends emerging during the COVID-19 crisis. This has involved coordinating and training other Criminal Division and USAO prosecutors and offering support to their investigations and cases, including data analytics support. The HCF Unit expects that the COVID-19 working group will continue to generate criminal prosecutions in several areas, including COVID-19 test bundling schemes, securities fraud cases involving health care technology companies, and Health Resources and Services Administration (HRSA) fraud cases. In conjunction with this effort, the Fraud Section and the U.S. Attorney's Office for the Northern District of California charged the president of Arrayit Corporation, a publicly traded medical technology company, for his role in causing the submission of false and fraudulent claims to Medicare and other insurers as a result of misrepresentations regarding the existence and performance of a purported revolutionary finger-stick blood test for allergies and COVID-19, and in paying illegal kickbacks to promote such testing.

On November 17, 2020, The Department of Justice announced the expansion of the Criminal Division, Fraud Section's existing Gulf Coast Health Care Fraud Strike Force to include the Eastern District of Texas. In addition to existing resources already allocated in New Orleans and Baton Rouge, Louisiana, and Hattiesburg, Mississippi, the Gulf Coast Strike Force will be made up of prosecutors and data analysts with the HCF Unit, prosecutors with the U.S. Attorney's Offices for the Eastern District of Texas, and special agents with the FBI, HHS-OIG and DEA. The Gulf Coast Strike Force will also work closely with other various federal law enforcement agencies. The Strike Force will focus its efforts on aggressively investigating and prosecuting cases involving fraud, waste, and abuse within our federal health care programs, and cases involving illegal prescribing and distribution of opioids and other dangerous narcotics.

Since 2007, the HCF Unit has deployed data analytics combined with investigative intelligence to great success. In 2018, the HCF Unit formed its own in-house data team, which now consists of eight analysts with deep experience in Medicare and Medicaid data analysis, as well as

financial analysis, who identify egregious health care fraud and prescription opioid-related targets to ensure the HCF Unit and its partners efficiently identify the worst offenders. The concept and structure of the Data Analytics Team is regarded as ground-breaking for the Department. The team uses data to identify billing patterns, suspicious prescribing practices, and curious relationships between doctors and patients that signify high-risk targets. The investigations are then prosecuted by HCF Unit prosecutors or referred to USAOs and law enforcement partners in a “targeting package,” which includes data summaries and descriptions of why a pattern is suspect, such as submission of claims for dead beneficiaries, beneficiaries who live a great distance from the clinic they purportedly regularly attended in person, etc.³⁹ To date, the team has completed approximately 1,712 requests for data analysis assistance from USAOs. During this same time, it has also created hundreds of specific district-by-district targeting packages to help advance the HCF Unit’s mission.

The Organized Crime and Gang Section (OCGS)

The Criminal Division’s Organized Crime and Gang Section (OCGS) supports and conducts investigations of health care fraud and abuse targeting private sector health plans sponsored by employers and/or unions as well as health care fraud and abuse perpetrated by domestic and international organized crime groups. There are more than 2.3 million such private sector health plans which cover some 135 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 RICO statute to combat health care fraud and abuse.

In FY 2020, five OCGS attorneys conducted health care fraud prosecutions and investigations.

In Knoxville, Tennessee, two OCGS attorneys working with the USAO for the Eastern District of Tennessee conducted a three-month trial ending in February 2020 with convictions of a pain clinic co-owner and three nurses for their roles in running “pill mills.” The co-owner was found guilty of RICO conspiracy, a drug conspiracy, money laundering, and maintaining drug-involved premises. The drug conspiracy involved the operation of four clinics which were basically pill mills which distributed over 11 million tablets of oxycodone, oxymorphone, and morphine that generated over \$21.0 million in clinic revenue, with a corresponding street value of \$360.0 million. The three nurses were convicted of maintaining drug involved premises. Sentencing is scheduled for FY 2021. Two part-owners charged with RICO conspiracy remain under indictment. This partnership between OCGS and the Eastern District of Tennessee has resulted in the investigation and prosecution of over 140 individuals. This case was part of the Department's Organized Crime Drug Enforcement Task Force (OCDETF) and the FBI High Intensity Drug Trafficking Area (HIDTA) programs. OCDETF is the primary weapon of the

³⁹ For a medical professional, for example, the targeting package includes: (1) the fraud scheme(s) the individual is likely to be operating, (2) the patients and amount of money involved, (3) additional medical professionals and health care entities tied to the alleged scheme(s), (4) the location of entities involved in the scheme(s), and (5) areas for follow up by the prosecutor/agent team.

