U.S. Department of Justice
Office of the Attorney General

U.S. Department of Health and Human Services
Office of the Secretary

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

Health Care Fraud and Abuse Control Program FY 2022

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

Health Care Fraud and Abuse Control Program
Annual Report for Fiscal Year 2022

November 2023

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GENERAL NOTE

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

EXECUTIVE SUMMARY

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a national Health Care Fraud and Abuse Control Program (HCFAC or the Program) under the joint direction of the Attorney General and the Secretary of the Department of Health and Human Services (HHS),[1] acting through the Inspector General, designed to coordinate Federal, state, and local law enforcement activities with respect to health care fraud and abuse. In its 26th year of operation, the Program's continued success confirms the soundness of a collaborative approach to identifying and prosecuting the most egregious instances of health care fraud, preventing future fraud and abuse, and protecting program beneficiaries.

During Fiscal Year (FY) 2022 civil health care fraud settlements and judgments under the False Claims Act exceeded $1.6 billion,[2] in addition to other health care administrative impositions won or negotiated by the Federal Government. Because of these efforts, as well as those of preceding years, more than $1.7 billion was returned to the Federal Government or paid to private persons in FY 2022. Of this $1.7 billion, the Medicare Trust Funds[3] received transfers of more than $1.2 billion during this period, in addition to over $126.1 million in Federal Medicaid money that was transferred separately to the Centers for Medicare & Medicaid Services (CMS).

Enforcement Actions

In FY 2022, the Department of Justice (DOJ) opened more than 809 new criminal health care fraud investigations. Federal prosecutors filed criminal charges in over 419 cases involving at least 680 defendants. More than 477 defendants were convicted of health care fraud related crimes during the year. Also, in FY 2022, DOJ opened more than 774 new civil health care fraud investigations and had over 1,288 civil health care fraud matters pending at the end of the fiscal year. Federal Bureau of Investigation (FBI) investigative efforts resulted in over 499 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 132 health care fraud criminal enterprises.

In FY 2022, investigations conducted by HHS's Office of Inspector General (HHS-OIG) resulted in 661 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid, and 726 civil actions, which include false claims, unjust-enrichment lawsuits filed in Federal district court, and civil monetary penalty (CMP) settlements. HHS-OIG excluded 2,332 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 (983) or to other health care programs (433), for beneficiary abuse or neglect (305), and as a result of state health care licensure revocations (372).

[1] Hereafter, referred to as the Secretary.

[2] The amount reported only reflects the Federal settlements and judgments and therefore does not reflect state Medicaid monies won or negotiated as part of any global Federal state settlements. As in prior years, the reported settlements and judgments include matters the United States pursued, as well as matters pursued by relators/whistleblowers under the qui tam provisions of the False Claims Act.

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

Sequestration Impact

Sequestration of mandatory funding generally results in DOJ, FBI, HHS, and HHS-OIG having fewer resources to fight fraud and abuse of Medicare, Medicaid, and other health care programs. Due to partial sequester suspension in FY 2022, no funds were sequestered from the HCFAC program from October 1, 2021, to March 31, 2022.[4] However, a combined total of $160.1 million in mandatory funds have been sequestered in the past ten years. Including funds sequestered from the FBI ($74.5 million in the past ten years), $234.6 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; the Medicare sequester moratorium included in P.L. 117-7 extended the suspension again until December 31, 2021; and the Protecting Medicare and American Farmers from Sequester Cuts Act (P.L. 117-71) extended the suspension for the last time through March 31, 2022. This sequester adjustment was meant to provide an economic boost to Medicare providers treating patients during the COVID-19 public health emergency and has resulted in additional funding for the HCFAC program. The four bills overlapped to cover the entirety of FY 2021 and half of FY 2022.

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 FY 2022 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 (Public Law (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 2022, the Secretary and the Attorney General certified $322.7 million in mandatory funding to the Account. (This reflects sequester suspension per footnote four.) Additionally, Congress appropriated $873.0 million in discretionary funding. A detailed breakdown of the allocation of these funds is set forth later in this report. HCFAC appropriations generally supplement the direct appropriations of HHS that are devoted to health care fraud enforcement and have supported over three-fourths of DOJ's health care fraud funding and over three-fourths of HHS-OIG's appropriated budget in FY 2022. (Separately, the FBI, which is discussed in the Appendix, received $152.9 million from HIPAA, including sequester suspension). 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.117-103, Consolidated Appropriations Act, 2022) 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

Monetary Results

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 2022, more than $1.7 billion was deposited with the Department of the Treasury (Treasury) and CMS, transferred to other Federal agencies administering health care programs, or paid to private persons during the fiscal year. Monetary results from these transfers and deposits are provided in the table below:

Monetary Results: Total Transfers / Deposits by Recipient FY 2022	
Department of the Treasury	
Deposits to the Medicare Trust Fund, as required by HIPAA:	
Gifts and Bequests	$33
Amount Equal to Criminal Fines	8,551,075
Civil Monetary Penalties	23,911,906
Asset Forfeiture	138,948,411
Penalties and Multiple Damages	432,136,798
Subtotal	**$603,548,221**
Centers for Medicare & Medicaid Services	
HHS/OIG Audit Disallowances: Recovered–Medicare	230,981,050
Restitution/Compensatory Damages*	399,662,832
Subtotal	**$1,234,192,102**
Total Transferred to the Medicare Trust Funds	
Restitution/Compensatory Damages to Federal Agencies	
TRICARE	$26,155,403
HHS/CMS	20,643,435
Department of Labor	11,695,536
Department of Veterans Affairs	8,235,502
U.S. Postal Service	7,511,402
Other Agencies	27,135,093
Subtotal	**$101,376,370**
Centers for Medicare & Medicaid Services	
Federal Share of Medicaid	126,100,863
HHS/OIG Audit Disallowances: Recovered–Medicaid	92,842,480
Subtotal	**$218,943,343**
Total	**$320,319,713**
Relators' Payments**	**$170,457,876**
GRAND TOTAL MONETARY RESULTS***	**$1,724,969,691**

*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 26th year of operation, the Secretary and the Attorney General certified $322.7 million in mandatory funding as necessary for the Program, after accounting for mandatory sequester suspension as required by P.L. 116-136, P.L. 116-260, P.L. 117-7, and P.L. 117-71. In addition, Congress appropriated $873.0 million in discretionary funding. Allocation by recipient is below:

FY 2022 ALLOCATION OF HCFAC APPROPRIATION				
	Mandatory Allocation[6]	**Discretionary Allocation**	**Funds Sequestered[7]**	**Total Allocation**
Department of Health and Human Services				
Office of the Inspector General	$234,829,612	$102,145,000	($6,314,180)	$330,660,432
Office of the General Counsel	7,717,000	0	0	7,717,000
Administration for Community Living	2,000,000	30,000,000	0	32,000,000
Food and Drug Administration	11,855,000	0	0	11,855,000
Centers for Medicare & Medicaid Services	0	628,648,000	0	628,648,000
Assistant Secretary for Planning and Evaluation	5,000,000	0	0	5,000,000
Unallocated Funding	1,801,595	0	(1,207,663)	593,932
Subtotal	**$263,203,207**	**$760,793,000**	**($7,521,843)**	**$1,016,474,364**
Department of Justice				
United States Attorneys	$32,423,135	$40,762,075	$0	$73,185,210
Civil Division	17,248,860	32,326,123	0	49,574,983
Criminal Division	13,674,307	25,664,305	0	39,338,612
Civil Rights Division	3,535,304	5,365,714	0	8,901,018
Justice Management Division	132,000	0	0	132,000
Federal Bureau of Investigation	0	7,144,840	0	7,144,840
Office of the Inspector General	0	943,943	0	943,943
Unallocated Funding	1,971,461	0	(1,971,461)	0
Subtotal	**$68,985,067**	**$112,207,000**	**(1,971,461)**	**$179,220,606**
TOTAL	**$332,188,274**	**$873,000,000**	**($9,493,304)**	**$1,195,694,970**

Overall Settlements, Judgments, and Recoveries

During FY 2022, civil health care fraud settlements and judgments under the False Claims Act exceeded $1.6 billion, and the Federal Government attained additional administrative

[6] As of FY 2007, mandatory funds are available until expended. Discretionary funds are available for two years.
[7] The sequester amounts reflect P.L. 117-71 sequester suspension from October 1, 2021, to March 31, 2022.

impositions in health care fraud cases and proceedings.[8] Because of these efforts, as well as those of preceding years, more than $1.7 billion was returned to the Federal Government or private persons. Of this $1.7 billion, the Medicare Trust Funds received transfers of over $1.2 billion during this period; approximately $126.1 million in Federal Medicaid money was transferred to the CMS separately.[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 (2020–2022) is $2.90 returned for every $1.00 expended. The ROI has been adversely impacted by the COVID-19 pandemic. Unique factors associated with the pandemic, such as court closures, interrupted or slowed criminal and civil enforcement and other HCFAC activities. Consequently, recoveries, disallowances, and restitutions covered by this reporting period are lower compared to recent years. 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. Civil and criminal enforcement that stops ongoing fraud saves the Program from future losses. Even actions that do not result in recoveries, for example, a search warrant, an indictment, or an arrest, may prevent 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 deters 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 prescription opioid distribution and diversion schemes. 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

[8] The amount reported only reflects the Federal settlements and judgments and therefore does not reflect state Medicaid monies won or negotiated as part of any global Federal-state settlement. As in prior years, the reported settlements and judgments include matters the United States pursued, as well as matters pursued by relators/whistleblowers under the qui tam provisions of the False Claims Act.

[9] Note that some of the judgments, settlements, and administrative actions that occurred in FY 2022 will result in transfers in future years, just as some of the transfers in FY 2022 are attributable to actions from prior years.

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. First established in March 2007, Strike Force teams currently operate in 27 districts across the United States, including, but not limited to: Los Angeles, California; Miami and Tampa and Orlando, Florida; Chicago, Illinois; Ft. Mitchell, Kentucky; Baton Rouge and New Orleans, Louisiana; Detroit, Michigan; Concord, New Hampshire; Brooklyn, New York; Newark, New Jersey and Philadelphia, Pennsylvania; Nashville, Tennessee; and Houston, San Antonio, Dallas, and the Rio Grande Valley, Texas; along with the National Rapid Response Strike Force (NRRSF) located in Washington, D.C.

The NRRSF was established in September 2020, as 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. It is comprised of dedicated prosecutors who target large-scale and multi-jurisdictional schemes occurring across the country. Since its creation, the NRRSF has organized and led several of the Health Care Fraud Unit's (HCF Unit) nationwide initiatives involving billions of dollars of fraud and pressing national priorities, including leading the Department's nationwide enforcement actions involving telemedicine, sober homes, and COVID-19. Examples of the types of cases prosecuted by NRRSF include the recent conviction at trial of the President of a Silicon Valley technology company who claimed to have invented revolutionary technology to detect allergies and COVID-19 using a single drop of blood; trial conviction of two defendants in a $1.4 billion rural hospitals fraud matter in the Middle District of Florida (one of the largest health care fraud cases ever charged); convictions in three separate trials (between December 2021 and June 2022) of sober homes operators and doctors who were responsible for hundreds of millions in loss; the prosecution of telemedicine company executives and medical professionals in 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.

The NRRSF also has led the Department's efforts to combat health care fraud arising from the COVID-19 pandemic. The NRRSF leads the COVID-19 Health Care Fraud Working Group, which is chaired by the Criminal Division's Fraud Section, HCF Unit, and comprised of leadership from over 10 key government agencies, including Food and Drug Administration (FDA), HHS, CMS, the Small Business Administration (SBA), the Department of Veterans Affairs (VA), FBI, the Drug Enforcement Administration (DEA), and Homeland Security Investigations (HSI), among others. The purpose of the Working Group is to identify, investigate, and prosecute COVID-19 health care fraud schemes, and enable coordination, deconfliction, and efficient staffing of COVID-19 health care fraud investigations. Since the beginning of the pandemic, the Strike Force has charged 45 defendants with over $340.0 million in COVID-19 fraud. This includes cases charged in two COVID-19 Health Care Fraud Enforcement Actions in 2021 and 2022.

The NRRSF and its team members (prior to NRRSF's creation) also have led nationwide efforts to combat fraud committed using or exploiting telemedicine (the use of telecommunications technology to provide health care services remotely) and ensure that needed access to care supported by this technology is not compromised by wrongdoers. In the past three and a half

years, the HCF Unit has charged over $10.0 billion in fraud committed using or exploiting telemedicine, including the following major nationwide enforcement actions: 2019's Operation Brace Yourself, 2019's Operation Double Helix, 2020's Operation Rubber Stamp, the telemedicine component of the 2021 National Health Care Fraud Enforcement Action, and the 2022 Telemedicine, Clinical Laboratories, and Durable Medical Equipment Enforcement Action. The deterrent impact of these actions has saved the pubic fisc substantial amounts of money. Specifically, the Operation Brace Yourself Telemedicine and Durable Medical Equipment Takedown alone resulted in a savings of more than $1.9 billion in the amount paid by Medicare for orthotic braces in the 20 months following that enforcement action.

Each Strike Force team brings the investigative and analytic resources of the FBI, HHS-OIG, the CMS Center for Program Integrity (CMS-CPI), the Defense Criminal Investigative Service (DCIS), the Federal Deposit Insurance Corporation Office of the Inspector General (FDIC-OIG), the Internal Revenue Service (IRS), and other agencies, together with the prosecutorial resources of the Criminal Division's Fraud Section and the U.S. Attorneys' Offices (USAOs) to bring cases in Federal district court. During FY 2022, Strike Force accomplishments in the areas noted above, as well as USAO accomplishments included:[10]

- Filing 266 indictments, criminal informations and complaints[11] involving charges against 392 defendants who allegedly collectively billed Federal health care programs and private insurers approximately $2.2 billion [12]
- Obtaining 395 guilty pleas and litigating 42 jury trials, with guilty verdicts against 48 defendants; and
- Securing imprisonment for 323 defendants sentenced, with an average sentence of over 53 months.

Since its inception, Strike Force prosecutors and USAOs in Strike Force districts filed more than 2,700 cases charging more than 5,400 defendants who collectively billed Federal health care programs and private insurers approximately $27.0 billion, more than 3,700 defendants pled guilty and over 460 others were convicted in jury trials,[13] and more than 3,300 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.

During FY 2022, the Strike Force coordinated three separate enforcement actions, in collaboration with USAOs, HHS-OIG, FBI, the DEA, and other Federal and state partners. On April 20, 2022, and on May 4, 2022, Assistant Attorney General Kenneth A. Polite Jr. announced the 2022 COVID-19 Health Care Fraud and Opioid Enforcement Actions, respectively. In the 2022 COVID-19 Enforcement Action, criminal charges were brought

[10] The summary statistics in this document exclude sealed cases.
[11] This number does not include complaints filed by USAOs.
[12] This alleged loss amount figure only reflects the amounts of alleged loss in cases handled by the Criminal Division, Fraud Section.
[13] These numbers do not include guilty pleas and verdicts obtained by USAOs where the defendant had not been sentenced before the end of FY 2022.

against 21 defendants, in nine Federal districts across the United States, for their alleged participation in various health care related fraud schemes that exploited the COVID-19 pandemic. These cases allegedly resulted in over $149.0 million in COVID-19-related false billings to Federal programs and theft from Federally funded pandemic assistance programs. In connection with the enforcement action, the department seized over $8.0 million in cash and other fraud proceeds. CMS-CPI separately took adverse administrative action against 28 providers for their alleged involvement in fraud, waste, and abuse schemes related to the delivery of care for COVID-19, as well as schemes that capitalize upon the public health emergency. In the 2022 Opioid Enforcement Action, criminal charges were brought against 14 defendants, 12 of which were medical professionals, in eight Federal districts across the United States, for their alleged involvement in crimes related to the unlawful distribution of opioids. Additionally, CMS-CPI took adverse administrative action against six providers for their alleged involvement in these offenses. Finally, the Criminal Division announced the 2022 Telemedicine, Clinical Laboratory, and Durable Medical Enforcement Action on July 20, 2022, wherein criminal charges were brought against 36 defendants, in 13 Federal districts across the United States, for more than $1.2 billion in alleged schemes that involved fraud committed using or exploiting telemedicine, cardiovascular and cancer genetic testing, and durable medical equipment. Additionally, CMS-CPI took adverse administrative action against 52 providers involved in similar schemes. In connection with the enforcement action, the department seized over $8.0 million in cash, as well as luxury vehicles and other fraud proceeds.

In October 2018, the Criminal Division announced the formation of the Appalachian Regional Prescription Opioid (ARPO) Strike Force, a joint effort between DOJ, FBI, HHS-OIG, DEA, and state and local law enforcement to combat health care fraud and the opioid epidemic in parts of the country that have been particularly harmed by addiction. Since its inception, the ARPO Strike Forces (North and South) have charged 115 defendants with crimes related to the unlawful distribution of prescription opioids. Together, these defendants issued prescriptions for over 115 million controlled substance pills. Sixteen defendants were charged in FY 2022, including 14 medical professionals. As of September 2022, 62 of the ARPO defendants have entered guilty pleas, with more pleas scheduled. Eight additional defendants have been convicted at trial, including five trial convictions, and sixteen ARPO defendants were sentenced in FY 2022.

Opioid Fraud and Abuse Detection Unit

The Opioid Fraud and Abuse Detection Unit (OFAD) AUSA program focuses specifically on opioid-related health care fraud using data to identify and prosecute individuals that are contributing to the prescription opioid epidemic. In FY 2022, OFAD AUSAs handled a variety of investigations and prosecutions involving medical professionals. OFAD attorneys filed 42 cases, against 72 defendants, alleging various charges including health care fraud, drug trafficking, and money laundering. For example, on September 12, 2022, a Michigan doctor who attempted to flee to Mexico was sentenced to four years in prison for unlawfully selling 12,500 opioid pills. The doctor pleaded guilty to conspiring with patient recruiters and others to distribute prescription opioid pills in violation of his medical and DEA licenses. He unlawfully prescribed 12,500 hydrocodone pills without regard to medical necessity and outside the course

of professional medical practice. In another matter, on January 21, 2022, a former Tennessee clinic owner was sentenced to 168 months in prison for unlawfully distributing opioids. The clinic owner was found guilty of six counts of unlawfully distributing controlled substances and one count of maintaining a drug-involved premises. Evidence presented at the trial showed that he unlawfully prescribed approximately 15,000 opioid pills to three women with whom he had sexual relationships. He also prescribed pills to a male patient who later passed away.[14]

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. The 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 HEAT mission 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/or 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 Medicaid Fraud Control Units (MFCUs), which play a critical role in the many fraud cases involving both Medicare and Medicaid. For example, MFCUs participated in 10 cases during the FY 2022 enforcement actions.

[14] This case was handled in conjunction with ARPO, led by the Department of Justice's Criminal Division.

The 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 communities of older adults 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.

Healthcare 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 267 public, private, and state partner organizations at the end of FY 2022. Seventy-five of the current partners are actively submitting claim level data.

The HFPP commenced or completed studies using multiple partners' data to address fraud, waste, and abuse in FY 2022, 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 virtual information-sharing sessions (due to the Public Health Emergency). These meetings are 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. In addition, the HFPP held focus groups to ascertain from Partners their thoughts on the strategic direction of the Partnership. See the CMS HFPP section for more information on HFPP activities.

COVID-19 Pandemic-Related Enforcement

Since the start of the COVID-19 Public Health Emergency (PHE) in March 2020, CMS has examined how the PHE—and more specifically, the waivers and flexibilities offered by the

Agency—may create new fraud risks in Federal health programs. CMS has developed a robust fraud risk assessment process, using principles outlined in the Government Accountability Office (GAO) Fraud Risk Management Framework, 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, targeted investigations, development of Fraud Prevention System (FPS) models and edits, and implementation of new policies. CMS, DOJ, HHS-OIG, and other law enforcement agency partners are working together to investigate and prosecute frauds from identified risks and related schemes. Examples of potential risks and vulnerabilities include:

- Additional, unnecessary services: Offering COVID-19 tests to Medicare beneficiaries in exchange for personal details, including Medicare information, when the services are unapproved and illegitimate. Fraudsters are targeting beneficiaries in a number of ways, including telehealth for Evaluation and Management up-coding or services not rendered, 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. Fraudsters used telemedicine to facilitate fraud schemes for unnecessary items and services. 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.

- Unnecessary laboratory testing: Performing additional tests when conducting COVID-19 tests, such as expensive tests or services that may or may not be related to COVID-19. For example, some laboratories are billing a COVID-19 test with other far more expensive tests, such as Respiratory Pathogen Panels (RPP), which test for a variety of respiratory infections along with COVID-19, and antibiotic resistance tests. Other potentially unnecessary tests being billed along with COVID-19 tests include allergy, genetic and cardiac panel testing. Some laboratories are also billing respiratory, gastrointestinal, genitourinary, and dermatologic pathogen code tests.

- Health care technology schemes: False and fraudulent representations about COVID-19 testing, treatments, or cures that are used to defraud Federal health programs.

- 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 (PPP), or the Economic Impact Disaster Loan (EIDL) program.

Highlights of Significant Criminal and Civil Investigations

Our respective Departments successfully pursued criminal, including Strike Force, 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.**

Clinics

In February 2022, the owner of a South Florida medical clinic was sentenced to 10 years in prison for submitting over $40.0 million in false and fraudulent claims to United Healthcare. In addition to the prison sentence, the defendant was ordered to forfeit to the United States property traceable to proceeds of his health care fraud scheme, including over $12.0 million and two Winnebago motor coaches, and to pay more than $12.0 million in restitution to United Healthcare. The clinic owner pled guilty in 2021 to one count of conspiracy to commit health care fraud and one count of conspiracy to commit money laundering. According to court documents, the defendant's medical clinic purported to provide antigen therapy and other allergen immunotherapy services, such as allergy testing and allergy shots, to commercial insurance beneficiaries. The defendant offered and paid kickbacks to co-conspirators to induce them to refer beneficiaries to his clinic, so that his clinic could bill the insurers for services that it never provided. The defendant used the proceeds of his fraud to purchase a $3.0 million home in the Ocean Reef Club in Key Largo, Florida, two Winnebago motor coaches, and a 37-foot yacht.

In August 2022, the owner of a Miami medical clinic was sentenced to five years in prison for submitting nearly $40.0 million in false and fraudulent claims to United Healthcare and Blue Cross Blue Shield. In addition to the prison sentence, the defendant was ordered to forfeit to the United States property traceable to proceeds of his health care fraud scheme, including nearly $8.0 million, four real estate properties including a beachfront condominium unit in Pompano Beach, and numerous luxury vehicles. According to court documents, the clinic owner submitted nearly $40.0 million in false and fraudulent claims for reimbursement for infusions of Infliximab, known by the brand name Remicade, a prescription immunosuppressive approved for the treatment of adult and pediatric Crohn's disease, adult and pediatric ulcerative colitis, rheumatoid and psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis. Infliximab is one of the most expensive prescription drugs on the market—a single dose can have a retail price of nearly $10,000. Despite claiming nearly $40.0 million in reimbursements for infusions of Infliximab purportedly provided to patients of the defendant's clinic, the defendant admitted as part of his guilty plea to conspiracy to commit health care fraud that he never provided even a single infusion of the drug, nor did patients of the clinic require the medication.

COVID-19 Related Enforcement

In May 2022, a physician who attempted to profit from the pandemic by marketing what he described as a "miracle cure" for COVID-19, was sentenced to 30 days of custody and one year of home confinement for trying to smuggle hydroxychloroquine into the United States to sell in his coronavirus "treatment kits." The physician pleaded guilty to one count of importation contrary to law, admitting that he worked with a Chinese supplier to try to smuggle into the United States a barrel that he believed contained over 26 pounds of hydroxychloroquine powder

by mislabeling it as "yam extract." The defendant admitted that he intended to sell the hydroxychloroquine powder in capsules as part of his business venture selling COVID-19 "treatment kits" in March and April 2020, at the beginning of the global pandemic.

In June 2022, MorseLife Health System Inc. (MorseLife), a Florida-entity that oversees a nursing home and assisted living facility on its campus, agreed to pay the United States $1.8 million to resolve allegations that in 2020 and 2021 it violated the civil FCA by facilitating COVID-19 vaccinations under the Centers for Disease Control and Prevention's (CDC) Pharmacy Partnership for Long-Term Care Program (LTC PPP) for hundreds of individuals ineligible to receive them, but who MorseLife targeted for donations. The LTC PPP was specifically designed to vaccinate long-term care facility residents and staff when doses of COVID-19 vaccine were in limited supply early in the pandemic. MorseLife allegedly knew this but nevertheless invited and facilitated the vaccination of hundreds of ineligible persons at the clinic by falsely characterizing them as "staff" and "volunteers," many of whom MorseLife targeted for donations. Specifically, the United States alleged that MorseLife (1) characterized board members and their spouses, children, family members and friends as "staff," (2) directed the organization's fundraising arm to invite donors and potential donors to the vaccination clinic, and (3) allowed the Vice Chairman of MorseLife's board and his brother to invite close to 300 individuals who neither worked or lived on MorseLife's campus, and most of whom did not volunteer or have any other prior affiliation with MorseLife, to receive the vaccine. A significant number of these invitees were members of the same country club as the Vice Chairman and his brother.

Diagnostic Testing

In December 2021, a former doctor and his company were found guilty after trial of scheming to defraud private insurance companies and the TRICARE health care program by fraudulently submitting an estimated $355.0 million in claims. The company, Surgery Center Management LLC, focused on the promotion and performance of Lap-Band weight-loss surgeries. At the direction of the defendants, employees pushed patients to undergo sleep studies regardless of medical necessity and falsified thousands of sleep study results to reflect that the patients had obstructive sleep apnea, which was a co-morbidity that would help convince insurance companies to cover a patient's Lap-Band surgery. The falsified sleep study reports were then submitted to insurers in support of pre-approval requests for Lap-Band surgeries, as well as claims for apnea machines, and for the sleep studies themselves, which were usually billed at exorbitant rates of $14,000 to $18,000 per study. In total, defendants caused the submission of over $354.0 million in fraudulent claims for which insurers paid more than $71.0 million.

In July 2022, Inform Diagnostics, Inc., (Inform), a clinical laboratory headquartered in Irving, Texas, agreed to pay $16.0 million to resolve civil FCA allegations that it submitted false claims for payment to Medicare and other Federal health care programs. According to the settlement, Inform admitted that between 2013 and 2018 it routinely and automatically conducted additional tests on biopsy specimens prior to a pathologist's review and without an individualized determination regarding whether additional tests were medically necessary. Inform's policy of conducting routine additional tests caused Inform to perform many tests that were medically

unnecessary. Inform submitted these medically unnecessary tests for payment, causing Federal health care programs to pay for false claims.
(SF) In July 2022, the owner of a diagnostic laboratory was convicted of one count of conspiracy to pay and receive for his role in an illegal kickback scheme involving medically unnecessary genetic testing in which Medicare was billed at least $7.9 million and paid $4.7 million for kickback-tainted genetic testing. The defendant awaits sentencing.

Drug Companies
In November 2021, kaléo Inc. (kaléo), a Virginia-based pharmaceutical manufacturer, agreed to pay the United States $12.7 million to resolve civil FCA allegations that it caused the submission of false claims to the Medicare program and other Federal health care programs for the drug Evzio, an injectable form of naloxone hydrochloride indicated for use to reverse opioid overdose. Evzio was the highest-priced naloxone hydrochloride product on the market, and insurers frequently required the submission of prior authorization requests before they would approve coverage for Evzio. The United States alleged that, between March 14, 2017, and April 30, 2020, kaléo directed prescribing doctors to send Evzio prescriptions to certain preferred pharmacies that in turn submitted false prior authorization requests to insurers. The prior authorization requests allegedly misrepresented that the prescribing physicians submitted the request when the pharmacies did so and/or contained false or misleading assertions about the patients' medical histories, such as false statements that patients had previously tried and failed less costly alternatives to Evzio. The pharmacies also allegedly dispensed Evzio without collecting or attempting to collect required copayments from government beneficiaries. The United States contends that kaléo knew of or deliberately ignored this pharmacy misconduct, but nevertheless kept directing business to these pharmacies. The United States also alleged that kaléo provided illegal remuneration to prescribing physicians and their office staff in violation of the Anti-Kickback Statute (AKS) to induce and reward their prescribing of Evzio.

In March 2022, pharmaceutical company Mallinckrodt ARD LLC, previously Questcor Pharmaceuticals Inc. (collectively, Mallinckrodt), agreed to pay $260.0 million to resolve separate allegations that it violated the civil FCA by knowingly (1) underpaying Medicaid rebates due for its drug H.P. Acthar Gel (Acthar), and (2) paying kickbacks in the form of copay subsidies for Acthar in violation of the AKS. With respect to the former, the settlement resolved allegations that from 2013 until 2020 Mallinckrodt paid rebates for Acthar as if it was a "new drug" as of 2013, as opposed to a preexisting drug for which Mallinckrodt had significantly raised the price in years prior, from approximately $40 per vial to over $28,000 per vial by the end of 2013, and to approximately $40,000 per vial thereafter. This practice allegedly resulted in significant Medicaid rebate underpayments for the amounts Mallinckrodt owed on account of these price increases but did not pay. With respect to the latter, the settlement resolved allegations that, from 2010 through 2014, Mallinckrodt knowingly used a foundation as a conduit to pay illegal kickbacks in the form of copay subsidies for Acthar so it could market the drug as "free" to doctors and patients while increasing its price significantly. Under the settlement, Mallinckrodt admitted that Acthar was not a new drug as of 2013 and agreed to pay rebates on the pre-2013 price increases going forward. Mallinckrodt also entered into a five-year CIA with HHS-OIG in connection with the settlement.

In September 2022, Akorn Operating Company LLC (Akorn) agreed to pay the United States $7.9 million to resolve alleged civil FCA violations that it caused the submission of false claims to Medicare Part D for three generic drugs that were no longer eligible for Medicare coverage. FDA-approved "prescription only" (Rx-only) drugs may be dispensed only upon a prescription and are reimbursed by Medicare Part D, whereas "over the counter" (OTC) drugs may be purchased by retail customers without a prescription and are not reimbursed by Medicare Part D. Subject to FDA approval, companies may seek to fully convert a brand-name Rx-only drug to an OTC drug. After FDA's approval of a drug's full conversion to OTC status, the drug is no longer considered an Rx-only product and makers of generic equivalents are then required either to seek FDA approval for their own OTC switch or to seek withdrawal of their generic's Rx-only approval and cease marketing it. As part of the settlement, Akorn admitted to the following facts: Akorn continued to sell three generic drugs under obsolete Rx-only labeling after the brand name equivalents of these generic drugs had already been approved for OTC status by the FDA. In particular, Akorn delayed seeking the required OTC conversions for the generics because it believed that continuing to sell them as Rx-only would have been more profitable. Accordingly, Akorn continued to sell newly manufactured units of the generics under obsolete Rx-only labeling, rather than beginning the process of converting them to OTC or withdrawing their approval and ceasing their distribution. In connection with the settlement, Akorn was credited under the Department of Justice's guidelines for taking disclosure, cooperation, and remediation into account in FCA cases, Justice Manual §4-4.112.

Durable Medical Equipment (DME)

(SF) In November 2021, the owner and operator of durable medical equipment brace suppliers and purported marketing companies, was convicted of one count of conspiracy to commit health care fraud for his role in paying and receiving health care kickbacks and bribes for doctors' orders of medically unnecessary orthotic braces. To conceal the kickbacks and bribes, the defendant and others concealed the scheme by entering into sham marketing and business process outsourcing contracts and by creating sham invoices. The defendant and others caused Federal health care programs to pay more than $33.0 million for medically unnecessary orthotic braces. In May 2022, the defendant was sentenced to 120 months imprisonment.

In November 2021, two business owners were sentenced for their roles in a conspiracy to defraud Federal health benefit programs, including Medicare and the Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA). The first business owner was sentenced to 78 months in Federal prison and the second business owner was sentenced to 63 months in Federal prison. As part of their sentences, the court also entered a monetary judgment against the defendants in the amount of $2.1 million and $3.0 million, respectively, which were proceeds of the conspiracy. The business owners were also ordered to pay restitution, jointly and severally with each other and other conspirators, in the amount of $29,020,304. According to court documents, from around October 2016 through around April 2019, the business owners ran a telemarketing company in Tampa that targeted older adults to generate thousands of medically unnecessary physicians' orders for durable medical equipment (DME) and cancer genetic testing (CGx). The business owners also created and operated a "telemedicine" company through which they illegally bribed physicians to sign the orders regardless of medical necessity. The business owners then illegally sold the signed physicians'

orders to client-conspirators for use as support for false and fraudulent claims submitted to Medicare and CHAMPVA. The conspiracy resulted in the submission of at least $134.0 million in fraudulent claims to the Federal health benefit programs, resulting in approximately $29.0 million in payments.

(SF) In December 2021, two owners of two of DME supply companies were each sentenced to 151 months imprisonment stemming from a June 2021 conviction following a jury trial resulting from their involvement in a scheme to defraud Medicare. According to court documents, the defendants paid kickbacks and bribes in exchange for signed doctors' orders for orthotic braces that were not medically necessary. To conceal the kickbacks and bribes, the defendants and their co-conspirators executed sham contracts and created fake invoices appearing to be for legitimate "marketing" or "business process outsourcing" services. The defendants' DME companies collectively billed Medicare Parts B and C over $59.0 million.

In December 2021, a business owner was sentenced to 78 months in prison for health care fraud and conspiracy to commit health care fraud. The court also ordered the business owner to forfeit $7.1 million and to repay more than $16.1 million in restitution. According to documents filed by the government, on October 17, 2016, the business owner signed a written agreement in which he agreed to be excluded from the Medicare Program for 10 years. The exclusion agreement provided that Medicare would not pay claims submitted by anyone who employed the business owner in a management or administrative role. Nevertheless, from 2016 until 2021, the business owner committed health care fraud by continuing to manage and control pharmacies that submitted claims for payment to Medicare. In order to avoid detection, the business owner ensured that those submitting Medicare enrollment/revalidation paperwork for these pharmacies would not disclose the business owner's ownership interest or managerial role in these pharmacies. From October 17, 2016, to August 16, 2021, Medicare paid over $16 million to the pharmacies in which the business owner had an ownership interest or managerial role.

In April 2022, a Florida DME company owner was sentenced in Boston to 96 months in prison and required to pay $35.6 million in forfeiture and $30 million in restitution. The defendant pleaded guilty in October 2020 to one count of health care fraud and one count of payment of kickbacks in connection with the submission of more than $109.0 million in false and fraudulent claims for DME. The defendant instructed his employees to establish shell companies in more than a dozen different states, listing his mother, wife and yacht captain as corporate directors and using fictitious names to register the shell companies as DME providers. The defendant purchased Medicare patient data from foreign and domestic call centers that targeted older patients and instructed call centers to contact the Medicare beneficiaries with an offer of ankle, arm, back, knee, and/or shoulder braces "at little to no cost." He then submitted Medicare claims for those patients without obtaining a prescriber's order to ensure that the braces were medically necessary. The defendant submitted blatantly fraudulent claims, including claims for deceased patients and repeat claims for the same patient and the same DME. The defendant failed to provide any DME for more than $7.5 million in claims. When the defendant did provide DME to patients, he typically billed insurance policies more than 12 times the average price of the DME that he provided to the patient. Six other individuals who played a role in the defendant's

fraudulent scheme also pled guilty and were ordered to pay a combined total of over $30.0 million in restitution.

