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 2023

The Department of Health and Human Services
and
The Department of Justice
Health Care Fraud and Abuse Control Program
Annual Report for Fiscal Year 2023

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CONTENTS

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 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 27th 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) 2023, civil health care fraud settlements and judgments under the False Claims Act exceeded $1.8 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 $3.4 billion was returned to the Federal Government or paid to private persons in FY 2023. Of this $3.4 billion, the Medicare Trust Funds[3] received transfers of almost $974 million during this period, in addition to over $257.2 million in Federal Medicaid money that was transferred separately to the Centers for Medicare & Medicaid Services (CMS).

Enforcement Actions

In FY 2023, the Department of Justice (DOJ) opened more than 802 new criminal health care fraud investigations. Federal prosecutors filed criminal charges in over 346 cases involving at least 530 defendants. More than 476 defendants were convicted of health care fraud related crimes during the year. Also, in FY 2023, DOJ opened more than 770 new civil health care fraud investigations and had over 1,147 civil health care fraud matters pending at the end of the fiscal year. Federal Bureau of Investigation (FBI) investigative efforts resulted in over 620 operational disruptions of criminal fraud organizations and the dismantlement of more than 127 health care fraud criminal enterprises.

In FY 2023, investigations conducted by HHS's Office of Inspector General (HHS-OIG) resulted in 651 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid, and 733 civil actions, which include false claims, unjust-enrichment lawsuits filed in Federal district court, and civil monetary penalty (CMP) settlements. HHS-OIG excluded 2,112 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 (871) or to other health care programs (314), for beneficiary abuse or neglect (203), and as a result of state health care licensure revocations (531).

[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 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.

[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. A combined total of $180.5 million in mandatory funds have been sequestered in the past 11 years. Including funds sequestered from the FBI ($84.2 million in the past 11 years), $264.7 million has been sequestered from mandatory HCFAC funds since FY 2013.

STATUTORY BACKGROUND

The Annual Report of the Attorney General and the Secretary detailing expenditures and revenues under the Health Care Fraud and Abuse Control Program for FY 2023 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, Section 303) amended the Act so that funds allotted from the Account are "available until expended." TRHCA also allowed for yearly increases to the Account based on the change in the consumer price index for all urban consumers (all items, United States city average) (CPI-U) over the previous fiscal year for fiscal years 2007 through 2010.[4]

In FY 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act (P.L. 111-148, ACA) extended permanently the yearly increases to the Account based upon the change in the consumer price index for all urban consumers, or CPI-U.

In FY 2023, the Secretary and the Attorney General certified $338.0 million in mandatory funding to the Account. Additionally, Congress appropriated $893.0 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 2023. (Separately, the FBI, which is discussed in the Appendix, received $160.2 million from HIPAA.) Under the joint direction of the Attorney General and the Secretary, the Program's goals are:

(1) To coordinate Federal, state, and local law enforcement efforts relating to health care fraud and abuse with respect to health plans;

(2) To conduct investigations, audits, inspections, and evaluations relating to the delivery of and payment for health care in the United States;

(3) To facilitate enforcement of all applicable remedies for such fraud; and

[4] Section 6402 of the ACA (P.L. 111-148) indexed Medicare Integrity Program funding for inflation starting in FY 2010.

(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. 117-328, Consolidated Appropriations Act, 2023) that this report, "include measures of the operational efficiency and impact on fraud, waste, and abuse in the Medicare, Medicaid, and CHIP programs for the funds provided by this appropriation."

PROGRAM RESULTS AND ACCOMPLISHMENTS

As required by the Act, HHS and DOJ must detail in this Annual Report the amounts deposited to the Medicare Trust Funds and the source of such deposits. In FY 2023, more than $3.4 billion was deposited with the Department of the Treasury and CMS, transferred to other Federal agencies administering health care programs, or paid to private persons during the fiscal year. Monetary results from these transfers and deposits are provided in the table below:

Monetary Results

Total Transfers / Deposits by Recipient FY 2023

Department of the Treasury	
Deposits to the Medicare Trust Fund, as required by HIPAA:	
Gifts and Bequests	$126
Amount Equal to Criminal Fines	13,131,761
Civil Monetary Penalties	32,777,960
Asset Forfeiture	119,012,380
Penalties and Multiple Damages	396,932,019
Subtotal	**$561,854,246**
Centers for Medicare and Medicaid Services	
HHS/OIG Audit Disallowances: Recovered—Medicare	22,917,268
Restitution/Compensatory Damages*	389,183,600
Subtotal	**$412,100,868**
Total Transferred to the Medicare Trust Funds	**$973,955,114**
Restitution/Compensatory Damages to Federal Agencies	
TRICARE	$19,244,376
HHS/OIG	12,461,551
Department of Labor	9,350,997
Department of Veterans Affairs	3,871,303
U.S Personnel Management	2,915,748
Other Agencies	16,711,379
Subtotal	**$64,555,354**
Centers for Medicare and Medicaid Services	
Federal Share of Medicaid	257,244,954
HHS/OIG Audit Disallowances: Recovered—Medicaid	1,650,221,936
Subtotal	**$1,907,466,890**
Total	**$1,972,022,244**
Relators' Payments**	**$462,717,484**
GRAND TOTAL MONETARY RESULTS***	**$3,408,694,842**

*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.

Note: The FY 2022 Monetary Results reported the HHS/OIG Audit Disallowances: Recovered Medicare and Recovered Medicaid amounts in error. It should have stated Medicare as $57,037,659 and Medicaid as $266,785,871. This error did not affect the total Monetary Results nor the Return on Investment calculation.