United States against the highest-level drug trafficking organizations operating within the United States, importing drugs into the United States, or laundering the proceeds of drug trafficking. 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. The union official was severed for a trial in January 2020 which resulted in a hung jury. The defendants have been rejoined for trial scheduled in FY 2021.

Another OCGS attorney was involved in an investigation of health care fraud, embezzlements and other criminal abuses involving third party administrators to private sector health plans, 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 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 which may exceed \$48 million. The scheme involved the fraudulent sale of the health plan to employers at low cost with false representations that the plan was funded by a loan arrangement that would greatly lower the employers' and employees' taxable income. In November 2019, the marketing director of the MEWA was indicted. The operators of the MEWA, an accountant and the corporation previously pleaded guilty and await sentencing. As part of their guilty pleas, the defendants agreed to forfeit approximately \$6.3 million in assets and pay restitution for the loss.

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 cover 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 2020 the Civil Rights Division was allocated \$8.4 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 residential institutions owned or operated by or for state or local governments, 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 2020 Accomplishments

Key litigation and enforcement accomplishments in FY 2020 of the Civil Rights Division are:

- Number of matters in active enforcement: 14;
- Cumulative estimate of individuals with disabilities affected: 52,990; and

- Number of institutional facilities affected: 2,094.

Special Litigation Section

In fiscal year 2020, the Section's enforcement efforts affected more than 1,400 health care facilities in seven states, and included post-trial remedial efforts involving the unnecessary segregation of people with serious mental illness, the opening of two new investigations, the submission of two statements of interest, and monitoring compliance with six agreements impacting over 25,000 individuals with disabilities.

In *United States v. Mississippi*, 400 F. Supp.3d 546 (S.D. Miss. Sept. 3, 2019), following a successful four-week trial on the merits, the Section continues to enforce the rights of thousands of individuals with serious mental illness who are unnecessarily institutionalized in Mississippi's four State Hospitals. The Section is currently working with the State and a court appointed Special Master on a proposed remedial order to address the ADA violations identified in the Court's September 2019 judgement following trial.

In November of 2019, the Section opened an investigation of Glenwood Resource Center, in Glenwood, Iowa, and Woodward Resource Center, in Woodward Iowa, under CRIPA and the ADA, and is examining whether Iowa engages in a pattern or practice of violating the federal rights of Glenwood residents by subjecting them to: (1) harmful and uncontrolled human subject experiments; (2) inadequate medical and nursing care, physical and nutritional management, and behavioral health care; (3) needless and harmful restraint practices; and (4) incidents causing needless physical injury; and whether Iowa violates the rights of Glenwood and Woodward Resource Centers under the ADA by not providing services to those residents in the most integrated setting appropriate.

In April of 2020, the Section opened an investigation into the Holyoke Soldiers Home in Holyoke, Massachusetts under CRIPA to examine whether the Soldiers Home engages in a pattern or practice of violating the constitutional rights of residents by denying them appropriate medical care generally, and during the coronavirus pandemic in particular.

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

In its existing ADA consent decree with the Commonwealth of Virginia regarding the delivery of community-based services to people with IDD, the Section successfully completed a year-plus long negotiation process to define, in precise, measurable terms, the indicators by which the Commonwealth's compliance with outstanding provisions of the consent decree would be measured.

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.

In its pending litigation with the State of Texas regarding the right to receive community-based services for people with intellectual and developmental disabilities (IDD) housed in Texas nursing facilities, *Steward et al v. Young et al*, 5:10-cv-1025, (W.D. Tex. 2010), the Section awaits a ruling from a trial completed in FY 2019.

Disability Rights Section

In FY 2020, the Disability Rights Section monitored compliance with four settlement agreements, under which more than 16,100 people collectively will obtain relief; issued a letter of findings in one investigation; continued litigation of another case involving unnecessary segregation of people with disabilities; and submitted a statement of interest in pending private litigation.