In May 2022, a Florida man was sentenced in Newark, New Jersey, to 120 months in prison for his role in a health care fraud and kickback scheme. The defendant and co-conspirators had financial interests in multiple DME companies. The DME companies paid kickbacks to suppliers of DME orders, including the defendant, in exchange for DME orders, which the DME companies subsequently fraudulently billed to Medicare, TRICARE, CHAMPVA, and other health care benefit programs. Defendants and co-conspirators owned and operated multiple call centers through which they obtained DME orders for beneficiaries of Medicare and other Federal health care programs. The call centers paid illegal kickbacks and bribes to telemedicine companies to obtain DME orders for these beneficiaries. The telemedicine companies then paid physicians to write medically unnecessary DME orders. The DME orders were provided to DME supply companies owned by defendant and others in exchange for bribes. The DME supply companies in turn provided the braces to beneficiaries and fraudulently billed the health care programs. The defendant and co-conspirators caused losses to Medicare, TRICARE, and CHAMPVA of approximately $50.0 million. In addition to the prison term, the defendant was ordered to pay restitution of $33,777,799.67 and forfeit $9,477,925.

(SF) In May 2022, a jury convicted the owners and operators of four orthotic brace suppliers in Texas and Arkansas for a $6.5 million illegal kickback scheme. The evidence presented at trial showed that the defendants concealed the scheme by entering into sham agreements with purported marketing companies that characterized the illegal payments for doctors' orders as "marketing" expenses. The defendants await sentencing.

In August 2022, Philips RS North America, LLC, formerly Respironics, Inc., a durable medical equipment (DME) manufacturer based in Pittsburgh, Pennsylvania, agreed to pay $24.8 million to resolve civil FCA allegations that it knowingly provided unlawful kickbacks to DME suppliers to induce them to select Respironics' respiratory equipment. Specifically, the settlement resolves allegations that from November 2014 through April 2020 Respironics caused DME suppliers to submit claims for ventilators, oxygen concentrators, CPAP and BiPAP machines, and other respiratory-related medical equipment that were false because Respironics provided inducements to them. The inducements allegedly came in the form of prescribing data that Respironics provided free of charge yet knew was valuable in assisting DME suppliers' marketing efforts to physicians. In connection with the settlement, Respironics entered into a five-year CIA with HHS-OIG.

In August 2022, Vision Quest Industries, Incorporated (VQ) agreed to pay the United States $2.3 to resolve civil FCA allegations that VQ, a DME manufacturer, caused Osteo Relief Institutes (ORI) to bill Medicare for knee braces that were tainted by illegal kickbacks. VQ also entered into a five-year Corporate Integrity Agreement. The case involved allegations that between 2011 and 2018, VQ paid kickbacks to an independent VQ sales representative and his company, Results Laboratories, LLC, in the form of commission payments that ranged from 20–35 percent of VQ's net revenue on each knee brace ordered by the ORI Clinics. The government alleged

that VQ understood that the sales representative was in a position to tell the ORIs which braces to order and that this arrangement locked in millions of dollars in annual brace sales for VQ.

Genetic Testing/RPP Testing

(SF) In November 2021, a purported marketer was convicted of one count of conspiracy to commit health care fraud for his role in an illegal scheme to obtain doctors' orders for medically unnecessary genetic tests in exchange for the payment of millions of dollars in kickbacks. The defendant arranged for the doctors' orders to be sold to laboratories in Louisiana, which submitted over $132.0 million in fraudulent claims to Medicare. The defendant is awaiting sentencing.

Home Health Providers

(SF) In September 2021, the managing employee of a Pakistan-based home health care "consulting" company was convicted of one count of health care fraud and one count of conspiracy to commit money laundering for his role in a home health care scheme in which Medicare paid more than $40.0 million for home health care services that were not provided. The defendant then laundered the proceeds of this fraud scheme by causing the transmittal of payments from the home health care agencies within the United States to bank accounts in Pakistan for his benefit and the benefit of other scheme participants. In February 2022, the defendant was sentenced to 12 years imprisonment.

In November 2021, an employee of a home health care company was sentenced to 56 months in prison and ordered to pay $6.3 million in restitution for her participation in a conspiracy to commit health care and wire fraud. According to court documents and the evidence presented at trial, the employee worked at a home health care company owned by a husband and wife. The husband and wife were previously sentenced to 84 months and 60 months in prison, respectively, for their role in the conspiracy. Between 2011 and 2017, the home health care company fraudulently billed Medicare at least $6.3 million. At trial, the government demonstrated that around 90 percent of the home health care company's patients were not homebound and did not qualify for the types of care that the company had billed to Medicare. Further, many patients received cash bribes to receive home health "visits," some of which were performed in the visiting nurse's car. The employee facilitated the conspiracy by falsifying patient visit records that were used to support claims billed to Medicare. She was convicted by a Federal jury on February 14, 2020.

In March 2022, two Brooklyn based home care services agencies, All American Homecare Agency (All American) and Crown of Life Care NY LLC (Crown of Life), paid over $5.4 million to the United States and New York State to resolve False Claims Act liability arising from their falsely claiming that they paid their health care aides minimum wages required by law. The agencies had received millions of dollars in funding from Medicaid and much of that money was meant to pay the wages and benefits of their aides. Home health aides perform all aspects of personal care for sick or homebound patients and frequently work long shifts lasting up to 24 hours. The tasks performed in caring for patients are demanding and can consist of assisting or lifting patients out of bed and bathing, dressing, grooming, preparing meals and, in some instances, feeding them. Importantly, in addition to paying multiple damages to the

government, All American and Crown of Life are now paying their aides the wages and benefits they were required to pay under New York State's Wage Parity Law. Under the terms of settlement, American and Crown expressly accepted responsibility for their conduct.
In May 2022, Signature Home Health Services of Florida LLC and its related entities (collectively, Signature) paid $2.1 million to the United States government to resolve civil FCA allegations that Signature improperly billed the Medicare Program for home health services provided to beneficiaries living in Florida. Signature, whose corporate headquarters is located in Louisville, Kentucky, operated home health care services in Florida. The government alleged that between 2013 and 2017 Signature knowingly submitted false or fraudulent claims seeking payment from the Medicare Program for home health services to Medicare beneficiaries who: (1) were not homebound. (2) did not require certain skilled care, (3) did not have a valid or otherwise appropriate plans of care in place, and/or (4) did not have appropriate face-to-face encounters needed in order to be appropriately certified to receive home health services.

Hospice Care
In October 2021, Geisinger Community Health Services (GCHS) agreed to pay $18.5 million to resolve allegations of common law civil liability for submitting claims to Medicare for hospice and home health services that violated Medicare rules and regulations. GCHS voluntarily disclosed the violations. According to the voluntary disclosures, between January 2012 and December 2017, GCHS submitted claims, through several affiliated entities, to Medicare for hospice and home health services that violated Medicare rules and regulations regarding physician certifications of terminal illness, patient elections of hospice care, and physician face-to-face encounters with home health patients.

In November 2021, Carrefour Associates LLC and its related companies, which operate under the name Crossroads Hospice in multiple states including Ohio and Tennessee (Crossroads Hospice), agreed to pay $5.5 million to resolve civil FCA allegations by submitting claims to Medicare for non-covered hospice services. The settlement resolved allegations that Crossroads Hospice knowingly submitted false claims to Medicare for hospice services for patients who were not terminally ill. The United States alleged that from January 1, 2012, to December 31, 2014, Crossroads Hospice billed Medicare for hospice care for certain patients with a diagnosis of dementia or Alzheimer's disease at its Ohio and Tennessee locations who were not terminally ill for at least a portion of the more than three years that the patients received care at these locations.

In August 2022, 13 defendants were sentenced to a combined 84 years in Federal prison for their roles in causing $27.0 million in fraudulent hospice services claims to be paid by Medicare and Medicaid between July 2012 to May 2016. The defendants included the CEO of Novus Health Services, a Dallas-based hospice agency, as well as other company officers, nurses and physicians serving as medical directors. As a part of the scheme, defendants submitted false claims for hospice services, submitted false claims for continuous care hospice services, recruited ineligible hospice beneficiaries by providing kickbacks to referring physicians and health care facilities, violated HIPAA to recruit potential hospice patients, dispensed Schedule II controlled substances to patients without the oversight of medical professionals, and used a new company to bill Medicare in order to avoid a Medicare suspension.

Hospitals and Health Systems

In November 2021, Flower Mound Hospital Partners LLC (Flower Mound Hospital), a partially physician-owned hospital in Flower Mound, Texas, agreed to pay $18.2 million to resolve allegations that, between July 2019 and June 2021, it violated the civil FCA by knowingly submitting claims to the Medicare, Medicaid, and TRICARE programs that resulted from violations of the Physician Self-Referral Law (the Stark Law) and the AKS. The settlement resolves allegations that Flower Mound Hospital violated the Stark Law and the AKS when it repurchased shares from physician-owners aged 63 or older and then resold those shares to younger physicians. The United States alleges that Flower Mound Hospital impermissibly considered the volume or value of certain physicians' referrals when it (1) selected the physicians to whom the shares would be resold and (2) determined the number of shares each physician would receive. In connection with the settlement, Flower Mound entered into a five-year CIA with HHS-OIG.

In March 2022, Providence Health & Services Washington (Providence), a large health care and hospital system operating in seven western U.S. states, agreed to pay $22.7 million to resolve civil FCA allegations that it fraudulently billed Medicare, Medicaid, and other Federal health care programs for medically unnecessary neurosurgery procedures. The settlement resolved allegations that between 2013 and 2018 Providence St. Mary's Medical Center in Walla Walla, Washington, employed certain neurosurgeons and paid them based on a productivity metric that provided them a financial incentive to perform more surgical procedures of greater complexity. The government alleged that Providence falsely billed Medicare, Washington State Medicaid, and other Federal health care programs for deficient and medically unnecessary neurosurgery procedures performed by these neurosurgeons. In connection with the settlement, Providence entered into a five-year CIA with HHS-OIG.

In April 2022, BayCare Health System Inc. and entities that operate four affiliated Florida hospitals (collectively, BayCare) agreed to pay $20.0 million to resolve civil FCA allegations that BayCare improperly funded the state's share of Medicaid payments to BayCare through donations to the Juvenile Welfare Board of Pinellas County (JWB). Under Federal law, Florida's share of Medicaid payments must consist of state or local government funds, and not "non-bona fide donations" from private health care providers, such as hospitals. The settlement resolved allegations that, between October 2013 and September 2015, BayCare made improper, non-bona fide cash donations to JWB knowing that JWB would and then did transfer a portion of the cash donations to the State of Florida's Agency for Health Care Administration for Florida's Medicaid Program. The government alleged that funds transferred by JWB to the state were "matched" by the Federal Government before being returned to the BayCare hospitals as Medicaid payments, and BayCare was thus able to recoup its original donations to JWB and also receive Federal matching funds, in violation of the Federal prohibition on non-bona fide donations. Accordingly, BayCare's donations to JWB allegedly violated the civil FCA by increasing Medicaid payments received by BayCare without any actual expenditure of state or local funds.

Laboratory Testing

In October 2021, Nevada-based MD Spine Solutions LLC d/b/a MD Labs Inc. (MD Labs) and

two of its owners agreed to pay up to $16.0 million to resolve civil FCA allegations that MD Labs submitted false claims for Medicare and other Federal health care programs for medically unnecessary urine drug testing (UDT). In particular, under the settlement, MD Labs and the owners admitted that between 2015 and 2019, MD Labs regularly billed Federal health care programs for medically unnecessary UDT. MD Labs performed two types of UDT—presumptive testing, a relatively inexpensive test that quickly provides qualitative results, and confirmatory testing, an expensive test that is designed to confirm quantitatively the results of presumptive UDT—at approximately the same time and then simultaneously submitted the results to health care providers. MD Labs and the owners knew that doctors would not review presumptive UDT results when they already had the more precise confirmatory UDT results. MD Labs and the owners also knew that, absent a presumptive UDT result, there was often nothing to confirm, and so there was no basis to bill for a confirmatory UDT result. Under the terms of the settlement agreement, MD Labs and the owners will pay the government and various states no less than $11.6 million and up to $16.0 million, depending on MD Labs' financial circumstances over time.

(SF) In February 2022, a Detroit man was convicted of one count of health care fraud for operating a kickback scheme for a clinical laboratory, in which he paid marketers to solicit urine samples from physicians for comprehensive urine drug testing. The fraudulent conduct resulted in $28.2 million worth of improper claims submitted to Medicare, for which Medicare paid the laboratory $2.1 million during the fraud period. The defendant is awaiting sentencing.

In March 2022, Radeas LLC, a North Carolina-based clinical laboratory, agreed to pay $11.6 million to resolve civil FCA allegations that it submitted false claims for payment to Medicare for medically unnecessary UDT. Radeas admitted that between January 2016 and September 2021, it performed on the same samples, at or near the same time, both presumptive UDT and definitive or confirmatory UDT. Radeas then reported both the presumptive and definitive UDT results back to health care providers at the same time for the same or similar substances, often providing overlapping information for presumptive and definitive UDT. Radeas also admitted to compensating sales organizations on a commission basis for their referrals of UDT to the company, from May 10, 2013, through April 30, 2021.

In May 2022, the CEO of Northwest Physicians Laboratory was sentenced to serve 24 months in prison and ordered to pay $7.6 million in restitution for conspiracy to solicit kickbacks from medical testing labs in exchange for referring government testing business to the labs. The CEO helped the laboratory obtain more than $3.7 million in kickback payments by steering urine drug test specimens to two labs that billed the government for testing, resulting in government payments to those two labs of more than $6.5 million. According to records filed in the case, between January 2013 and July 2015, those two labs, which were not physician owned, made payments to the Laboratory in exchange for referrals of Medicare and TRICARE program business, in violation of the AKS. Paying remuneration to medical providers or provider-owned laboratories in exchange for referrals encourages providers to order medically unnecessary services. The AKS functions, in part, to discourage such behavior. The Laboratory was physician-owned, and for that reason could not test urine samples for patients covered by government health programs such as Medicare, Medicaid, and TRICARE. In order to conceal

the payment of the kickbacks, the CEO and other co-conspirators described the fees as being for marketing services; however, no marketing services were performed. To date, the labs and individuals involved in this investigation have agreed to pay more than $14.0 million to settle related civil allegations.

In July 2022, Metric Lab Services LLC and Metric Management Services LLC (collectively, Metric), Spectrum Diagnostic Labs LLC (Spectrum), clinical laboratories in Mississippi and Texas, respectively, and two of their owners and operators agreed to pay $5.7 million to resolve allegations that they caused the submission of false claims to Medicare by paying kickbacks in return for genetic testing samples. The United States alleged that the defendants participated in a genetic testing fraud scheme with various marketers that solicited genetic testing samples from Medicare beneficiaries. The marketers arranged to have a physician fraudulently attest that the genetic testing was medically necessary, and Metric and Spectrum would process the tests, receive reimbursement from Medicare and pay a portion of that reimbursement to the marketers. The individual defendants each previously pleaded guilty to one count of conspiracy to defraud the United States in connection with this scheme and are awaiting sentencing.

In July 2022, an owner and operator of a youth mentoring program known as Do-It-4-The Hood Corporation (D4H) was sentenced to 70 months in prison and two years of supervised release and ordered to pay restitution for his part in defrauding Medicaid programs in North Carolina, South Carolina, and Georgia of more than $5 million. From January 2016 through November 2018, D4H paid students from Historically Black Colleges to recruit at-risk youths, in particular children who were Medicaid eligible in North Carolina and Georgia, for its program. Once enrolled, children were required to submit urine specimens for drug testing. The defendant then conspired with certain laboratories in Georgia, North Carolina, and Virginia to perform medically unnecessary drug testing on the enrolled children's urine specimens and received kickbacks once the laboratories were reimbursed by the state Medicaid programs. The South Carolina scheme preceded the North Carolina and Georgia urine testing scheme. The defendant and co-conspirators became owners of a Wrights Care Services LLC (Wrights Care) franchise in Columbia. Starting in or around 2014 and continuing until January 2016, the defendant and his conspirators defrauded the South Carolina Medicaid program by filing fraudulent claims for mental health counseling or other services that were either not provided, partially provided, or did not qualify for Medicaid reimbursement. They submitted falsified patient billing records and fake medical notes to support their fraudulent reimbursement claims. Over the course of the scheme, the defendant and his co-conspirators submitted thousands of fraudulent claims to Medicaid programs in the three states totaling over $17.0 million and received over $5.0 million in fraudulent reimbursements. In addition, they received $1.8 million in kickbacks from the laboratories that participated in the conspiracy.

Managed Care

In August 2022, Ventura County Medi-Cal Managed Care Commission d/b/a Gold Coast Health Plan (Gold Coast), a county organized health system, Ventura County, California, Dignity Health, and Clinicas del Camino Real Inc., agreed to pay a total of $70.7 million to the government and California pursuant to three separate civil settlements. These settlements resolved allegations that the entities violated the civil FCA and state analogue by knowingly

submitting or causing the submission of false claims to California's Medicaid Program (Medi-Cal) for "Additional Services" provided to Adult Expansion Medi-Cal members, stemming from the Medicaid Adult Expansion under the Patient Protection and Affordable Care Act (ACA) between January 1, 2014, and May 31, 2015. The United States and California alleged that the payments were not "allowed medical expenses" under Gold Coast's contract with the state, were pre-determined amounts that did not reflect the fair market value of any Additional Services provided. and/or the Additional Services were duplicative of services already required to be rendered. In connection with the settlement, Gold Coast and Ventura County entered into five-year CIAs with HHS-OIG. This is the first resolution of its kind involving Medicaid Adult Expansion fraud.

Medical Devices

In November 2021, Arthex, Inc. (Arthex), a Florida-based medical device company, agreed to pay $16.0 million to resolve civil FCA allegations that from August 2010 through March 5, 2021, it paid kickbacks that caused the submission of false claims to the Medicare program. According to the settlement, Arthex, which specializes in orthopedic products, allegedly paid kickbacks to a Colorado-based orthopedic surgeon. The settlement resolves allegations that the medical device company agreed to provide remuneration to the surgeon in the form of royalty payments purportedly for the surgeon's contributions to Arthex's SutureBridge and SpeedBridge products when the remuneration was in fact intended to induce the surgeon's use and recommendation of Arthex's products. The United States contended that the medical device company's participation in this arrangement violated the Federal AKS and, in turn, the civil FCA, by causing the submission of false or fraudulent Medicare claims. In connection with the settlement, the medical device company entered into a five-year corporate integrity agreement with HHS-OIG.

In December 2021, the CEO of a North Georgia medical group and Entellus Medical, a medical device manufacturer, resolved criminal and civil allegations that they entered into unlawful kickback arrangements. The unlawful remuneration included cash payments and all-expense paid trips in return for the CEO's agreement to require the practice group physicians to exclusively use the medical device company's sinuplasty medical devices, increase the number of sinuplasty procedures conducted on the practice group's patients and order medically unnecessary lab tests. The civil case was settled for $4.2 million. The CEO was sentenced to three years in prison followed by three years of supervised release.

In April 2022, Eargo Inc. (Eargo), a company headquartered in California that sells and dispenses hearing aid devices to customers nationwide, agreed to pay $34.4 million to resolve civil FCA and common law allegations that from January 1, 2017, until September 22, 2021, it submitted or caused to be submitted claims containing unsupported diagnosis codes to the Federal Employees Health Benefits Program (FEHBP) for the reimbursement of its hearing aid devices. In particular, the government alleged that these claims lacked support for patients' diagnoses of hearing loss, which is required by FEHBP health insurance plans to trigger hearing aid device reimbursement.

In June 2022, Oregon-based medical device manufacturer Biotronik, Inc. (Biotronik) agreed to

pay $13.0 million to resolve civil FCA allegations that, from January 1, 2013, through October 1, 2013, it caused the submission of false claims to Medicare and Medicaid by paying kickbacks to physicians to induce and reward their use of Biotronik's implantable cardiac devices, including pacemakers and defibrillators. In particular, the United States alleged that Biotronik abused a new employee training program by paying physicians for an excessive number of trainings and, in some cases, for training events that either never occurred or were of little or no value to trainees. The United States further alleged that Biotronik made these payments despite concerns raised by its own compliance department, which warned that salespeople had too much influence in selecting physicians to conduct new employee training and that the training payments were being over-utilized. The settlement also resolved allegations that Biotronik violated the AKS when it paid for physicians' holiday parties, winery tours, lavish meals with no legitimate business purpose, and international business class airfare and honoraria in exchange for making brief appearances at international conferences.

In August 2022, Essilor International, Essilor of America Inc., Essilor Laboratories of America Inc., and Essilor Instruments USA (collectively, Essilor), headquartered in Dallas, agreed to pay $22.0 million to resolve civil FCA allegations that the company caused claims to be submitted to Medicare and Medicaid that resulted from violations of the AKS. The United States alleged that between January 1, 2011, and December 31, 2016, Essilor, which manufactures, markets, and distributes optical lenses and equipment used to produce optical lenses, knowingly and willfully offered or paid remuneration to eye care providers, such as optometrists and ophthalmologists, to induce those providers to order and purchase Essilor products for their patients, including Medicare and Medicaid beneficiaries, in violation of the AKS. In connection with the settlement, Essilor entered into a five-year CIA with HHS-OIG.

Nursing Homes and Facilities

In June 2022, TCPRNC, LLC d/b/a Plaza Rehab and Nursing Center (Plaza Rehab Center) and Citadel Consulting Group LLC d/b/a Citadel Care Centers LLC (Citadel) agreed to pay the United States $7.9 million to resolve civil FCA allegations that Plaza Rehab Center, acting at the direction of Citadel, fraudulently switched the type of Medicare coverage in which older residents were enrolled in order to maximize the Medicare payments that the skilled nursing facility would receive. The Government specifically alleged that Plaza Rehab Center staff disenrolled many residents from their self-selected Medicare Advantage Plans and enrolled them in Original Medicare (e.g., fee-for-service Medicare) without obtaining the consent of the residents or their authorized representatives. This change had the potential to impact the residents' out-of-pocket payments, the scope of the services and care covered, and their drug coverage plan. As part of the settlement, Citadel agreed to take steps to ensure that all skilled nursing facilities that are Citadel Care Centers comply with applicable guidance on Medicare health plan disenrollments and enrollments. Plaza Rehab Center and Citadel also entered into a CIA with HHS-OIG.

Pharmacies

In December 2021, an executive who owned and operated two compounding pharmacies was sentenced to three years in Federal prison and ordered to pay more than $3.0 million in restitution to the IRS for evading the payment of approximately $5.5 million in personal income

taxes and submitting false reimbursement claims to CVS Caremark, a national pharmacy benefit manager. According to court documents, HHS OIG, the Oregon Department of Justice's Medicaid Fraud Unit, and other agencies pursued a multi-year investigation into alleged illegal kickback arrangements at compounding pharmacies owned by the executive and members of his family in several states. Two such pharmacies were located in Southeast Portland. The investigation ultimately revealed that the executive had devised various indirect means of incentivizing health care providers to write prescriptions for compounded drugs—custom-mixed medications that generate outsized reimbursement from Medicare, Medicaid, and other health care-benefit programs—and to direct those prescriptions to his pharmacies for dispensing. These arrangements proved enormously profitable for the executive's pharmacies.

In January 2022, a Milwaukee-based pharmacy chain and its two owners agreed to pay $2.0 million to resolve allegations that it violated the civil FCA by submitting false claims to Medicare and Medicaid for prescription medications in 2019. The United States alleged that the pharmacy submitted false claims to Medicare and Medicaid for two prescription medications, a topical cream consisting of iodoquinol, hydrocortisone, and aloe, and a multivitamin with the trade name Azesco. During the relevant time period, Medicaid paid thousands of dollars per prescription for the iodoquinol-hydrocortisone-aloe cream, and Medicare paid hundreds of dollars per prescription for Azesco. The United States alleged that the pharmacy switched Medicaid and Medicare patients from lower cost medications to the iodoquinol-hydrocortisone-aloe cream and Azesco without any medical need and/or without a valid prescription. In addition to paying over $2.0 million to resolve the allegations concerning these false claims, the pharmacy agreed to conduct annual training concerning waste, fraud and abuse, and compliance with rules concerning medication switches.

In April 2022, a business owner was sentenced to 77 months in prison for carrying out multiple schemes to defraud health care programs, including obtaining more than $6.5 million from Medicare Part D plans and Medicaid drug plans. According to court documents, the individual was the owner and operator of five pharmacies. Between 2015 and 2020, the owner utilized these pharmacies to engage in schemes that defrauded health care programs, including Medicare and Medicaid, by submitting claims for prescription drugs that were not dispensed, not prescribed as claimed, not medically necessary, or dispensed during a time when the pharmacy was no longer registered with the State of New York. The fraudulent claims included claims for expensive prescription drugs for the treatment of the human immunodeficiency virus (HIV). The owner and her family used proceeds of the scheme to purchase luxury items such as a Cadillac Escalade SUV, a Mercedes Benz sedan, a Porsche Turbo coupe, as well as jewelry and real property in Queens and Pocono Pines, Pennsylvania.

In August 2022, Dunn Meadow LLC, a New Jersey licensed retail pharmacy that sent controlled substances and other prescription medications to patients via mail throughout the United States, pleaded guilty to its role in a conspiracy to illegally distribute prescription opioids, including highly addictive and dangerous transmucosal immediate release fentanyl (TIRF) medications, and to give kickbacks to health care providers. Dunn Meadow had contracts with and received payments from pharmaceutical companies that marketed and sold TIRF medications, including INSYS Pharma Inc. From 2015 through 2019, Dunn Meadow knowingly filled prescriptions for

controlled substances, including TIRF medications, for patients exhibiting suspicious and drug-seeking behavior, including patients that repeatedly requested early refills, paid thousands of dollars in cash for their prescriptions, or requested that prescriptions be sent to suspicious or inappropriate locations including hotels, casinos, and elementary schools. Dunn Meadow also admitted that it conspired to offer kickbacks to health care providers and pharmaceutical company sales representatives in violation of the Federal AKS, in the form of lunches, dinners, and happy hours to induce them to send TIRF prescriptions to Dunn Meadow, causing a loss to Federally funded health care programs of over $4.5 million. In addition, Dunn Meadow and its parent company, Allegheny Pharma LLC entered a civil settlement with the United States to resolve Dunn Meadow's civil liability for violations of the False Claims Act and the Controlled Substances Act. Dunn Meadow's criminal restitution payment will be applied to the civil resolution. Dunn Meadow has agreed to pay up to $50.0 million dollars over the next five years to resolve its civil liability if it generates future revenue.

Physical Therapy

In May 2022, the co-owners of a South Florida physical therapy clinic were each sentenced to 135 months in prison for using their clinic as a vehicle for both health care fraud and CARES Act fraud. In addition to the prison sentence, the clinic owners were ordered to pay over $3.0 million in restitution to a health insurance company and over $1.0 million in restitution to the U.S. Small Business Administration (SBA), as well as to forfeit to the United States property traceable to proceeds of the health care and wire fraud schemes. The clinic owners were convicted at trial on all charged crimes (one count of conspiracy to commit health care fraud and wire fraud, seven counts of health care fraud, and two counts of wire fraud). In addition, an office manager and two patient recruiters pled guilty to conspiracy to commit health care fraud and received both prison sentences and orders to pay restitution. According to evidence introduced in court, the billing fraud conspiracy resulted in more than $8.0 million in false claims submissions. Most of the claims were for unneeded or never-provided physical therapy treatments, such as electrical stimulation, ultrasound therapy, and therapeutic exercise, as well as for durable medical equipment. Additionally, the evidence showed that in 2021, the clinic owners fraudulently applied for a $607,585 PPP loan as well as a $500,000 EIDL from the SBA. As a result of this fraud, the clinic owners received over $1.0 million through these COVID-19 relief programs, stealing money that was meant for legitimate small businesses suffering from the devastating effects of the COVID-19 pandemic.

(SF) In August 2022, a jury convicted an office manager/recruiter for participating in a scheme to defraud several private health insurers of millions of dollars. The defendant paid kickbacks and bribes to patient recruiters and patients with private insurance in exchange for allowing four Miami physical therapy clinics to bill for medical services that were never actually provided to those patients. The defendant and co-conspirators falsified medical records to give the impression that the physical therapy services were medically necessary, prescribed by a doctor, and actually rendered. In truth and fact, virtually none of the purported services had been provided. The defendant and co-conspirators submitted approximately $34.6 million in false and fraudulent claims to several private insurers for those nonexistent physical therapy services, of which the insurers paid approximately $7.7 million. The defendant awaits sentencing.

Physician and Other Practitioners

In November 2021, 24 individuals and entities agreed to pay more than $28.0 million to resolve civil FCA allegations that the subjects—which included anesthesia providers and outpatient surgery centers—entered into a series of kickback arrangements in which the anesthesia providers paid for medications, supplies, and labor expenses incurred by the outpatient surgery centers in exchange for the centers' referral of their patients to the anesthesia providers. The Government alleged that between 2005 and 2015, Ambulatory Anesthesia of Atlanta, LLC (AAA) and Northside Anesthesiology Consultants, LLC (NAC) made payments for drugs, supplies, equipment, and labor, and provided free staffing to a number of Georgia outpatient surgery centers in order to induce the centers to select AAA and NAC as their exclusive anesthesia providers. The Government alleged that these arrangements violated the AKS and caused the submission of false claims in violation of the civil FCA.

In December 2021, a Montana vascular surgeon and his business, Bellamah Vein & Surgery, PLLC, doing business as Bellamah Vein Center, agreed to pay the government $3.7 million to resolve civil FCA allegations that he knowingly performed unnecessary vein ablation surgeries on many Medicare, Medicaid, Department of Veteran's Affairs, and TRICARE beneficiaries. The Government alleged that the defendant used improper techniques to conduct and analyze ultrasounds and used false ultrasound findings to conduct and bill for medically unreasonable and unnecessary services related to the diagnosis and treatment of venous reflux disease and varicose veins.

In March 2022, Physician Partners of America LLC (PPOA), headquartered in Tampa, Florida, its founder, and its former chief medical officer, agreed to pay $24.5 million to resolve civil FCA allegations that (1) between October 1, 2015 and November 8, 2021 they billed Federal health care programs for unnecessary medical testing and services and paid unlawful remuneration to its physician employees, and (2) on April 10, 2020, made a false statement in connection with a loan obtained through the SBA's PPP. In particular, the United States alleged that PPOA caused the submission of claims for medically unnecessary UDT by requiring its physician employees to order multiple tests at the same time without determining whether any testing was reasonable and necessary, or even reviewing the results of initial testing (presumptive UDT) to determine whether additional testing (definitive UDT) was warranted. The United States further alleged that PPOA's affiliated toxicology lab billed for the highest-level UDT and that PPOA incentivized physicians to order UDT by paying them 40 percent of the profits of testing, in violation of the Stark law. PPOA allegedly also required patients to submit to genetic and psychological testing before patients were seen by physicians, without a medical determination as to the medical necessity of such tests. PPOA also required its physician-employees to schedule unnecessary telehealth evaluation and management appointments. In connection with the settlement, PPOA entered into a five-year CIA with HHS-OIG.

(SF) In April 2022, a physician was sentenced to 93 months of imprisonment for defrauding Medicare, re-packaging single-use catheters for re-use on patients, and submitting false declarations in a bankruptcy proceeding. According to court documents, from August 2012 to August 2015, the defendant billed Medicare $12.4 million for medically unnecessary vein ablation procedures and was paid $4.5 million. The defendant recruited Medicare beneficiaries

to his clinics, falsely diagnosed the beneficiaries, and provided them with the medically unnecessary procedures, while also billing the procedures using an inappropriate code in order to obtain a higher reimbursement, a practice known as "upcoding." In addition, the defendant re-packaged used, contaminated catheters for re-use on patients. These catheters had been cleared by the Food and Drug Administration for marketing as single-use only and the re-use of these devices put patients at risk of infection and other bodily injury.

In July 2022, a dentist practicing in a rural community outside Milwaukee, Wisconsin, was sentenced to 54 months in prison for health care fraud. Following trial in March 2022, a jury convicted the dentist of five counts of health care fraud and two counts of making false statements in connection with health care matters arising out of a years' long scheme in which the dentist convinced patients that they needed crown procedures that, in fact, they did not need. Insurance typically covers a crown procedure only if the patient's tooth is so damaged by decay or fracture that it cannot be repaired with a filling. In order to obtain insurance coverage for the unnecessary crowns, once the dentist convinced a patient to receive a crown, he used his dental drill to break off a portion of the patient's tooth, then stopped to take an x-ray or photo of the damage he caused, and ultimately submitted that image of the now-damaged tooth to insurance in order to get paid for the procedure. In addition to the prison sentence, the dentist was ordered to pay $1,043,229 in forfeiture to the United States to account for the proceeds of the fraudulent scheme. The dentist will also pay restitution to insurance companies and patients in an amount to be determined by the court, but which will likely exceed $400,000.

In May 2022, a physician was sentenced to 20 years in prison followed by five years of supervised release, and was ordered to pay a $40,000 fine and almost $4.0 million in restitution for running a prescription "pill mill" from 2015 to 2018 from his Philadelphia medical practice. In January 2020, the physician pleaded guilty to 19 counts of health care fraud and 23 counts of distributing oxycodone outside the course of professional practice and without a legitimate medical purpose. The defendant fraudulently billed insurers for medically unnecessary physical therapy, acupuncture, chiropractic adjustments, and prescription drugs, and also fraudulently billed for treatments that were not provided at all. Regardless of their medical complaint, at every visit, patients received a "goodie bag" filled with prescription drugs for which the physician submitted pharmacy claims through his company. The goodie bags typically included a combination of drugs such as topical analgesics Relyyt and/or Lidocaine, muscle relaxers such as Chloroxazon and/or Cyclobenzaprine, anti-inflammatories such as Celecoxib and/or Nalfon. Schedule IV controlled substances such as Tramadol for pain, and/or Eszopiclone and Quazepam for insomnia and anxiety. The defendant obtained payments from insurers of more than $4,000 for each bag by falsely asserting that the drugs were for the benefit of the patient. As part of the fraud scheme, the physician also prescribed oxycodone to "pill-seeking" patients in exchange for their tacit approval that he would submit excessive claims to the patient's insurer for the goodie bag and other medically unnecessary services. The defendant is also subject to a civil judgment under which he is obligated to pay approximately $1.8 million as a result of civil FCA liability for false claims submitted to Medicare, and is subject to a permanent prohibition on prescribing, distributing, or dispensing controlled substances.