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 27th year of operation, the Secretary and the Attorney General certified $338.0 million in mandatory funding as necessary for the Program, after accounting for mandatory sequester as required by law. In addition, Congress appropriated $893.0 million in discretionary funding. Allocation by recipient is below:

FY 2023 ALLOCATION OF HCFAC APPROPRIATION

	Mandatory Allocation*	Discretionary Allocation*	Funds Sequestered	Total Allocation
Department of Health and Human Services				
Office of the Inspector General	$253,557,277	$105,145,000	($13,588,772)	$345,113,505
Office of the General Counsel	8,041,114	0	0	8,041,114
Administration for Community Living	1,300,000	35,000,000	0	36,300,000
Food and Drug Administration	9,973,282	0	0	9,973,282
Centers for Medicare & Medicaid Services	3,000,000	630,648,000	0	633,648,000
Assistant Secretary for Planning and Evaluation	1,500,000	0	0	1,500,000
Office of Civil Rights	4,025,574	0	0	4,025,574
Unallocated Funding	2,599,015	0	(2,599,015)	0
Subtotal	**$283,996,262**	**$770,793,000**	**($16,187,787)**	**$1,038,601,475**
Department of Justice				
United States Attorneys	$33,900,000	$33,391,094	$0	$67,291,094
Civil Division	17,500,000	43,333,283	0	60,833,283
Criminal Division	16,054,075	27,677,264	0	43,731,339
Civil Rights Division	2,396,847	8,995,226	0	11,392,073
Justice Management Division	341,176	0	0	341,176
Federal Bureau of Investigation	0	7,580,502	0	7,580,502
Office of the Inspector General	0	1,229,631	0	1,229,631
Unallocated Funding	4,242,789	0	(4,242,789)	0
Subtotal	**$74,434,887**	**$122,207,000**	**($4,242,789)**	**$192,399,098**
TOTAL	**$358,431,149**	**$893,000,000**	**($20,430,576)**	**$1,231,000,573**

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

Overall Settlements, Judgments, and Recoveries

During FY 2023, civil health care fraud settlements and judgments under the False Claims Act exceeded $1.8 billion, and the Federal Government attained additional administrative impositions in health care fraud cases and proceedings.[5] Because of these efforts, as well as those of preceding years, more than $3.4 billion was returned to the Federal Government or private persons. Of this $3.4 billion, the Medicare Trust Funds received transfers[6] of almost $974 million during this period; approximately $257.2 million in Federal Medicaid money was transferred to the CMS separately. 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 (2021–2023) is $2.80 returned for every $1.00 expended. The ROI continues to be adversely impacted by unique factors associated with the COVID-19 pandemic, such as court closures, and interrupted or slowed criminal and civil enforcement, among other HCFAC activities. Although FY 2023 recoveries, disallowances, and restitutions have increased from recent years, because the ROI is determined by a three-year rolling average it continues to reflect the pandemic affected collections from FY 2021 and FY 2022. The DOJ and HHS use the three-year rolling average ROI for results because the annual ROI varies from year to year depending on the number and type of cases that are settled or adjudicated during that year. 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

The Strike Force Teams are comprised of over 80 experienced white collar prosecutors in Criminal Division's Fraud Section who partner with U.S Attorneys' offices (USAOs), the HHS-OIG, the FBI, and other law enforcement agencies to focus solely on prosecuting the nation's most complex health care fraud matters and the illegal prescription, distribution, and diversion of opioids. The Strike Force's core mission is to protect the public fisc from large-scale health care fraud, protect patients from egregious fraudulent schemes that result in patient harm, and to detect, limit, and deter fraud and illegal prescription, distribution, and diversion offenses. The Strike Force routinely prosecutes defendants who orchestrate schemes that result in the loss of

[5] 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.

[6] Note that some of the judgments, settlements, and administrative actions that occurred in FY 2023 will result in transfers in future years, just as some of the transfers in FY 2023 are attributable to actions from prior years.

hundreds of millions or billions of dollars, the distribution of tens of millions of opioids, and complex money laundering, tax, and other associated financial crime offenses. In FY 2023, the Strike Force conducted a record number of trials.

The Criminal Division Fraud Section's Health Care Fraud Unit (HCF Unit), of which the Strike Force is a part, is a leader in using advanced data analytics and algorithmic methods to identify newly emerging health care fraud schemes and to target the most egregious fraudsters. The HCF Unit's team of dedicated data analysts work with prosecutors to identify, investigate, and prosecute cases using data analytics. This novel approach has led to some of the Fraud Section's largest cases and initiatives. The Strike Force uses advanced data analysis techniques to identify aberrant billing levels in health care fraud hot spots—cities with high levels of billing fraud—and target suspicious billing patterns, as well as emerging schemes and schemes that migrate from one community to another.

First established in March 2007, Strike Force teams currently operate in 16 Strike Forces across the United States, including, but not limited to: Los Angeles, California; Miami, 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; 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 HCF Unit's 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.

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 HCF Unit, and comprised of leadership from over 10 key government agencies, including the 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 54 defendants with over $971.8 million in COVID-19 fraud. This includes cases charged in three annual COVID-19 Health Care Fraud Enforcement Actions from 2021 through 2023.

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 to ensure that needed access to care supported by this technology is not compromised by wrongdoers. In the past four and a half years, the HCF Unit, working with USAOs, has charged over $11 billion in fraud committed using or exploiting telemedicine, including the telemedicine cases charged in the 2023 National

Health Care Fraud 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 USAOs, to bring cases in Federal district court. During FY 2023, Strike Force accomplishments in the areas noted above, as well as USAO accomplishments included:[7]

- Filing 276 indictments, criminal informations and complaints[8] involving charges against 406 defendants who allegedly collectively billed Federal health care programs and private insurers approximately $3.9 billion;[9]
- Obtaining 387 guilty pleas and litigating 55 jury trials, with guilty verdicts against 45 defendants;[10] and
- Securing imprisonment for 300 defendants sentenced, with an average sentence of over 49 months.