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, 2020, 3,811 individuals had been diverted or moved from large adult care homes to permanent supported housing since the agreement went into effect in 2012. This total includes 1,963 individuals who 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 1,848 individuals who moved out of adult care homes into the community. Of the 3,811 individuals who have moved into permanent supported housing, 2,550 (or 67 percent) continue to receive services in the community. In addition, 5,412 individuals were receiving assertive community treatment services, and 2,491 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 two settlement agreements with the State of Rhode Island, 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. Thus far, 894 individuals have obtained competitive, integrated employment over the course of these agreements.

The Section, along with the USAO for the Eastern District of New York, continued monitoring a 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. Under 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*. These individuals can choose to live and receive services in the community, enabling them to live, work, and participate fully in community life. To date, more than 900 former adult home residents have transitioned to and received services in the community, and over 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 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 2020, it had reduced the census of segregated sheltered workshop settings to 68 and the total number of hours worked in such settings to 2,123. The State has also reported that through the end of June 2020, it had provided supported employment services and related employment services so that 1,023 individuals receiving sheltered workshop services have newly obtained competitive integrated employment, 4,199 transition-aged youths have received at least one new employment service, and 3,693 of those youths received an Individual Plan for Employment.

The Section awaits a ruling on the State's petition for rehearing filed with the U.S. Court of Appeals for the Eleventh Circuit in *United States v. Florida*. 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. Thereafter, the State petitioned for rehearing. *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.

In February 2020, the Section issued a letter of findings to the State of Maine, after completing an investigation of a complaint and concluding that the State was failing to provide the complainant with necessary services in the most integrated setting appropriate to his needs, placing him at serious risk of unnecessary segregation, and failing to reasonably modify its relevant service program to avoid discrimination.

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 has 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. A multi-year stay of that litigation was lifted in May 2020 and discovery is underway with the State. In another matter, the Section has issued multiple requests for information to the State of Alabama seeking information about the State's practice of placing children from the

foster care system in psychiatric residential treatment facilities based on a need for care spaces, and then providing educational services only at segregated on-site “schools.”

Office of the Inspector General

In FY 2020, the Office of the Inspector General (DOJ-OIG) was allocated \$750,000 in HCFA funding to address health care fraud as it directly impacts DOJ operations. DOJ spends over \$1.0 billion a year to provide health care to inmates of the Federal Bureau of Prisons (BOP) and the U.S. Marshals Service; and expends more than \$115.0 million a year in annual workers’ compensation payments related to disabled and injured DOJ employees and informants. The DOJ-OIG Investigations Division collaborates with the DOJ-OIG Audit Division’s Office of Data Analytics (ODA) to detect and deter fraud, waste and abuse in these contracts and programs. The DOJ-OIG ODA collects, cleans, validates, analyzes, and stores healthcare claims data to identify anomalous billing and prescription patterns and refers investigative leads to the Investigations Division for evaluation of investigative merit.

In FY 2018 and FY 2019, these efforts resulted in 11 cases for the Investigations Division and a Procedural Reform Recommendation (PRR) to BOP, recommending that BOP move toward electronic billing for healthcare claims data at all their facilities. More specifically, the PRR identified BOP’s incomplete and inadequate healthcare claims data and directly resulted in the BOP establishing a claims adjudication contract and a plan to begin collecting electronic claims data from all providers. This contract is expected to be implemented in FY 2021. Consequently, the DOJ-OIG will have more complete data and be able to provide more effective and efficient oversight in FY 2021 and FY 2022 and will likely see a steady increase in healthcare related audits, inspections, and investigations.

During FY 2020, the DOJ-OIG joined two healthcare fraud working groups and continued to collaborate with other federal agencies that investigate healthcare fraud. These efforts have provided opportunities for the DOJ-OIG to collaborate and share ideas with other organizations. Additionally, the DOJ-OIG sought and received additional sets of healthcare claims data directly from BOP comprehensive medical service providers. With each new data set received, the OIG built upon its comprehensive BOP healthcare data bank, ensuring the ability to use historical data as the foundation for predictive analytics efforts.

During this period, the DOJ-OIG established and continued to receive U.S. Department of Labor workers’ compensation claims data. This data was used to identify potentially fraudulent billing patterns by providers as well as anomalous prescription drug claims and will also serve as historical data as the DOJ-OIG builds its predictive analytics abilities. The analysis of the Department’s workers’ compensation data resulted in the initiation of multiple investigations.