In July 2022, the operator of medical billing companies was convicted after a six-week trial of eight counts related to perpetrating an over $600.0 million health care fraud scheme, which also included wire fraud and aggravated identity theft charges. The defendant operated medical billing companies to provide billing services for physicians (primarily plastic surgeons) throughout the United States, and used his companies to carry out a massive scheme to defraud insurance companies. As a third-party medical biller, the defendant submitted claims to insurance companies and when necessary, requested reconsideration or appeals of denied claims. He billed for procedures that were either more serious or entirely different than those his doctor-clients performed. For example, the defendant impersonated the National Football League's general counsel and a professional basketball player for the Boston Celtics of the National Basketball Association in calls the defendant made to insurance companies in which he exaggerated medical procedures. The defendant made thousands of impersonation calls resulting in over tens of millions of dollars in additional reimbursement to his doctor-clients and from which he received a percentage of the fraudulent proceeds. The defendant also directed his doctor-clients to schedule elective surgeries through the emergency room so that insurance companies would reimburse at substantially higher rates. When insurance companies denied the inflated claims, the defendant impersonated patients to demand that the insurance companies pay the outstanding balances of tens or hundreds of thousands of dollars.

Prescription Drugs and Opioids

(SF) In September 2021, a dentist was convicted of one count of unlawful distribution of controlled substances and one count of conspiracy to unlawfully distribute controlled substances based on the dentist's involvement in a conspiracy to illegally generate prescriptions for opioids and benzodiazepines in the names of co-conspirator dental assistants, their family members, and an unwitting office staff member using the dentist's DEA registration. These prescriptions were issued outside the usual course of professional practice and without a legitimate medical purpose, as the defendant and co-conspirators split the prescription drugs for personal use. In February 2022, the dentist was sentenced to 60 months of imprisonment.

(SF) In November 2021, the owner of a pain management clinic in Miami was convicted for his role orchestrating a pill mill conspiracy that resulted in the illegal distribution of more than 3 million pills of oxycodone and generated more than $9.0 million in drug proceeds. In April 2022, the defendant was sentenced to more than 16 years in prison.

In February 2022, a physician was sentenced to 24 months in Federal prison, to be followed by three years of supervised release for conspiring to violate the AKS in connection with a scheme to take bribes and kickbacks from a pharmaceutical company in exchange for prescribing a powerful fentanyl spray to his chronic pain patients. According to the plea agreement, beginning in late 2012 and continuing through November 2015, the defendant conspired with pharmaceutical company employees to take approximately $344,000 in bribes and kickbacks from the manufacturer of Subsys, a powerful sublingual fentanyl spray approved by the FDA in 2012 to treat breakthrough pain in cancer patients. The bribes were disguised as payments or honoraria for purportedly delivering educational speaker programs to the defendant's medical peers. In fact, the defendant often delivered no programs at all—at one point taking payments of over $40,000 from the manufacturer for 17 "programs" he allegedly delivered to his own staff at

his medical clinic. As part of the plea agreement, the defendant admitted that he entered into a quid pro quo relationship with the manufacturer, and that the payments affected his prescribing decisions. He abused his position of trust vis-à-vis his patients and the Federal health care programs in which he was enrolled, becoming one of the manufacturer's top revenue-generating prescribers. Prescriptions for Subsys typically cost thousands of dollars each month, and Medicare and Medicaid paid millions of dollars to cover Subsys prescriptions written by the physician. Fentanyl is at least 50 times more powerful than morphine, and to ensure patient safety, the FDA requires Subsys prescribers, patients, and pharmacies to enroll in and comply with the TIRF Risk Evaluation and Mitigation Strategy (TIRF REMS) program. The defendant disregarded the rules imposed by this program, failing to notify his patients of the risks posed by the Schedule II controlled substance.

(SF) In March 2022, a Delaware physician was sentenced to 240 months of imprisonment stemming from his July 2021 trial conviction of thirteen counts of unlawfully prescribing controlled substances, outside the usual course of professional practice and without a legitimate medical purpose, and maintaining a drug involved premises. In just over a year, he distributed/dispensed over one million pills, mostly oxycodone products, and mostly for cash.

(SF) In March 2022, the owner of a Houston cash-only, pill-mill was convicted at trial of one count of conspiracy to unlawfully distribute and dispense controlled substances, four counts of unlawfully distributing and dispensing controlled substances, one count of conspiracy to launder monetary instruments, and two counts of engaging in monetary transactions in property derived from specified unlawful activity. Throughout the duration of the conspiracy, approximately 739,000 hydrocodone pills and 344,000 oxycodone pills, almost all in their maximum strength, were distributed and dispensed not for a legitimate medical purpose. On June 24, 2022, the defendant was sentenced to 240 months of imprisonment.

In March 2022, a former doctor, was sentenced to 20 years in prison for unlawful drug distribution and maintaining a drug-involved premises. According to court documents and evidence presented at trial, the former doctor unlawfully distributed or dispensed a variety of powerful opioids—including fentanyl, morphine, methadone, OxyContin and oxycodone—outside the usual scope of professional practice and for illegitimate medical purposes. The former doctor operated an internal medicine practice where he frequently prescribed these dangerous controlled substances in high dosages, sometimes in combination with each other or in other dangerous combinations, mostly in exchange for cash. Evidence at trial showed that the former doctor distributed over 1 million opioid pills. Although these Schedule II drugs are approved for pain management treatment, the former doctor provided no meaningful medical care and instead prescribed these controlled substances to patients he knew were suffering from substance use disorder and/or who demonstrated clear signs that the prescribed drugs were being abused, diverted or sold on the street.

In September 2022, a former Hawaii pain doctor was sentenced to seven and a half years in prison. He had been found guilty in April 2022 of all 38 counts of an indictment charging him with conspiracy to distribute oxycodone and fentanyl and distribution of oxycodone and fentanyl outside the course of professional practice and without a legitimate medical purpose.

Immediately following the Federal jury's verdict, the defendant was remanded into custody. Following a three-week trial, the jury deliberated for less than one day and convicted him of distributing substantial quantities of oxycodone, a Schedule II controlled substance, to his close friends to sell to pay for tuition at one of the most expensive private schools in the State of Hawaii and to purchase cocaine.

In June 2022, an Arkansas physician was convicted on 22 of 22 counts including conspiracy, wire fraud, mail fraud, violating the AKS, lying to the FBI, falsifying records, and aggravated identity theft. This represented the tenth and final conviction in a massive compounded drug scheme. Recruiters bribed TRICARE beneficiaries to receive "free" compounded drugs and bribed health care providers, including the defendant, to rubber stamp the necessary prescriptions without ever consulting the "patient" or determining whether the drugs were even medically necessary. In less than one year, the scheme generated hundreds of bogus prescriptions in the names of TRICARE beneficiaries from coast to coast for which TRICARE paid over $12.0 million. When the FBI and HHS-OIG began investigating, the defendant and his co-conspirators responded by lying to the authorities, altering existing business records to conceal the link between recruiters and prescribers, and fabricating medical records to make it seem as if recipients of prescriptions were bona fide patients who had been consulted by their doctor. Co-conspirators sentenced thus far have received prison terms of 51 months, 48 months, and 15 months, respectively.

In August 2022, a former Registered Nurse was sentenced to 18 months in prison for tampering with opioid medications and placing her patients in danger. Between 2019 and 2020, while employed as an RN at a hospital in Moses Lake, Washington, the defendant used a syringe to remove morphine from vials in the hospital's controlled substance area, which she then used while on the job. The defendant replaced the morphine in the vials with saline solution and glued the caps back onto the vials to conceal her theft and tampering, which resulted in patients who required and were prescribed morphine instead receiving saline solution. This conduct resulted in at least one patient being admitted to the emergency room because he did not experience any pain relief from being administered what medical staff believed to be morphine but which was, instead, saline. The court specifically found that the defendant's conduct placed her patients at risk and caused serious harm.

Psychiatric and Psychological Testing and Services

In March 2022, a Licensed Professional Counselor was sentenced to 57 months of imprisonment for fraudulently billing the Connecticut Medicaid program for over $1.3 million of psychotherapy services that he never provided. The defendant operated group homes in Connecticut for victims of domestic violence, including women and their children. The defendant required the tenants to provide copies of the Medicaid cards for themselves and their children, and then used this information to bill Medicaid for over $500,000 in fraudulent services. The defendant also worked as a guidance counselor at the New Haven Adult and Continuing Education Center, where he improperly accessed a database of personal identifying information for students and former students, which he used to determine whether the students

were Medicaid members. He then used this information to fraudulently bill Medicaid for nearly $600,000 for psychotherapy services that were not provided.

(SF) In April 2022, a jury convicted a Texas husband and wife for a $1.0 million Medicare fraud scheme. According to court documents and evidence presented at trial, the defendants were patient recruiters who owned and operated group homes in which Medicare beneficiaries lived. In exchange for sending their group home residents to a community mental health center (CMHC) that purported to provide partial hospitalization services, the CMHC paid the defendants and other patient recruiters kickbacks often concealed as payment for "transportation" or other sham services. The defendants await sentencing.

In August 2022, the former chief operating officer of a Federally qualified health center based in Louisiana was convicted of one count of conspiracy to commit health care fraud for her role in a scheme to defraud Medicaid by providing educational services in school classrooms, but then billing Medicaid approximately $1.8 million for having falsely provided "group psychotherapy" services. After learning that a mental health diagnosis was required for reimbursement, the defendant and others directed the clinic's staff to assign false mental health diagnoses to the students to further the fraudulent scheme. The defendant is awaiting sentencing.

Substance Use Treatment Centers

(SF) In November 2021 and in March 2022, the two owners and the medical director of two South Florida addiction treatment facilities were convicted at separate trials for engaging in a scheme that fraudulently billed approximately $112 million for substance abuse services that were never provided or were medically unnecessary. The two owners obtained patients through patient recruiters who offered illegal kickbacks to patients, including free airline tickets, illegal drugs, and cash payments. The medical director, a medical doctor, and others admitted patients for medically unnecessary detox services, the most expensive kind of treatment the facilities offered. The defendants submitted and caused the submission of false and fraudulent claims for excessive, medically unnecessary urinalysis drug tests that were never used in treatment. The defendants shuffled a core group of patients between the two treatment facilities in a cycle of admissions and re-admissions to fraudulently bill for as much as possible. Patients were given a so-called "Comfort Drink" to sedate them, and to keep them coming back. Patients were also given large and potentially harmful amounts of controlled substances, in addition to the "Comfort Drink," to keep them compliant and docile, and to ensure they stayed at the facility. In March 2022, the owners were sentenced to 188 months and 97 months in prison, respectively, and in July 2022, the medical director was sentenced to 54 months in prison.

In March 2022, the owner of several substance abuse treatment clinics and a toxicology lab in Eastern Kentucky was sentenced to more than 10 years in prison for schemes in which he tricked opioid-addicted patients into paying millions of dollars for services already covered by their Medicaid insurance and billed unnecessary urine drug testing services to the Medicare and Medicaid programs. As Kentucky Medicaid-enrolled providers, the defendant's clinics were required by Kentucky law to bill that insurance program for services rendered to Medicaid patients. The defendant deceived indigent, opioid-addicted patients into paying $200-$300 per month in cash for treatment at his clinics, despite having Medicaid insurance, by falsely claiming

his clinics were not eligible to bill Medicaid for counseling and related services. Cash payments from Medicaid patients totaled around $3.8 million between May 2016 and October 2019 for services that should have been free to these Medicaid beneficiaries. At the same time, the defendant caused his clinics to bill Medicaid for addiction treatment services, receiving millions in reimbursements from that program as well. In addition to the cash-for-services scheme, the defendant, who was not a doctor or medical professional, caused his laboratory to bill for medically unnecessary urine drug testing of samples collected from patients at his clinics. None of the unnecessary testing was ordered by a physician and was done solely at the defendant's direction. As well as his 125-month prison sentence, the defendant was ordered to pay $5.7 million in restitution.

Telemedicine Exploitation and Fraud

In November 2021, a business owner was sentenced to 82 months in Federal prison and ordered to pay over $61.0 million in restitution for his role in a $73.0 million conspiracy to defraud Medicare by paying kickbacks to a telemedicine company to arrange for doctors to authorize medically unnecessary genetic testing. The scheme exploited temporary amendments to telehealth restrictions enacted during the COVID-19 pandemic that were intended to ensure access to care for Medicare beneficiaries. According to court documents, the business owner admitted that he conspired with other co-owners to pay kickbacks in exchange for his work arranging for telemedicine providers to authorize genetic testing orders for the laboratories. The owners entered into a sham contract for purported IT and consultation services to disguise the true purpose of these payments. They then exploited the temporary telehealth restriction amendments by offering telehealth providers access to Medicare beneficiaries, for whom they could bill Medicare for consultations. In exchange, these providers agreed to refer beneficiaries to the laboratories for expensive and medically unnecessary cancer genetic testing.

In June 2022, a business owner was sentenced to 14 years in prison for health care and wire fraud resulting in a loss of more than $20.0 million to Medicare, and for evading taxes. According to court documents, the individual owned and operated several telemarketing and telemedicine companies to market medically unnecessary genetic tests to Medicare beneficiaries, and to sell prescriptions (i.e., doctors' orders) for medically unnecessary genetic tests to laboratories in exchange for kickbacks and bribes. The business owner knew these laboratories would use these doctors' orders to bill Medicare for medically unnecessary goods and services. Through nominee owners, the business owner also operated and controlled other companies to market compounded prescription creams to customers with certain health conditions. Pharmacies and laboratories associated with this company filled the prescriptions, billed the customers' insurance companies, and paid the business owner kickbacks. The business owner used these company accounts to purchase luxury items such as high-end watches and diamond jewelry, classic and exotic cars, two yachts, and other items. The business owner also evaded paying over $2.5 million in personal income taxes for years dating back to 2000. When the IRS attempted to collect back taxes from the business owner, he tried to conceal assets by transferring property to trusts and individuals and by repeatedly opening and closing companies, among other things. In addition to the prison term and Medicare restitution, the business owner was ordered to pay more than $4.0 million in restitution to the IRS.

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 of 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 times. 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 has 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 noninstitutional care settings, such as home health and hospice care; and strengthening Medicaid program integrity, including working with state partners to enhance the effectiveness of the MFCUs. HHS-OIG is also strengthening oversight of nursing homes, Medicare Advantage (MA) managed care plans, Medicaid managed care programs, value-based models, Medicare hospital payments efficiency, telehealth and other remote care expansion, and cybersecurity.

A certain portion of the funds appropriated under HIPAA are, by law, set aside for the Medicare and Medicaid activities of HHS-OIG. In FY 2022, the Secretary and the Attorney General jointly allotted $214.6 million to HHS-OIG. HHS-OIG was allocated an additional $13.9 million in HCFAC mandatory funds from the Secretary. Additionally, Congress appropriated $102.1 million in discretionary funding for HHS-OIG HCFAC activities.

Emergency Preparedness, Response, and Recovery

OIG has repeatedly identified strengthening emergency preparedness and response capabilities as a top management challenge for HHS. During the COVID-19 pandemic, OIG acted swiftly to protect people from harm and to protect the millions of dollars flowing to or through HHS programs—such as the Provider Relief Fund and the Uninsured Fund—by preventing, detecting, and combating fraud. It will be critical to understand the efficacy of pandemic response efforts over time and the lessons learned for responding to future pandemics and broader emergency preparedness. 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 emergency response and recovery programs, including Medicare and Medicaid programs and beneficiaries. Oversight efforts include close coordination with key government partners, including the Pandemic Response Accountability Committee.

Additional information about the HHS-OIG COVID-19 Response Strategic Plan, fraud alert, and work related to COVID-19 is available online on the COVID-19 Portal.

HHS-OIG Priority Outcomes

HHS-OIG identifies priority outcomes to achieve the greatest impact across HHS's many programs. The priority outcomes are selected based on findings from past and ongoing HHS-OIG work, top challenges facing HHS as identified annually by HHS-OIG, availability of data, and the ability to influence outcomes. For each priority outcome, HHS-OIG develops strategies, drives action, unleashes organizational creativity, and measures impact to provide solutions and improve outcomes for HHS programs and the people they serve.

Results
HHS-OIG delivers financial savings to taxpayers while protecting the health and welfare of beneficiaries and safeguarding programs from mismanagement and fraud.

In FY 2022, HHS-OIG investigations resulted in 661 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid, as well as 726 civil actions that included 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 2022 HHS-OIG excluded a total of 2,332 individuals and entities, the details of which appear 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 2022, 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 $2.9 billion—of which $ 2.4 billion was in Medicare savings and $514.0 million was in savings to the Federal share of Medicaid. HHS-OIG's expected recoveries from its involvement in health care audits and investigations totaled more than $3.9 billion, which resulted in an ROI of about $11.00 to $1.00[15]

Additional information about savings achieved through such policy and procedural changes may be found in the HHS-OIG fall Semiannual Report to Congress that appears 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 settlements of False Claims Act cases, including settlements reached through negotiations of Corporate Integrity Agreements (CIAs). HHS-OIG works with 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.

[15]This ROI uses a three-year average of expected recoveries, fines, penalties, and stolen and misspent funds relating to HHS-OIG's health care oversight that is compared to 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 types and sizes of settlements and identified disallowances, complexity of schemes that are subject to HHS-OIG scrutiny in a given year, and heightened focus on high-value but low-dollar work addressing patient safety and quality of care.

Strike Force Operations

In FY 2022, HHS-OIG continued to staff and support Strike Force operations working in conjunction with the 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 and Philadelphia, Pennsylvania; along with the NRRSF in Washington, D.C. HHS-OIG supports Strike Force operations by providing investigative, analytic, and forensic resources.

In addition to fighting 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 July 2022, a nationwide enforcement action resulted in criminal charges against 36 defendants in 13 Federal districts across the United States for more than $1.2 billion in alleged fraudulent telemedicine, cardiovascular and cancer genetic testing, and DME schemes. HHS-OIG works alongside Strike Force partners to disrupt fraud schemes that use the guise of telehealth to expand the reach of kickback schemes designed to cheat Federally funded health care programs. The continued support of Strike Force operations is a top priority for HHS-OIG.

Combating the Opioid Epidemic

Fighting the opioid crisis and protecting beneficiaries from prescription drug abuse are among HHS-OIG's top priorities. Opioid-related matters comprise a substantial portion of HHS-OIG's investigations. In addition to the opioid-related nationwide enforcement actions, in FY 2022 HHS-OIG excluded 446 providers based on conduct related to opioid diversion and abuse.

Program Exclusions

One important mechanism that HHS-OIG uses to safeguard program beneficiaries and help ensure the quality of care provided to them is excluding providers and suppliers who have engaged in crimes related to Medicare or Medicaid, patient abuse or neglect, financial misconduct, or controlled substances, or who have had their licenses to provide health care revoked. This list of conduct is not exhaustive but identifies the most prevalent cases 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 2022, HHS-OIG excluded a total of 2,332 individuals and entities. In addition to those mentioned in the Enforcement Actions section above, exclusion actions by HHS-OIG included:

- **Louisiana:** On February 20, 2022, HHS-OIG excluded seven nursing homes in the State of Louisiana for an indefinite period of time based on the State's actions to revoke their

licenses to operate as nursing homes. Based on those exclusion actions, HHS-OIG excluded the owner of the nursing homes on May 22, 2022, under its authority to exclude owners of sanctioned entities. As background, the nursing homes lost their operating licenses following a series of documented violations identified in the aftermath of Hurricane Ida. Specifically, the nursing homes evacuated more than 800 residents of the facilities to a single warehouse where state inspectors observed residents living in inhumane conditions (e.g., residents were sleeping on mattresses near standing water, some were undressed or naked, and others were calling for help but had been left alone with full diapers). During these onsite visits, the owner attempted to threaten, intimidate and interfere with the assessment of the site, where seven residents eventually died.

- **Texas**: On February 20, 2022, HHS-OIG excluded a medical doctor who owned and operated several clinics in Texas for a minimum period of 35 years based on convictions related to operating a "pill mill" scheme that dispensed and distributed controlled substances for nine years. The court sentenced this physician to 240 months of incarceration, and the Texas Medical Board revoked his license to practice.

- **Virginia**: On March 30, 2022, HHS-OIG excluded a nurse for a minimum period of 25 years based on his conviction for sexual assaults of a 72-year-old bedridden patient over several months. The court sentenced this individual to serve eight years of incarceration, and the Virginia Department of Health Professions suspended this individual's license to practice.

- **Mississippi**: On April 20, 2022, HHS-OIG excluded a private business owner for a minimum period of 80 years based on a health care fraud conviction for defrauding TRICARE by causing fraudulent claims for compound medications to be submitted for high-dollar reimbursements without regard for patient need. The court sentenced this individual to 156 months of incarceration and ordered payment of approximately $184,407,600 in restitution.

- **North Carolina**: On May 19, 2022, HHS-OIG excluded the owner and operator of a billing agency for a minimum period of 30 years based on a conviction for health care fraud conspiracy. Specifically, the individual engaged in a scheme to defraud Medicaid by submitting claims that were false and fraudulent. The court ordered payment of approximately $6,121,600 in restitution, and the individual was sentenced to 84 months of incarceration.

- **Georgia**: On May 19, 2022, a dietary supplements company and its owner were excluded for a minimum period of three years based on their convictions for introducing a misbranded drug into interstate commerce in violation of the Federal Food, Drug, and Cosmetic Act. Specifically, the individual and company pleaded guilty to selling and distributing a Vitamin D product with false and misleading marketing claims, namely that it would lower consumer risk of contracting COVID-19.

- **Washington**: On July 20, 2022, a medical doctor in Seattle was excluded for a minimum period of 18 years based on a conviction by jury on multiple counts of wire fraud, bank fraud, and money laundering. Specifically, the physician submitted false and misleading loan applications as part of a fraud scheme to obtain funding from the Paycheck Protection Program and EIDL Program, which were authorized by the CARES Act to offset economic hardships caused by the COVID-19 pandemic. In addition, the court ordered payment of $1,438,000 in restitution and sentenced the doctor to 48 months of incarceration. The Washington Department of Health Medical Commission also suspended the doctor's license to practice.

- **Texas**: On August 18, 2022, HHS-OIG excluded a medical doctor for a minimum period of 25 years based on convictions for conspiracy to distribute a controlled substance and commit mail fraud. In addition to illegally dispensing controlled substances (e.g., hydrocodone), this physician conspired with others to unlawfully enrich themselves by submitting fraudulent claims to workers' compensation programs as well as other health insurers for medical services that were not rendered. The court ordered the medical doctor to pay approximately $376,300 in restitution and serve 144 months of incarceration.

- **Maine**: On September 20, 2022, HHS-OIG excluded a physician's assistant for a minimum period of 23 years based on a conviction of unlawful sexual contact with a minor patient. The court also sentenced the physician's assistant to seven years of incarceration, and the Maine State Board of Medical Licensure revoked the physician's license.

Civil Monetary Penalties Law

HHS-OIG has the authority to seek CMPs, assessments, and exclusions under the Civil Monetary Penalties Law (CMPL) against an individual or entity based on a wide variety of prohibited conduct. HHS-OIG brings CMP cases 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 its CMP authorities in three common ways: (1) false claims and kickback affirmative enforcement, (2) Emergency Medical Treatment and Labor Act (EMTALA) enforcement, and (3) the Self-Disclosure Protocol. In FY 2022, HHS-OIG concluded cases involving more than $65.1 million in CMPs and assessments.

Affirmative Litigation and Exclusion

HHS-OIG may seek a CMP or exclusion against an individual or entity that presents 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 an individual or entity that knowingly and willfully violates 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 2022, HHS-OIG recovered more than $15.2 million in false claims and kickback affirmative enforcement actions. HHS-

OIG also excluded 45 individuals and entities from participation in Federal health care programs based on allegations of false claims and kickbacks. Affirmative litigation examples include:

- In July 2022, a physician and the physician's practice entered into a $409,809 settlement agreement with HHS-OIG. The settlement agreement resolved allegations that the physician and practice submitted claims to Medicare for facet joint injections and denervations that exceeded the allowable number of sessions in a rolling 12-month period.

- In July 2022, an ambulance company entered into a $1,578,412 settlement agreement with HHS-OIG. The settlement agreement resolved allegations that the company presented claims to Medicare Part B for ambulance transportation to and from skilled nursing facilities (SNFs) where such transportation was already covered by the SNF consolidated billing payment under Medicare Part A.

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 an emergency department with an emergency medical condition. In FY 2022, HHS-OIG recovered more than $1.4 million in cases under the EMTALA statute. A patient dumping example follows:

- In December 2021, HHS-OIG entered into a settlement agreement for $725,000 with a 741-bed acute care hospital. HHS-OIG identified 29 incidents in which the hospital violated EMTALA. In each of these incidents, a patient presented to the hospital's Emergency Department (ED) with an unstable psychiatric emergency medical condition. In each incident, the hospital failed to provide—with the staff and facilities available at the hospital—further medical examination and treatment required to stabilize the patient's emergency medical condition. In two of these incidents, rather than admitting the patient to the hospital's inpatient psychiatric unit, which had the capability and capacity to treat the patient, the hospital discharged the patient home with an unstable emergency medical condition. For other presentments the hospital, rather than admitting the patient to the inpatient psychiatric unit, held the patient inappropriately in its ED for more than 24 hours before transferring the patient to other surrounding facilities. The decision to transfer the patient, and where to transfer the patient, was made by the hospital and was based, in part, on the patient's insurance status.

Self-Disclosure Protocol

HHS-OIG maintains the Self-Disclosure Protocol (the 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 persons to detect and prevent fraud internally and to bring potential fraud to HHS-OIG's attention. Under the Protocol, HHS-OIG provides these persons with speedy resolutions, reduced CMPs, and other benefits compared to affirmative cases brought by HHS-OIG or DOJ for similar conduct. HHS-

OIG collected $46.0 million under the Protocol in FY 2022. Self-disclosure examples include:

- In May 2022, an Illinois hospital network self-disclosed conduct to HHS-OIG and paid $6,232,195.50 for allegedly violating the Civil Monetary Penalties Law. HHS-OIG alleged that the hospital network knowingly submitted claims to Medicare Part A for inpatient psychiatric admissions that were not medically necessary.

- In May 2022, a Maryland based anesthesia medical group self-disclosed conduct to HHS-OIG and paid $1,117,684.50 for allegedly violating the Civil Monetary Penalties Law. HHS-OIG alleged that the group knowingly submitted claims to Federal health care programs for services provided by certified registered nurse anesthetists (CRNAs) who were not authorized to bill for their services on behalf of the group. Therefore, the group billed for these services under the name of another CRNA who was authorized to bill on behalf of the group.

- In February 2022, a Florida hospital self-disclosed conduct to HHS-OIG and paid $12,721,885.58 for knowingly submitting claims to the Medicare, Medicaid, and TRICARE programs for professional and technical fees for certain pain management procedures and evaluation and management services performed by two independent contractor-physicians at the hospital's facilities that did not meet Federal health care program coverage criteria. The specific procedures that were improperly billed by the hospital include epidurals, paravertebral facet joint blocks, implantable infusion pumps for treatment of intractable pain, sacroiliac joint injections, injection of trigger points, destruction of paravertebral facet joint nerves, and radiology services.

Corporate Integrity Agreements (CIAs) 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 compliance program and taking other specified steps to ensure future compliance with Federal health care program rules. The compliance programs are designed, in part, to prevent future fraud. HHS-OIG monitors providers' compliance with these agreements. Parties to CIAs are required to disclose certain "reportable events" which may implicate HHS-OIG's CMP authorities. HHS-OIG may impose penalties on entities that fail to comply with the requirements of their CIAs. HHS-OIG collected more than $2.4 million through reportable events under CIAs in FY 2022. Examples include:

- In June 2022, after it disclosed conduct to HHS-OIG pursuant to its CIA, a Michigan hospital agreed to pay $1,732,548 for allegedly violating the CMP by paying kickbacks. HHS-OIG alleged that the hospital: (1) paid remuneration to cardiologists in the form of excess compensation, and (2) paid remuneration to a medical practice in the form of free use of medical equipment and personnel.

- In December 2021, a large, nationwide pharmacy chain under a CIA agreed to pay $512,923 to resolve allegations that it reported under its CIA. The pharmacy reported that it paid improper remuneration to induce referrals in violation of the AKS and the Physician Self-Referral Law. From 2013 to 2019, the pharmacy paid remuneration in the form of discounts on retail product purchases at its locations in Puerto Rico to 1,719 health care professionals who wrote prescriptions for items that were paid for by a Federal health care program.

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 any one 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 alignments with strategic goals, etc. With respect to Medicare and Medicaid, HHS-OIG uses a risk assessment approach to focus oversight on protecting programs and patients from fraud and ensuring sound program management, payment accuracy, patient safety, and quality of care.

In FY 2022, HHS-OIG issued 114 audit reports and 43 evaluations, resulting in 445 new recommendations issued to HHS operating divisions, HHS grantees, and other entities. During this same time period, 431 HHS-OIG recommendations were implemented.

Select examples of HHS-OIG's audit and evaluation findings in FY 2022 are listed below and organized by reports that: (1) minimize risks to beneficiaries, and (2) safeguard programs from improper payments and fraud.

Minimize Risks to Beneficiaries

Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018. One in four Medicare patients experienced patient harm events during their hospital stays in October 2018. Patient harm events indicate that a patient's care resulted in an undesirable clinical outcome not caused by underlying disease. Forty-three percent of these harm events could have been prevented. Our findings can help the CMS and the Agency for Health care Research and Quality (AHRQ) track and reduce patient harm in hospitals and improve patient safety. CMS and AHRQ concurred with some but not all of our seven recommendations. We recommended that CMS: (1) update and broaden its hospital-acquired condition lists to capture common, preventable, and high-cost harm events; (2) explore expanding the use of patient safety metrics in pilots and demonstrations for health care payment and service delivery as appropriate; and (3) as the HHS-OIG previously recommended, develop and release interpretive guidance to surveyors for assessing hospital compliance with requirements to track and monitor patient harm. In addition, this report included four recommendations to AHRQ: (1) with support from HHS leadership, reassess patient safety efforts across the Department by ensuring that agencies update quality strategic plans, identify weaknesses, and address gaps in these efforts; (2) complete development and deployment of its new surveillance system to effectively

track and monitor patient harm events; (3) develop an effective model to disseminate information on national clinical practice guidelines or best practices to improve patient safety; and (4) continue efforts to identify and develop new strategies to prevent common patient harm events in hospitals. (OEI-06-18-00400)

Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care. Medicare Advantage Organizations (MAOs) sometimes denied prior authorization and payment requests that met Medicare coverage rules; we found that 13 percent of prior authorization requests that MAOs denied, and 18 percent of payment requests that MAOs denied, met Medicare coverage rules and/or MAO billing rules. When MAOs deny requests for Medicare-covered services, they may prevent or delay beneficiaries from accessing needed care and create administrative burden for both beneficiaries and providers. CMS concurred with our recommendations to: (1) issue new guidance on the appropriate use of MAO clinical criteria in medical necessity reviews; (2) update its audit protocols to address the issues identified in this report, such as MAO use of clinical criteria and/or examining particular service types; and (3) direct MAOs to take additional steps to identify and address vulnerabilities that can lead to manual review errors and system errors. (OEI-09-18-00260)

Most Medicare Beneficiaries Received Telehealth Services Only From Providers With Whom They Had an Established Relationship. From March 2020 through December 2020, most beneficiaries received telehealth services from providers with whom they had an established relationship. These beneficiaries tended to see their providers in person about four months prior to their first telehealth service, on average. Beneficiaries enrolled in traditional Medicare were more likely to receive services from providers with whom they had an established relationship, compared to beneficiaries in Medicare Advantage. This data snapshot provides information to policymakers and other stakeholders about the relationship between beneficiaries and providers of telehealth services. These data are critical to informing decisions about how to structure telehealth services in Medicare on a more permanent basis. (OEI-02-20-00521)

More Than One-Third of Medicaid-Enrolled Children in Five States Did Not Receive Required Blood Lead Screening Tests. In 5 States, we found that more than 380,000 Medicaid-enrolled children did not receive a blood lead screening test at 12 months or 24 months of age, as required by Medicaid's schedule. Prevention is key to avoiding the permanent developmental effects of lead exposure in children. Scheduled blood lead screening tests can help support early detection of elevated lead levels, timely follow-up, and improved outcomes. CMS concurred with all of our recommendations, which were: (1) monitor national Early and Periodic Screening, Diagnostic, and Treatment program performance data for blood lead screening tests and target efforts toward low-performing states to develop action plans for increasing the provision of blood lead screening tests, according to Medicaid's schedule; (2) ensure consistency across CMS guidance related to actionable blood lead reference values (i.e., the blood lead level at which public health actions should be initiated) and blood lead screening test definitions; and (3) coordinate with partners to develop and disseminate to state Medicaid agencies educational resources that reaffirm requirements and schedules for blood lead screening tests. (OEI-07-18-00371)

Many Medicare Beneficiaries Are Not Receiving Medication to Treat Their Opioid Use Disorder. About 1 million Medicare beneficiaries were diagnosed with opioid use disorder in 2020, yet less than 16 percent of these beneficiaries received medication to treat their opioid use disorder and even fewer received both medication and behavioral therapy. These findings show a need to increase the number of Medicare beneficiaries receiving treatment for opioid use disorder. CMS concurred with the following recommendations: (1) conduct additional outreach to beneficiaries to increase awareness about Medicare coverage for the treatment of opioid use disorder, (2) take steps to increase the number of providers and opioid treatment programs for Medicare beneficiaries with opioid use disorder, (3) create an action plan and take steps to address disparities in the treatment of opioid use disorder, and (4) collect data on the use of telehealth in opioid treatment programs. CMS did not explicitly indicate whether it concurred or nonconcurred with two recommendations: (1) assist the Substance Abuse and Mental Health Services Administration by providing data about the number of Medicare beneficiaries receiving buprenorphine in office-based settings and the geographic areas where Medicare beneficiaries remain underserved, and (2) take steps to increase the utilization of behavioral therapy among beneficiaries receiving medication to treat opioid use disorder. (OEI-02-20-00390)