Since the Strike Force's inception, prosecutors and Assistant U.S. Attorneys (AUSAs) in Strike Force districts filed more than 3,000 cases charging more than 5,800 defendants who collectively billed Federal health care programs and private insurers approximately $30 billion. More than 4,100 of these defendants have pleaded guilty, over 500 others have been convicted in jury trials, and more than 3,600 defendants have been sentenced to imprisonment for an average term of approximately 49 months. Medicare payment trends demonstrate the positive impact of Strike Force enforcement and prevention efforts.

During FY 2023, the Strike Force coordinated two separate enforcement actions, in collaboration with USAOs, HHS-OIG, FBI, DEA, and other Federal and state partners. In April 2023, the Strike Force announced criminal charges against 18 defendants in nine Federal districts for their alleged participation in various fraud schemes involving health care services that exploited the COVID-19 pandemic and allegedly resulted in over $490 million in COVID-19 related false billings to Federal programs and theft from Federally funded pandemic programs. In connection with the enforcement action, the DOJ seized over $16 million in cash and other fraud proceeds. The Center for Program Integrity of the Centers for Medicare & Medicaid Services (CPI/CMS) separately took adverse administrative actions in the last year against 28 medical providers for their alleged involvement in COVID-19 schemes.

In June 2023, the Strike Force announced a strategically coordinated, two-week nationwide law enforcement action that resulted in criminal charges against 78 defendants for their alleged

[7] The summary statistics in this document exclude sealed cases.
[8] This number does not include complaints filed by USAOs.
[9] This alleged loss amount figure only reflects the amounts of alleged loss in cases handled by the Criminal Division, Fraud Section.
[10] These numbers do not include guilty pleas and verdicts obtained by USAOs where the defendant had not been sentenced before the end of FY 2023.

participation in health care fraud and opioid abuse schemes that included over $2.5 billion in alleged fraud. The defendants allegedly defrauded programs entrusted for the care of the elderly and disabled, and, in some cases, used the proceeds of the schemes to purchase luxury items, including exotic automobiles, jewelry, and yachts. In connection with the enforcement action, the DOJ seized or restrained millions of dollars in cash, automobiles, and real estate.

In October 2018, the Criminal Division announced the formation of the Appalachian Regional Prescription Opioid (ARPO) Strike Force, a joint effort between the 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. In 2022, this effort was expanded with the creation of the New England Prescription Opioid Strike Force (NEPO). Since inception, the ARPO Strike Forces (North and South) and NEPO have charged 123 defendants with crimes related to the unlawful distribution of prescription opioids. Together, these defendants issued prescriptions for over 117 million controlled substance pills. Eight defendants were charged in FY 2023, including five medical professionals. As of September 2023, 68 of the ARPO defendants have entered guilty pleas, with more pleas scheduled. Nine additional defendants were convicted in nine trials, and nine ARPO defendants were sentenced in FY 2023.

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 2023, OFAD AUSAs handled a variety of investigations and prosecutions involving medical professionals. OFAD attorneys filed 29 cases against 50 defendants, alleging various charges including health care fraud, drug trafficking, and money laundering.

For example, in January 2023, an 83-year-old physician who served as the medical director of a pain management clinic was sentenced to home confinement for participating in a conspiracy to distribute oxycodone. The physician pleaded guilty to prescribing high doses of opioids for patients despite numerous red flags, including patients who tested positive for cocaine and heroin, patients who brought in other individuals' urine to attempt to pass drug screens, and patients who overdosed. The physician ignored warning signs, including pharmacies that refused to fill prescriptions and complaints that patients were selling drugs in the parking lot outside the facility. Two other health care providers from the clinic also pleaded guilty in connection with the scheme and received prison sentences.

In February 2023, a pharmacist was sentenced to 84 months in Federal prison for participating in a scheme in which he conspired to distribute over 25,000 opioid pills and laundered money. The pharmacist pleaded guilty to unlawfully filling prescriptions for a co-conspirator in exchange for cash and, in some instances, selling entire stock bottles of controlled substances. Another participant in the scheme received a 72-month sentence.

In March 2023, a physician and his wife were both sentenced to 20-year prison terms for participating in conspiracies to distribute controlled substances and to commit health care fraud, as well as other related offenses. At trial, evidence showed that the physician and his wife operated pain clinics in which patients often received pre-signed prescriptions that were issued to patients who went months or years without being seen by the doctor. The doctor was responsible for writing prescriptions for over 10 million opioid pills and he and his wife also participated in

fraud and kickback schemes that billed public and private insurance programs for over $270 million in fraudulent claims.

In April 2023, a former physician was sentenced to 120 months in prison for conspiring to unlawfully distribute drugs. Evidence at trial demonstrated that the physician was the medical director of a pain management clinic who would prescribe controlled substances to patients who exhibited obvious signs of diversion and abuse, including travelling over four hours to come to the clinic, waiting 10 hours or more to be seen, paying fees in the form of prepaid gift cards, and paying no show fees to avoid mandatory pill counts. Three other co-defendants, including another physician, also received sentences ranging from 60 to 84 months.

In another pill mill case, a doctor was convicted of drug distribution, money laundering, and filing a false tax return after a two-week trial in June 2023. Evidence at trial showed the doctor prescribed opioids to undercover DEA agents that were not for a legitimate medical purpose or in the ordinary course of medical practice. The doctor laundered the proceeds of this criminal activity in various ways, including buying real estate, and underreported the income of the medical practice by nearly $300,000. In October 2023, the defendant was sentenced to 92-months in prison, fined $100,000, and ordered to pay over $119,000 to the IRS.