In FY 2020, the DOJ-OIG initiated four additional investigations related to fraudulent activity in DOJ healthcare programs and contracts and facilitated a settlement of \$130,000 from a provider that overbilled the BOP for psychiatric visits. Since receiving initial funding, the DOJ-OIG has opened a total of 24 investigations related to DOJ healthcare-related activities and programs.

APPENDIX

Federal Bureau of Investigation

In FY 2020, the FBI was allocated \$145.1 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 826 positions (499 Agent, 327 Support). In addition, the FBI received \$7.7 million of the DOJ HCFAC funding.

In FY 2020, the FBI initiated 683 new Health Care Fraud (HCF) investigations and had 2,346 pending investigations. Investigative efforts produced 426 criminal HCF convictions and 537 indictments and prosecutor's informations. In addition, investigative efforts resulted in over 407 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 101 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 its collaboration efforts, the FBI maintains investigative and intelligence sharing partnerships with government agencies such as other DOJ components, HHS-OIG, state MFCUs, and other enforcement and regulatory agencies. The FBI conducts significant information sharing and coordination efforts with private insurance partners, such as the NHCAA, the National Insurance Crime Bureau, and private insurance investigative units. The FBI is also actively involved in the HFPP, an effort to exchange facts and information between the public and private sectors in order to reduce the prevalence of HCF.

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

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

The FBI's Health Care Fraud Unit (HCFU) oversees program efforts, including providing guidance to 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 five national initiatives, including the Health Care Fraud Task Force and Working Group Initiative, Prescription Drug Initiative, Large Scale Conspiracies Initiative, Major Provider Fraud Initiative, and the COVID-19 Anti-Fraud Initiative.

The Health Care Fraud Task Force and Working Group Initiative was established to encourage the formation of Joint Health Care Fraud Task Forces and Working Groups. Joint Task Forces and Working Groups combine Federal, state, and local law enforcement and regulatory resources to address Health Care Fraud. Task forces serve as a force multiplier for FBI efforts by bringing the experience, expertise, and resources of our Federal, state, local, and tribal partners to bear to mitigate the HCF threat. Task forces and working groups result in improved sharing of threat-related intelligence among participating agencies and expand criminal and civil tools for participants to use to identify and disrupt criminal activity. Task force participants and their employing agencies will also benefit from increased access to FBI training and equitable sharing arrangements. FBI Field offices are encouraged to partner with DOJ, HHS-OIG, State Attorneys General and MFCUs, CMS, and local and state police, where appropriate, when forming TFs and WGs.

At a national level, the FBI participates in a HEAT effort. As noted on pp. 11-12, the HEAT is comprised of top-level law enforcement agents, prosecutors, attorneys, auditors, evaluators, as well as staff from DOJ, FBI and HHS, and is dedicated to facilitating 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. The FBI coordinates with the DOJ and HHS-OIG on funding, resource allocation, Strike Force expansion, target identification, training, and operations. The FBI supports DOJ HCF Strike Forces located in Florida (Miami, Tampa, Orlando), Los Angeles, Texas (Houston, Dallas, McAllen/Rio Grande), the Gulf Coast (New Orleans, Baton Rouge, and Southern Mississippi), Detroit, Brooklyn (NYC), Chicago, Newark, Philadelphia, ARPO North (Kentucky, Ohio, Virginia, and West Virginia), ARPO South (Tennessee and Northern Alabama), and Washington DC (National Rapid Response Strike Force). In addition to funding agent resources, the FBI funds undercover operation expenses, financial and investigative analysis support, offsite TF 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 FY 2020, the FBI participated in a DOJ national HCF takedown charging 80 subjects, including 56 doctors, nurses, and other licensed medical professionals, for their alleged participation in HCF schemes involving approximately \$1.8 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, Prescription Drug, and COVID-19 Anti-Fraud Initiatives.

As part of the DOJ ARPO Strike Force initiative to address the illegal diversion of prescription opioids in the Appalachian Region, DOJ provided additional funding to the FBI to support the deployment of Special Agents dedicated to identifying and investigating individuals, including medical professionals, who divert prescription opioids, and thus contribute to the nation's opioid epidemic. The ARPO Strike Force operates in Cincinnati, Louisville, Pittsburgh, Knoxville, Memphis, and Birmingham. In one case led by the ARPO SF in Birmingham, a physician was sentenced to 30 years in prison and ordered to forfeit approximately \$3.5 million in ill-gotten gains, for running a "pill mill" operation out of his medical clinic and for billing more than \$7.8 million over a two-and-a-half year period to Medicare and private health insurers in connection with an allergy fraud scheme.