Certain Medicare Beneficiaries, Such as Urban and Hispanic Beneficiaries, Were More Likely Than Others to Use Telehealth During the First Year of the COVID-19 Pandemic. Beneficiaries in urban areas were more likely than those in rural areas to use telehealth during the first year of the pandemic. Beneficiaries in Massachusetts, Delaware, and California were more likely than beneficiaries in some other states to use telehealth. Dually eligible beneficiaries (i.e., those eligible for both Medicare and Medicaid), Hispanic beneficiaries, younger beneficiaries, and female beneficiaries were also more likely than others to use telehealth. In addition, beneficiaries almost always used telehealth from home or other non-health-care settings. Furthermore, almost one-fifth of beneficiaries used certain audio-only telehealth services, with the vast majority of these beneficiaries using these audio-only services exclusively. Older beneficiaries were more likely to use these audio-only services, as were dually eligible and Hispanic beneficiaries. As CMS, HHS, Congress, and other stakeholders consider permanent changes to Medicare telehealth services, it is important that they balance concerns about issues such as access, quality of care, health equity, and program integrity. CMS did not explicitly indicate whether it concurred with our four recommendations. Our recommendations were for CMS to: (1) take appropriate steps to enable a successful transition from current pandemic-related flexibilities to well-considered long-term policies for the use of telehealth for beneficiaries in urban areas and from the beneficiary's home; (2) temporarily extend the use of audio-only telehealth services and evaluate their impact; (3) require a modifier to identify all audio-only telehealth services provided in Medicare; and (4) use telehealth to advance health care equity. (OEI-02-20-00522)

Opioid Overdoses and the Limited Treatment of Opioid Use Disorder Continue To Be Concerns for Medicare Beneficiaries. About 50,400 Medicare Part D beneficiaries experienced an opioid overdose in 2021. Also, almost a quarter of Part D beneficiaries received opioids during 2021. In addition, more than 1 million Medicare beneficiaries had a diagnosis of opioid use disorder in 2021, yet fewer than one in five received medication to treat their opioid use

disorder. At the same time, the number of beneficiaries receiving prescriptions for naloxone—a drug that reverses opioid overdoses—through Part D grew. Monitoring opioid use and access to medications for the treatment of opioid use disorder as well as to naloxone are critical to addressing the opioid crisis. A December 2021 HHS-OIG report recommended that the CMS take steps to improve access to medications for the treatment of opioid use disorder and other support services. We continue to call attention to the importance of implementing these recommendations and to ensuring access to treatment for opioid use disorder. (OEI-02-22-00390)

Six of Eight Home Health Agency Providers Had Infection Control Policies and Procedures That Complied With CMS Requirements and Followed CMS COVID-19 Guidance To Safeguard Medicare Beneficiaries, Caregivers, and Staff During the COVID-19 Pandemic. Six of the eight selected Home Health Agency (HHA) providers had infection control policies and procedures that complied with CMS requirements and followed CMS guidance to safeguard HHA staff, Medicare beneficiaries, and caregivers during the COVID-19 pandemic. However, one HHA provider did not comply with CMS requirements or follow CMS COVID-19 guidance. Specifically, this HHA provider's infection control policies and procedures did not: (1) require staff to follow one of the standard precautions to prevent the transmission of infections and communicable diseases, (2) include documentation of surveillance methods used for identifying and tracking infections and improvement activities to prevent infection, (3) include COVID-19 screening protocols for staff in accordance with CMS guidance, and (4) include information about how to care for patients with known or suspected COVID-19 in accordance with CMS guidance. In addition, this provider and another HHA provider's COVID-19 screening protocols for patients were not consistent with CMS guidance. As a result, the patients and staff at these two HHA providers were at an increased risk of infection. (A-01-20-00508)

Inaccuracies in Medicare's Race and Ethnicity Data Hinder the Ability to Assess Health Disparities. We found that Medicare's enrollment race and ethnicity data are less accurate for some groups, particularly for beneficiaries identified as American Indian/Alaska Native, Asian/Pacific Islander, and Hispanic. Data that are not accurate limit the ability to assess health disparities. Limited race and ethnicity categories and missing information contribute to inaccuracies in the enrollment data. Although the use of an algorithm improves the existing data to some extent, it falls short of self-reported data. Finally, Medicare's enrollment data on race and ethnicity, primarily sourced from the Social Security Administration (as the entity responsible for enrolling Medicare-eligible individuals into Medicare), are inconsistent with Federal data collection standards, which inhibits the work of identifying and improving health disparities within the Medicare population. Advancing health equity is a priority for CMS and the Department. Race and ethnicity data are foundational to identifying and understanding health disparities among Medicare beneficiaries and to assessing the effectiveness of efforts to reduce such disparities. It is critical that these data are accurate, complete, and comprehensive. Therefore, CMS must improve the accuracy of its race and ethnicity data collection; though a significant undertaking, the need for better data is pressing. Accordingly, we recommend that CMS: (1) develop its own source of race and ethnicity data, (2) use self-reported race and ethnicity information to improve data for current beneficiaries, (3) develop a process to ensure that the data are as standardized as possible, and 4) educate beneficiaries about CMS's efforts to

improve the race and ethnicity information. CMS did not explicitly concur with the first recommendation and concurred with the other three recommendations. (OEI-02-21-00100)

Audits of Nursing Home Life Safety and Emergency Preparedness in Eight States Identified Noncompliance With Federal Requirements and Opportunities for the Centers for Medicare & Medicaid Services to Improve Resident, Visitor, and Staff Safety. We identified a total of 2,233 areas of noncompliance with life safety and emergency preparedness requirements at 150 of the 154 nursing homes we visited. Specifically, we identified 1,094 areas of noncompliance with life safety requirements and 1,139 areas of noncompliance with emergency preparedness requirements. These deficiencies occurred because of several factors, including inadequate oversight by management, staff turnover, inadequate oversight by state survey agencies, and a lack of any requirement for mandatory participation in standardized life safety training programs. As a result, residents, visitors, and staff at the nursing homes were at increased risk of injury or death during a fire or other emergency. CMS subsequently followed up with state survey agencies to determine whether they had addressed the recommendations included in our prior audits and, according to CMS, the States had already taken acceptable actions to address our recommendations. We identified several opportunities for CMS to expand on its life safety requirements for nursing homes to improve the safety of residents, visitors, and staff. Among other findings, CMS could propose regulations requiring nursing homes to install carbon monoxide detectors according to national standards. We also noted areas in which CMS could improve its support for state survey operations and nursing home training. CMS could work with state survey agencies to address issues preventing more frequent surveys of high-risk facilities and require mandatory participation in standardized nursing home staff training. (A-02-21-01010)

An Estimated 91 Percent of Nursing Home Staff Nationwide Received the Required COVID-19 Vaccine Doses, and an Estimated 56 Percent of Staff Nationwide Received a Booster Dose. As of the week ended March 27, 2022, we determined for the 1,000 nursing home staff members in our sample that 884 had received the required vaccine doses (506 of these staff members had also received a booster dose); 78 had been granted an exemption from receiving the vaccine based on a sincerely held religious belief, practice, or observance (religious exemption); 12 were partially vaccinated; 3 had been granted an exemption from receiving the vaccine based on a medical condition (medical exemption); and 3 had applied for an exemption that was being reviewed by a nursing home. For the remaining 20 staff members in our sample, the nursing homes did not provide us with documentation related to the staff members' vaccination status, or the documentation provided did not clearly identify the staff members' vaccination status. As a result, we were not able to determine the vaccination status of these staff members. On the basis of our sample results, we estimated that 91 percent of staff nationwide had received the required vaccine doses, 56 percent of staff nationwide had received a booster dose, and 6 percent of staff nationwide had been granted a religious exemption. We did not estimate the percentages among the small number of staff members (i.e., 38) in our nationwide sample results who were partially vaccinated, who were granted a medical exemption, who applied for an exemption that was being reviewed, or for whom the vaccination status could not be determined. In addition, the estimated percentages of staff who received the required vaccine doses, staff who received a booster dose, and staff who were granted a religious exemption varied depending on the location

(i.e., the HHS region) of the nursing homes in which they worked. (A-09-22-02003)

Arkansas Did Not Fully Comply With Federal and State Requirements for Reporting and Monitoring Critical Incidents Involving Medicaid Beneficiaries With Developmental Disabilities. Arkansas did not fully comply with Federal Medicaid waiver and State requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities who resided in community-based settings. Specifically, Arkansas did not: (1) ensure that community-based providers properly reported all incidents of suspected adult or child abuse to the appropriate hotline, (2) provide evidence of review and follow-up action on all incidents of adult or child abuse, and (3) review all deaths of beneficiaries receiving waiver services. These issues occurred because Arkansas did not have controls in place to ensure that incidents of abuse, neglect, or death were reviewed and reported to the appropriate authority. Additionally, Arkansas did not ensure that all incidents involving Medicaid beneficiaries, including incidents of death, were reported because its waiver did not clearly require that incidents that occurred outside of State custody or State facilities be reported. Also, Arkansas did not have adequate internal controls in place to detect unreported incidents. (A-06-17-01003)

Massachusetts Implemented Our Prior Audit Recommendations and Generally Complied With Federal and State Requirements for Reporting and Monitoring Critical Incidents. Massachusetts implemented the five recommendations from our prior audit and generally complied with Federal and state requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities residing in group homes. However, the corrective actions for one recommendation in our prior audit were not effective in addressing one of our previous findings. Specifically, Massachusetts did not ensure all reasonable suspicions of abuse or neglect were reported to the Disabled Persons Protection Commission. One possible reason that this issue occurred is because the Massachusetts Department of Developmental Services and group home staff were only required to take mandated reporter training on reporting reasonable suspicions of abuse and neglect (a corrective action) once rather than periodically. Because Massachusetts did not ensure that all reasonable suspicions of abuse or neglect were reported, it did not fulfill all of the participant safeguard assurances it provided to CMS in the Medicaid Home and Community-Based Services Intensive Supports waiver along with the State requirements incorporated under the waiver. (A-01-20-00003)

Certain Nursing Homes May Not Have Complied With Federal Requirements for Infection Prevention and Control and Emergency Preparedness. Selected nursing homes may not have complied with Federal requirements for infection prevention and control and emergency preparedness. Specifically, 28 of the 39 nursing homes had possible deficiencies. We found 48 instances at 25 nursing homes of possible noncompliance with infection prevention and control requirements and 18 instances at 18 nursing homes of possible noncompliance with emergency preparedness requirements related to all-hazards risk assessments and strategies to address emerging infectious diseases. The nursing homes attributed the possible noncompliance to: (1) nursing home inadequate internal controls, (2) nursing home inadequate management oversight, (3) nursing home administrative and leadership changes, (4) inadequate communication and training from the CMS, and (5) inconsistent and confusing regulations. (A-01-20-00005)

CMS Should Take Further Action To Address States With Poor Performance in Conducting Nursing Home Surveys. Slightly more than half of State survey agencies (states) repeatedly failed to meet requirements for conducting nursing home surveys during FYs 2015-2018, yet CMS rarely imposed higher-level sanctions in contrast to the more frequently used remedies and alternative sanctions, such as training or improvement plans. Without effective oversight of nursing homes by the States, residents may be at increased risk for harm and poor care. CMS concurred with the following recommendations: (1) actively monitor the use and effectiveness of States' corrective action plans and other remedies, with a focus on making the remedies specific and outcome-oriented; (2) establish guidelines for progressive enforcement actions, including the use of sanctions, when persistent or egregious performance problems emerge; (3) engage with senior State officials earlier and more frequently to address State performance problems; and (4) revise the State Operations Manual to reflect current CMS practices in overseeing State survey performance. CMS did not concur or nonconcur with the remaining recommendation to disseminate results of State performance reviews more widely to ensure stakeholders become aware of problems. (OEI-06-19-00460)

Maine Implemented Our Prior Audit Recommendations and Generally Complied With Federal and State Requirements for Reporting and Monitoring Critical Incidents. Maine implemented the seven recommendations from our prior audit and generally complied with Federal and State requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities. In addition, the corrective actions implemented in response to five of the seven recommendations were effective in addressing the related findings. However, Maine's corrective actions for two recommendations were not fully implemented by the conclusion of our current audit period and, therefore, were only partially effective in addressing two of our previous findings. We concluded that the corrective actions were not fully effective in addressing these findings because Maine did not ensure that all follow-up reports were completed by community-based providers within 30 days of each incident and that the Mortality Review Committee conducted a trend analysis based on completed Mortality Review Form aggregate data. As a result, Maine did not fulfill all of the participant safeguard assurances it provided to CMS in the Medicaid Home and Community-Based Services Waiver along with the state requirements incorporated under the waiver. (A-01-20-00007)

Certain Life Care Nursing Homes May Not Have Complied With Federal Requirements for Infection Prevention and Control and Emergency Preparedness. Selected Life Care nursing homes may not have complied with Federal requirements for infection prevention and control and emergency preparedness. Specifically, 23 of the 24 nursing homes selected had possible deficiencies. Actual deficiencies can only be determined following a thorough investigation by trained surveyors. At 22 nursing homes, we found 35 instances of possible noncompliance with infection prevention and control requirements related to annual reviews of the Infection Prevention and Control Program, training, designation of a qualified infection preventionist, and Quality Assessment and Assurance Committee meetings. We also found at 16 nursing homes 20 instances of possible noncompliance with emergency preparedness requirements related to the annual review of emergency preparedness plans and annual emergency preparedness risk assessments. Life Care officials attributed the possible noncompliance to: (1) leadership turnover, (2) staff turnover. (3) documentation issues (i.e., information was not documented or

documentation was either lost or misplaced), (4) staff members who were unfamiliar with requirements (i.e., requirements stipulating that there is no grace period for infection preventionists to complete specialized training and that emergency preparedness plans needed to be reviewed annually), (5) qualified personnel shortage, and (6) challenges related to the COVID-19 public health emergency. We also believe that many of the conditions noted in our report occurred because CMS did not provide nursing homes with communication and training for complying with the new, phase 3 infection control requirements, or clarification about the essential components to be integrated in the nursing homes' emergency plans. (A-01-20-00004)

Selected Dialysis Companies Implemented Additional Infection Control Policies and Procedures To Protect Beneficiaries and Employees During the COVID-19 Pandemic. The nine selected dialysis companies surveyed (representing 83 percent of the end-stage renal disease (ESRD) facilities that had a Medicare or Medicaid certification at any point during 2020) implemented additional infection control policies and procedures in accordance with CMS and CDC recommendations to protect high-risk ESRD beneficiaries and employees during the COVID-19 pandemic. We found all nine companies had infection control policies and procedures in place to protect beneficiaries and employees, and when recommended by CMS and CDC, the companies implemented additional policies and procedures. However, while two companies provided education about the importance of hand hygiene, they did not emphasize the importance of hand hygiene immediately before and after any contact with a facemask or cloth face covering, as recommended by CDC. (A-05-20-00052)

End-Stage Renal Disease Network Organizations' Reported Actions Taken in Response to the COVID-19 Pandemic. The 18 ESRD Network Organizations that we surveyed provided information about the actions they took to aid dialysis clinics and patients and keep CMS informed about quality-of-care issues that arose during the COVID-19 pandemic. Network Organizations also reported to us challenges they encountered in taking those actions during the pandemic. Despite the unprecedented challenges faced by the Network Organizations during the pandemic, they took actions to ensure continuity of services in a safe manner for high-risk ESRD beneficiaries. Network Organizations served a key role in addressing the additional demands on dialysis clinics during the pandemic through actions such as: (1) disseminating changing guidance, (2) aiding dialysis clinics to address the increased concerns and grievances related to the pandemic, and (3) promoting safe alternative treatment options. Network Organizations also kept CMS informed of quality-of-care issues by communicating through established communication processes and processes modified for better use during the pandemic. (A-05-20-00051)

<u>Safeguard Programs From Improper Payments and Fraud</u>

Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks. We identified 1,714 providers whose billing for telehealth services during the first year of the pandemic poses a high risk to Medicare. Each of these 1,714 providers had concerning billing on at least one of seven measures we developed that may indicate fraud, waste, or abuse of telehealth services. In addition, more than half of the high-risk providers we identified are a part of a medical practice with at least one other provider whose billing poses a high risk to Medicare. Furthermore, 41 providers whose billing poses a high risk appear to be associated with telehealth

companies. Although these high-risk providers represent a small proportion of all providers who billed for a telehealth service, these findings demonstrate the importance of strong, targeted oversight of telehealth services. CMS concurred with our recommendation to follow up on the providers identified in this report, but CMS did not explicitly indicate whether it concurred with the other four recommendations. Our recommendations were for CMS to: (1) strengthen monitoring and targeted oversight of telehealth services, (2) provide additional education to providers on appropriate billing for telehealth services, (3) improve the transparency of incident-to-services when clinical staff primarily delivered the telehealth service, (4) identify telehealth companies that bill Medicare, and (5) follow up on the providers identified in this report. (OEI-02-20-00720)

Medicare and Beneficiaries Pay More for Preadmission Services at Affiliated Hospitals Than at Wholly Owned Settings. Because the DRG window policy does not cover affiliated hospitals, Medicare and beneficiaries paid $168.0 million and $77.0 million, respectively, in 2019 for admission-related outpatient services that—if provided at wholly owned hospitals—would not have required separate outpatient payments. (The policy states that if a beneficiary is furnished outpatient hospital services and is admitted to the hospital shortly afterward for the same condition, the outpatient services are considered part of the admission and are included in the pre-set inpatient payment amount, rather than resulting in separate payments for the outpatient services). These findings indicate that Medicare and beneficiaries may be overpaying for these services, as affiliated settings are similar to wholly owned settings in key ways. CMS neither concurred nor nonconcurred with our recommendation, which was for it to evaluate the potential impacts of updating the DRG window policy to include affiliated hospitals and seek the necessary legislative authority to update the policy as appropriate. (OEI-05-19-00380)

Facility-Initiated Discharges in Nursing Homes Require Further Attention. Our findings raise concerns about weaknesses in the safeguards to protect nursing home residents from harm that may result from inappropriate facility-initiated discharges. Our findings can help ACL assist Ombudsmen with responding to potentially inappropriate facility-initiated discharges. Our findings can also help CMS improve its oversight of inappropriate facility-initiated discharge in nursing homes. CMS concurred with our recommendations to: (1) provide training for nursing homes on Federal requirements for facility-initiated discharge notices, (2) assess the effectiveness of its enforcement of inappropriate facility-initiated discharges, and (3) implement its deferred initiatives to address inappropriate facility-initiated discharges. ACL concurred with our recommendations to: (1) assist State ombudsman programs in establishing a data-collection system for facility-initiated discharge notices, and (2) establish guidance for analysis and reporting of data collected by state ombudsman programs from facility-initiated discharge notices. ACL and CMS did not explicitly state whether they concurred with our joint recommendation to coordinate to strengthen safeguards to protect nursing home residents from inappropriate facility-initiated discharges. ACL and CMS concurred with our joint recommendation to ensure all State ombudsmen, state agencies, and CMS regional offices have an ongoing venue to share information about facility-initiated discharges and potentially other systemic problems in nursing homes. (OEI-01-18-00250)

COVID-19 Tests Drove an Increase in Total Medicare Part B Spending on Lab Tests in 2020, While Use of Non-COVID-19 Tests Decreased Significantly. Medicare Part B spent $1.5 billion on COVID-19 tests in 2020, while at the same time, spending on non-COVID-19 tests declined by $1.2 billion. The result was a net spending increase of four percent, but the decrease in utilization of non-COVID-19 tests raises questions about the potential impact on beneficiary health. Our data brief contained no recommendations. (OEI-09-21-00240)

Medicare Part D and Beneficiaries Would Realize Significant Spending Reductions With Increased Biosimilar Use. Biosimilars—lower cost, highly similar alternatives to existing biologic drugs approved by FDA—have the potential to significantly reduce costs for Medicare Part D and beneficiaries if their use becomes more widespread. Yet biosimilars are used far less frequently than their higher cost biologic alternatives, and a lack of biosimilar coverage on Part D formularies could limit wider utilization. Our findings can help CMS and beneficiaries capitalize on potential savings associated with the increased use of biosimilars instead of existing biologics. CMS concurred with our first recommendation and neither concurred nor nonconcurred with our second recommendation. Our recommendations were for CMS to encourage Part D plans to increase access to and use of biosimilars and monitor Part D plans' submitted formularies to determine whether they discourage beneficiaries from using biosimilars. (OEI-05-20-00480)

Part D Plan Preference for Higher-Cost Hepatitis C Drugs Led to Higher Medicare and Beneficiary Spending. Medicare Part D beneficiaries are much less likely than Medicaid beneficiaries to receive lower-cost versions of the same drugs (i.e., authorized generics)—as well as other widely used, lower-cost brand name drugs—to treat hepatitis C. Part D's programmatic structure may lead plan sponsors to prefer higher-cost versions of hepatitis C drugs, which resulted in beneficiaries paying thousands more out-of-pocket and nearly double Medicare reinsurance in 2020. Increasing the use of lower-cost hepatitis C drugs could generate significant savings for Medicare and its beneficiaries. CMS concurred with HHS-OIG's recommendations that CMS: (1) encourage Part D plans to increase access to and use of the authorized generic versions of Epclusa and Harvoni, within the authorities granted under statute; and (2) pursue additional strategies—such as educating providers and pharmacies—to increase access to and use of lower-cost hepatitis C drugs in Part D. (OEI-BL-21-00200)

Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2020 Average Sales Prices. Because CMS did not implement all eligible drug price reductions based on 2020 average sales prices (ASPs) for Part B drugs, savings that should have totaled $2.8 million over one year amounted to only $8,158. (Generally, Part B-covered drugs are those that are injected or infused in physicians' offices or outpatient settings.) ASPs generally serve as the basis for reimbursement for Part B drugs. CMS has a price-substitution policy under which HHS-OIG's comparisons of ASPs with average manufacturer prices (AMPs) can—depending on the difference—result in the substitution of a lower calculated rate. The use of this policy serves as a mechanism for monitoring market prices and limiting potentially excessive payment amounts.) Although the $8,158 amount is small, Medicare and its beneficiaries have saved $73.1 million for Part B-covered drugs since the price-substitution policy went into effect in 2013. These total savings highlight the impact of HHS-OIG's mandated quarterly ASP-AMP

comparisons and the implementation of CMS's current price-substitution policy. This data snapshot contains no recommendations. However, HHS-OIG continues to support a previous recommendation that CMS expand the price-substitution criteria. (OEI-03-22-00170)

Reducing Medicare's Payment Rates for Intermittent Urinary Catheters Can Save the Program and Beneficiaries Millions of Dollars Each Year. In Medicare Part B, suppliers of intermittent urinary catheters received $407.0 million in fiscal year 2020, more than three times the suppliers' estimated acquisition costs of $121.0 million. Our findings demonstrate that Medicare and its beneficiaries have the opportunity to achieve substantial savings while allowing suppliers adequate payments for the items and services they provide. CMS did not explicitly indicate whether it concurred with our recommendation; instead, CMS stated that it will take our recommendation under consideration as it determines appropriate next steps. Our recommendation was for CMS to lower Medicare's payment rates for intermittent urinary catheters. (OEI-04-20-00620)

CMS Has Opportunities To Strengthen States' Oversight of Medicaid Managed Care Plans' Reporting of Medical Loss Ratios. States' oversight of Medicaid managed care plans' annual reporting of medical loss ratios (MLRs) is critical to improve fiscal transparency, monitor costs, and promote high-quality care in Medicaid managed care. (The Federal MLR is the percentage of premium revenue that a managed care plan spent on covered health care services and quality-improvement activities in a 12-month period.) Although states reported that most of their plans submitted MLR reports, we found that nearly half of plans' MLR reports were incomplete. The data element for non-claims costs, generally defined as plans' expenses for administrative services, accounted for the majority of incomplete MLR reports. In addition, some states did not review selected MLR data elements for accuracy. We made four recommendations to strengthen states' oversight of MLR reporting and better ensure that plans are using Federal dollars for patient care. CMS concurred with all four recommendations, which were for it to: (1) design an annual MLR reporting template for states to provide to their Medicaid managed care plans, (2) clarify that States should verify the completeness of their plans' MLR reports, (3) clarify that states should review their plans' MLR reports to verify the accuracy of reported data elements, and (4) provide additional guidance to states regarding plans' reporting of non-claims costs in MLR reports. (OEI-03-20-00231)

Medicaid Fraud Control Units Fiscal Year 2021 Annual Report. This annual report provides statistics that highlight the accomplishments of the 53 MFCUs during FY 2021. MFCUs reported 1,105 convictions in FY 2021. Fraud cases accounted for about 70 percent of the MFCU convictions, while about 30 percent involved patient abuse or neglect. Approximately 42 percent of the 780 MFCU fraud convictions involved personal care services attendants and agencies. MFCUs were responsible for 716 civil settlements and judgments, 36 percent of which involved pharmaceutical manufacturers. MFCUs reported approximately $1.7 billion in criminal and civil recoveries. Although MFCUs reported continuing operational challenges attributable to the COVID-19 pandemic, they also mentioned that those challenges had begun to subside. In an appendix to the report, HHS-OIG summarizes beneficial practices identified by HHS-OIG in its reviews or inspections that may be useful to other MFCUs. (OEI-09-22-00020)

Medicare Overpaid $636 Million for Neurostimulator Implantation Surgeries. More than 40 percent of the health care providers covered by our audit did not comply with Medicare requirements when they billed for neurostimulator implantation surgeries. On the basis of our sample results, we estimated that during calendar years (CYs) 2016 and 2017 providers received $636.0 million in unallowable Medicare payments associated with neurostimulator implantation surgeries, and beneficiaries paid $54.0 million in related unnecessary copays and deductibles. These unallowable payments occurred because providers did not include sufficient documentation in the medical records to support that Medicare coverage requirements were met. (A-01-18-00500)

Medicare Improperly Paid Suppliers an Estimated $117 Million Over 4 Years for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Provided to Hospice Beneficiaries. For 121 of 200 sampled durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items, Medicare improperly paid suppliers for DMEPOS items they provided to hospice beneficiaries. These items should have been provided directly by the hospices or under arrangements between the hospices and the suppliers. The improper payments occurred because: (1) the majority of the suppliers were unaware that they had provided DMEPOS items to hospice beneficiaries, (2) the system edit processes that should have prevented the improper payments were not effective or did not exist, and (3) the suppliers inappropriately used the GW modifier. On the basis of our sample results, we estimated that Medicare could have saved $116.9 million in payments during our audit period, and beneficiaries could have saved $29.8 million in deductibles and coinsurance that may have been incorrectly collected from them or from someone on their behalf. (A-09-20-03026)

Medicare Could Have Saved Approximately $993 Million in 2017 and 2018 If It Had Implemented an Inpatient Rehabilitation Facility (IRF) Transfer Payment Policy for Early Discharges to Home Health Agencies. Medicare could have saved approximately $993.0 million in CYs 2017 and 2018 if CMS had expanded its IRF transfer payment policy to apply to early discharges to home health care. We determined that this payment policy would generally result in payments to IRFs that would cover their costs to provide care. When CMS announced its proposed IRF transfer payment policy in 2001, it stated that it would analyze claim data to compare billing patterns prior to and after its implementation and refine IRF payments in the future, if warranted. For this audit, CMS officials did not explain why CMS has not expanded the IRF transfer payment policy to cover discharges to home health care. CMS also did not analyze claims data to compare billing patterns prior to and after the implementation of the prospective payment system for IRFs in January 2002, which could have provided information in support of expanding the IRF transfer payment policy to include early discharges to home health care. (A-01-20-00501)

Hospitals Did Not Always Meet Differing Medicare Contractor Specifications for Bariatric Surgery. Not all hospitals' inpatient claims for bariatric surgeries met Medicare national requirements or Medicare contractors' eligibility specifications. Differing eligibility specifications for bariatric surgery contributed to differences in the number of claims that did not meet the specifications among Medicare contractor jurisdiction groups. Jurisdiction groups with more restrictive specifications had more claims that did not meet the eligibility specifications and

more specifications that were not met. The Medicare contractors may have issued differing eligibility specifications because CMS's national coverage determination requirements were not specific. On the basis of our sample results, we estimated that Medicare could have saved $47.8 million during our audit period if Medicare contractors had disallowed claims that did not meet Medicare national requirements or Medicare contractor specifications for bariatric surgery. (A-09-20-03007)

Medicare Payments of $6.6 Billion to Nonhospice Providers Over 10 Years for Items and Services Provided to Hospice Beneficiaries Suggest the Need for Increased Oversight. Our analysis of trends and patterns in payments for items and services provided to Medicare beneficiaries outside the Medicare hospice benefit during a hospice period of care (which we refer to as nonhospice payments) demonstrate an increase in Medicare nonhospice payments for beneficiaries. Nonhospice payments for Medicare Part A services and Part B items and services totaled $6.6 billion from 2010 through 2019. If providers bill Medicare for nonhospice items and services that potentially should be covered by hospices, Medicare could pay for the same items or services twice. Our prior work on Medicare Part D drugs and DMEPOS provided to hospice beneficiaries demonstrated that these duplicate payments are, in fact, occurring. In three prior reports, we made several recommendations to CMS to establish oversight and scrutiny of Medicare nonhospice payments. Implementing the recommendations from those reports and considering the information in this data brief may help CMS further evaluate the need to potentially restructure the hospice payment system to reduce duplicate payments for items and services that should be included in the hospice per diem payment. The information in this data brief may also help CMS determine whether the hospice benefit is operating consistent with its longstanding position that services unrelated to a hospice beneficiary's terminal illness and related conditions should be exceptional, unusual, and rare given the comprehensive nature of the services covered under the Medicare hospice benefit. (A-09-20-03015)

CMS's System Edits Significantly Reduced Improper Payments to Acute-Care Hospitals After May 2019 for Outpatient Services Provided to Beneficiaries Who Were Inpatients of Other Facilities. Medicare inappropriately paid acute-care hospitals $39.3 million for outpatient services they provided to beneficiaries who were inpatients of other facilities (i.e., long-term care hospitals, IRFs, inpatient psychiatric facilities, and critical-access hospitals). None of the $39.3 million should have been paid because the inpatient facilities were responsible for payment. Each type of inpatient facility covered by our audit must: (1) provide directly all services furnished during an inpatient stay, or (2) arrange for services to be provided on an outpatient basis by an acute-care hospital and include those outpatient services on its inpatient claims submitted to Medicare. Before May 2019, the system edits were not working properly. However, after CMS modified the edits in May 2019, only $3.4 million (less than 9 percent of the $39.3 million in improper payments for the entire audit period) was inappropriately paid to acute-care hospitals from June 2019 through December 2021. (A-09-22-03007)

Medicare Advantage Compliance Audit of Diagnosis Codes That SCAN Health Plan (Contract H5425) Submitted to CMS. HHS-OIG found that SCAN did not submit some diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. HHS-OIG identified some diagnosis codes that SCAN submitted to CMS but that were not supported

in the medical records. HHS-OIG also identified diagnosis codes that were supported in the medical records that SCAN should have submitted to CMS but did not. As a result, we estimated that SCAN received at least $54.3 million in net overpayments for 2015. (A-07-17-01169)

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS. HHS-OIG found that Cariten, with respect to nine groups of diagnosis codes that were at high risk for being miscoded, did not submit most diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. HHS-OIG identified, for 206 of the sampled 270 enrollee-years, diagnosis codes that Cariten submitted to CMS but were not supported in the medical records. As a result, we estimated that Cariten received at least $9.2 million in net overpayments for 2016 and 2017. (A-02-20-01009)

California Improperly Claimed at Least $23 Million of $260 Million in Total Medicaid Reimbursement for Opioid Treatment Program (OTP) Services. California claimed Medicaid reimbursement for some OTP services that did not meet Federal and State requirements. Of the 130 sample items, 88 had services that were all allowable, but 42 had services that were unallowable. On the basis of our sampled results, we estimated that California claimed at least $23.1 million in unallowable Federal Medicaid reimbursement for OTP services during our audit period. In addition, we identified deficiencies in three areas that did not result in unallowable services but could impact the quality of care provided to beneficiaries receiving OTP services. (A-09-20-02009)

Tennessee Medicaid Claimed Hundreds of Millions of Federal Funds for Certified Public Expenditures That Were Not in Compliance With Federal Requirements. Tennessee did not comply with Federal requirements for claiming certified public expenditures (CPEs) for public hospital unreimbursed costs. Of the $2 billion in CPEs that Tennessee claimed during our audit period, $909.4 million was allowable and supported. However, the remaining $1.1 billion ($767.5 million Federal share) exceeded the amount allowed. This amount included $482.1 million ($337.5 million Federal share) of excess CPEs that Tennessee claimed but did not return after calculating actual CPEs. In addition, the actual CPEs that Tennessee calculated included another $609.4 million ($430 million Federal share) that exceeded the allowable amount. It was composed of $522.3 million ($370.1 million Federal share) of unsupported net costs of caring for institutions for mental diseases (IMD) uninsured patients, $53.6 million ($37.9 million Federal share) of unallowable net costs of caring for TennCare IMD patients between the ages of 21 and 64, and $33.5 million ($22.0 million Federal share) of overstated costs because of incorrect calculations. (A-04-19-04070)

New Mexico Did Not Claim $12.4 Million of $222.6 Million in Medicaid Payments for Services Provided by Indian Health Service Facilities in Accordance With Federal and State Requirements. New Mexico claimed $12.4 million in IHS expenditures that did not meet Federal and State requirements. Specifically, New Mexico claimed: (1) $6.2 million in unsupported expenditures under its older waivers, which New Mexico did not identify because it did not reconcile initial expenditures with IHS encounter data; (2) $3.6 million in unsupported

expenditures under its current waiver because its reconciliations did not account for encounter data adjustments; and (3) $2.6 million in expenditures for encounter data MCOs submitted beyond the two-year limit outlined in the MCO contracts. Additionally, New Mexico may have claimed $750,811 for inpatient encounter data with dates-of-service spans that did not support the number of paid inpatient days. (A-06-19-09005)

Prior Audits of Medicaid Eligibility Determinations in Four States Identified Millions of Beneficiaries Who Did Not or May Not Have Met Eligibility Requirements. Our previous audits of four states' Medicaid eligibility determinations found that during 2014 and 2015 Medicaid payments were made on behalf of 109 of 460 sampled newly eligible beneficiaries and 98 of 515 sampled non-newly eligible beneficiaries who did not meet or may not have met Medicaid eligibility requirements. We determined that both human and system errors, as well as a lack of policies and procedures, contributed to these improper or potentially improper payments. Although the states concurred with all 31 recommendations from our prior audits to address these deficiencies, 15 of these recommendations remain unimplemented. On the basis of our sample results, we estimated that the four states made Federal Medicaid payments on behalf of newly eligible beneficiaries totaling almost $1.4 billion for more than 700,000 ineligible or potentially ineligible beneficiaries. We also estimated that the four States made Federal Medicaid payments on behalf of non-newly eligible totaling more than $5.0 billion for almost five million ineligible or potentially ineligible beneficiaries. (A-02-20-01018)

More Than 90 Percent of the New Hampshire Managed Care Organization and Fee-for-Service Claims for Opioid Treatment Program Services Did Not Comply With Medicaid Requirements. New Hampshire claimed Medicaid reimbursement for OTP services that did not comply with Federal and state requirements. Of the 100 OTP services we sampled, six complied with Federal and State requirements, but 94 did not meet applicable Federal and State requirements. These deficiencies occurred because New Hampshire did not have the resources to oversee providers and enforce the OTP requirements. Providers said high personnel turnover, difficulty attracting and retaining personnel, and difficulty keeping patients engaged in counseling services contributed to the lack of adherence to state requirements. Furthermore, New Hampshire did not always provide guidance regarding State OTP requirements. On the basis of our sample results, we estimated that New Hampshire improperly claimed at least $7.9 million in Federal Medicaid reimbursement for OTP services during our audit period. (A-01-20-00006)