Healthcare 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 17 cases during the FY 2023 enforcement actions.

The DOJ and HHS have expanded data-sharing and improved information-sharing procedures 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, 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 300 public, private, and state partner organizations at the end of FY 2023.[11] Eighty-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 2023, providing partners with detailed results that can be evaluated for investigative purposes within their organizations. The HFPP continued to foster collaboration among partners by hosting virtual information-sharing sessions; hybrid meetings are being prepared for FY 2024. Partners share fraud schemes and provider alerts, provide updates on law enforcement activities, and strategize ways to broaden the HFPP's impact in the private and public sectors. 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. Using principles outlined in the Government Accountability Office (GAO) Fraud Risk Management Framework, CMS has developed a robust fraud risk assessment process to identify potential risks and vulnerabilities

[11] For a list of current partners, please visit: https://www.cms.gov/medicare/medicaid-coordination/healthcare-fraud-prevention-partnership/about/current-partners.

associated with PHE and unintended consequences of the waivers and flexibilities. 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 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. These individuals 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.
- 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.
- 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.

Ambulances

In February 2023, an Emergency Medical Technician (EMT) in Texas was sentenced to 48 months of incarceration, followed by three years of supervised release, and ordered to pay restitution of over $1.1 million. The woman had previously pled guilty to one count of conspiracy to commit health care fraud and one count of health care fraud. The woman worked as an EMT and supervisor for an ambulance company and wrote and signed hundreds of false ambulance run sheets which were used to send fraudulent bills to Medicare and to the Texas Medicaid program for non-emergency ambulance services that were not provided or were improperly provided. In total, between January 2013 and October 2015, the EMT caused over $2.3 million in false claims to be submitted to the Medicare and Medicaid programs, of which over $1.1 million was paid.

Clinics

(SF) In March 2023, following a two-week trial, two doctors were convicted for orchestrating a health care fraud scheme at a pain clinic in northern Kentucky in which they submitted fraudulent claims to Medicaid for medically unnecessary urinalysis testing for their patients, including urinalysis testing conducted on faulty machinery. The pain clinic submitted $93 million in claims for urinalysis testing during this scheme, of which at least $8.8 million was paid by Medicaid.

In April 2023, SouthEast Eye Specialists, PLLC, and related Tennessee-based companies providing ophthalmology services and related ambulatory surgical centers (SEES) agreed to pay

the United States $17 million to resolve civil FCA allegations that the SEES provided kickbacks to optometrists in exchange for referrals. The kickbacks allegedly took the form of inappropriately engaging in co-management with optometrists and providing meals, outings, gifts, and other items of value to referral sources during the period from March 2010 through November 2022.

COVID-19 Related Enforcement

In December 2022, a physician and his medical practice, DOCS Medical Group, Inc., paid $4.3 million to resolve civil FCA and common law allegations that, from 2014 through 2020, they submitted false and improper claims for payment to Medicare and Connecticut Medicaid allegedly: (1) billing for level 3 E&M services on the same dates that patients received COVID tests, when those level 3 services were not provided; (2) submitting claims for medically unnecessary annual re-testing of allergy patients; (3) providing medically unnecessary and unsupervised allergy immunotherapy services; and (4) submitting claims for medical services performed by the physician on dates of service when he was out of the country.

In December 2022, a principal of a suburban Chicago company that sold personal protective equipment was sentenced to 57 months in prison and three years of supervised release, and was ordered to pay over $1.9 million in restitution, after pleading guilty to one count of wire fraud and one count of money laundering. The defendant helped secure sales contracts with two university hospitals for nearly $7 million worth of N95 masks at the outset of the COVID-19 pandemic, but the masks were never delivered. Instead, funds intended for the purchases were deposited into an account controlled by the defendant, who spent part of the money for his personal benefit, including purchasing three luxury cars, paying nearly $189,000 to credit card companies, withdrawing more than $147,000 in cash, and paying $20,000 to a friend.

Diagnostic Testing

(SF) In October 2022, the owner of multiple diagnostic testing laboratories pled guilty to conspiracy to commit health care fraud and money laundering in connection with the submission of more than $134 million in fraudulent claims for diagnostic tests, including urine drug analysis and tests for respiratory illness during the COVID-19 pandemic, that were medically unnecessary, not ordered by medical providers, and not provided as represented. Medicare paid approximately $38 million based on these claims. In June 2023, the owner was sentenced to 15 years in prison.

In December 2022, BioTelemetry Inc. and its subsidiary CardioNet LLC, both headquartered in Pennsylvania (collectively BioTelemetry), agreed to pay $44.9 million to resolve civil allegations that they violated the FCA from January 2013 through June 2022 by knowingly submitting claims to Medicare, TRICARE, the Veterans Health Administration, and the Federal Employee Health Benefits Program for heart monitoring tests that were performed, in part, outside the United States—in violation of Federal law that prohibits payment for services furnished outside the United States and, in many cases, by technicians who were not qualified to perform such tests. More specifically, the government alleged that in 2013, CardioNet contracted with a company located in India for the provision of diagnostic and analysis services of heart monitoring data. At certain times thereafter, and with the knowledge of then-senior management, BioTelemetry diverted certain Federal beneficiaries' testing data to India for review by technicians located in India. Although BioTelemetry began implementing technological controls in late 2015 to prevent such diversion, those controls were insufficient and

technicians in India allegedly continued to review and analyze some testing data for Federal health care program beneficiaries. In connection with the settlement, BioTelemetry entered into a five-year Corporate Integrity Agreement (CIA) with the HHS-OIG.