The Prescription Drug Initiative (PDI) 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. An example is a case from the Buffalo Field Office where a physician was convicted for prescribing opioids outside the normal practice of medicine and in violation of the Controlled Substances Act. Between 2007 and 2014, this physician's practice issued more prescriptions for controlled substances annually than any other prescriber, or prescribing entity, in New York State, including hospitals. In a four-year period, this physician wrote 70,000 opioid prescriptions which resulted in seven million dosage units and six patient deaths as a direct result of his overprescribing of opioids. The FBI coordinated efforts in this case with HHS-OIG and DEA. 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. In FY 2020, the FBI opened 94 new PDI related investigations, had 397 pending investigations and obtained 146 indictments and informations, 127 arrests, 83 convictions, \$9.9 million in seizures, and \$1.6 million in forfeitures.

The Large Scale Conspiracies Initiative seeks to identify and target criminal enterprises and other groups whose schemes result in significant losses to government health care benefit programs and private health insurance plans. include the sharing and selling of beneficiaries' identifying information and multi-tiered kickback schemes involving fraudulent referral and billing for medically unnecessary services or services never provided. 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 a case worked

under this initiative is a nationwide investigation led by the FBI involving over \$480 million in fraudulent claims for genetic testing, orthotic braces, pain creams, and other items. In addition, some of the subjects conspired to pay kickbacks to medical providers, like physicians and nurse practitioners, in exchange for obtaining orders for DME that were then sold to DME providers and, ultimately, billed to Medicare. To date over 15 subjects have been charged including physicians, nurse practitioners, operators of telemedicine companies, brokers of patient data, and owners of DME companies. This is a joint investigation with HHS-OIG, DEA, US Secret Service, and US Postal Service.

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 Novartis Pharmaceuticals Corp. Novartis provided doctors with cash payments, recreational outings, lavish meals, and expensive alcohol to induce them to prescribe Novartis cardiovascular and diabetes drugs reimbursed by federal healthcare programs. The case resulted in a \$678.0 million settlement of civil investigations for violating the FCA and the AKS.

In FY 2020, the FBI developed the COVID-19 Anti-Fraud Initiative because of the COVID-19 pandemic. This initiative seeks to identify and target medical providers engaging in health care-related fraud linked to COVID-19 treatments such as overbilling, price gouging, billing for services not rendered, up-coding services, billing for medically unnecessary services, medical identity theft, etc. An example of these type of cases is an investigation from the Newark Field Office into a subject who willfully hoarded designated scarce materials. Newark worked with the USAO and the DOJ Hoarding and Price Gouging Task Force to successfully seize 11.2 masks. The subject was given a deferred prosecution agreement and all masks were resold to the public at a price established by DOJ.

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 2020, more than 500 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.

COVID-19 Fraud Schemes:

The FBI and its law enforcement partners have identified multiple health care fraud schemes by bad actors seeking to take advantage of the currently overburdened health care system and the public's fear over the COVID-19 pandemic. These fraud schemes target both government and private health insurers as well as private individuals to commit traditional health care fraud schemes such as overbilling, upcoding, unbundling of services, and billing for services not provided and/or which were not medically necessary. Some of the more prevalent health care fraud-related schemes identified as of April 2020 are as follows:

- Fraud actors are engaging in schemes to obtain and exploit individuals' identity information, including their insurance information (PII), and PHI. The FBI has identified fraud schemes involving robo-callers who promote or offer "free" test kits, fake cures or drugs that allegedly offer protection against COVID-19, in exchange for PII or cash.
- Fraudsters are also obtaining information and identifying potentially vulnerable targets from social media posts where someone discusses symptoms, health status or frustrations over treatment and testing. Fraudsters use this information to obtain PPI and PHI that is later used in fraudulent billing schemes or selling medically unnecessary and fake cures or protection from the virus to the unsuspecting and vulnerable public.
- The FBI has identified threat actors perpetrating numerous health care fraud schemes through the use of telemedicine platforms. Compounded medicine schemes, genetic testing schemes, and DME-related schemes have all been perpetrated through telemedicine. In light of the current COVID-19 pandemic, providers increasingly are moving toward remote visits and health plans accordingly are adjusting their policies to expand telemedicine coverage. While these expansions are necessary, they may also open the door to an increase in fraud through telemedicine platforms. Calls and home visits offering telemedicine consultations for COVID-19 are also on the rise, with bad actors soliciting insurance information, most notably Medicare ID numbers and/or other PPI like driver license information.
- Health care providers have also been paying kickbacks to marketers (recruiters) in exchange for patient referrals, services such as promoting/selling fake COVID-19 test kits, supplies and equipment, and for signing/forging prescriptions that are medically unnecessary/outside the normal bounds of medical practice.
- The FBI has also noted scammers creating fake shops, websites, social media accounts, and email addresses claiming to sell medical supplies currently in high demand and in short supply such as N-95 respirator masks, gloves, and other PPE. In these scams, suppliers solicit money up front, pocketing the money without providing the supplies.
- There has been an uptick in prescribing of hydroxychloroquine, an anti-malaria drug being touted as a potential cure for COVID-19. The FBI is aware some physicians are prescribing hydroxychloroquine for themselves and their families without medical