Texas Did Not Report and Return All Medicaid Overpayments for the State's Medicaid Fraud Control Unit Cases. Texas did not correctly report and return the Federal share of all MFCU-determined Medicaid overpayments identified for the period October 1, 2016, through September 30, 2018. Texas should have reported MFCU-determined Medicaid overpayments totaling $24.3 million (at least $13.9 million Federal share) for the 65 cases with Medicaid restitution during the period that we reviewed. Texas correctly reported $46,369 ($26,982 Federal share) in MFCU-determined Medicaid overpayments for two of the 65 cases and did not correctly report the remaining 63 cases. For the 63 cases, Texas did not report and return overpayments totaling $19.0 million ($11.1 million Federal share) for 26 cases for our audit period. As a result of our audit, Texas later returned the Federal share on the FY 2020 and FY 2021 Form CMS-64s. In addition, Texas did not report $5.2 million (at least $2.7 million

Federal share) for 37 cases within the required timeframe. These issues occurred because Texas did not have adequate internal controls to ensure that it always reported MFCU-determined Medicaid overpayments in accordance with Federal requirements. (A-06-20-04004)

New Jersey's Medicaid School-Based Cost Settlement Process Could Result in Claims That Do Not Meet Federal Requirements. New Jersey's methodology for claiming Medicaid school-based costs, as described in the Process Guide, does not comply with Federal requirements. Specifically, the Process Guide's methodology for conducting random moment time studies (RMTSs): (1) does not meet Federal requirements for statistical sampling, (2) defines one Medicaid administrative activity code as including activities not necessary for the administration of the Medicaid State plan, and (3) does not ensure that RMTS responses and Medicaid cost allocation ratios are supported. In designing its Process Guide, New Jersey did not address deficiencies identified during our prior audit of its school-based program, follow CMS guidance, and ensure that its Medicaid cost allocation ratios could be supported. Therefore, if CMS does not work with New Jersey to address the deficiencies identified in this report, Medicaid claims submitted for reimbursement by New Jersey school districts will not meet Federal requirements and the risk of improper payments could increase by tens of millions of dollars per year. (A-02-20-01012)

The Centers for Medicare & Medicaid Services' Eligibility Review Contractor Adequately Determined Medicaid Eligibility for Selected States Under the Payment Error Rate Measurement (PERM) Program. We determined that CMS's eligibility review contractor correctly determined Medicaid eligibility for the beneficiaries associated with all 100 sampled claims. Based on our sample results, we concluded that CMS's eligibility review contractor adequately determined Medicaid eligibility for three States (Connecticut, Pennsylvania, and Virginia) under CMS's PERM program in accordance with Federal and State requirements. (A-02-20-01006)

Montana Claimed Federal Medicaid Reimbursement for More Than $5 Million in Targeted Case Management (TCM) Services That Did Not Comply With Federal and State Requirements. Montana did not always claim Federal Medicaid reimbursement for TCM services during FYs 2018 through 2020 in accordance with Federal and State requirements. Of the 150 randomly sampled grouped line items, 43 sample items were at least partially unallowable because they had at least 1 error related to case managers lacking required experience or qualifications, unsupported services, unallowable services, or an ineligible recipient. Montana had policies and procedures in place for the administration of TCM services that, if followed, would have ensured compliance with Federal and State requirements. Based on our sample results, we estimated that Montana claimed at least $7.7 million (more than $5.0 million Federal share) in unallowable Medicaid reimbursement for these services. (A-07-21-03246)

Nearly All States Made Capitation Payments for Beneficiaries Who Were Concurrently Enrolled in a Medicaid Managed Care Program in Two States. All 47 States reviewed made capitation payments on behalf of Medicaid beneficiaries who were concurrently enrolled in two States. Specifically, capitation payments were made on behalf of 208,254 concurrently enrolled beneficiaries in August 2019 and 327,497 concurrently enrolled beneficiaries in August 2020. The Medicaid program incurred costs of approximately $72.9 million in August 2019 and

$117.1 million in August 2020 for capitation payments associated with beneficiaries in one of the two concurrently enrolled States. The significant increase in these payments from August 2019 to August 2020 coincided with an overall increase in Medicaid enrollment during that time, and new Federal requirements and flexibilities that were available to states during the COVID-19 public health emergency. CMS does not actively monitor beneficiaries' concurrent Medicaid managed care enrollments; instead, it relies on the States to identify concurrent enrollments and potential erroneous payments. CMS does not provide States with Transformed Medicaid Statistical Information System (T-MSIS) national enrollment data that would assist them in identifying beneficiaries who were concurrently enrolled in a Medicaid managed care program in two States. Two States often made capitation payments for the same Medicaid beneficiary in part because states did not have full access to data they needed to identify beneficiaries who were concurrently enrolled in another State. Therefore, CMS does not take all available steps, either directly or through the States, to identify and prevent state capitation payments for non-resident beneficiaries. CMS did not concur with our recommendations. (A-05-20-00025)

New York Generally Determined Eligibility for Its Basic Health Program (BHP) Enrollees in Accordance With Program Requirements. New York generally determined eligibility for its BHP enrollees in accordance with Federal and State requirements. Specifically, for 145 of 150 sampled policies, New York correctly determined that the associated enrollees were eligible for the program. However, for five sampled policies, New York enrolled individuals who were ineligible or potentially ineligible for the program and received improper monthly payments totaling $8,615. Specifically, for three sampled policies, New York enrolled individuals who were eligible for Medicaid. For one sampled policy, New York did not properly verify income. For the remaining sampled policy, New York received BHP payments from the CMS on behalf of a disenrolled deceased enrollee. According to New York, system defects prevented controls that were in place from working as intended. On the basis of our sample results, we estimated that the financial impact of the incorrect or potentially incorrect eligibility determinations made by New York for its BHP during the audit period totaled $69.9 million. (A-02-20-01028)

Texas Claimed or May Have Claimed More Than $30 Million of $9.89 Billion in Federal Funds for Medicaid Uncompensated Care (UC) Payments That Did Not Meet Federal and State Requirements. Texas claimed $16.9 billion ($9.9 billion Federal share) in UC payments in accordance with applicable Federal and State requirements. However, Texas incorrectly claimed $18.9 million ($11.0 million Federal share). Specifically, Texas claimed: (1) $12.9 million ($7.5 million Federal share) because it did not refund the full Federal share of overpayments, and (2) $6.0 million ($3.5 million Federal share) because it did not collect overpayments it identified. Additionally, the State agency may have incorrectly claimed $33.8 million ($19.7 million Federal share) because it did not reduce hospitals' actual UC costs by Medicare payments the hospitals received. (A-06-19-09002)

New York Claimed $196.0 Million, Over 72 Percent of the Audited Amount, in Federal Reimbursement for NEMT Payments to New York City Transportation Providers That Did Not Meet or May Not Have Met Medicaid Requirements. Seventeen of the 100 sampled payments complied with Federal and State requirements. However, for 41 sampled payments, non-emergency medical transportation (NEMT) payments did not comply with Federal and State

requirements and were therefore unallowable. For the remaining 42 sampled payments, we could not determine whether the services complied with Federal and State requirements. On the basis of our sample results, we estimated that New York improperly claimed at least $84.3 million in Federal Medicaid reimbursement for payments to NEMT providers that did not comply with certain Federal and State requirements. In addition, we estimated that New York claimed $112.0 million in Federal Medicaid reimbursement for payments to NEMT providers that may not have complied with certain Federal and State requirements. (A-02-21-01001)

Medicare Improperly Paid Physicians for Spinal Facet-Joint Denervation Sessions. Medicare did not pay physicians for selected facet-joint denervation sessions in accordance with Medicare requirements. In total, Medicare improperly paid physicians $9.5 million. CMS plans to recover these overpayments for claims. CMS established oversight mechanisms to prevent or detect improper payments to physicians for more than: (1) two facet-joint denervation sessions related to the lumbar spine or cervical/thoracic spine per beneficiary during a rolling year, and (2) the allowed number of facet joints per denervation session. These mechanisms, include implementing system edits and a fraud prevention system model to prevent or detect improper payments for facet-joint denervation sessions. In addition, CMS plans to direct its Supplemental Medical Review Contractor to review a small sample of claims to determine whether Medicare appropriately paid for denervation sessions with dates of service after our audit period that were before the implementation of the oversight mechanisms. (A-09-21-03002)

Psychotherapy Services Billed by a New York City Provider Did Not Comply With Medicare Requirements. We estimated that the New York City provider received $1.1 million in Medicare overpayments for psychotherapy services, that did not comply with Medicare requirements for all 100 sampled beneficiary days. For example, the beneficiaries' treatment plans associated with these services were not provided or did not contain required elements (e.g., frequency or duration of services). This heightens the risk that treatments were inappropriate or unnecessary and could have a significant effect on the beneficiaries' quality of care received. We also found that services billed to Medicare did not meet incident-to requirements or were conducted by a therapist that was not licensed or registered in New York State. CMS followed up with the New York City provider regarding the steps taken to address our recommendations. The provider implemented a compliance program and implemented corrective action plans. For example, the provider has taken steps to develop policies and procedures, as well as a training program for its therapists, to ensure that treatment plans: (1) contain all required elements, (2) are maintained and signed by the treating physician, (3) the performing therapists and supervising physicians comply with the requirements related to incident-to-services, (4) include psychotherapy services conducted by therapists that meet Medicare qualification requirements, (5) document time spent on psychotherapy services, and (6) include treatment notes signed and maintained to support the services billed. (A-02-21-01006)

Medicare Improperly Paid Durable Medical Equipment (DME) Suppliers an Estimated $8 Million of the $40 Million Paid for Power Mobility Device (PMD) Repairs. Not all suppliers complied with Medicare requirements when billing for PMD repairs. Suppliers submitted PMD repair charges that did not comply with Medicare requirements when billing for PMD repairs. Specifically, documentation did not adequately support the charges for PMD repairs, the labor

time associated with PMD repairs was not documented, or PMD repair charges were not reasonable and necessary. We also identified questionable charges for PMD repairs associated with the sampled beneficiaries. Although the billing of these PMD repairs did not reflect noncompliance with Medicare requirements, suppliers did not meet documentation standards established by guidance or submitted charges that may not have been reasonable and necessary, resulting in questionable Medicare payments and associated beneficiary coinsurance payments. On the basis of our sample results, we estimated that $7.9 million of the $40.1 million paid for PMD repairs was improperly paid. We also estimated that Medicare could have saved as much as an additional $3.7 million for questionably paid PMD repairs. In addition, we estimated that Medicare beneficiaries could have saved as much as $3.0 million in coinsurance for the improperly and questionably paid PMD repairs.

We recommended that CMS instruct the DME Medicare contractors to recover the overpayments for PMD repairs and to notify suppliers to refund the coinsurance. Further, based upon the results of this audit we recommended that CMS notify appropriate suppliers so that they can exercise reasonable diligence to identify, report, and return any overpayments. We also recommended that CMS work with the DME Medicare contractors to improve the education of suppliers on Medicare requirements for PMD repairs, implement system edits, and establish Medicare requirements that include documentation standards, specify that accumulated costs of repairs made during their five-year reasonable useful lifetime must not exceed a certain threshold, and specify that suppliers must provide warranties for repairs made to PMDs. (A-09-20-03016)

Medicare Critical Care Services Provider Compliance Audit: Lahey Clinic, Inc. Lahey complied with Medicare billing requirements for 36 of the 92 critical care services that we reviewed. However, Lahey did not comply with Medicare billing requirements for the remaining 56 critical care services. All 10 of the inpatient admissions reviewed included at least 1 critical care service that did not comply with Medicare billing requirements. Specifically, Lahey billed for 54 critical care services for patients whose conditions did not indicate that the critical care services were medically necessary or for which the physician did not directly provide services that were at the level of care required for critical care services. In addition, Lahey billed for two critical care services that were billed using an incorrect Current Procedural Terminology code for the critical care service provided. These billing errors resulted in Lahey receiving $6,015 in unallowable Medicare payments. Lahey indicated partial concurrence with our first recommend-dation and full concurrence with our procedural recommendations. Lahey concurred with our results for 16 of the 56 critical care services, agreed that $1,461 should be refunded, and stated that it addressed or is in the process of addressing the procedural recommendations. Lahey did not concur with the remaining 40 critical care services. After review and consideration of Lahey's comments, and because Lahey did not provide any additional medical record documentation to support its rebuttal of these 40 services, we maintain that our original findings remain valid. (A-03-20-00002)

Trends in Genetic Tests Provided Under Medicare Part B Indicate Areas of Possible Concern. Our analysis of nationwide trends in genetic testing under Medicare Part B showed that payments for genetic tests, the number of genetic tests performed, the number of laboratories that

received more than $1.0 million for performing genetic tests, and the number of providers ordering genetic tests for beneficiaries all increased during our audit period (CYs 2016 through 2019). Although there are legitimate reasons that genetic testing has increased, these increases indicate areas of possible concern, such as excessive genetic testing and fraud, which may negatively affect beneficiaries. In addition, Medicare requirements and guidance related to coverage of genetic testing have been limited and have varied among Medicare Administrative Contractor (MAC) jurisdictions. Oversight by CMS and the MACs is critical to prevent fraud, waste, and abuse related to genetic testing and to protect Medicare beneficiaries. The information in this data brief may help CMS and other stakeholders to identify changes in the Medicare program, such as increased oversight, that could prevent fraud, waste, and abuse and protect Medicare beneficiaries. Because this report contains no recommendations, CMS did not provide written comments on our draft report but did provide technical comments, which we addressed as appropriate. (A-09-20-03027)

Medicare and Beneficiaries Paid Substantially More to Provider-Based Facilities in Eight Selected States in Calendar Years 2010 Through 2017 Than They Paid to Freestanding Facilities in the Same States for the Same Type of Services. Both the Medicare program and its beneficiaries could have realized significant savings for Evaluation and Management (E&M) services if those services had been paid as if provided at freestanding facilities. If the physicians in the selected States had been paid at the freestanding PFS non-facility rate and hospitals paid nothing under the Outpatient Prospective Payment System for our audit period, the Medicare program could have realized cost savings of $1.3 billion and its beneficiaries could have realized cost savings of $334.0 million, for combined savings totaling more than $1.6 billion. In addition, beneficiaries would have been required to make only one coinsurance payment rather than two (as they are currently required to do), and the cost-sharing would generally be lower because it would be based only on the freestanding facility rate. CMS has taken some steps intended to equalize payments. If these changes had been in effect during the period covered by our audit, the potential cost savings of these changes for E&M services in the selected States for our audit period could have been a combined $1.4 billion for the Medicare program and its beneficiaries. However, the combined $1.4 billion in potential cost savings would still have been less than the $1.6 billion in potential cost savings if E&M services had been paid at the freestanding PFS non-facility rate. We recommend that CMS pursue legislative or regulatory changes to lower costs for both the Medicare program and beneficiaries, by equalizing payments as appropriate between provider-based facilities and freestanding facilities for E&M services. CMS did not directly agree or disagree with our recommendation; it referred to regulatory action it had taken and added that any changes to further implement our recommendation "may require legislative action." We commend CMS for the regulatory action it has taken and note that its comments are closely aligned with our findings and recommendation. (A-07-18-02815)

Medicare Dialysis Services Provider Compliance Audit - Dialysis Clinic, Inc. (DCI). DCI claimed reimbursement for dialysis services that did not comply with Medicare requirements for 70 of the 100 sampled claims. Specifically, DCI submitted claims for which: (1) comprehensive assessments or plans of care did not meet Medicare requirements, (2) dialysis treatments were not completed, (3) dialysis services were not documented, (4) beneficiaries' height or weight measurements did not comply with Medicare requirements, and (5) the medical record did not

have a monthly progress note by a physician or other qualified professional. While DCI had established corporate-wide internal controls to monitor and maintain complete, accurate, and accessible medical records at all its facilities, these controls were not always effective in ensuring that DCI's claims for dialysis services complied with Medicare requirements. We estimated that DCI received unallowable Medicare payments of at least $14,193,677 for dialysis services that did not comply with Medicare requirements. Many of the errors we identified did not affect DCI's Medicare reimbursement for the services since they were reimbursed on a bundled per treatment basis or related to Medicare conditions for coverage. However, the deficiencies could have a significant impact on the quality of care provided to Medicare beneficiaries and could result in the provision of inappropriate or unnecessary dialysis services. We recommend that DCI refund an estimated $14,193,677 to the Medicare program. We also made a series of recommendations to strengthen DCI's internal controls to ensure that dialysis services comply with Medicare requirements. In written comments on our draft report, DCI did not concur with our recommendations but described actions it has taken and plans to take to address some of them. (A-05-20-00010)

Other HHS-OIG Fraud and Abuse Prevention Activities

Data Analytics

HCFAC 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; (4) optimize HHS-OIG processes; and (5) support mission needs. HHS-OIG's team of highly trained data analysts, data scientists, statisticians, and data engineers 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, leverages dashboards, machine learning, and AI capabilities including neural networks and text mining to identify and support prosecutions of sophisticated fraud schemes as well as potential audit and evaluation findings by utilizing high-value health care, grant, contract, law enforcement, and operational data. More than 760 unique staff members used HHS-OIG analytic tools for mission-focused work to generate more than 44,000 provider-specific reports and claims exports, page views, and other analytic insights, during the fiscal year.

HHS-OIG's ability to use data proactively has become even more important during the COVID-19 pandemic. HHS-OIG analytics have helped to inform a range of Medicare-focused topics that are subjects of recent and future HHS-OIG reports including COVID-19 testing; possible fraud, waste, and abuse in laboratory billing; the use of telehealth services; emergency preparedness; the challenges of COVID-19 in nursing homes; audits and investigations involving the CARES Act Provider Relief Fund , Uninsured Individuals Program; Paycheck Protection Program; and other programs.

HHS-OIG analytics staff quickly pivoted to monitor COVID-19 testing, treatment, and billings for 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 more than 130 agency investigative actions that led to criminal charges filed in U.S. courts including telemedicine and genetic testing schemes totaling more than $400.0 million in false claims and a nationwide coordinated law enforcement action to combat health care-related COVID-19 fraud involving charges against 21, defendants contributing to $149.0 million in COVID-19 related false billings announced by DOJ and HHS in April 2022. Furthermore, HHS-OIG's data analytics continue to identify and support cases filed as part of the ARPO and the NEPO Strike Force efforts. These included opioid-related law enforcement actions involving charges against 14 defendants, including 12 medical professionals for their alleged participation in the illegal prescription and distribution of opioids in May 2022.

Our data and technical experts are also partnering with HHS-OIG auditors and evaluators to provide custom data and analytics support focused on pandemic- and mission-related work. As of September 30, 2022, HHS-OIG analytics staff had supported 56 audits, 21 evaluations, and 137 criminal investigations across the Medicare and Medicaid portfolios as well as 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 opinions on the application of the Federal AKS and other HHS-OIG administrative enforcement authorities to existing or proposed health care financial arrangements.

During FY 2022, HHS-OIG, in consultation with DOJ, issued 25 advisory opinions. During the 26 years of the HCFAC program, HHS-OIG has issued more than 400 advisory opinions, modified 23 advisory opinions, terminated four opinions, and rescinded one opinion.

Collaborations With Private Sector Partners

HHS-OIG regularly engages with public stakeholders to combat fraud. For example, HHS-OIG is an active partner in HFPP, described in more detail elsewhere in this report, and with the National Health Care 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 combating 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 DEA to provide antifraud 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 delivered presentations at conferences in 50 states and Puerto Rico. Furthermore, HHS-OIG regularly delivered presentations at various health care compliance conferences across the country.

American Indian/Alaska Native Compliance Trainings
OIG provides a free online training series, *Improving Health and Well-Being in American Indian and Alaska Native Communities Through Compliance*, for grantees and health care providers who serve American Indian/Alaska Native (AI/AN) communities. The training series covers topics such as compliance; fraud, waste, and abuse; and health care quality, including how OIG works with the AI/AN community to combat the opioid epidemic and to protect patients from sexual abuse. The training series includes web-based trainings, job aids, and videos, which can be accessed on OIG's AI/AN Training website.

HHS-OIG also engages with stakeholders to seek insights regarding how to promote compliance while encouraging innovation in the health care industry. For instance, HHS-OIG published a Request for Information in 2021 seeking to identify ways that it could modernize the accessibility and usability of our publicly available information.[16] HHS-OIG then coordinated with the Health Care Compliance Association and the American Health Law Association to host roundtables with stakeholders in early 2022 to solicit further feedback on this topic. During these roundtables, HHS-OIG heard from an experienced and diverse group of participants and gathered information that will inform HHS-OIG as it proceeds with its modernization efforts.

Centers for Medicare & Medicaid Services

In FY 2022, Congress appropriated CMS $658.6 million in discretionary funds to support its comprehensive program integrity strategy for Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and the Health Insurance Marketplaces. In FY 2022, Congress continued to direct HHS to fund the Administration for Community Living's (ACL) Senior Medicare Patrol (SMP) Program; therefore, $30.0 million of CMS's $658.6 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. With the HCFAC funds, CMS works to ensure that accurate payments are made to legitimate individuals and entities for allowable services or supplies provided to eligible beneficiaries of Federal health care programs.

CMS also performs many program integrity activities that are beyond the scope of this report because they are not funded directly by the HCFAC Account or discretionary HCFAC funding. This includes activities such as the Recovery Audit Program and Medicare Secondary Payer. CMS's 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.[17]

[16] HHS-OIG, OIG Modernization Initiative To Improve Its Publicly Available Resources—Request for Information, 86 Fed. Reg. 53072 (Sept. 24, 2021). https://www.govinfo.gov/content/pkg/FR-2021-09-24/pdf/2021-20558.pdf.
[17] https://www.cms.gov/About-CMS/Components/CPI/CPIReportsGuidance

Address the Full Spectrum of Fraud, Waste, and Abuse

Program integrity focuses on paying the right amount, to legitimate providers and suppliers, for covered, reasonable and necessary services provided to eligible beneficiaries, while concurrently 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.

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 that CMS investigates instances of suspected fraud, waste, and abuse in Medicare and Medicaid is through the activities of the UPICs. CMS contracts with the UPICs for the prevention, detection and deterrence of fraud, waste and abuse by Medicare and Medicaid providers through investigation and audits, both proactively and from referrals. Currently, the UPICs are carrying out program integrity activities in all five geographic jurisdictions: Midwest, Northeast, West, Southeast, and Southwest. UPICs undertake activities including provider and beneficiary interviews and site visits, recommending appropriate Medicare 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, the UPIC reviews are uniquely focused on fraud detection and investigation. For example, the UPICs look for possible falsification of documents from providers and suppliers that may be associated with an attempt to defraud the Medicare and Medicaid programs. 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 publishes savings from UPIC activities in the Annual Report to Congress on the Medicare and Medicaid Integrity Programs.

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, potential fraud referrals to law enforcement, and other referrals for state administrative action.

Fraud Prevention System (FPS)

FPS is the predictive analytics technology required under the Small Business Jobs Act of 2010.[18] FPS analyzes FFS claims using sophisticated algorithms to target investigative resources; generate alerts for suspect claims or providers and suppliers; and provide information to facilitate and support investigations of the most egregious, suspect, or aberrant activity. CMS uses the FPS information to prevent and address improper payments using a variety of

[18] Public Law 111-240.

administrative actions, including claim denials, payment suspensions, Medicare billing privilege revocations, and law enforcement referrals.

During FY 2022, the FPS generated alerts that resulted in 960 new leads for program integrity contractors and augmented information for 759 existing leads or investigations. The program integrity contractors reported initiating FPS-attributable actions against 786 providers in FY 2022.

Medicare FFS and Medicaid National Correct Coding Initiative (NCCI)

NCCI promotes national correct coding methodologies and reduces improper coding that may result in inappropriate payments in Medicare FFS. NCCI Procedure-to-Procedure edits prevent inappropriate payment for billing code pairs that should not generally be reported together by the same provider for the same beneficiary and date of service, while NCCI Medically Unlikely Edits define for each HCPCS/CPT code the maximum units of service reported on the vast majority of appropriately reported claims by the same provider/supplier for the same beneficiary for 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.[19]

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

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

One PI provides CMS program integrity contractors, law enforcement personnel, HHS-OIG investigators, and other organizations a centralized single access point to analytical tools and data needed to fight Medicare and Medicaid fraud, waste, and abuse. One PI provides access to Medicare and Medicaid data from the Integrated Data Repository (IDR), which allows users to investigate improper payments, identify fraud schemes, create and enhance fraud prevention models, take administrative actions, pursue civil and criminal penalties, and more to protect Medicare and Medicaid taxpayer dollars. One PI augments the Medicare Parts A, B (including DME and home health claims), Part C encounter data, and Part D prescription drug event records, as well as beneficiary data that is available in the IDR to provide a comprehensive view of claims data, beneficiary data, and prescription drug information as well as T-MSIS data and Medi-Medi formats. CMS is currently working to integrate One PI with the Unified Case Management (UCM) system and the FPS to become the centralized reporting hub for CMS. One PI is a critical element of CMS's efforts to ensure program integrity.

Coordinated Program Integrity Activities

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

[19] https://www.cms.gov/About-CMS/Components/CPI/CPIReportsGuidance.

of collaboration has contributed to several successful coordinated law enforcement actions and helped CMS to better identify national fraud trends and program vulnerabilities.

As a result of the MCC, there has been a marked increase in the number and quality of law enforcement referrals from CMS. Since implementation of the MCC, there have been over 4,000 cases reviewed at MCC, and law enforcement partners have made over 2,600 requests for CMS to refer reviewed cases. CMS program integrity activities and investigations continue to contribute to law enforcement investigations, CMS administrative actions and CMS initiatives. In FY 2022, CMS reviewed 1,109 cases at MCC meetings, and law enforcement partners made 512 requests for CMS to refer reviewed cases.

Examples of the ways in which CMS has provided support to the HHS-OIG and DOJ throughout FY 2022 include:

- On April 20, 2022, DOJ announced criminal charges against 21 defendants for their alleged participation in various health care related fraud schemes that exploited the COVID-19 pandemic in a coordinated law enforcement action with the HHS-OIG and CMS. CMS took administrative actions against over 29 providers for their involvement in health care fraud schemes relating to abuse of CMS programs during the pandemic.

- On May 4, 2022, DOJ announced criminal charges against 14 defendants for their alleged involvement in crimes related to the unlawful distribution of opioids in a coordinated law enforcement action with the HHS-OIG and CMS. CMS took administrative actions against six providers for their alleged involvement in these offenses.

- On July 20, 2022, DOJ announced criminal charges against 36 defendants for more than $1.2 billion in alleged fraudulent telemedicine, cardiovascular and cancer genetic testing, and DME schemes in a coordinated law enforcement action with the HHS-OIG and CMS. CMS took administrative actions against 52 providers involved in similar schemes.

Provider Compliance

- Accuracy reviews
  CMS uses the Medical Review Accuracy Contractor (MRAC) to conduct medical reviews of claim determinations made by the MACs, UPICs, and the Supplemental Medical Review Contractor (SMRC). The MRAC helps CMS by measuring the accuracy rate for each contractor to ensure the contractors are consistent in their medical review decisions in compliance with Medicare and Medicaid coverage, coding, payment, and billing policies. It also feeds information into the MAC Award Fee Component to determine where policy/issues/medical review inconsistencies may be present. Because CMS is only able to perform a limited number of accuracy reviews using its own clinicians, the MRAC is able to help CMS complete more accuracy reviews and provide 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.

  In FY 2022, CMS continued the prior authorization of certain DMEPOS items. CMS requires prior authorization as a condition of payment on 40 power mobility device codes, five pressure reducing support service codes, and six lower limb prosthetic codes. Six additional power mobility device codes were selected for required prior authorization and began nationwide on April 13, 2022. Additionally, on April 13, 2022, prior authorization of five prosthetic codes were required in California, Florida, Illinois, and New York. Prior authorization for these codes expanded to Arizona, Georgia, Kentucky, Maryland, Michigan, Missouri, New Jersey, North Carolina, Ohio, Pennsylvania, Texas, and Washington on July 12, 2022, and will expand nationwide to all remaining states and territories in FY 2023. 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 a final rule, CMS finalized a prior authorization process for certain hospital outpatient department (HOPD) services as a method to control unnecessary increases in volume. In FY 2022, CMS continued to require, nationwide, prior authorization of Blepharoplasty, Botulinum Toxin Injections, Panniculectomy, Rhinoplasty, Vein Ablation, Implanted Spinal Neurostimulators, and Cervical Fusion with Disc Removal. Moreover, CMS proposed the addition of Facet Joint Interventions to the list of services that require prior authorization, as part of the CY 2023 Outpatient Prospective Payment System/ Ambulatory Surgical Center (OPPS/ASC) proposed rule, published on July 26, 2022. 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 Part B Trust Fund. These reports compare an individual provider or supplier's billing and/or prescribing practices for a specific billing code, providers about Medicare coding, billing, and coverage guidelines and strategies for implementing self-audit processes into their practices, where appropriate. Currently, CBRs are available for download by the provider or supplier on a secure electronic portal as well as mailed in full via postal mail. Since 2011, CBRs have been issued on topics such as opioid prescriptions, physical therapy, and eye exam 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 GAO and HHS-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.

In FY 2022, CMS issued a total of ten CBRs on eight unique topic areas including critical care, lipid panel testing, ambulance ground transport, and cataract surgery.

Outreach and Education

CMS's provider education and outreach helps reduce the Medicare improper payment rate by giving Medicare providers the timely and accurate information needed 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 and 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 in ways that explain how to avoid improper payments and also alert stakeholders to fraud, waste and abuse schemes protect the financial security of CMS's programs by reducing improper payments and curtailing emerging fraud schemes. By offering regular in-person and virtual events and trainings, as well as clear and concise information online, CMS continues to provide needed information that is responsive to the realities of clinical practice.

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's role in the provider and supplier enrollment process differs between the Medicare and Medicaid programs. CMS directly administers Medicare and oversees the provider enrollment and screening process for providers and suppliers participating in the Medicare FFS program. CMS uses provider and supplier enrollment information in a variety of ways, such as claims payment and fraud prevention programs. States directly oversee the provider screening and enrollment process for their Medicaid programs, and CMS provides regulatory guidance and technical assistance to states. 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 program and ensure that only eligible providers are caring for beneficiaries and receiving payment. CMS also works with states to support proper enrollment and accurate billing practices to detect and combat fraud, waste, and abuse in their Medicaid programs.

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, and 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 2022, CMS resumed FCBCs, although the PHE remained in effect. CMS denied approximately 718 enrollments and revoked four 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 2022, APS utilization resulted in more than 7.7 million screenings. These screenings generated more than 3,000 criminal alerts for potentially fraudulent providers and suppliers for further review by CMS. APS review resulted in approximately 134 revocations based on a felony conviction, 317 revocations based on a state medical license action, and 24 deactivations based on a state medical license action.

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 2022 this work resulted in about 225 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 2022, CMS deactivated approximately 123,000 enrollments and revoked 2,290 enrollments. Site visits, revalidation, and other initiatives have contributed to the deactivation[20] and revocation[21] 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 update 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

[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.

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 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), UCM, Pricing, Data Analysis and Coding (PDAC), One PI, IDR, Health Information Technology for Economic and Clinical Health (HITECH), and other data analysis teams. 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 and standardize interfaces with systems internal and external to CMS.

In FY 2022, CMS made significant changes to PECOS to simplify access, improve usability and enhance the security of the system, including the following changes:

- Updated PECOS to validate Clinical Laboratory Improvement Amendments (CLIA) numbers to improve accuracy of CLIA numbers entered into PECOS;
- Implemented necessary enhancements to ensure all Part B and DMEPOS Medical Records Correspondence Address data that flows to the claims system comes directly from PECOS;
- Updated PECOS to systematically increase the screening level of high-risk Providers/Suppliers to ensure that they are properly screened;
- Implemented the enhancements necessary to ensure all Part A, DMEPOS CMS-588 Electronic Funds Transfer (EFT) data that flows to the claims system comes directly from PECOS;
- Updated PECOS in support of regulation to allow Physician Assistant's to directly bill Medicare and be directly reimbursed for their services;
- Created a new Data Mart report to identify Clinics/Groups Practices without reassignments and/or Physician Assistants for 90 or more days for MACs to take appropriate action upon;
- In support of rule CMS-1734-F that expanded deactivation authorities, PECOS added two new deactivation status Reasons and updated the descriptions of three existing deactivation status reasons;
- Implemented various updates that improved the reporting process and data quality of the DMEPOS accreditation data loaded into PECOS;

- Updated PECOS to allow users to list the Home Infusion Therapy (HIT) services rendered in patients homes in multiple states.

Medicaid Provider 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 2022, 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 individual state calls, clarifying guidance in the Medicaid Provider Enrollment Compendium (MPEC), continuing monthly Technical Assistance Group (TAG) calls, and continuing to facilitate 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, 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 continuously works to enhance this service, and more recent enhancements include tailoring the type of comparison to meet a state's specific needs (for example, supplying provider ownership information reported to Medicare, practice location information, deactivated National Provider Identifiers (NPIs) and deceased providers).

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. This system stores all state-submitted for cause terminations as well as all Medicare revocations, HHS-OIG exclusion data, provides states access to the Social Security Administration's Death Master File, and enhances collaboration, improves reporting, and creates transparency through this process. In FY 2022, CMS continued the Medicaid screening pilot process to screen Medicaid-only providers through its APS system on behalf of states and produce a report of providers with licensure issues, criminal activity, and Do Not Pay activity. CMS believes centralizing this process will improve efficiency and coordination across Medicare and Medicaid, reduce state and provider burden, and addresses one of the biggest sources of error as measured by the PERM program today. In

FY 2022, CMS provided APS alerts to Iowa, Missouri, Oklahoma, Nevada, North Dakota, Tennessee, Colorado, Rhode Island, Oregon, and West Virginia.

CMS provides ongoing guidance, education, and outreach through targeted technical assistance to states on Federal requirements for Medicaid screening and enrollment. In addition, CMS continues to publish updates to the MPEC, which is sub-regulatory guidance designed to assist states in applying certain regulatory requirements. The latest update published in March 2021 clarified Medicaid screening and enrollment policies and procedures for the state Medicaid agencies.[22]

Continue to Build States' Capacity to Protect Medicaid

CMS assists states in building their internal capacity to conduct program integrity activities for their Medicaid programs. CMS continues to use HCFAC program discretionary funds and other funding sources to develop and implement enterprise systems that support state Medicaid programs. In particular, there is an initiative called the Medicaid and CHIP Business Information Solution (MACBIS) which is a CMS enterprise-wide initiative providing product development efforts and services to modernize and transform information and data exchanges with states and other key stakeholders aimed at ensuring that CMS protects access to coverage and care, advances healthy equity, and drives innovation and whole person care in Medicaid and CHIP. Through MACBIS, CMS, stakeholders, and states are provided the ability to gather and analyze data to improve monitoring, oversight, evaluation and to assess program integrity of the overall Medicaid and CHIP programs. MACBIS provides operational, financial, pharmacy, quality, and business performance data through products and services such as the T-MSIS, Medicaid and CHIP Program (MACPRO), Medicaid and CHIP Financial (MACFin), and the Medicaid Drug Program to assist in preventing fraud, waste, and abuse.