In March 2023, in Alabama, the former owner of a nerve conduction testing company was sentenced to 80 months in prison and ordered to pay more than $9 million in restitution after pleading guilty to one count of conspiracy to commit health care fraud and one count of conspiracy to receive kickbacks. Between 2012 and 2018, the defendant's company was paid over $9 million for medically unnecessary electro-diagnostic testing. The defendant's company paid providers a per-patient fee for the tests they ordered that insurers reimbursed. The payments were disguised as hourly payments for the provider's time and the time of the provider's staff, but the provider was actually paid a fee per patient who received a test.

In March 2023, Ellis Pain Center (EPC), a pain management practice based in Athens, Georgia, agreed to pay $5 million to resolve civil FCA allegations that EPC submitted claims for urine drug tests to Medicare that were false because the urine drug tests were either not performed or not medically necessary. The settlement also resolved allegations that EPC violated the FCA by submitting claims to Medicare for diagnostic tests that were not medically necessary. The government alleged that from January 2012 through December 2015: (1) EPC billed Medicare for individual and expensive quantitative urine drugs tests that it did not actually conduct and, in fact, could not have conducted on the equipment utilized by EPC; and (2) EPC billed Medicare for the same urine drug tests and diagnostic procedures on its patients without regard to the patients' unique signs, symptoms, and medical needs.

In September 2023, Cardiac Imaging, Inc. (CII), headquartered in Illinois, and its founder and owner, who serves as CII's CEO, agreed to pay a total of $85.5 million to resolve civil FCA allegations that they paid referring cardiologists excessive fees to supervise cardiac Positron Emission Tomography (PET) scans in violation of the Anti-Kickback Statute (AKS) and the Physician Self-Referral Law (Stark Law). The United States alleged that between March 1, 2014, and May 31, 2023, CII and its owner knowingly caused false or fraudulent claims to Federal health care programs arising from violations of the AKS and the Stark Law. Specifically, with the owner's oversight and approval, CII allegedly paid kickbacks to referring cardiologists in the form of above-fair market value fees of $500 or more per hour, ostensibly for the cardiologists to supervise the PET scans for the patients they referred to CII. The United States alleged these fees substantially exceeded fair market value for the cardiologists' services because CII paid the referring cardiologists for each hour CII spent scanning the cardiologists' patients, including time the cardiologists were away from CII's mobile scanning units providing care for other patients or were not even on site. CII's fees also purportedly compensated the cardiologists for additional services that were not actually provided. CII purported to rely on a consultant's fair market value analysis that the United States alleged CII knew was premised on fundamental inaccuracies about the services referring physicians provided and that the consultant ultimately withdrew. In connection with the settlement, CII and its owner entered into a five-year CIA with the HHS-OIG.

Durable Medical Equipment (DME)

In January 2023, United Seating and Mobility, LLC, d/b/a Numotion, a wheelchair and mobility equipment company based in Missouri, agreed to pay $7 million to resolve civil FCA allegations that it submitted false claims that failed to disclose actual costs of "manually priced" (i.e., priced

based on actual cost) durable medical equipment to the Kentucky, Missouri, and the District of Columbia (D.C.) Medicaid programs. The United States alleged that Numotion omitted discounts that it received for manually priced durable medical equipment during the authorization and reimbursement process to Kentucky Medicaid from January 1, 2013, to June 26, 2019; to Missouri Medicaid from January 1, 2013, to May 31, 2022; and to D.C. Medicaid from November 7, 2014, to May 15, 2022.

In April 2023, AdaptHealth LLC, formerly known as QMES, LLC, a durable medical equipment provider based in Plymouth Meeting, Pennsylvania, agreed to pay $5.3 million to resolve civil FCA allegations that it submitted allegedly false claims to Federal health care programs for respiratory devices that patients did not need or use, in violation of Federal health care program requirements. The government alleged that between 2013 and 2017, AdaptHealth (known during the period as QMES and Tri-County Medical Equipment and Supply LLC), knowingly and willfully billed Federal payors for non-invasive ventilators (NIVs) when a patient was instead prescribed and used a BiPAP machine, for which Federal payors reimburse suppliers thousands of dollars less per year. The settlement also resolved allegations that AdaptHealth continued billing Federal payors for ventilators after patients no longer needed or were using them, and double-billed Federal payors for some ventilator rentals in violation of program requirements.

(SF) In April 2023, a Florida chiropractor and a Florida physician were sentenced for their respective roles in a scheme to defraud Medicare by submitting over $31 million in claims for expensive DME that Medicare beneficiaries did not want or need and that were procured through the payment of kickbacks. The chiropractor was convicted at trial of health care fraud conspiracy, conspiracy to pay kickbacks, health care fraud, payment of kickbacks, and false statements relating to health care matters. He was sentenced to eight years and one month in prison and ordered to pay $1.4 million in restitution. The physician was convicted at trial of false statements relating to health care matters, was sentenced to two years and nine months in prison, and was ordered to pay $315,704 in restitution.

(SF) In May 2023, in Miami, Florida, the owner of several companies pleaded guilty to conspiracy to commit health care fraud for his role in a DME and telemarketing fraud scheme. The defendant owned several DME companies through which he purchased doctors' orders for medically unnecessary orthotic braces in exchange for kickbacks and bribes, and billed Medicare and Medicaid for this DME. The defendant also sold doctors' orders to other DME companies in exchange for kickbacks and bribes. The defendant's DME companies and the DME companies to which he sold doctors' orders billed Medicare and Medicaid approximately $22.1 million, of which approximately $9.5 million was paid. As part of his plea, the defendant agreed to forfeit two homes in Boca Raton, Florida, as well as pay a $9.2 million money judgment. The defendant is awaiting sentencing.