necessity. This has resulted in short supplies with adverse consequences for those who need the drug for lupus, rheumatoid arthritis and other chronic conditions.

Joint COVID-19 Fraud Mitigation Strategy

The FBI has taken a number of steps to work across the Department, with HHS-OIG, CMS, and other HCF partners to mitigate COVID-19 frauds. These include:

- Establishing a HCF Program COVID-19 Anti-Fraud National Initiative to encourage addressing it. The FBI has been actively involved in a weekly coordination/deconfliction meetings with DOJ Fraud Section Trial Attorneys, CMS, HHS-OIG, FDA and at least 12 other federal agencies where emerging threats and new cases were shared with everyone involved.
- Establishing a HCF Virtual Command Center (VCC) to maintain COVID-19-related FBI HCF cases, HHS-OIG cases, DCIS cases, and other civil and regulatory matters in order to deconflict enforcement activity. These cases have been briefed during the weekly DOJ Fraud Section coordination/deconfliction calls as well as communicated to the respective USAOs.
- Work with CMS and HHS-OIG to conduct Data Analytics critical in identifying HCF, to drive the opening of HCF investigations with DOJ and the USAOs.
- Disseminate a Monthly Rolling Schemes Information Sheet produced by the FBI and HHS-OIG and distributed to other Agencies and DOJ to ensure proper awareness of the latest intelligence and threat information.

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 119).
- 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 seven 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 2020, 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 provided for informational purposes only. 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 Resources⁴⁰	Fiscal Year 2020
Office of Inspector General	\$205,326,186
Health and Human Services Wedge ⁴¹	39,271,090
Medicare Integrity Program ⁴²	923,527,095
<i>MIP/Medicare (non-add)</i>	<i>852,486,550</i>
<i>Medi-Medi (non-add)</i>	<i>71,040,545</i>
Department of Justice Wedge ⁴¹	64,108,488
Federal Bureau of Investigation ⁴³	145,129,768
Subtotal, Mandatory HCFAC	\$1,377,362,627
Discretionary Resources	
Office of Inspector General	\$93,000,000
CMS Program Integrity	610,000,000
<i>CMS Program Integrity (non-add)</i>	<i>592,000,000</i>
<i>Senior Medicare Patrols (ACL non-add)</i>	<i>18,000,000</i>
Department of Justice	83,000,000
Subtotal, Discretionary HCFAC	786,000,000
Grand Total, HCFAC	\$2,163,362,627

⁴⁰ All mandatory resources are post-sequester and reflect Section 3709 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Public Law 116-136) temporary suspension of Medicare sequestration from May 1, 2020 until December 31, 2020; the Consolidated Appropriations Act, 2021 (Public Law 116-260), which extended this suspension to March 31, 2021; and the extension of the Medicare sequester moratorium until December 31, 2021 that was signed by President Joe Biden in April 2021. This sequester adjustment has resulted in additional funding for the HCFAC program. Funding sequestered reflects sequester suspension from May 1, 2020 to September 30, 2020.

⁴¹ 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.

⁴² 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 these activities.

⁴³ 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.

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

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

HEAT—Health Care Fraud Prevention & Enforcement Action Team

HFPP—Health care Fraud Prevention Partnership

HHA—Home Health Agency

HHS—The Department of Health and Human Services

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

HI—Hospital Insurance Trust Fund

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

MA – Medicare Advantage

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