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 for technical assistance and education;
- Webinars;
- Medicaid Integrity Institute (MII);
- Provider screening and enrollment strategies;
- Onsite/virtual focused program integrity reviews;
- Provider audits and investigations through the five UPICs;
- Desk reviews of state processes and procedures; and
- PERM corrective action plan and Medicaid Eligibility Quality Control (MEQC) oversight.

[22] March 2021 Medicaid Provider Enrollment Compendium
https://www.medicaid.gov/sites/default/files/2021-05/mpec-3222021.pdf

CMS also identifies areas of improvement and works with states to make sure their integrity programs are robust.

State Audit Compliance and Financial Management Oversight

The State Audit Compliance and Financial Management Oversight projects began in September 2020. To support this project, CMS acquired 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 and CHIP programs to assist CMS in better identifying high risk policy areas. CMS is actively engaged with contractors on both of these initiatives and anticipates continued contractor engagement in these areas through FY 2023.

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 regulation[23] and guidance, including the Medicaid Information Technology Architecture (MITA) framework, several standards and conditions,[24] and certification criteria. Adhering to these mandates promotes the consistency of business and technical processes and IT platforms, as well as standards across the Medicaid Enterprise. As noted above, CMS is working closely with states to support the delivery of comprehensive digital service products for MACBIS, 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 technical assistance to states with respect to IT and policy requirements, including monitoring and oversight, 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. CMS State Officers remain closely engaged with

[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

states during the implementation as well as the operation phase of the IT initiative. As part of the engagement, project reports and evidence are reviewed on a regular basis to identify risks, challenges, barriers and/or 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). 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. On April 14, 2022, CMS released updated Medicaid Enterprise Systems (MES) Certification guidance to ensure a more comprehensive analysis of CMS funded state systems functionality. The release of the Streamlined Modular Certification for Medicaid Enterprise Systems demonstrates CMS focus on increasing accountability and state flexibility by creating an outcomes-based oversight model for state systems certification.[25] This approach focuses 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 number 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 the root causes of errors and deficiencies in an effort to reduce improper payments.

In the HHS FY 2022 Agency Financial Report (AFR),[26] CMS reported the national Medicaid improper payment rate based on measurements conducted in FYs 2020, 2021, and 2022. The FY 2022 national Medicaid improper payment rate was 15.6 percent, representing $80.6 billion in gross Federal improper payments. The FY 2022 national Medicaid improper payment rates by component are 10.4 percent for Medicaid FFS, 0.03 percent for Medicaid managed care, and 11.9 percent for Medicaid eligibility. The FY 2022 national CHIP improper payment rate was 26.7 percent, representing $4.3 billion in gross Federal improper payments. The FY 2022

[25] https://www.medicaid.gov/Federal-policy-guidance/downloads/smd22001.pdf
[26] https://www.hhs.gov/about/agencies/asfr/finance/financial-policy-library/agency-financial-reports/index.html

national CHIP improper payment rates by component are 11.2 percent for CHIP FFS, 0.6 percent for CHIP managed care, and 24.0 percent for CHIP eligibility.

The areas driving the FY 2022 Medicaid and CHIP improper payment estimates are as follows:

- **Insufficient Documentation:** Represents situations where the required verification of eligibility data, such as income, was not done at all and where there is an indication that eligibility verification was initiated but the state provided no documentation to validate the verification process was completed. This includes situations where medical records were either not submitted or were missing required documentation to support the medical necessity of the claim. Insufficient documentation accounted for 13.6 percent or $70.0 billion of total errors cited in Medicaid FFS, Medicaid managed care and Medicaid eligibility in FY 2022.
- **State Non-Compliance:** Represents noncompliance with Federal eligibility redetermination requirements, enrolled providers not appropriately screened by the state, providers not appropriately rescreened at revalidation, providers not enrolled, and/or providers without the required NPI on the claim. State compliance with provider enrollment or screening requirements has improved as the Medicaid FFS component improper payment estimate decreased from 13.9 percent in FY 2021 to 10.4 percent in FY 2022. COVID-19 review flexibilities afforded to states should also be considered in the identified decrease in the Medicaid FFS and eligibility components between FY 2021 and FY 2022.
- **Improper Determinations (CHIP-specific):** represents situations where the beneficiary was inappropriately claimed under Title XXI (CHIP) rather than Title XIX (Medicaid), mostly related to incorrect state calculations based on beneficiary income, the presence of third-party insurance, or household composition/tax filer status.

See additional information regarding the eligibility component and establishment of a baseline measurement on pages 225-226 and 230-231 of HHS' 2021 AFR.[27]

A majority of Medicaid and CHIP improper payments were due to instances where information required for payment was missing, an eligibility determination was missing from the state system, states did not follow the appropriate process for enrolling providers, and/or states did not follow the appropriate process for determining beneficiary eligibility. However, these improper payments do not necessarily represent payments to illegitimate providers or on behalf of ineligible beneficiaries. Had the missing information been on the claim and/or had the state complied with the enrollment or redetermination requirements, then the claims may have been payable. Conversely, had the missing documentation been available, it could have affirmatively indicated whether a provider or beneficiary was ineligible for Medicaid and/or CHIP reimbursement and, therefore, the payment was improper. A smaller portion of improper payments are considered a known monetary loss to the program, which are claims where CMS has sufficient information to determine that the Medicaid or CHIP payment should not have occurred or should have been made in a different amount.

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

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 2022 Agency Financial Report[28] and CMS websites.[29]

Medical Loss Ratio Examinations

CMS conducts examinations of Medicaid managed care plans' financial reporting in selected states, focused on Medical Loss Ratio (MLR) and rate setting. CMS conducted a risk-based analysis to select additional states for review beginning in FY 2021. In January 2021, CMS initiated a review of Oregon's 16 Coordinated Care Organizations' MLR reporting for the Medicaid managed care population, and this review is currently ongoing. In FY 2022, CMS also conducted a risk-analysis to identify additional states for review beginning in FY 2023.

Medicaid 1115 Financial Oversight

Medicaid section 1115 demonstrations are an increasingly important vehicle for state innovation in Medicaid program development, expansion and financing. Forty-nine states and the District of Columbia operate at least one section 1115 demonstration, and there are approximately 82 active demonstrations representing estimated Federal outlays of $186.0 billion in FY 2022. 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.

CMS is exploring refinements to its section 1115 demonstration budget neutrality policy to assure fiscal integrity and to better accommodate certain investments through the use of section 1115 expenditure authority to strengthen the provider safety net and make advancements in closing health disparity gaps. The goal is to develop a budget neutrality policy that can adapt to real-world factors and maintain a balance between integrity and flexibility.[30] In addition, to strengthen the review of state-submitted quarterly budget neutrality performance reports, CMS has developed and continues to maintain a standardized budget neutrality reporting tool for states that will need to be updated for any modifications to budget neutrality policy.

CMS continues to modify and improve this tool based on user feedback to continue improving consistency in state reporting and CMS tracking of spending under section 1115 demonstrations. The section 1115 IT reporting system, Performance Metrics Database and Analytics (PMDA), continues to be updated to support this revised workflow and the documentation of findings from the budget neutrality reviews. Most recently, CMS engaged contractor support on an internal initiative to more thoroughly document and train staff on the underlying principles, assumptions

[28] https://www.hhs.gov/about/agencies/asfr/finance/financial-policy-library/agency-financial-reports/index.html
[29] https://www.cms.gov/ImproperPayments
[30] https://www.medicaid.gov/sites/default/files/Federal-policy-guidance/downloads/smd18009.pdf

and data to be used in the formulation of the budget neutrality parameters reflected in the demonstration approval documents.

Beyond budget neutrality, CMS continues to expand and make more robust its oversight of the integrity of demonstration implementations. This has included the continued training on and implementation of standard operating procedures, as well as continuing to utilize user feedback to make updates and refinements to 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 continues to provide technical assistance to states to assure they understand and implement these more robust monitoring standards.

CMS staff also continue to develop specific monitoring metrics for demonstrations testing high profile policy areas such as substance use disorder and severe mental illness. CMS staff and states are provided with training to understand the impact of these metrics.

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.

Investigations Medicare Drug Integrity Contractor (I-MEDIC)

As part of CMS's ongoing efforts to ensure effective oversight of the Medicare Part C and Part D programs, CMS contracts with two Medicare Drug Integrity Contractors (MEDICs). 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 Part C and Part D by focusing primarily on complaint intake and response, data analysis, investigative activities, referrals to law enforcement partners, and law enforcement support, which includes requests for information . In FY 2022, the I-MEDIC initiated 651 investigations; submitted 77 recommendations for provider revocations; submitted 162 referrals to law enforcement, including 31 immediate advisements; and submitted 167 referrals to other entities, such as state pharmacy and medical boards, Medicare quality improvement organizations, and other Medicare contractors.

Plan Program Integrity Medicare Drug Integrity Contractor (PPI MEDIC)

The PPI 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 PPI MEDIC's data analysis projects and Part D plan sponsor self-audits, $640,833 was recovered from Part D sponsors in the first eight months of FY 2022.

Contract-Level Risk Adjustment Data Validation (RADV) Audits

RADV audits are CMS's primary corrective action to recoup overpayments in Medicare Part C. 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 FY 2022, CMS conducted a preliminary analysis of medical record review results for the payment year (PY) 2014 RADV audits and continued reviewing medical records for the PY 2015 RADV audits.

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 Medicare Advantage Organizations (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.

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 2022, 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.

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 to the industry 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.

Fraud, Waste and Abuse Oversight and Education

CMS conducts audits of Medicare Part C and Part D plan sponsors, with a focus on reducing improper payments and targeting drugs that are at high risk of improper payments. Each type of audit is different in scope but has the same goal of educating Part C and D plan sponsors on issues of fraud, waste, and abuse, as well as identifying, reducing, and recovering inappropriate payments. In FY 2022, CMS conducted 13 Part C and D audits.

CMS also conducts outreach and training sessions for Medicare Part C and Part D sponsors on program integrity initiatives, investigations, data analyses, and potential fraud schemes. CMS held Opioid Education Missions in October 2021 and May 2022; a COVID-19 fraud, waste, and abuse webinar in February 2022; and an MA Organization and Prescription Drug Plan fraud, waste, and abuse webinar in September 2022. CMS also provides Part C and D plan sponsors with a Fraud, Waste and Abuse Quarterly Plan Report that includes information related to schemes and trends that can be used to identify suspicious activities in their own organizations, including those related to opioid overprescribing. CMS released the first Fraud, Waste and Abuse Quarterly Plan Report in FY 2022.

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 7,300 Part C plan benefit packages on June 6, 2022, and project to cover nearly 31.8 million enrollees in contract year 2023. Bid and plan benefit submissions are reviewed to ensure they do not discriminate against beneficiaries and comply with CMS regulations. Plan standards are established and communicated annually, and the following reviews are performed:

- Low Enrollment Plans—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)—CMS evaluates increases in beneficiary cost sharing or decreases in plan benefits from one year to the next. This evaluation ensures 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)—CMS conducts this review to examine the maximum out-of-pocket costs for enrollees in Part C and protect beneficiaries from very high out of pocket medical costs.

- Service Category Cost-Sharing Standards—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—CMS conducts several reviews 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 benefit review standards and processes are intended to protect beneficiaries from discrimination and to ensure that Part C plans provide value to enrollees.

Encounter Data Processing System

CMS requires MAOs to submit encounter data for each item and service provided to MA plan enrollees. CMS established and maintained the Encounter Data System (EDS), which to date, has collected approximately eight billion encounter data records (EDRs).

The encounter data detail each item and service provided to MAO enrollees. These records are comparable in format and detail to claims FFS providers submit to the MACs. The encounter data collected by the EDS allows CMS to make accurate payments reflecting the patterns of care and the predicted costs of diseases for MA enrollees. CMS also uses the information to evaluate service utilization, assess quality of care, and assess the MAOs' performance.

In CY 2015, CMS began to use encounter data as an additional source of diagnoses to risk adjust payments to MAOs. For PACE organizations, CMS has continued the policy of using encounter data as an additional source of diagnoses for risk score calculation through CY 2024. For organizations other than PACE, CMS began the transition from Risk Adjustment Processing System (RAPS) to encounter data in CY 2016 by calculating risk scores using both 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 2022, CMS completed the transition to encounter data by calculating MAO risk scores using diagnoses entirely from encounter data and FFS data.

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 MAOs' encounter data submissions.

Improper Payment Rate Measurement 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 Improper Payment Measure (IPM) is an annual measurement of payment error for the Medicare Advantage (MA) program due to inaccurate diagnoses submitted by MA plans. To calculate the projected IPM error rate, CMS selects a random sample of enrollees with one or more CMS Hierarchical Condition Categories (CMS-HCCs) and requests medical records to support each condition. Independent coders abstract diagnoses from medical records, and the analytical contractor calculates corrected risk scores based on the abstracted diagnoses. The difference between the original and corrected risk scores forms the basis to calculate the IPM.

For FY 2022 (based on the 2020 payment year), the projected Part C improper payment estimate is 5.4 percent, representing $13.9 billion in improper payments. In FY 2022, CMS finalized policy regarding treatment of new additional CMS-HCCs in the improper payment rate calculation. Diagnoses that were not submitted to CMS for payment have been excluded from the payment error calculation to get a true measure of payment error. In previous years, these potential payments were included in the underpayment rate and overall payment error calculation, biasing the IP rate upward, resulting in an overstatement. The implemented policy for FY 2022 contributed to a decrease in the projected improper payment rate, representing a new baseline for Part C.

The Part D gross improper payment estimate reported for FY 2022 (based on the 2020 payment year) was 1.5 percent or $1.4 billion, 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.

Beginning in FY 2022, HHS simplified the standard error calculation simulation process to adhere to statistical best practice, resulting in a lower margin of error and more accurate estimate. Further, HHS updated the data sources used to calculate the denominator in FY 2022; ensuring the calculation only considers Part D expenditures that may be identified through IPM clinical validation of PDE cost and payment amounts.

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

- Training: In FY 2022, 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.
- Outreach: CMS continued formal outreach to plan sponsors with respect to invalid or incomplete documentation. CMS 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 Medicare Part C and Part D improper payments can be found in the FY 2022 Agency Financial Report[31] and CMS website.[32]

Ensure Program Integrity in the CMS Marketplace

The Federally Facilitated Marketplace (FFM) and the State-based Marketplaces (SBMs) continued to expand their focus on program integrity. In FY 2022, CMS triaged more than 25,000 complaints from consumers who alleged they were enrolled in FFM policies without their consent or that incorrect information was submitted on an application by an agent or broker, or that other misconduct had occurred. Issuers confirmed that over 11,000 of these policies met the unauthorized enrollment criteria and subsequently cancelled the policies. Furthermore, issuers identified more than 23,000 additional policies attributable to fraud through their own investigations resulting in more than 34,000 overall policies being cancelled due to consumers being enrolled into a policy without their consent or knowledge in FY 2022. CMS and its program integrity contractors continuously analyzed plan enrollments and other types of data to identify trends and early warning signs of fraud, conducted dozens of investigations of outlier and high-risk agents and brokers, and made recommendations for administrative action, such as termination of an agent's and/or broker's registration to sell policies on the FFM. CMS also performed over 700 license verifications to identify agents and brokers potentially noncompliant with states' licensure statutes and regulations and reported license non-compliance to the appropriate state Department of Insurance (DOI). CMS also supported ongoing HHS-OIG and DOI investigations by fulfilling requests for records regarding consumer FFM enrollments and financial assistance, complaints, and results of CMS investigations. Sixty-one (61) such requests

[31] https://www.hhs.gov/about/agencies/asfr/finance/financial-policy-library/agency-financial-reports/index.html
[32] https://www.cms.gov/ImproperPayments

were received and fulfilled in FY 2022. Lastly, CMS hosted bi-monthly meetings with SBMs to share best practices for identifying and deterring fraud and notifying SBMs of specific schemes being investigated by the FFM and/or one or more SBMs.

Following an FY 2016 risk assessment, HHS concluded the Advance Payment of the Premium Tax Credit (APTC) program is susceptible to significant improper payments and is required to establish and report an improper payment estimate. In FY 2021, the Department commenced the improper payment measurement program for the Federally Facilitated Exchange (FFE) and reported for the first time in the FY 2022 AFR. HHS continues to develop the improper payment measurement methodology for the State-based Exchanges (SBEs). As with similar HHS programs, developing an effective and efficient improper payment measurement program requires multiple time-intensive steps, including contractor procurement; developing measurement policies, procedures, and tools; and extensive pilot testing to ensure an accurate improper payment estimate.

The Exchange Improper Payment Measurement (EIPM) is an annual measurement of payment error for the FFE to determine if it properly paid APTC benefits under the regulatory requirements relating to eligibility and payment determinations. CMS performs the reviews on a statistically valid random sample of 2,000 applications. The improper payment rate and amounts estimated from this sample reflect all health insurance applications with APTC payments processed by the FFE for CY 2020. States that do not use the FFE to administer the APTC program, and instead have elected to operate independent SBEs, were not considered in the sample.

FFE improper payment estimate for FY 2022, for measurement of CY 2020, is 0.6 percent or $255.8 million. The improper payment estimate due to lacking or insufficient documentation is 0.04 percent or $16.8 million, representing 6.6 percent of total improper payments. The estimated percentage of APTC dollars paid correctly was 99.4 percent. This means the FFE paid an estimated $41.0 billion correctly in FY 2022.

The primary cause of overpayments was manual errors associated with determining consumer eligibility for APTC payments, representing 94.3 percent of overpayments, or $222.6 million. Most health insurance applications have consumer eligibility verified using automated processes. Automated processes refer to those functions which are executed using computer programming, and do not involve manual intervention. Certain eligibility verifications consist of electronically comparing information provided by a consumer to that of third-party databases and determining if any inconsistencies exist that may impact a consumer's eligibility. For certain applications, manual eligibility verifications are necessary because of the circumstances of a consumer's application (for example, an application submitted past the open enrollment period due to certain qualifying life events), or because the automated verification process identified a need for additional information to be provided by the consumer to verify their eligibility. Manual verifications involve complex rules and a large variety of documentation types and formats, and therefore have a heightened risk of error.

Combined Improper Payment Data

The APTC program represents the first of two potential payment streams for the overall Premium Tax Credit program. The second payment stream relates to additional Premium Tax Credit amounts claimed by taxpayers at the time of their tax filings, referred to as "Net Premium Tax Credits" (Net PTC). That is, total Premium Tax Credit outlays are equal to APTC payments plus Net PTC claims. The Internal Revenue Service measures improper payments associated with Net PTC claims, and for CY 2020 reported Net PTC claims of $1.3 billion, improper payments of $342.1 million, and an improper payment rate of 27.4 percent. The combined APTC and Net PTC improper payment estimate is $597.9 million out of $42.5 billion total Premium Tax Credit outlays/claims, or 1.4 percent. Note that similarly to the APTC improper payment information provided above, this combined APTC and Net PTC improper payment information does not reflect payments made by SBE.

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

- Systems Automation: Some errors relate to the actual generation of APTC payments and others relate to the application of policies or procedures to the automated processes associated with APTC. HHS's corrective actions include identifying and remediating system defects within the Exchanges that may impact APTC payments. These defects become known through various mechanisms, including internal quality control activities and external reviews of APTC eligibility determinations made by the Exchanges. HHS continually evaluates the policies and procedures that underlie the automated processes associated with APTC to identify and address weaknesses that may surface as they become operationalized. HHS implemented process automation to reduce human error introduced during adjudication and processing of supporting documentation. HHS will continue to encourage and require that additional tasks be automated to further reduce manual errors and improve the accuracy and quality of required adjudication tasks.

- Training: All eligibility support contractor personnel undergo a rigorous training when onboarded to the workforce. They also receive annual refreshers and quick training lessons when program policy or operations are updated. Ad hoc training is added as additional training needs are identified. HHS conducted additional training sessions related to Data Matching Issues verifications, casework, and outreach.

- Audits: Both the automated and the manual processes of the exchanges are subject to rigorous annual testing of key internal controls as required by OMB Circular A-123, Appendix C. External audits by HHS-OIG and GAO are another common mechanism that help to identify potential payment integrity risks within the exchanges, specifically by evaluating APTC eligibility determinations made by the exchanges within the context of Federal statute and regulations.

- Predictive Analytics: The Marketplace Program Integrity Contractor has implemented a risk model, which incorporates many risk factors that may be indicative of potential fraud or misconduct by agents or brokers. The result is a risk profile and weighted risk score for each agent or broker. Those that pose the highest risk, based on weighted risk score, are prioritized for investigations. The risk profile is also leveraged as part of a prioritized

investigation and significant discoveries may be used to inform interview questions or as supporting evidence in overall case findings.

Additional information on FFE improper payments can be found in the FY 2022 Agency Financial Report and CMS website.

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 promising practices and lessons learned in program integrity. Increased transparency and accountability ensure program efficiency and effectiveness.

Health care Fraud Prevention Partnership (HFPP)

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 protect the public by identifying and reducing health care fraud, waste, and abuse through collaboration, data and information sharing, and cross payer research studies. The HFPP delivers actionable data to Partners to develop strategies to proactively disrupt existing and emerging fraud trends and contribute to cost savings. This is achieved 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 HFPP resources and relationships to generate real-time, comprehensive approaches that materially impact efforts to reduce health care fraud, waste, and abuse.

Section 1128C(a) of the Social Security Act (42 U.S.C. 1320a–7c(a)) was amended by the Consolidated Appropriations Act, 2021 to provide explicit statutory authority for the HFPP including the potential expansion of the public-private partnership analyses.

In FY 2022, the HFPP reached a total membership level of 267 partner organizations, comprised of six Federal agencies, 73 law enforcement agencies, 15 associations, 117 private payers, and 56 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 began collecting pharmacy claims to be used in studies beginning in FY 2022.

Over 56 billion professional claim lines were submitted by partners through FY 2022 for the purpose of conducting cross-payer analyses, and the HFPP has commenced 13 studies during FY 2022 providing participating partners with detailed results that can be used for corrective actions within their organizations. Examples of studies initiated in FY 2022 include the identification of problematic billing in the following areas:

- COVID-19 add-on laboratory testing;
- Psychotherapy, physical therapy/occupational therapy improbable days;
- Applied Behavioral Analysis (ABA) therapy;
- Footbaths;
- Substance Use Disorder (SUD) treatment; and
- Psychotropics in nursing facilities.

The HFPP also continued its efforts to foster collaboration among partners in FY 2022 by hosting five virtual information-sharing sessions, small group discussions, and quarterly Executive Board meetings. These meetings are 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. In addition, the HFPP held focus groups to ascertain from Partners their thoughts on the strategic direction of the Partnership.

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 (collectively referred to as reporting entities) and physicians, physician assistants, advanced practice nurses, and teaching hospitals (collectively referred to as covered recipients). Open Payments data includes payments and other transfers of value (such as gifts, honoraria, consulting fees, research grants, and travel reimbursements) that reporting entities provide to covered recipients, 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 the data on the public website, where the reported data can be searched, downloaded, and evaluated.

The Program Year 2021 data publication was the first publication that included the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act's expanded definition of covered recipients adding five provider types to the Open Payments data. The additional provider types as of Program Year 2021 and going forward are: physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified nurse midwives. Within the Open Payments program, the added provider types are collectively referred to as "non-physician practitioners" or "NPPs."

For Program Year 2021 (January 1, 2021-December 31, 2021), CMS published $10.90 billion in payments and ownership and investment interests that were made from reporting entities to covered recipients. This amount is comprised of approximately 12.10 million total records attributable to 533,056 physicians, 233,471 non-physician practitioners and 1,237 teaching hospitals. Payments in the three major reporting categories included:

- $2.55 billion in general (i.e., non-research related) payments;
- $7.09 billion in research payments; and
- $1.26 billion of ownership or investment interests held by physicians or their immediate family members. Ownership or Investment Interests include those held by physicians or their immediate family members. This category is not applicable to non-physician practitioner covered recipients or teaching hospitals.

Over the past seven years, CMS has published a total of 78.8 million records, accounting for $63.2 billion in payments and ownership and investment interests.

Administration for Community Living

The mission of the Senior Medicare Patrol (SMP) program is to empower and assist Medicare beneficiaries, their families, and caregivers to prevent, detect, and report health care fraud, errors, and abuse through outreach, counseling, and education. In FY 2022, HHS allocated $30.0 million in HCFAC appropriations, plus an additional $48,226 in carryover funding from FY 2021 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 2021, Congress increased the floor for SMP funding to $20.0 million from CMS discretionary HCFAC appropriations, and again in FY 2022 to $30.0 million. In addition, Congress provided ACL, for the first time in FY 2021, with authority to be funded from CMS discretionary appropriations, wedge funding, or both. Based on that authority, in FY 2022, ACL requested and received $2.0 million for a one-time effort supported by wedge funding to expand efforts of the program both nationally and at the state and local level to reach people in underserved communities.

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 2022, 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. Due to the increased in funding for this fiscal year, grantees also received administrative supplements totaling $11,453,839. The additional funding was distributed using the SMP grant formula which considers the number of Medicare beneficiaries in each state and territory. SMP projects proposed to use this funding to increase base grant activities.

COVID-19 Fraud Schemes

Fraud schemes relating to COVID-19 became prevalent beginning in March 2020 and continued throughout FY 2021 and FY 2022. The majority of complaints received by the SMP grantees continued to relate to COVID-19 treatments, testing, vaccines, and cures, followed by other pandemic related fraud. Other COVID-19 related fraud identified by the SMP program included fraud related to health insurance solicitation, false charities and investments schemes, and financial scams. Additional schemes reported included those related to general COVID-linked medical services or pandemic supplies and equipment. Most reported COVID-19 fraud or schemes occurred in-person, followed by fraud via text and telephone attempts. Though the SMP program's education and outreach activities were largely limited to virtual methods during this period as opposed to typical face-to-face means, grantees 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, CMS, FBI, and SSA.

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. The SMP National Resource Center developed, released, and continually updated COVID-19 Consumer Fraud Alerts focused on COVID-19 fraud schemes occurring nationally in order to warn Medicare beneficiaries and their families to take precautions. Covered fraud schemes involve topics such as unsolicited marketing tactics to enroll beneficiaries in hospice services, COVID-19 vaccines and treatments, and genetic testing. Produced materials advise beneficiaries to be suspicious of strangers who offer unsolicited COVID-linked items, services, or testing. They also advise beneficiaries to be wary of scare tactics used to pressure them into acting, and to be cautious about sharing their personal information, including their Medicare identification number. In addition, these materials warn that personal information could be used to fraudulently bill Medicare and Medicaid. Materials include consumer tip sheets on a variety of general and specific COVID-19-focused topics, Medicare coverage FAQs, infographics, and videos, most of which are available in both English and Spanish. As reported in the most recent HHS-OIG report on SMP (OIG Final Report: 2021 Performance Data for the Senior Medicare Patrol Projects (OEI-02- 22-00310)), the SMP projects conducted 645 group education events covering COVID-19 fraud issues in 2021, reaching a total of 26,704 people. In addition, they conducted 144 instances of media outreach on this topic, reaching an estimated 17.2 million people.

Genetic Testing Fraud Schemes

Genetic testing fraud continued to be a widespread issue nationally in FY 2022 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. In mid-FY 2021, scammers started offering Medicare beneficiaries cardiac genetic testing (cardiogenetics) in order to obtain their Medicare information for fraudulent purposes and this scheme continued and intensified in FY 2022. 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 targeted public education and outreach efforts on this topic during this period along with the HHS-OIG. A topic-focused fraud alert was developed as part of this effort. The alert cautions beneficiaries about sharing personal information that can be used fraudulently. The SMP projects conducted 505 group education events covering genetic testing fraud issues in 2021; these events reached 24,562 people. In addition, they conducted 144 instances of media outreach on this topic, reaching 17.2 million people.

Annual SMP OIG Report

Each year, the HHS-OIG completes an annual performance report on the SMP program and grantees. The most recent report covers CY 2021 (OEI-02-22-00310). In CY 2021, the SMP projects had a total of 5,346 active team members who conducted 12,660 group outreach and education events, reaching an estimated 556,980 people. In addition, the projects had 239,625 individual interactions with, or on behalf of, a Medicare beneficiary. For CY 2021, the SMP projects reported $2.5 million in expected Medicare recoveries. Over half of these recoveries came from one project that uncovered a genetic testing fraud scheme in which residents of a senior house complexes were persuaded to submit genetic testing specimens to a laboratory without sufficient involvement of a health care professional.

Since the SMP program's inception, the program has received more than 3.7 million inquiries from Medicare beneficiaries about preventing, detecting, and reporting billing errors, potential fraud, or other discrepancies. SMP projects have also educated more than 42.6 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 2020-2022 reports 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 $148.5 million in savings attributable to the SMP program since its inception in 1997.

Medicare Fraud Prevention Week

In FY 2022, the first Medicare Fraud Prevention Week was held June 5-11, 2022, marking the SMP program's 25th anniversary year. When it was identified that no event existed that included similar scope, mission, and key players, ACL and the SMP Resource Center took on this important inaugural task. The event focused on the actions that everyone could take to prevent Medicare fraud, errors, and abuse. Each day of the week focused on a different audience with different messages and action steps around fraud prevention. Medicare beneficiaries, caregivers, families, partners/professionals, health care providers, and the community were all targeted audiences. For this first Medicare Fraud Prevention Week, the goals were to:

- Engage SMP projects and create excitement around participating;
- Create resources for SMP and public use;
- Increase social media follows, reach, impressions, and video views across all social media platforms; and
- Work with partners in sharing the SMP program information.

Overall, this awareness week was an incredible success. Analytics were closely tracked and included outcomes such as:

- Many national-level resources developed including paid advertisements, general informational program videos and infographics, two new topic-specific videos focused on How to Read Your Medicare Summary Notice and How to Use a My Health Care Tracker;
- 14,988 Google page views from 2,992 users;
- 130,652 Facebook reach including 923 event responses and 72,222 Twitter impressions from paid ad campaigns;
- 5,925,477 Hulu ad impressions;
- 354 new YouTube viewers including 575 video views for a 2,200 percent increase in views; and
- 23 national level partners and 80 local agencies and organizations participating electronically.

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). In FY 2022, the Center received a continuation award totaling $850,000. In addition, the Center received base and HCFAC Wedge supplements totaling $700,000 to focus on the continuation of previously planned grant activities and increases in diversity, equity, and inclusion efforts internally and among state SMP projects. 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 comprehensive 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 mobile 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 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 2022, 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 developed a request for proposals to award a new expanded State Health Insurance Assistance Program (SHIP)[33] and SMP National Beneficiary Satisfaction Survey contract. The goal of this contract, which entered Year 3 in FY 2022, is to ascertain the quality and effectiveness of the services provided by the SHIP and SMP program. The scope of the Beneficiary Surveys is to evaluate and measure satisfaction with SHIP and SMP educational presentations and Medicare one-on-one counseling sessions. The surveys assess how beneficiaries value the services and information they receive, identify opportunities for continuous improvement, and comply with regulatory requirements regarding data collection. The evaluation includes two types of surveys: (1) for individual counseling sessions with Medicare Beneficiaries, and (2) for individuals that attended an educational presentation. The results will create a baseline understanding of satisfaction with counseling services and educational presentations and identify opportunities for recognition as well as overall network improvements.

The second year of the surveys indicate high rates of satisfaction with both the one-on-one interactions and group outreach conducted by the SMP projects nationally. The average national ratings were as follows (1= Strongly Disagree, 5 = Strongly Agree):

Group Outreach Activities:

- 4.74 – "This Presentation provided me with useful information"
- 4.75 – "Overall, I am satisfied with the presentation today"
- 4.65 – "I would contact the presenter for help or information"
- 4.75 – "I would recommend this presentation to others"

[33] The SHIP (State Health Insurance Assistance Program) is a sister program to the SMP administered by ACL that provides direct assistance to Medicare beneficiaries and their families to help them understand, enroll in, and navigate their Medicare benefits. The ACL Medicare beneficiary satisfaction surveys are administered together given the similarities and overlap between the SHIP and SMP programs.

One-on-One Interactions:

- 4.07 – "I was able to find and contact SMP in a timely fashion
- 4.28 – "The information provided to me was useful
- 4.24 – "SMP provided me with useful information"
- 4.36 – "Overall, I was satisfied with my interaction with SMP"
- 4.12 – "I would contact SMP again for assistance"
- 4.26 – "I would recommend SMP's service to others"

The overall survey 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.

Office of the General Counsel

In FY 2022, HHS allocated the Office of the General Counsel (OGC) $7.7 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 2022 helped the Government establish approximately $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, Medicaid, and CHIP 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 2022, OGC worked collaboratively with DOJ and HHS-OIG on numerous FCA matters regarding a variety of issues such as: price-fixing drugs, physician self-referral, supplier billing of tests and services that were not rendered or that were medically unnecessary, failure to report discounted prescription drug prices, misrepresentations under the Medicare Electronic Health Records (EHR) incentive programs, kickbacks and other unlawful marketing practices in connection with the marketing of EHR products, billing for grossly substandard skilled nursing services, and billing for rehabilitation therapy services that were not reasonable, necessary, or skilled. OGC efforts on these and other FCA matters in FY 2022 helped the Federal Government recover approximately $1.14 billion.

Civil Monetary Penalties

CMS is responsible for administering CMP laws that are 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 affect the quality of care provided to affected beneficiaries, save program funds, and set precedents that demonstrate HHS's commitment to policing this area.

OGC obtained several favorable outcomes regarding the imposition of CMPs during FY 2022, as the COVID-19 pandemic continues to spotlight health care facilities' responses to infection control issues. OGC has advised CMS on numerous actions related to facilities' responses to infection outbreak and has also worked with CMS on nursing home enforcement actions involving infection control, including cases associated with COVID-19 and other pathogens. For example, OGC successfully defended CMS's determination of immediate jeopardy and its imposition of CMPs totaling $427,950 for a facility's failure to implement its infection prevention and control program. Forty-four (44) residents tested positive for COVID-19 and 14 of them died in less than a month. Yet the facility defended its failure to follow its infection control policies by arguing that the interventions were useless and too difficult to follow. The administrative law judge (ALJ) ultimately upheld CMS's findings, including that the facility failed to: (1) provide signs for doors of residents' rooms showing they were under droplet precautions, (2) establish an effective method of communicating COVID-19 positive status to staff, and (3) isolate multiple symptomatic residents from asymptomatic residents.