In May 2023, the owner of a DME company was sentenced to 65 months in prison, ordered to pay forfeiture of $3.9 million, and restitution of $7 million to the Medicare program for his role in a conspiracy to commit health care fraud by fraudulently trafficking in orders for DME such as back, knee, and wrist braces. According to statements made in court and publicly filed documents in this case, from at least August 2019 through May 2021, the owner and his co-defendant engaged in a scheme to defraud Medicare by illegally obtaining and selling fraudulent orders for DME paid for by Medicare. Using a business that he jointly owned and operated with the co-defendant, and a call center based in the Dominican Republic, the owner illegally

generated and purchased fraudulent orders for DME and then sold those fraudulent orders to pharmacies and DME suppliers, including suppliers in New York City. Those pharmacies and DME suppliers then used those fraudulent orders as the basis for at least $7 million in fraudulent claims to Medicare. Many of these fraudulent orders used names and personal health information of actual Medicare beneficiaries, without the beneficiaries' authorization or prior knowledge. Many of these fraudulent orders also contained professional information of doctors and other health-care providers enrolled in the Medicare program, as well as the purported electronic signatures of these providers, which were falsified and created without the authorization or knowledge of these providers. During the scheme, the owner and his co-defendant received more than $3.8 million in illegal kickbacks from DME suppliers, who made these payments to a marketing company controlled by the owner and his co-defendant.

In August 2023, Lincare Holdings, Inc., a medical supply company based in Clearwater, Florida, agreed to pay $29 million to resolve civil FCA allegations that Lincare fraudulently billed Medicare Advantage plans and Medicare Part B for oxygen equipment rental payments. The settlement included a detailed set of factual admissions in which Lincare admitted that between 2016 and 2022, Medicare Part B and many Medicare Advantage plans capped oxygen equipment rental payments at 36 months, meaning that after Lincare had claimed and received payment for 36 months of rental payments for oxygen equipment, Lincare was not permitted to further bill Medicare for that equipment for that beneficiary, or to bill additional co-pays to the patient. Lincare further admitted that it submitted false and fraudulent claims for payment from Medicare Advantage and from Medicare Part B, and fraudulently billed and collected beneficiary co-pays, even after it had already received 36 months of payments for the equipment, because it did not have or implement appropriate internal controls to stop billing after 36 months. As part of the settlement, Lincare also agreed to identify and refund all beneficiaries from whom it had wrongfully collected co-pays, protecting a vulnerable elderly and disabled population of beneficiaries that Lincare fraudulently victimized as part of the scheme.

(SF) In August 2023, in the Eastern District of Louisiana, a defendant pled guilty to health care fraud. The defendant, through his DME supply company, billed Medicare and Medicaid approximately $11.4 million for DME that was medically unnecessary. That included equipment for respiratory support and nutritional support, including ventilators, tracheostomy supplies, and feeding tubes. In reality, those items were medically unnecessary, not ordered, or not provided as represented. In some instances, the patients had already died. To cover up his scheme, the defendant directed the falsification of documents, including medical records, order forms, and supporting documentation, in response to Medicare audits and record requests. The falsification of documents included forging provider signatures, medical notes, and dates, as well as using tape, white-out, and scissors, to make it falsely appear that the audited DME was ordered and delivered. The defendant was sentenced to three years' imprisonment in December 2023.

Electronic Health Records

In November 2022, Modernizing Medicine Inc. (ModMed), an electronic health record (EHR) technology vendor located in Boca Raton, Florida, agreed to pay $45 million to resolve allegations that it violated the civil FCA by accepting and providing unlawful remuneration in exchange for referrals and by causing its users to report inaccurate information related to claims for Federal incentive payments. The United States alleged that ModMed violated the FCA and the AKS through three marketing programs. First, ModMed solicited and received kickbacks from a life sciences company (Life Sciences Company) in exchange for recommending and

arranging for ModMed's users to utilize Life Sciences Company's pathology lab services. Second, ModMed conspired with Life Sciences Company to improperly donate ModMed's EHR to health care providers in an effort to increase lab orders to Life Sciences Company and simultaneously add customers to ModMed's user base. Third, ModMed paid kickbacks to its current health care provider customers and to other influential sources in the health care industry to recommend ModMed's EHR and refer potential customers to ModMed. Additionally, under HHS' EHR Incentive Programs, HHS offered incentive payments to health care providers that adopted certified EHR technology and met certain requirements relating to their "meaningful use" of that technology. Eligibility for incentive payments required health care providers to use certified EHR technology that, among other things, utilized certain standard vocabularies for drugs (RxNorm) and clinical terminology (SNOMED CT) to conduct certain transactions. The United States alleged that ModMed knew that its EHR did not always allow physician users to electronically record medical records using the required standard vocabularies, thereby causing certain of its users to submit false claims for incentive payments under that program. As a result of this conduct, different portions of which occurred during various periods between January 2010 and July 2017, the Government alleged that ModMed improperly generated sales for itself and for Life Sciences Company, while causing health care providers to submit false claims for reimbursement to the Federal Government for pathology services, and for incentive payments from HHS for the adoption and meaningful use of ModMed's EHR technology.

In July 2023, NextGen Healthcare Inc. (NextGen), an electronic health record (EHR) technology vendor, agreed to pay $31 million to resolve allegations that NextGen violated the civil FCA by misrepresenting the capabilities of certain versions of its EHR software and providing unlawful remuneration to its users to induce them to recommend NextGen's software. To obtain certification for their product for purposes of the Medicare and Medicaid EHR Incentive Programs, companies that develop and market EHR technology are required to demonstrate that their product satisfies all applicable HHS-adopted certification criteria and identify any software components on which their EHR technology relies to perform the criteria. The United States alleged that NextGen falsely obtained certification for its EHR technology by relying during testing on an auxiliary product designed only to perform the certification of test scripts, while the EHR technology that NextGen ultimately released to its users lacked certain required functionalities needed to obtain the required certification. The government also alleged that NextGen provided illegal remuneration, in violation of the AKS, in the form of: (1) credits, often worth as much as $10,000, to current customers whose recommendation of NextGen's EHR software led to a new sale; and (2) tickets to sporting events and entertainment to induce purchases and referrals of the product.