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 providers and suppliers who have committed certain conduct or acts or against whom there are credible allegations of fraud 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 2022, OGC successfully defended CMS's revocation of a supplier based on improper prescribing practices, in particular, over-prescription of opioids. As part of a CMS audit, the physician was flagged as a practitioner who frequently prescribed drugs, including opioids, to Medicare beneficiaries. Review of his medical records indicated generic and vague justifications for his prescriptions, with little to no follow-up when patients exhibited other risk factors for potential drug misuse. The ALJ issued a decision upholding CMS's action, finding that every factor CMS relied upon for revocation was supported by the record.

Part C and Part D Compliance

During FY 2022, OGC provided extensive advice to CMS on a variety of Part C and Part D compliance issues, including identifying enforcement options against plan sponsors that were noncompliant or violated program rules. When challenged, OGC defends CMS's 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 C plans and Part D sponsors, which include warning letters, imposition of corrective action plan letters, intermediate sanctions, CMP notices, and non-renewal or termination notices. OGC also defends CMS non-renewal or termination actions of Part C and Part D plan contracts.

Regulatory Review and Programmatic Advice

In FY 2022, 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:

- Generally, OGC's COVID-19 related work subsided in FY 2022, as compared to 2021, nevertheless OGC continues to provide support and 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 for the provision of medical screening for emergencies, Emergency Medical Treatment and Labor Act requirements, survey and certification processes, including enforcement and oversight policies, provider/supplier enrollment, the COVID-19 Accelerated and Advanced Payments program, debt recovery requirements, improper payment measurement processes, waivers of the physician self-referral law, or the Stark Law, and other fraud and abuse requirements. OGC has provided expeditious responses to support the clearance of numerous rules that address the COVID-19 public health emergency. OGC worked extensively with CMS on issues related to "unwinding" certain PHE flexibilities.

- OGC advised CMS on multiple issues regarding the implementation of the COVID-19 Health Care Staff Vaccination rule (vaccine rule) (press, guidance, and enforcement), including providing advice on programmatic implications involving CMS and state oversight functions. Several states opposed the rule and would not permit state surveyors to conduct surveys to determine compliance.

- OGC spent extensive time advising DOJ in litigation before Federal district and appellate courts challenging CMS's vaccine rule for staff in health care facilities subject to the regulation. OGC attorneys provided exceptionally expeditious assistance reviewing briefs and other pleadings to ensure that legal propositions concerning CMS's programs are accurately stated. In March, the Supreme Court stayed a preliminary injunction against the rule and allowed it to go into effect nationwide.

- OGC continues to spend extensive time on various opioid-related issues, primarily related to Touhy requests and discovery in continuing opioid matters and 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, including proposed and final rules related to enrollment and medical review requirements, a new provider-type known as rural emergency hospitals (REH), and the establishment of survey and enforcement requirements for hospice programs.

- OGC continues to counsel the CMS Innovation Center, which tests payment and delivery models to reduce expenditures and preserve or enhance quality of care for Medicare, Medicaid, and CHIP beneficiaries. OGC provides ongoing advice regarding the development of contracts, the imposition of corrective action plans, participant screening, and recovery of funds for such models. In addition, OGC continues to provide counsel to CMS on program integrity issues in the Medicare Shared Savings Program, including advice regarding program integrity screenings for applicants to the program, appeals of application denials and the implementation of its Beneficiary Incentive Program.

- OGC continues to collaborate with DOJ and the Health Resources and Services Administration on issues arising in connection with the Provider Relief Fund created by the CARES Act, enacted in March 2020.

Physician Self-Referral (Stark Law)

In FY 2022, OGC provided extensive counsel to CMS regarding its Medicare Physician Self-Referral Disclosure Protocol (SRDP), 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 navigating the complexities of the Stark Law. In FY 2022, OGC continued to assist and advise CMS following the publication of its rule modernizing and clarifying the Stark regulations, which went into effect last year. Further, OGC provided advice related to the blanket waivers of sanctions under the Stark Law for COVID-19 purposes, which action provided vital flexibility for physicians and providers in the fight against COVID-19. 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 and Medicaid Third Party Liability

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 2022, 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. For example, in *Wilensky v. Becerra*, after proceeding through the administrative review process, the plaintiff appealed the denial of Medicare Part D coverage for a drug (Alosetran) to Federal district court. Coverage had been denied because the drug was not FDA-approved for the plaintiff's condition, and therefore the drug was not prescribed for a "medically accepted indication," as required for reimbursement under Medicare Part D. The plaintiff sought discovery in Federal court, arguing that the Secretary's reasons for denying coverage were pretextual and seeking information about possible past coverage of the drug. Plaintiff had requested the same information below, but the Medicare Appeals Council denied the request as irrelevant to the issue on appeal. The U.S. District Court for the District of Minnesota held that the plaintiff's request for discovery during the administrative review process was not supported by any authority requiring the Medicare Appeals Council to grant his request, and that the Council's refusal to allow discovery did not create a basis for permitting discovery in Federal court. Once the ruling was made, the plaintiff notified the court of his intent to voluntarily dismiss the case.

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 2022, OGC handled several matters involving issues arising under the COVID-19 Accelerated and Advanced Payments program and bankruptcy. OGC represented CMS and HRSA in the bankruptcy of *Gulf Coast Health Care LLC*, which included over fifty skilled-nursing facilities. OGC worked with DOJ to file objections to the financing order and management and operations transfer agreements because they did not provide full Medicare successor liability and because they intended to use provider-relief funds for improper purposes. OGC and DOJ negotiated changes in these documents so that the transactions complied with regulatory, statutory, and HRSA guidance and requirements. OGC also prepared and filed approximately 80 proofs of claim and administrative claims for the over $40.0 million in PRF payments the entities received.

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 reconsider-ations, and defense against Medicaid disallowance appeals before the Departmental Appeals Board. As a result of OGC's advocacy, CMS has prevailed in matters in FY 2022 that have upheld millions of dollars in disallowances.

In summary, OGC's efforts in FY 2022 directly supported the HCFAC program's goals. As part of its program integrity work, OGC coordinated with CMS, DOJ, and HHS-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 2022, $11.9 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. This 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 325 criminal HCFAC investigations. In FY 2022, OCI, through its PFP, opened 16 criminal investigations, including investigations involving drug compounders, clinical trials, and foreign and domestic medical-product manufacturers. FDA is committed to tackling emerging public health concerns. In FY 2022, the PFP has opened two COVID-19 related criminal investigations related to fraudulent treatment and prevention of COVID-19.

The 16 criminal investigations opened through PFP in FY 2022 are broken down as follows:

- Four investigations involving allegations of application fraud. One of the investigations involves fraudulent documents being submitted in support of an application by a biologic manufacturer. One investigation involves a biologic manufacturer exploiting the application process to avoid having to apply for an Investigational New Drug (IND). Another investigation is into a device manufacturer after FDA regulatory issued a recall due to serious malfunctioning that could result in severe injury or death. One

investigation is into a medical group that rendered the use of a medical device as misbranded and adulterated.

- Three investigations concerning allegations of flagrant manufacturing practices of human drugs. One investigation alleges significant current good manufacturing practices (cGMP) violations at a manufacturing facility. Another investigation is focusing on allegations of falsified records related to the manufacturing of prescription drug products knowing there were contamination issues. One investigation alleges the potential adulteration of manufacturing sterile injectable pharmaceuticals that placed patients at risk of serious injury and death.

- Five investigations involving allegations of clinical trial fraud. Two of the investigations involve firms operating clinical trials overseas suspected of falsifying data related to applications submitted to the FDA. One investigation is regarding a device manufacturer failing to report or reporting inaccurate information to FDA related to their medical device trial. One investigation alleges a clinical investigator was using blood samples and medical records from one individual to create and enroll multiple subjects. Another investigation is concerning an individual suspected of falsifying documents during a for-cause inspection related to a controlled study.

- Four investigations involving alleged fraudulent marketing schemes. One investigation alleges that a pharmacy is providing financial incentives for health care providers to write drug prescriptions. One investigation into a medical provider using unapproved regenerative medicine treatments to manage pain. Another investigation into a doctor advertising convalescent plasma therapy for the treatment of a variety of viruses, including Coronavirus. One investigation alleges a firm was administering unapproved cancer medications to patients.

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.

Significant prosecutions that occurred in FY 2022 are as follows:

- In November 2021, in the Central District of California, a physician was found guilty on 26 felony charges for fraudulently distributing an unapproved cancer treatment. The doctor submitted IND applications to FDA stating their intentions to engage in a clinical trial. The applications were placed on clinical hold due to deficiencies in the submissions. The doctor proceeded to mislabel the drug as a supplement and sell the product throughout the country and internationally.

- In January 2022, in the Northern District of California, a defendant was found guilty in connection to a multi-million-dollar scheme to defraud investors. The defendant courted investors by providing false representations regarding the accuracy and efficacy of a blood testing device. The defendant was convicted on wire fraud counts including a wire transfer totaling more than $140.0 million. An additional defendant was found guilty in July 2022 in the same scheme. In November 2022, the first defendant was sentenced to 135 months (11 years, 3 months) in Federal prison and three years of supervision following release from prison. In December 2022, the second defendant was sentenced to 155 months (12 years, 11 months) in Federal prison and three years of supervision following release from prison. Hearings to determine the amount of restitution to be paid by both defendants are pending.

- In January 2022, in the Southern District of Florida, a defendant was sentenced to 30 months confinement and ordered to pay $2.1 million in restitution for their role in falsifying clinical trial data. The defendant worked at a clinical research firm and falsified data related to several studies. Some of the data was made to appear as though subjects were participating in the trials when they were not. Two additional defendants entered guilty pleas in July 2022 related to the same clinical trial data falsification scheme.

- In June 2022, in the Northern District of Texas, a licensed pharmacist and owner of a compounding pharmacy was sentenced after entering a guilty plea in October 2021. The pharmacist pled guilty to distributing an adulterated drug used in cataract surgeries. The drug contained an excessive amount of inactive ingredient thus causing its purity and quality to fall below what was represented to the medical community. The pharmacist was sentenced to two years' probation, $40,000 criminal fine and $25 special assessment.

- In September 2022, in the Southern District of Florida, the former owner and CEO of a drug manufacturing company was sentenced to 37 months in Federal prison. The defendant was convicted of manufacturing and distributing medication that was contaminated with Burkholderia cepacian (B.cepacia). The defendant lied to FDA investigators about distributed products and steps the company had taken to mitigate future contamination. The contaminated products caused infections in pediatric patients at two children’s hospitals.

- In September 2022, in the Southern District of Florida, a defendant was sentenced after entering a guilty plea related to obstructing an FDA inspection. The defendant knowingly lied to FDA investigators during a regulatory inspection of the clinical research site. The site was testing asthma medication in children. The defendant falsely portrayed the clinical trial as having been conducted legitimately when they knew the trial had been falsified. Four defendants that have been sentenced were ordered to pay $555,214 in restitution. A fifth defendant is awaiting sentencing.

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. Due to the COVID-19 pandemic, FDA moved to a virtual training model to adapt to the needs of its workforce. Examples of the training that occurred in FY 2022 are listed below:

- In October 2021, FDA conducted a one-day training session for newly hired criminal investigators in Charleston, South Carolina, at the Federal Law Enforcement Training Center. Training topics included health care fraud and PFP-related material.

- In March 2022, FDA conducted a one-day training session for the Office of Regulatory Affairs, Consumer Safety Officers for New Hire Fundamentals. This training addressed proactive initiatives and investigative priorities in the PFP. The course objectives included providing new Consumer Safety Officers with an awareness of how regulatory inspections, electronic resources, and evidence obtained during regulatory activities, can result in the identification of health care fraud.

- In June 2022, FDA conducted a one-day training session for the Center for Biologics and Evaluation Research for new and existing Consumer Safety Officers. The training provided opportunities to discuss investigative priorities associated with the PFP and the best practices for identifying potential criminal violations.

DEPARTMENT OF JUSTICE

United States Attorneys

The United States Attorneys were allocated $73.2 million in FY 2022 HCFAC funding for civil and criminal health care fraud enforcement efforts. These funds supported Assistant U.S. 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 enjoin ongoing fraud, deter future fraud, and to recover funds wrongfully taken through fraud and false claims from the Medicare Trust Funds, other taxpayer-funded health care providers, and private insurers. In addition to protecting the public fisc, many cases handled by USAOs stopped ongoing patient harm and protected vulnerable victims from exploitation by health care providers. USAOs play a central role in bringing civil penalty actions against pharmaceutical manufacturers, distributors, pharmacies and providers for violations of the Controlled Substances Act including the diversion of opioids. USAOs also criminally prosecute health care providers contributing to the opioid crisis through pill mills and other illegal prescribing practices.

Criminal Prosecutions[34]
In FY 2022, USAOs opened 809 new criminal health care fraud investigations and filed criminal charges in 419 cases involving 680 defendants. During that same time period, 477 defendants were convicted of health care fraud-related crimes.

Civil Matters and Cases[35]
In FY 2022, USAOs opened 774 new civil health care fraud investigations and had 1,288 civil health care fraud matters pending at the end of the fiscal year.

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 whistle-blower) 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 cross district borders, to combat new schemes marketed to and taken up by providers nationwide.

[34] FY 2022 numbers are actual data through the end of September 2022. This data includes records classified with the 03G–Health Care Fraud program code.
[35] FY 2022 numbers are actual data through the end of September 2022. This data includes records classified with the FRHC–Health Care Fraud civil code.

Qui tam cases and other civil health care fraud FCA cases either are handled jointly with trial attorneys in the Department's Civil Fraud Section or litigated independently by USAOs. Civil AUSAs also handle civil penalty cases alleging violations of the Controlled Substances Act against defendants ranging from manufacturers down to individual licensed providers.

USAOs handle most criminal cases independently, but also partner with the Department's Criminal Division on Medicare Fraud Strike Force Teams which currently operate in 27 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 and law enforcement agencies.

Since 2018, the USAOs for 10 Federal districts in six states[36] have joined with Criminal Division attorneys, as well as law enforcement partners at 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, the USAO allocation supports AUSAs in 11 districts under the Opioid Fraud and Abuse Detection Unit (OFAD) program. OFAD focuses specifically on opioid-related health care fraud using data to identify and prosecute individuals that are contributing to the prescription opioid epidemic.

USAOs partner with the Civil and Criminal Divisions on major initiatives. In FY 2022, USAOs continued their pursuit of civil and criminal investigations for gross failure of care as part of the National Nursing Home Initiative. USAOs also take an active part in nationwide criminal health care fraud enforcement actions.

Since March 2020, USAOs have been actively pursuing pandemic-related fraud, including using civil injunctions and seizures to shut down fraudsters and their websites hawking phony cures, vaccines, and PPE; criminally prosecuting COVID-19-related scams; investigating failure of care at nursing facilities impacted by COVID-19; and investigating civil and criminal matters alleging fraud on Medicare, Medicaid, HRSA, and other Federal payors related to the pandemic or stimulus health care funding.

Examples of successful health care fraud cases are discussed above, but, notably, many of these cases involve vulnerable victims and risk of patient harm in addition to financial fraud. This year, USAOs prosecuted cases involving schemes that exploited or harmed:

- Children who were recruited for unnecessary drug testing and, in another case, were used for falsely recording mental health diagnoses so defendants could fraudulently bill

[36] 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.

Medicaid;
- Older adults who were disenrolled from Medicare Advantage plans without their consent in order to obtain higher payments from traditional Medicare, potentially impacting the residents' out-of-pocket payments, the scope of the services and care covered, and their drug coverage plan;
- Addicted patients who paid cash to defendants for services that were also paid for by Medicaid;
- Dental patients whose teeth were broken so that the defendant dentist could fraudulently bill for crowns;
- Hospital patients who were provided saline for pain because a Registered Nurse had stolen morphine from the vials; and
- Home health aides who were paid less than lawful wages and benefits despite their employers receiving millions of dollars in Medicaid funding intended to pay them.

Moreover, USAOs are also handling complex, resource-intensive cases involving a number of emerging trends including:

- Multi-district telehealth, COVID-19 testing, genetic testing, and DME schemes;
- Electronic Health Record kickback and other schemes;
- Medicare Part C fraud involving the manipulation of diagnosis codes of millions of beneficiaries;
- Sophisticated kickback and other fraud schemes involving complex ownership structures of health care entities, including by private equity and real estate investment vehicles;
- Nationwide investigations of alleged Controlled Substances Act violations; and
- 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 AUSAs, auditors, paralegals and investigators, the Executive Office for U.S. Attorneys (EOUSA) provides critical support for these complex health care fraud investigations and litigation. Using HCFAC funds, EOUSA supports contract forensic investigators and auditors, as well as nurse consultants, who have been indispensable to the USAOs' successes in complex cases. EOUSA partners with the Civil Division to provide support for other initiatives, including sophisticated data analytics (which have been instrumental in many large opioid prescribing investigations), and nursing home consultants to assist on the Nursing Home Initiative. EOUSA provides other tools to USAOs, including the Special Investigation Resource and Intelligence System (SIRIS) Resource Center, which gives USAO personnel access to the NHCAA's SIRIS database.

As well as managing national-level support, EOUSA provides districts with case-specific funding for litigation support for extraordinary needs. In FY 2022, HCFAC money funded more than 55 such requests from USAOs totaling more than $3.0 million. This support pays for consultants in such highly technical areas as software experts in EHR cases, economic experts in pharmaceutical pricing cases, and medical consultants in highly paid specialties, and is essential to investigating and developing these complex cases.

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 conduct 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 in-person training was not possible in FY 2022, EOUSA presented webinars throughout the year focused on emerging health care fraud issues.

Civil Division

The Civil Division received approximately $49.6 million in FY 2022 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 2022, civil health care fraud settlements and judgments under the False Claims Act exceeded $1.6 billion.[37]

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 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. For example, the Fraud Section resolved allegations that drug company Mallinckrodt paid kickbacks in the form of copay subsidies for its drug Acthar Gel, in violation of the AKS, from 2010 through 2014, so it could market the drug as "free" to doctors and patients while increasing its price significantly. Since acquiring Acthar, Mallinckrodt allegedly raised its price from approximately $40 per vial to over $28,000 per vial by the end of 2013 and to approximately $40,000 per vial thereafter. The United States also resolved allegations that medical device company Biotronik paid kickbacks to physicians in the form of, among other things, holiday parties, winery tours, and lavish meals with no legitimate business purpose. Other matters

[37]As stated earlier, the amount reported only reflects the Federal settlements and judgments and therefore does not reflect state Medicaid monies won or negotiated as part of any global Federal-state settlements. As in prior years, the reported settlements and judgments include matters the United States pursued, as well as matters pursued by relators/whistleblowers under the qui tam provisions of the False Claims Act.

related to AKS violations involved drug companies (kaléo), medical device companies (Respironics, Arthrex, Essilor, Reliance), and hospitals (Flower Mound Hospital Partners).

The Fraud Section also continues to pursue schemes impacting Medicaid, which provides health care for the financially neediest Americans and is jointly funded by the Federal Government and the states. This work often includes cases where the same alleged fraudulent conduct harms both Medicaid and other Federal health care programs (for example, the Flower Mound, Providence, Biotronik, and Essilor matters discussed earlier). But, as in years past, the Fraud Section also pursued matters involving fraud schemes specifically targeting and harming Medicaid (such as the Mallinckrodt Medicaid rebate, Baycare, and Gold Coast matters discussed earlier).

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. For example, the MD Labs, Radeas, Providence, and PPOA matters discussed earlier all involved allegations that either hospitals, laboratories, or other providers defrauded Medicare into paying for medically unnecessary services. Relatedly, the Fraud Section also pursues schemes involving the use of medically unsupported diagnosis codes as a way to bill Federal health care programs, for example, the Eargo matter discussed above.

The Fraud Section also continues to pursue matters involving schemes perpetrated by managed care health systems, networks, or providers, including those participating in Medicare Part C or Medicaid managed care. For example, as discussed above, this year the Fraud Section secured the first settlement of its kind involving Medicaid Adult Expansion fraud against several defendants, including the Ventura County Medi-Cal Managed Care Commission d/b/a Gold Coast Health Plan (the Gold Coast matter discussed above). The Fraud Section is also continuing to investigate or litigate a number of significant matters involving alleged FCA violations concerning Medicare Part C plans or providers, covering a large variety of allegedly fraudulent conduct resulting in inflated federal reimbursements. These matters include whistleblower actions filed under the qui tam provisions of the FCA. In pursing these matters, the Fraud Section is coordinating closely with HHS-OIG and CMS.

In addition, the Fraud Section is continuing to investigate potential FCA violations in connection with fraudulent schemes targeting government programs arising from the COVID-19 pandemic. This past year, the Fraud Section opened investigations into a wide array of COVID-19 related schemes, including allegations of health care providers billing for unproven or medically unnecessary tests or providing or causing the provision of COVID-19 vaccines to ineligible persons, ineligible providers exploiting HHS pandemic-related waivers, and fraud on COVID-19 relief programs. The Fraud Section's investigations of pandemic-related allegations include whistleblower actions filed under the qui tam provisions of the FCA. In investigating potential FCA violations arising from the COVID-19 pandemic, the Fraud Section is closely coordinating with HHS-OIG and CMS, as well as non-Federal entities, including state Attorneys General and state MFCUs.

Because the Fraud Section receives every FCA complaint filed by whistleblowers 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 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 HHS-OIG and CMS on interagency initiatives and proposed rules and regulations.

Finally, the Department of Justice's Elder Justice Initiative is housed in the Civil Division. The Elder Justice Initiative helps to support and coordinate the Department's nursing home failure of care investigations and prosecutions. The Initiative also supports the efforts of state and local elder fraud prosecutors, law enforcement, and other elder justice professionals to combat elder abuse, neglect, financial exploitation, and fraud through the development of resources, training and tools. These include a curriculum for law enforcement on conducting forensic interviews of older adults, a toolkit for probate judges to collect relevant information for guardianship proceedings, and a free online resource for law enforcement on investigating elder abuse and fraud. All of the Initiative's resources, trainings and tools can be found on the Department's Elder Justice Website (justice.gov/elderjustice).

The Consumer Protection Branch

The Consumer Protection Branch (CPB or the Branch) enforces consumer protection laws to deter and punish dangerous practices that both risk and result in harm to Americans. The Branch aggressively pursues both civil and criminal cases against those who unlawfully manufacture, distribute, or sell pharmaceuticals, medical devices, or dietary supplements causing harm and loss to consumers and the government. As the Department component charged with enforcing the Federal Food, Drug, and Cosmetic Act (FDCA), the Branch works closely with the FDA to investigate matters. It also partners extensively with the DEA and other law enforcement agencies. The Branch coordinates closely with the USAOs and the Commercial Litigation Branch's Fraud Section to prosecute matters, including major health care fraud cases. In recent years, especially in FY 2022, the Branch has dedicated particular focus to advancing civil and criminal actions against individuals and entities up and down the prescription opioid supply chain, seeking to hold accountable those responsible for the opioid crisis and to recoup billions of dollars for the United States and victims, and resulting in more than $125.0 million in fines, forfeitures, and penalties for the Federal fisc.

With respect to opioid-related work, the Branch continues to lead a number of multi-component investigations and active cases against pharmaceutical opioid manufacturers, wholesale distributors, pharmacies, and health care providers. The Branch is advancing this work through state-of-the-art data analysis and evidence-review tools, a large contract staff, and an enormous commitment of prosecutorial resources. Indeed, Branch prosecutors dedicated more than 30,000

hours to the matters in FY 2022, a substantial increase over our already-robust FY 2021 numbers. Each of the matters has the potential to return hundreds of millions, or even billions, of dollars to the Federal Government. The Branch also is continuing coordination responsibilities established through the Department's Prescription Interdiction and Litigation Task Force.

With respect to chain pharmacies, the Branch led a multi-component effort that, in December 2020, filed suit against Walmart, Inc., asserting nationwide violations of the Controlled Substances Act in the dispensing of opioids from, and distribution of opioids to, Walmart's more than 5,500 pharmacies. The complaint details Walmart's substantial contribution to the opioid epidemic and seeks billions of dollars for the government and significant injunctive relief. The case is now in litigation, taking up thousands of hours of Federal attorney and contractor time each month and requiring a significant litigation-support apparatus. Several similarly large investigations are well underway. The Branch is litigating subpoena demands and engaging in settlement discussions with other national manufacturers, distributors, and national chain pharmacies. The Branch expects in the coming year to reach resolutions, or advance investigations and litigation, as to numerous other companies in the opioid supply chain. Each of these matters will likely require a resource commitment as large as that of the Walmart litigation.

Branch attorneys also continued over the past year to partner regularly with USAOs on local-impact civil and criminal cases involving community pharmacies and practitioners. The Branch and its partners successfully enjoined and secured money judgments from individuals and entities involved in the illegal dispensing of opioids in North Carolina and Florida. Through this work, the Branch immediately curtailed opioid diversion—and related unlawful billing to Federal health care programs—by identifying and shutting down actors fueling the opioid abuse epidemic in their communities. The Branch is advancing a number of other similar actions around the country and expects to bring more actions next year.

CPB is also developing a number of initiatives to combat the surge of counterfeit pills laced with fentanyl that are killing people in record numbers in this country. An increasing portion of overdose deaths are among teens who buy pills over social media. Fentanyl used as an undeclared ingredient in counterfeit pills is incredibly dangerous and increasingly prominent. The DEA Laboratory has found that of the fentanyl-laced fake prescription pills analyzed in 2022, six out of ten now contain potentially lethal doses of fentanyl. This is not surprising, given that as little as 2 milligrams is considered a lethal dose. Use of these products does not always involve the telltale signs of abuse that parents and friends might traditionally notice. Overdoses have supplanted suicide, traffic accidents, and gun violence to become the leading cause of preventable death among people ages 18 to 45. According to the Journal of the American Medical Association, although experimental drug use by teenagers in the United States has been dropping since 2010, teen deaths from fentanyl went up almost 300 percent from 2015 to 2019. CPB's counterfeit pill initiatives are designed to disrupt the sale of certain chemical precursors, equipment, and even the pills themselves over e-commerce and social media platforms.

In addition to its opioid enforcement efforts, the Branch continued to lead the Department in prosecuting pharmaceutical, dietary supplement, food, and medical device manufacturers and their executives for violations of the FDCA in the manufacturing and marketing of their

products. These efforts include the Branch's response to consumer fraud related to the COVID-19 pandemic. In FY 2022, CPB invested almost 65,000 hours into public health and safety work. This work included numerous criminal trial victories in areas CPB enforces, such as compounding pharmacies, clinical trial fraud, dietary supplements, and food safety.

This year, the Branch continued its work with the USAO for the Southern District of Florida to advance a major initiative to address fraud affecting clinical trials for prescription drugs and medical devices. In one such case, the Branch obtained a conviction at trial against a clinical research coordinator who made false statements to FDA investigators regarding her role in a fraudulently conducted clinical trial purportedly studying the effectiveness of asthma drugs in children. This fiscal year also saw the resolution of many other clinical trial fraud matters through guilty pleas and sentencings. The Branch is advancing numerous other investigations in the clinical trial fraud arena as part of one of its largest ongoing criminal initiatives. The results obtained in these actions have sent a powerful message against fraud in clinical trials and drug-approval submissions to FDA.

The Branch's work under the FDCA touches a wide variety of fraudulent conduct. For example, in December 2021, following a month-long trial, a Federal jury convicted a pharmacy owner of conspiracy to commit health care fraud, multiple counts of mail fraud, and felony misbranding of a medication. The owner and his 16 co-conspirators conspired to defraud pharmacy benefit managers, such as Express Scripts and CVS Caremark, by billing for fraudulent prescriptions. As part of the scheme, the conspirators procured the prescriptions by using telemarketers to call consumers and deceive them into agreeing to accept drugs, such as pain creams, scar creams, and vitamins, and providing their personal health insurance information. As a co-owner of a pharmacy, the defendant purchased bogus prescriptions from a telemedicine company, knowing that those prescriptions were not issued under valid doctor-patient relationships. He and his co-defendants then shipped medications from compounding pharmacies they owned to thousands of unsuspecting patients across the country, all without collecting the required co-pays. He and his co-conspirators billed over $900.0 million to private and public insurers, collecting over $174.0 million of those invoices. In addition to securing convictions against the defendant and his co-defendants, CPB and the USAO for the Eastern District of Tennessee obtained seven corporate guilty pleas, each agreeing in pleading guilty to implement substantial enhanced compliance measures and, collectively, to pay more than $100.0 million in fines, forfeiture, and restitution.

In December 2021, a Federal jury in Fort Lauderdale convicted a Florida man of one count of conspiracy to defraud the FDA and one count of conspiracy to distribute controlled substances. He was the eleventh defendant convicted in connection with Blackstone Labs, LLC, a Boca Raton company that sold millions of dollars of products falsely labeled as dietary supplements. The trial followed a years-long investigation into Blackstone that showed that the company and its executives conspired to defraud the FDA and to manufacture and distribute research chemicals and anabolic steroids that were controlled substances under the Designer Anabolic Steroid Control Act. Multiple other corporate and individual defendants pleaded guilty and were sentenced in the run-up to trial, including both Blackstone Labs and Ventech Labs. Collectively, the defendants have been ordered to pay nearly $9.0 million in restitution, forfeiture, and fines.

CPB also enforces the FDCA as it regulates food producers and distributors. In May 2022, a court in the Western District of Michigan entered a consent decree of permanent injunction against Abbott Laboratories (Abbott) and three high-ranking Abbott executives that allowed the company to resume manufacturing powdered infant formula at its Sturgis, Michigan, facility, but also requires it to take specific measures designed to increase safety and ensure compliance with the FDCA. After investigating the case, CPB alleged that Abbott manufactured powdered infant formula under conditions and using practices that failed to comply with regulations designed to ensure the quality and safety of infant formula, including protection against the risk of contamination from bacteria.

In another substantial food safety matter, in September 2022, Branch attorneys and the USAO for the Eastern District of Washington secured an indictment of the now-closed company Valley Processing Inc. (VPI) in Yakima, Washington, and the owner of that company, charging 12 felony counts of fraud, conspiracy, false statements, and violating the FDCA by distributing adulterated and misbranded food products and failing to register certain company facilities.

Branch attorneys also obtained injunctive relief to stop the adulteration and misbranding of dietary supplements, the adulteration of animal food, and the introduction of unapproved new drugs into interstate commerce.

In December 2021, a Federal court permanently enjoined a New Jersey organization and two individual defendants from distributing unapproved and misbranded drugs touted as COVID-19 treatments. The Government alleged that Natural Solutions Foundation and the two individual defendants, distributed a "nano silver" solution product that they claimed, without scientific evidence, would prevent, treat, or cure COVID-19. The defendants agreed to a consent decree of permanent injunction and instituted a recall for their nano silver products.

Criminal Division

The Criminal Division was allocated $39.3 million in FY 2022 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 HCF Unit employs criminal prosecutors who focus exclusively on investigating and prosecuting health care fraud matters and prescription opioid distribution and diversion schemes. 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 2022, the HCF Unit's Strike Force program provided attorney staffing, litigation support, and leadership and management to the Strike Forces operating in 27 Federal judicial districts across the United States. The current Strike Forces include operations in cities including, but not limited to, Miami and Tampa and Orlando, Florida; Nashville, Tennessee; Ft. Mitchell, Kentucky; Los Angeles, California; Detroit, Michigan; Houston, San Antonio and Dallas, Texas; Concord, New Hampshire; Brooklyn, New York; Baton Rouge and New Orleans, Louisiana; Chicago, Illinois; Newark, New Jersey and Philadelphia, Pennsylvania, along with the NRRSF located in Washington, D.C.

In 2018, the HCF Unit created the ARPO Strike Force, 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. As of September 30, 2022, ARPO has charged 115 defendants involving more than 115 million controlled substance pills. These efforts have resulted in 62 guilty pleas and 9 trial convictions.

In FY 2022, the HCF Unit achieved the following results:

- Filed 126 indictments, criminal informations and complaints involving charges against 163 defendants who allegedly collectively billed Federal health care programs and private insurers approximately $2.2 billion;
- Obtained 218 guilty pleas and litigated 32 jury trials, with guilty verdicts against 36 defendants; and
- Securing imprisonment for 152 defendants sentenced, with an average sentence of over 55 months.

Since its inception, Strike Force prosecutors and USAOs in Strike Force districts filed more than 2,700 cases charging more than 5,400 defendants who collectively billed Federal health care programs and private insurers approximately $27.0 billion, more than 3,700 defendants pled guilty and over 460 others were convicted in jury trials, and more than 3,300 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 in 2020 developed and launched the NRRSF: 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 cases prosecuted by NRRSF include the recent conviction at trial of the President of a Silicon Valley technology company who claimed to have invented revolutionary technology to detect allergies and COVID-19 using a single drop of blood, trial conviction of two defendants in a $1.4 billion rural hospitals fraud matter in the Middle District of Florida (one of the largest health care fraud cases ever charged), convictions in three separate trials (between December 2021 and June 2022) of sober homes operators and doctors who were responsible for hundreds of millions in loss, the prosecution of telemedicine company executives and medical professionals in 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.

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 PRF fraud cases.

The HCF Unit coordinated three separate, targeted enforcement actions during FY 2022: COVID-19 Health Care Fraud; Opioid; and Telemedicine, Clinical Laboratory, and Durable Medical Equipment Enforcement Actions. These enforcement actions were conducted on April 20, 2022, May 4, 2022, and July 20, 2022, respectively. In the 2022 COVID-19 Health Care Fraud Enforcement Action, criminal charges were brought against 21 defendants for their alleged participation in various health care related fraud schemes that exploited the COVID-19 pandemic. These cases allegedly resulted in over $149 million in COVID-19-related false billings to Federal programs and theft from Federally funded pandemic assistance programs. In the 2022 Opioid Enforcement Action, criminal charges were brought against 14 defendants (12 medical professionals) for their alleged involvement in crimes related to the unlawful distribution of opioids. In the 2022 Telemedicine, Clinical Laboratory, and Durable Medical Enforcement Action, criminal charges were brought against 36 defendants for more than $1.2 billion in alleged fraudulent telemedicine, cardiovascular and cancer genetic testing, and DME schemes.

As part of the COVID-19 Enforcement Action, for example, several cases involved defendants who allegedly offered COVID-19 testing to induce patients to provide their personal identifying information and a saliva or blood sample. The defendants are alleged to have then used the information and samples to submit false and fraudulent claims to Medicare for unrelated, medically unnecessary, and far more expensive tests or services. In one such scheme in the Central District of California, two owners of a clinical laboratory were charged with a health care fraud, kickback, and money laundering scheme that involved the fraudulent billing of over $214.0 million for laboratory tests, over $125.0 million of which allegedly involved fraudulent claims during the pandemic for COVID-19 and respiratory pathogen tests. In two separate cases

in the District of Maryland and the Eastern District of New York, owners of medical clinics allegedly obtained confidential information from patients seeking COVID-19 testing at drive-thru testing sites and then submitted fraudulent claims for lengthy office visits with the patients that did not, in fact, occur. The proceeds of these fraudulent schemes were allegedly laundered through shell corporations in the United States, transferred to foreign countries, and used to purchase real estate and luxury items.