Genetic Testing/RPP Testing

(SF) In December 2022, in Miami, Florida, the owner of LabSolutions, LLC, a clinical laboratory, was found guilty of various Federal health care and money-laundering offenses for his role in a scheme to defraud Medicare by submitting genetic and other laboratory tests that patients did not need and that were procured through the payment of kickbacks. The defendant conspired with patient brokers, telemedicine companies, and call centers to target Medicare beneficiaries with telemarketing calls falsely stating that Medicare covered expensive cancer genetic tests. After the Medicare beneficiaries agreed to take a test, the defendant paid kickbacks and bribes to patient brokers to obtain signed doctors' orders authorizing the tests from telemedicine companies. To conceal the kickbacks, the defendant required patient brokers to

sign contracts that falsely stated that they were performing legitimate advertising services for his lab. From July 2016 through August 2019, LabSolutions submitted more than $463 million in claims to Medicare, including for medically unnecessary genetic tests, of which Medicare paid over $187 million. In that timeframe, the defendant personally received over $21 million in Medicare proceeds. In August 2023, the defendant was sentenced to 27 years' imprisonment.

In March 2023, Laboratory Corporation of America (Labcorp) agreed to pay the United States $2.1 million to resolve allegations that it violated the civil FCA by overbilling the Department of Defense (DoD) for genetic tests performed by GeneDx, LLC, a third-party reference laboratory used by Labcorp to perform genetic tests for military members. In 2012, LabCorp entered a contract with DoD to perform laboratory testing at all DoD Military Treatment Facilities throughout the world. Certain specialized tests performed on the DoD contract, including genetic tests involving fetuses and parents, were performed by GeneDx as a reference lab for Labcorp. GeneDx would invoice Labcorp for these genetic tests and Labcorp would in turn invoice DoD. According to the settlement agreement, from December 1, 2013, through June 30, 2021, LabCorp double and/or triple billed DoD for genetic tests performed by GeneDx; overcharged DoD for genetic tests performed by GeneDx; and inappropriately billed DoD for tests performed by GeneDx when LabCorp could not later locate evidence of: (1) a DoD requisition form, (2) a GeneDx test result, and/or (3) a corresponding GeneDx invoice.

In June 2023, the owner of telemedicine provider recruiting company was sentenced to 60 months in prison and ordered to pay more than $61 million in restitution for his role in a $73 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 owner admitted that he conspired with co-defendants to receive kickbacks in exchange for his work arranging for telemedicine providers to authorize genetic testing orders for his co-defendant's laboratories. The owner and his co-defendants entered into a sham contract for purported IT and consultation services to disguise the true purpose of these payments. The owner exploited temporary amendments to telehealth restrictions enacted during the pandemic 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 laboratories for expensive and medically unnecessary genetic testing.

In August 2023, a laboratory owner in Pittsburgh, Pennsylvania, was sentenced to 18 months of incarceration, followed by three years of supervised release, and was ordered to forfeit more than $9 million and pay more than $77 million in restitution. The laboratory owner previously pled guilty to three counts of conspiring to commit offenses against the United States and one count of offering and paying kickbacks in connection with a Federal health care program. The laboratory owner and other conspirators paid kickbacks to marketers in exchange for Medicare patient swabs to be used in cancer-genomic and pharmacogenetic testing. The laboratory owner and other conspirators also paid kickbacks to another conspirator, who ensured that telemedicine physicians wrote scripts for cancer-genomic and pharmacogenetic testing relating to the patients whose swabs were already obtained. In all, the schemes in which the laboratory owner was involved caused a loss of more than $60 million to the United States.

Home Health Providers

In October 2022, two Illinois home health care company owners were sentenced as part of a $6.7 million home health care fraud scheme. One owner, a registered nurse, was sentenced to two years in prison and ordered to pay $6.6 million in restitution. The other owner was sentenced to 18 months in prison and ordered to pay $1.6 million in restitution. The two individuals owned and operated three home health companies in Indiana. From approximately January 2009 to June 2018, the owners secretly paid bribes and kickbacks to patient marketers in exchange for referrals of Medicare beneficiaries to the companies.

In March 2023, a district court entered a civil FCA judgment of more than $25 million against the defendant and his home visiting physician company, Docs at the Door, P.C. The civil judgment followed a related criminal case against the defendant, in which he was charged with care plan oversight fraud. Care plan oversight is a covered Medicare service, where a physician who has certified a plan of care for a home health patient spends an additional 30 minutes in a calendar month performing certain oversight functions that are not related to the certification itself or a face-to-face visit with the patient, which are separately billed. In pleading guilty in the criminal case, the defendant admitted that Medicare paid Docs at the Door $523,600 as the result of 4,367 false claims for the care plan oversight service that the defendant caused to be submitted, although he knew those services had not been rendered. The civil judgment was based upon the defendant's guilty plea and the admissions in the plea agreement, and it included more than $24 million in civil penalties levied for each of the false claims.

In May 2023, following a jury trial, a judge ordered a doctor and his wife to pay more than $3 million in civil damages and penalties for violating the civil FCA and AKS. The doctor owns Boycin Medical Clinic in Chicago, and his wife serves as the clinic's administrator. The United States alleged that in 2009 and 2010, the defendants asked for and received money and other items of value from Grand Home Health (Grand), a home health agency, as payment for the doctor's referrals of Medicare patients, in violation of the AKS. Grand then provided home health services to those patients and billed Medicare, in violation of the False Claims Act. The defendants personally took more than $80,000 in kickbacks from Grand in connection with the doctor's referrals.