In another type of COVID-19 health care fraud scheme charged during the 2022 COVID-19 Health Care Fraud Enforcement Action, defendants allegedly exploited policies that the CMS put in place to enable increased access to care during the COVID-19 pandemic. For example, in the Southern District of Florida, one medical professional was charged with a health care fraud, wire fraud, and kickback scheme that allegedly involved billing for sham telemedicine encounters that did not occur and agreeing to order unnecessary genetic testing in exchange for access to telehealth patients. Late last year, one defendant previously was sentenced to 82 months in prison in connection with this scheme.

Finally, during the 2022 COVID-19 Health Care Fraud Enforcement Action, charges were brought against manufacturers and distributors of fake COVID-19 vaccination record cards who intentionally sought to obstruct the HHS and the CDC in their efforts to administer the nationwide vaccination program and provide Americans with accurate proof of vaccination. For example, in the Northern District of California, three defendants were charged in a scheme to sell homeoprophylaxis immunizations for COVID-19 and falsify COVID-19 vaccination record cards to make it appear that customers received government-authorized vaccines. One defendant, a naturopathic doctor, pleaded guilty for her role in offering and selling fraudulent immunizations and directing individuals on how to fill out false COVID-19 vaccination record cards, and is pending sentencing. A second defendant was charged for his role in assisting the naturopathic doctor in offering and selling fraudulent immunization and is awaiting trial. A third defendant admitted to, and was sentenced to a term of probation for misusing her position as the Director of Pharmacy at a northern California hospital to obtain real lot numbers for the Moderna vaccine that were then used by the naturopathic doctor to falsify COVID-19 vaccination record cards.

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 nine 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.[38] In FY 2022, the team has completed approximately 2,682 requests for data analysis assistance. During this same time, it has also created a multitude 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 and prosecutions 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 that 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 2022, six OCGS attorneys conducted health care fraud prosecutions and investigations. In Knoxville, Tennessee, two OCGS attorneys continued working with the USAO for the Eastern District of Tennessee on the prosecution of a pain clinic co-owner and nurses for their roles in running "pill mills." The co-owner and three nurse practitioners were convicted following a three-month trial. In October 2020, the clinic co-owner was sentenced to more than 33 years in prison and forfeiture of $3.6 million for her convictions of RICO conspiracy, two counts of drug conspiracy, money laundering offenses, and maintaining drug-involved premises. In December 2020, three nurse practitioners were sentenced to prison terms ranging from 30 to 42 months for their convictions of maintaining drug involved premises. The drug conspiracy involved the operation of four clinics which were pill mills that 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. Two investor-owners charged with RICO conspiracy were extradited from Italy and pled guilty in November 2022. This partnership between OCGS and the Eastern District of Tennessee has resulted in the investigation and prosecution of over 140 individuals.

In July 2021, two OCGS attorneys handled the retrial, in the District of Columbia, of a former union official resulting in a conviction for health care fraud. The health care fraud charge stemmed from the union official's arranging for his girlfriend to be fraudulently placed on the union's health plan knowing that she was not a full-time employee of the union and, therefore, not eligible to participate in the health plan. More than $66,000 in medical reimbursements were allegedly paid out of the union's health plan on behalf of his girlfriend to which she was not entitled. In October 2021, the union official was sentenced to serve 24 months of imprisonment

[38] 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.

and ordered to pay the remaining restitution of losses in the amount of $155,000 following his jury conviction of health care fraud and a guilty plea in 2018 to embezzlement of union funds.

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. 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 multiple employer welfare arrangements (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

The Civil Rights Division was allocated $8.9 million in FY 2022 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 2022 Accomplishments

Key litigation and enforcement accomplishments in FY 2022 of the Civil Rights Division are:

- Number of matters in active enforcement: 20
- Cumulative estimate of individuals with disabilities affected: 78,501
- Number of institutional facilities affected: 2,276

Special Litigation Section

In FY 2022, the Section's enforcement efforts affected more than 1,400 health care facilities in seven states, and included the opening of one new investigation, the filing of a statement of interest, and monitoring compliance with six agreements impacting over 25,000 individuals with disabilities.

In December 2021, the Section issued a findings report concluding there is reasonable cause to believe that the State of Iowa violates Title II of the ADA by failing to provide services to people with IDD in the most integrated setting appropriate to their needs. As a result, many people with IDD are institutionalized in state facilities or placed at serious risk of institutionalization because of the lack of community-based services. The Section and the State are discussing necessary remedial measures.

The Section worked to negotiate appropriate remedial measures in two matters. In December 2020, the Section issued a CRIPA findings report concluding that there is reasonable cause to believe the State of Iowa subjects Glenwood Resource Center residents to unreasonable harm and risk of harm, in violation of their Fourteenth Amendment rights. In April 2021, the Section issued a findings report concluding there is reasonable cause to believe that Alameda County, California is violating the ADA in its provision of mental health services.

The Section continued monitoring implementation of settlements and court orders in Georgia, Louisiana, Mississippi, New Hampshire, Virginia, and West Virginia that are helping individuals with intellectual, developmental, and mental health disabilities avoid unnecessary institutionalization. In addition, the Section continued monitoring implementation of a settlement in Texas regarding conditions and care within institutions for people with intellectual and developmental disabilities.

In support of its enforcement mandates, in October 2021, the Section filed a statement of interest in *Z.S. v. Durham County*, 1:21-cv-663, (M.D. N.C.), in which an infant with disabilities alleged that Durham County discriminated against him by keeping him in a segregated, congregate setting. The statement of interest clarified that: (1) the integration mandate of the ADA and the Rehabilitation Act prohibits discrimination in the form of unnecessary segregation, regardless of the intent of the agency placing individuals with disabilities in institutional settings; (2) there are multiple ways to demonstrate that community placement is appropriate for an individual, only one of which is a determination by the public entity's treatment professionals; and (3) a plaintiff who alleges that access to an existing community-based service will prevent unnecessary institutionalization has alleged a plausible reasonable modification under the ADA and the Rehabilitation Act. In March 2022, the court denied a motion to dismiss the plaintiff's claims in a ruling consistent with the statement of interest.

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 2022, the Disability Rights Section issued a letter of findings in two investigations, submitted statements of interest in pending private litigation, successfully concluded a settlement agreement, filed an amended complaint in *United States v. Florida*, No. 12-cv-60460 (S.D. Fla.), and monitored compliance with seven settlement agreements under which more than 24,900 people collectively will obtain relief.

In March 2022, the Section concluded an investigation into complaints from Coloradans, and issued a letter of findings stating that Colorado is violating Title II of the ADA by unnecessarily segregating a significant number of adults with physical disabilities—including older adults—in Medicaid funded nursing homes and failing to ensure that individuals have a meaningful opportunity to live in community-based settings appropriate to their needs.

In June 2022, the Section issued a letter of findings to the State of Maine, notifying the State that it is violating Title II of the ADA by unnecessarily segregating children with behavioral health needs in psychiatric hospitals, residential treatment facilities, and a state-operated juvenile detention facility, and placing other children at serious risk of placement in these facilities, even though many of these children could stay in their homes with sufficient community-based services.

In December 2021, the Section's litigation in *United States v. Florida*, which had been dismissed sua sponte in September 2016, became active again when the U.S. Court of Appeals for the Eleventh Circuit denied the State's motion for rehearing en banc. In June 2022, the Section filed an amended complaint and has engaged in extensive pre-trial discovery. The amended complaint alleges that Florida unnecessarily segregates children with complex medical needs in nursing facilities, and places other children at risk of such segregation, in violation of Title II of the ADA. Trial is scheduled for May 2023.

In January 2022, the Section filed a statement of interest in *A.A. v. Bimestefer*, 21-cv-2381 (D. Colo.). The case was brought on behalf of children with mental health disabilities who allege they are unnecessarily institutionalized in Psychiatric Residential Treatment Facilities and other institutions. The statement explained that (1) plaintiffs who are segregated or at serious risk of segregation due to a lack of medically necessary services can establish they have an injury in fact sufficient to confer standing, and (2) unnecessary segregation constitutes discrimination on the basis of disability under the ADA and the Rehabilitation Act.

In May 2022, the Section, along with the USAO for the District of Rhode Island, entered a settlement agreement with the State of Rhode Island, resolving a complaint that the State failed to provide a child with autism with the community-based Medicaid services that Rhode Island had authorized, resulting in the child's placement in an out-of-state residential treatment facility for several months. Under the agreement, Rhode Island will modify its policies so that children with autism and other developmental disabilities will receive authorized Medicaid services to allow them to live with their families. The complainants' son will also receive $75,000 in damages.

The Section completed monitoring an ADA settlement agreement with the State of Oregon after the State successfully implemented reforms substantially increasing supported employment services to help individuals with intellectual and developmental disabilities (IDD) obtain competitive integrated employment services, rather than work in sheltered workshops. At the end of the agreement, Oregon had provided supported employment services so that over a thousand sheltered workshop workers received jobs in the community and had provided supported employment services to more than 7,000 people—including more than 4,900 youth exiting school--according to State data. In August 2022, the Court dismissed the case.

In addition, the Section continued to monitor implementation of settlements in Maine, New York, North Carolina, North Dakota, and Rhode Island.

For example, under an agreement with North Dakota, reached in December 2020, the State has transitioned 149 individuals from skilled nursing facilities to community homes and diverted over 400 individuals from unnecessary nursing facility admission by providing community-based services. All told, North Dakota has provided state or Federally funded home and community-based services to over 5,000 unduplicated adults since the signing of the settlement agreement.

Educational Opportunities Section

In May 2020, a multi-year stay of litigation was lifted in pending litigation against the State of Georgia. The Section alleges that the State is violating Title II of the ADA in its use of segregated educational services for approximately 4,000 Georgia students with emotional and behavioral disabilities. Trial is now anticipated in FY 2024.

Finally, as part of a new enforcement effort to combat unlawful seclusion, EOS has resolved two investigations into districts that unnecessarily segregate children based on behavior that is related to their disability. The agreements are in Frederick County, Maryland, and Cedar Rapids, Iowa. In response to the problems that led to improper seclusions in Frederick, the state legislature passed a statewide ban on the use of seclusion rooms in public schools. We are negotiating similar agreements in Spokane, Washington; Anchorage, Alaska; and Okaloosa, Florida. These districts routinely segregate students with disabilities for long periods of time through seclusion and restraint practices in violation of the ADA.

Office of the Inspector General

The Office of the Inspector General (DOJ-OIG) was allocated $0.9 million in FY 2022 HCFAC funding to address health care fraud as it directly impacts the DOJ operations. The 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 (USMS), and expends more than $115.0 million a year in annual workers' compensation payments related to disabled and injured DOJ employees and informants.

DOJ-OIG pursues a comprehensive approach to reducing fraud, waste, and abuse in the oversight of health care fraud among DOJ components. One means by which DOJ-OIG accomplishes this is through the issuance of public reports that highlight internal control risks and recommend corrective actions on issues found. The DOJ-OIG conducted two audits of BOP comprehensive medical services (CMS) contractors. The objective of these audits was to assess BOP's administration of the contracts, and the contractor's performance and compliance with the terms, conditions, laws, and regulations applicable to these contracts.

Additionally, 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 health care claims data to identify anomalous billing and prescription patterns and refers investigative leads to the Investigations Division for evaluation of investigative merit. Although the DOJ-OIG can obtain standardized data for workers' compensation payments and USMS health care claims data, BOP lacks a centralized system of inmate health care claims data. Thus, the DOJ-OIG ODA invests additional resources to stand-up an IT infrastructure that securely stores and standardizes health care claims data received via OIG subpoena from numerous BOP CMS contractors. The BOP, USMS, and workers' compensation health care related data reside in a DOJ-OIG ODA data lake that contains stringent controls to safeguard this sensitive data.

In FY 2022, the DOJ-OIG increased its outreach efforts and conducted health care fraud training to the BOP workers' compensation and health services administration personnel. The goals for the health care fraud briefings were to increase the awareness of the existence of health care fraud, share fraud indicators and schemes, and provide an open line of communication with DOJ-OIG customers to report suspected fraud. The DOJ-OIG conducted four health care fraud briefings.

During FY 2022, the DOJ-OIG continued participating in two health care fraud working groups and continued to collaborate with other Federal agencies that investigate health care fraud. These efforts have provided opportunities for the DOJ-OIG to collaborate and share ideas with other organizations.

The DOJ-OIG sought refreshed health care claims data directly from the BOP CMS providers. The additional data will help to build upon the DOJ-OIG's comprehensive BOP health care data bank, ensuring the ability to use historical data as the foundation for predictive analytics efforts.

After an extended interruption of U.S. Department of Labor workers' compensation claim data caused by the COVID-19 pandemic, the DOJ-OIG resumed a regular schedule of receiving workers' compensation data. The analysis of the Department's workers' compensation data resulted in the multiple investigative leads for health care providers. The DOJ-OIG continues to build upon its predictive analytics abilities.

In FY 2022, the DOJ-OIG secured the services of a subject matter expert (SME) to review health care claims for two open and ongoing investigations. The SME will help to determine if two BOP CMS providers billed the BOP at the appropriate level for the services rendered. With the precedent set by the successful FY 2021 False Claims Act settlement (nearly $700,000), the DOJ-OIG has established relationships with prosecutors to pursue similar settlements with other CMS providers overbilling the BOP. Since receiving initial funding, the DOJ-OIG has opened a total of 25 investigations related to DOJ health care-related activities and programs.

In February 2022, the DOJ-OIG issued a Management Advisory Memorandum (MAM) to the BOP advising of concerns regarding potential overpayment by BOP for inmate health care services. Specifically, CMS providers selecting the billing code level on behalf of the subcontractor that performed the services.

In February 2022, the DOJ-OIG issued a MAM to the BOP advising of concerns identified during the course of an ongoing audit of the BOP procurements awarded to NaphCare, Inc. (NaphCare) for medical services provided to Community Corrections Management (CCM) inmates, which includes inmates in residential reentry centers (RRCs) and under home confinement. The procurements awarded to NaphCare since October 2016 exceed $91.0 million. The audit assessed BOP and contractor compliance with applicable guidance in the areas of acquisition planning and procurement; contract management, oversight, and monitoring; billing and payments; and contractor performance. The DOJ-OIG identified significant concerns with the acquisition planning and oversight of invoices, of particular interest given the BOP's impending acquisition for the next medical services award and provided two recommendations.

Since that time, the DOJ-OIG identified additional concerns related to acquisition planning and administration of the procurements awarded to NaphCare for medical services. In September 2022, the DOJ-OIG issued a final audit report that included six recommendations for the BOP to address these concerns.

In March 2022, the DOJ-OIG issued an audit report of the BOP Comprehensive Medical Services Contracts Awarded to the University of Massachusetts (UMass) Medical School. The objectives of this audit were to assess the BOP's award and administration of the contracts, and UMass's compliance with the terms, conditions, laws, and regulations applicable to the contracts. The report contains 15 recommendations to assist the BOP in improving its acquisition process for medical services, contract administration, management of contract performance, and billing.

In September 2022, the DOJ OIG issued a multi-discipline MAM to notify the BOP of concerns related to its procurement of medical services. The MAM addressed deficiencies identified over years in connection with 11 DOJ Office Inspector General audits and reviews since 2016 regarding the BOP's strategy for its medical service contracts. In several of these audits and reviews, the DOJ-OIG has repeatedly observed deficiencies in the BOP's planning, administering, and monitoring of medical contracts that have led to inefficient management, suboptimal contractor performance, and ultimately a waste of taxpayer dollars.

FY 2022 Accomplishments

Key oversight accomplishments in FY 2022 for the DOJ-OIG include:

- Management Advisory Memoranda issued to reduce program waste: 3, and
- Audits performed to reduce program waste: 2

APPENDIX

Federal Bureau of Investigation

The Federal Bureau of Investigation (FBI) was allocated $152.9 million in HCFAC Program funding in FY 2022 to support the facilitation, coordination and accomplishment of the goals of the program. In addition, the FBI received $7.1 million in DOJ FY 2022 Discretionary HCFAC funding, which was primarily used by the FBI to align FBI investigative resources with DOJ prosecutive resources to address the health care fraud (HCF) threat. The majority of the HCFAC funding the FBI received in FY 2022, was used to support a total of 837 positions (505 Agent and 332 Support). In addition to funding personnel resources, the FBI utilized HCFAC Program funding to support both covert and undercover investigations and operations, financial and investigative analysis support, operational travel, and other investigative and operational costs.

In FY 2022, the FBI opened 625 new HCF investigations, and 3,103 investigations were pending at the end of FY 2022. Investigative efforts throughout the fiscal year produced 495 criminal convictions, 389 indictments, and 190 informations. In addition, investigative efforts resulted in over 499 operational disruptions of criminal fraud organizations and the dismantlement of more than 132 HCF criminal enterprises.

The FBI is the primary Federal agency responsible for identifying and investigating HCF targeting both public health care benefit programs and private health insurance plans of all sizes. HCF investigations are considered a top priority within the FBI's Complex Financial Crime Program. Each of the FBI's 56 field offices has personnel assigned to identify and investigate HCF matters.

The FBI approaches the HCF crime problem in a threat-based, intelligence-driven manner. This approach requires the prioritization of threats and the development of detailed threat mitigation plans at both the national and field office levels. This process is designed to ensure limited analytical and investigative resources are focused on the most significant entities committing health care fraud, waste, and abuse, in order to have the greatest impact on the threat. As part of the HCF threat review and prioritization process, the FBI gathers relevant data and information from a variety of sources to gain an understanding of the impact of the HCF crime problem nationally and in each FBI Field Office's area of responsibility. Each field office conducts a similar analysis to review and prioritize threats in their geographic area of responsibility, including setting forth the specific actions they will take to mitigate them. This process also reveals intelligence gaps and areas which require additional research and analysis. The process is on-going and requires collaboration not only among FBI components, but also with the public and private sectors. As a result of the process, the FBI has determined that large-scale criminal enterprises; corporate-level fraud, waste, and abuse; and public safety and patient harm matters, to include those arising from the ongoing prescription opioid abuse epidemic, remain priority HCF threat areas of focus.

FBI field offices throughout the U.S. address the HCF threat through joint investigative efforts; the collection, analysis, and sharing of intelligence; and the utilization of advanced and sophisticated investigative techniques. FBI field offices participate in DOJ-led Medicare Fraud Strike Forces, FBI-led HCF task forces, and HCF working groups with Federal, state, and local law enforcement and regulatory partners, including local USAOs, HHS-OIG, DEA, IRS, FDA, and state MFCUs. The FBI also conducts significant information sharing and coordination efforts with private insurance partners through the National Health Care Anti-Fraud Association (NHCAA), the National Insurance Crime Bureau (NICB), and private insurance special investigative units. The FBI is also actively involved in the HFPP, an effort to exchange information between the public and private sectors to reduce the prevalence of HCF.

These collaborative relationships facilitate information sharing and coordination among the government agencies and private entities involved in addressing the HCF threat. Moreover, these relationships allow for the identification of HCF threat trends and the initiation of new cases against the most egregious offenders involved in health care fraud, waste, and abuse.

The FBI's Health Care Fraud Unit (HCFU), which is housed within the Criminal Investigative Division's Financial Crimes Section, manages the FBI's HCF program, including providing operational and administrative support and guidance to 56 field offices to assist them in their efforts to identify and investigate health care fraud. The FBI's HCFU also establishes national HCF program initiatives to ensure a coordinated approach to addressing the HCF threat. In support of joint agency activities and general threat mitigation efforts, the HCFU established four national program initiatives in FY 2022, to include the Health Care Fraud Task Force and Working Group Initiative, Prescription Drug Initiative, Major Provider and Large-Scale Conspiracies Initiative, and the Health Care Fraud Outreach and Liaison Initiative.

The Health Care Fraud Task Force and Working Group Initiative

The Initiative was established to encourage the formation of FBI led Joint Health Care Fraud (HCF) Task Forces and HCF Working Groups throughout the country. Joint Task Forces and Working Groups combine Federal, state, and local law enforcement and regulatory resources to address Health Care Fraud and other complex financial crimes (CFC). 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 and CFC threats. 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 also benefit from increased access to FBI training and equitable sharing arrangements. In FY 2022, the FBI opened 245 joint HCF investigations with task force and working group partners, more than 125 of which were opened and investigated by 17 established FBI HCF task forces. To further this initiative, FBI personnel also participate on DOJ-led HCF Strike Forces throughout the country.

FBI Participation in DOJ-Led Strike Forces

As noted above, the FBI participates in DOJ Medicare Fraud Strike Forces throughout the country, the ARPO Strike Force in Appalachia, and the newly created New England Prescription Opioid (NEPO) Strike Force. Specifically, FBI personnel serve on DOJ Medicare Fraud Strike

Forces located in Florida (Miami, Tampa, Orlando), Los Angeles, Texas (Houston, Dallas, McAllen/Rio Grande Valley), the Gulf Coast (New Orleans, Baton Rouge, and Southern Mississippi), Northeast Regional (Newark/ Philadelphia), Detroit, Brooklyn (NYC), Chicago, and the NRRSF based in Washington, DC.

In FY 2021, the FBI established the Health Care Fraud National Rapid Response Team (HCFNRT), a specialized team comprised of experienced Special Agents, Intelligence Analysts, and other professional staff members who are charged with investigating, or assisting in the investigation of, complex health care fraud cases throughout the county. HCFNRT members work closely with the DOJ prosecutors serving on the DOJ National Rapid Response Strike Force, thus aligning FBI investigative resources with DOJ resources to address the growing health care fraud threat, which increasingly transcends field office areas of responsibility.

As noted earlier in this report, in July 2022, the DOJ Criminal Division's Fraud Section, in coordination with the FBI and other state and Federal agencies announced the results of the 2022 National Health Care Fraud Telemedicine Fraud and Laboratory Fraud Law Enforcement Action (LEA). The LEA was a rolling operation, which spanned 13 Federal judicial districts and involved health care fraud investigations in 12 FBI field offices. The LEA resulted in charges filed against over 36 fraudsters, including more than 12 licensed medical professionals, as well as other co-conspirators engaged in schemes to defraud public and private health insurance companies and vulnerable patients. The total amount of fraudulent billing to public and private health programs was approximately $1.2 billion, approximately $440.0 million of which was fraudulently paid.

In addition to being charged criminally, three of the 12 medical providers charged received payment suspension notices from CMS. Fifty-two medical providers, who were not charged criminally, received payment suspension notices from CMS in connection with the investigations underlying this LEA. However, their actions did not rise to the level of criminal conduct. $8 million in assets were seized during this LEA. This operation was conducted jointly with HHS-OIG, CMS, VA-OIG, IRS-CI, DEA, DCIS, and our state and local partners, including various state MFCUs. The continued support of DOJ 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 and Major Provider Fraud Initiative and the Prescription Drug Initiative.

Appalachian Region Prescription Opioid (ARPO) Strike Force

FBI personnel also serve on the ARPO North (Kentucky, Ohio, Virginia, and West Virginia), ARPO South (Tennessee and Northern Alabama), and NEPO (Boston/New Hampshire/Vermont) Strike Forces.

As part of the DOJ ARPO Strike Force initiative to address the illegal diversion of prescription opioids in Appalachia, DOJ provided funding to the FBI to support the deployment of 14 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 continues to operate in the Birmingham, Cincinnati, Knoxville, Louisville, Memphis, Pittsburgh, and Richmond Field Office areas of responsibility.

In May 2022, the FBI participated the Department of Justice ARPO Enforcement Action, which charged 14 defendants in eight Federal districts across the United States for their involvement in crimes related to the unlawful distribution of opioids. Twelve of the defendants were medical professionals. One of the cases charged a Kentucky dentist with unlawfully prescribing morphine. In August 2020, this dentist issued three opioid prescriptions to a 24-year-old patient in a five-day period. The patient died from a morphine overdose from one of the prescriptions the dentist issued during those five days.

New England Prescription Opioid (NEPO) Strike Force

In June 2022, the FBI, along with the DEA and HHS-OIG, began serving on the newly established New England Prescription Opioid (NEPO) Strike Force. The NEPO Strike Force was formed to address prescription opioid diversion cases in New England. The NEPO Strike Force operates in a similar manner to the existing ARPO Strike Force currently operating in Appalachia. NEPO, however, will operate in a manner that more closely adheres to the Strike Force concept where investigators and agents come into the area for a finite period of time to take on some of the biggest cases in order to have the greatest impact and a deterrent effect.

The Prescription Drug Initiative

The Prescription Drug Initiative was established to identify fraud and prosecute health care providers, individuals associated with health care providers, legitimate pharmaceutical wholesalers and manufacturers, and others involved in the fraudulent diversion of controlled substances, namely those listed in Schedule II through V of the Controlled Substances Act (CSA), including highly addictive opiates, from their lawful purpose into illicit drug traffic.

In furtherance of this initiative, in July 2022, the FBI Pittsburgh Field Office opened an investigation into an individual who was reportedly leading an illegal prescription pill distribution network. To advance the scheme, the individual obtained addictive prescription pain medications from physicians under the false pretense that he needed the medications and intended to use them himself. His true intention, however, was to sell the medications to others suffering from addiction to make a profit. The individual utilized a minor to transport some of the pills. Ultimately, he was convicted in Federal court of violating Federal narcotics, firearms and health care fraud laws and sentenced to 25 years of imprisonment.

The Major Provider and Large-Scale Conspiracies Initiative

The purpose of this initiative is to encourage the initiation of traditional health care fraud cases involving the most significant schemes impacting public and private health insurance programs and plans. This includes pursuing civil qui tam matters filed pursuant to the False Claims Act, Title 31 U.S.C. § 3729, by private individuals, or "whistleblowers," with knowledge of fraud committed against the Federal Government. Pursuant to this initiative, the FBI used all available resources to identify and target major medical providers, such as corporations, companies, and other groups, engaged in significant medical billing fraud and other schemes that resulted in, or were intended to result in, large monetary losses to private health plans and taxpayer funded,

government health care benefit programs. Investigations targeting major providers are typically identified and initiated based upon data analytics, including the review of qui tam filings, and coordination with HHS-OIG and DOJ's civil and criminal components. Under this initiative, the FBI also sought to identify large-scale HCF conspiracies and investigate criminal enterprises and other organized groups who co-opt medical providers to collaborate in fraud schemes. Such schemes include, among other things, the sharing and selling of beneficiaries' personally identifiable information (PII), multi-tiered kickback schemes involving fraudulent referrals and billing for medically unnecessary services, or billing for services never provided.

In FY 2022, FBI Boston initiated an investigation into a pharmaceutical company, based on allegations that the company knowingly underpaid rebates to insurers for a specialty drug. Pursuant to the Medicaid Drug Rebate Program, drug manufacturers are required to pay quarterly rebates to state Medicaid programs in exchange for Medicaid's coverage of the manufacturers' drugs. The statute requires manufacturers to pay inflation-based rebates for drugs, which are designed to insulate the Medicaid program from drug price increases outpacing inflation. These rebates are calculated by comparing the drug's Base Date Average Manufacturer Price (AMP), which is the drug's price on the date that the "dosage form and strength" of the drug was first marketed or 1990, whichever is later, to its current price. According to the complaint, the company and its predecessor began paying rebates for the drug in 2013 as if it was a "new drug" first marketed in 2013, rather than a drug that had been approved since 1952. Allegedly, this practice meant the companies ignored all pre-2013 price increases when calculating and paying Medicaid rebates for the drug from 2013 until 2020. The company's decision to disregard all previous price increases for Medicaid rebate purposes significantly lowered Medicaid rebate payments the company paid for the drug. In 2016, CMS began warning the company against this practice and continued to warn the company. Despite the warnings, the company did not take corrective action. In March 2022, the company agreed to pay approximately $233.7 million as part of a settlement to resolve allegations that it violated the False Claims Act. This was a joint investigation with HHS-OIG.

In FY 2022, the FBI Knoxville initiated an investigation into a large-scale conspiracy involving several medical providers and companies engaged in a billing fraud scheme involving the prescription of expensive compound medications to patients. In many cases, the prescribers had never met or even spoken with the patients. The providers sent the prescriptions to a pre-determined pharmacy, and the pharmacy billed the insurance carriers' high dollar amounts for the compounded medications. The investigation revealed that from June 2015 through April 2018, the providers and others, utilizing their companies, conspired to deceive tens of thousands of patients and more than 100 doctors located in the Eastern District of Tennessee and elsewhere for the purpose of defrauding health care benefit programs. The subjects submitted over $930,000,000 in fraudulent claims for payment and received over $174.0 million. In May 2022, one of the subjects was sentenced to 14 years of imprisonment, ordered to pay over $24.6 million in restitution, and forfeit assets valued at $2.5 million. This case was investigated with HHS-OIG, OPM-OIG, FDA-OCI HSI, and USPIS-OIG.

Health Care Fraud Outreach and Awareness Initiative

This national program initiative was established to ensure the FBI initiates and maintains ongoing and frequent contact with the general public, as well as our law enforcement, regulatory, and private sector partners regarding the health care fraud threat. As the primary Federal agency responsible for identifying and investigating health care fraud targeting both public health care benefit programs and private health care plans, the FBI must undertake measurable outreach efforts to educate the public about the HCF threat, including increasing public awareness of potential indicators of health care fraud activity so that they are able to identify it when it is occurring and are aware of how to report it. Further, the FBI must also establish and maintain liaison relationships with our law enforcement and regulatory partners, including conducting and attending HCF threat awareness briefings, exchanging threat information, and sharing best practices for addressing the threat. Under this initiative, the FBI also established tripwire contacts within private health plans and with medical providers.

To advance this initiative, HCFU worked with the FBI's Office of Public Affairs to launch a campaign to increase public awareness of potential indicators of health care fraud. The campaign consisted of information designed to assist the public in identifying health care fraud activity and in reporting it. The campaign also provided guidance to the public through various media advertisements, including a social media outreach component. Furthermore, the HCFU updated the FBI.gov website with helpful information such as common health care fraud schemes and tips on how to avoid becoming a victim of health care fraud scams. The FBI is also working with the CMS Administration for Community Living, Office of Health care Information and Counseling to reach the public regarding the HCF threat.

COVID-19 Anti-Fraud Program

Much like traditional HCF, COVID-19 related HCF schemes targeted government sponsored health care programs, particularly Medicare and Medicaid, private health insurance plans, and other government-sponsored pandemic relief programs. Throughout the pandemic, medical providers engaged in common health care-related fraud including overbilling, billing for services not rendered, upcoding services, billing for medically unnecessary services, etc., particularly as more beneficiaries sought treatment and vaccinations. Additionally, the expansion of "telehealth/telemedicine" coverage for beneficiaries amid COVID-19 resulted in greater instances of fraud, as physicians, clinics, and labs billed for services not rendered or paid kickbacks to marketers in exchange for patient referrals. Medical identity theft and fraud related to the production and sale of vaccine cards also occurred. This program is designed to prioritize cases involving COVID-19 related HCF and the COVID-19 Anti-Fraud team will continue to coordinate closely with the DOJ Fraud Section in combatting pandemic-related investigations.

In April 2022, the DOJ Criminal Division's Fraud Section, in coordination with the FBI and multiple Federal agencies announced the results of the 2022 National Health Care Fraud COVID-19 Law Enforcement Action. The cases included fraudulent billing, the sale of fake COVID-19 vaccination cards, theft from pandemic assistance programs, and kickback schemes. Several HCF Strike Force field offices took part in investigating the cases. The operation, which spanned nine Federal judicial districts and five FBI field offices, resulted in charges filed against over 21 fraudsters, to include three licensed medical professionals, as well as other co-

conspirators engaged in schemes to defraud public and private insurance companies and vulnerable patients. The total amount of fraudulent billing to public and private health programs was approximately $149.0 million. As a result of the operation, $8.0 million in cash and other fraud proceeds were seized. This operation was conducted with the HHS-OIG, CMS, DOI-OIG, FDA-OIG, DOL-OIG, DCIS-OIG, USPIS, VA-OIG and HSI.

HCF Training & Enrichment Efforts

The FBI actively provides training and guidance on HCF matters. The FBI has partnered with the DOJ, HHS-OIG, 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. In FY 2022, the HCFU continued its virtual trainings to address the educational needs of the FBI personnel throughout the pandemic in lieu of in-person training. The virtual training platform made training more accessible to FBI personnel. In FY 2022, eight virtual training sessions were held, and over 722 FBI employees participated in the training sessions. Additionally, three virtual conferences were hosted in which 440 individuals participated from the FBI, DOJ, HHS/CMS, and VA-OIG. A virtual training was also held for FBI Intelligence Analysts, Forensic Accountants, and Support Operations Specialists working in support of HCF investigations.

Some of the topics covered included current trends in HCF, working with private insurance special investigations units, and HCF data analytics, among others. The FBI HCF program will continue to support employee's attendance to qualified virtual and in-person training offered by Federal and local law enforcements agencies along with the private sector.

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 133).

- 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 2022, including sequester suspension. 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 Resources[39]	**Fiscal Year 2022**
Office of Inspector General	$214,630,678
Health and Human Services Wedge[40]	41,050,686
Medicare Integrity Program[41]	963,369,475
MIP/Medicare (non-add)	*889,264,130*
Medi-Medi (non-add)	*74,105,345*
Department of Justice Wedge[40]	67,013,606
Federal Bureau of Investigation[42]	152,924,358
Subtotal, Mandatory HCFAC	**$1,438,988,803**
Discretionary Resources	
Office of Inspector General	$102,145,000
CMS Program Integrity	658,648,000
CMS Program Integrity (non-add)	*628,648,000*
Senior Medicare Patrols (ACL non-add)	*30,000,000*
Department of Justice	112,207,000
Subtotal, Discretionary HCFAC	**$873,000,000**
Grand Total, HCFAC	**$2,311,988,803**

[39] Section 3709 of the CARES Act (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; the Medicare sequester moratorium included in P.L. 117-7 extended the suspension again until December 31, 2021; and the Protecting Medicare and American Farmers from Sequester Cuts Act (P.L. 117-71) extended the suspension for the last time through March 31, 2022.

[40] 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.

[41] The Medicare Integrity Program (MIP) and Medicaid Integrity Program funds fraud prevention and detection activities within Medicare and is not part of this report to Congress. A separate report to Congress addresses MIP, as well as the Medicaid Integrity Program.

[42] 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—Department of Justice

FBI—Federal Bureau of Investigation

FCA—False Claims Act

FDA—Food and Drug Administration

FFS—Fee-for-Service

FY—Fiscal Year

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

HEAT—Health Care Fraud Prevention & Enforcement Action Team

HFPP—Healthcare Fraud Prevention Partnership

HHA—Home Health Agency

HHS—Department of Health and Human Services

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

HI—Hospital Insurance Trust Fund

HIPAA—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—Health Care Fraud and Abuse Control Program

Secretary—Secretary of the Department of Health and Human Services

SMP—Senior Medicare Patrol

UPIC—Unified Program Integrity Contractor

USAO—United States Attorney's Office