In May 2023, a home health company owner was sentenced to 57 months in Federal prison, three years of supervised release, and ordered to pay $1.5 million in restitution after being convicted of conspiracy to commit health care fraud. At the time of his plea, the owner admitted to causing his home health care company to bill Medicare for home health services that were not medically necessary and not provided. He also acknowledged to furthering the scheme by unlawfully paying medical clinics for fraudulent home health certifications and unlawfully paying for patient referrals. The owner admitted to using the fraudulently obtained funds for his personal financial benefit and for the benefit of his family members.

In August 2023, Tucson, Arizona, based Watermark Retirement Communities, LLC, a senior living community operator that manages 79 retirement homes across the country, agreed to pay $4.3 million to resolve allegations that it violated the civil FCA by soliciting and receiving a kickback from a nationwide home health agency (HHA) operator to facilitate referrals from Watermark retirement homes. In September 2021, the HHA operator entered into a $17 million settlement with the United States to resolve the claims against it arising from the same transaction.

Hospice Care

In February 2023, a doctor from Mississippi was sentenced to serve 60 months in prison followed by three years of supervised release and ordered to pay almost $15.5 million in restitution. The doctor was convicted at trial in April 2022 of health care fraud and conspiracy to commit health care fraud. The doctor was a medical director for numerous hospice organizations in the Mississippi Delta. Hospice employees routinely transported prospective patients to the doctor's office, sometimes three or four patients at a time. The doctor saw the patients in his office and then referred them for hospice, claiming to be their primary care or attending physician. In almost all cases, the patients had no idea they were being placed on hospice and multiple patients testified at trial that the doctor did not explain hospice to them and did not tell them he was referring them to hospice care. During the course of the conspiracy charged in the indictment, hospice owners received over $15 million in Medicare funds based on the doctor's patient referrals and certifications.

(SF) In March 2023, the beneficial owner of a hospice company pleaded guilty to one count of health care fraud conspiracy related to fraudulent claims to Medicare for hospice services. According to court documents, from 2018 to 2021, the defendant and others submitted fraudulent enrollment records to Medicare to hide their ownership of two hospices in the names of straw owners whom the conspirators recruited. The defendant also paid kickbacks to patient recruiters for the referral of Medicare beneficiaries for purported hospice services. The defendant also submitted fraudulent loan applications to the Small Business Administration and a financial institution for EIDL and PPP, loans respectively, and stole funds deposited by the Health Resources and Services Administration as part of the Provider Relief Fund to help providers financially impacted by the COVID-19 pandemic. As a result of the fraudulent claims submitted by the conspiracy, Medicare paid the hospices approximately $9 million.

(SF) In April 2023, the former owner of a hospice company pleaded guilty to one count of conspiracy to defraud the United States through submitting false enrollment applications to Medicare that hid the real owners of fraudulent hospices. According to court documents, from 2018 to 2019, the owner and his co-conspirators submitted false enrollment records for a hospice to Medicare to conceal the beneficial owners and managers, knowing that it would obstruct Medicare from carrying out its functions, including by preventing Medicare from discovering who was responsible for fraudulent claims submitted by the hospice. Due to the fraudulent claims submitted by the hospice, Medicare paid approximately $3.7 million, of which $3.1 million was paid after the defendant filed or caused the filing of the false enrollment records.

Hospitals and Health Systems

In November 2022, Feel Well Health Center of Southington, P.C., and its physician owner (collectively, FWHC) agreed to pay over $2.6 million, plus interest, to resolve civil FCA allegations that FWHC caused false claims to be made to Medicare, Connecticut Medicaid, and Connecticut State Comptroller Healthcare Programs. The government alleged false claims billed to government payors for: (1) FWHC's operation of a gym staffed with a medically unlicensed coach or yoga instructor, but for which FWHC billed evaluation and management services, created false medical records, and attached false diagnosis codes to get the claims paid; (2) medically unnecessary testing and procedures, including neurofeedback, ultrasounds, and autonomic function testing; (3) in-office services billed under FWHC's owner's name when, in fact, the owner was out of the country, on vacation, or in a different office; and (4) telemedicine when the requirements for telemedicine were not met. The United States also alleged that

FWHC violated the AKS by receiving kickbacks in the form of processing and handling fee payments and excessive speaker fees in exchange for ordering medically unnecessary clinical laboratory services from Boston Heart Diagnostics Corporation, for which the resulting claims to Medicare were false. As part of the settlement, FWHC and its owner also entered into a three-year CIA with HHS-OIG.

In January 2023, Cornerstone Healthcare Group Holding Inc. and CHG Hospital Medical Center LLC, d/b/a Cornerstone Hospital Medical Center (Cornerstone) agreed to pay the United States $21.6 million to resolve civil FCA claims that from January 1, 2012, through December 31, 2018, the company improperly billed Medicare for unauthorized services, services not provided, and services so inadequate they were considered worthless. Cornerstone Medical Center was formerly a long-term acute care facility located in Houston that operated as a long-term care hospital.

In February 2023, the University of Pittsburgh Medical Center (UPMC), University of Pittsburgh Physicians (UPP), and a cardiothoracic surgeon agreed to pay $8.5 million, submit to a year-long audit, and implement a corrective action plan to resolve civil FCA allegations that UPMC (an integrated health care system and teaching hospital based in Pittsburgh), UPP (UPMC's physician practice group), and the surgeon (a teaching physician and longtime chair of UPMC's department of cardiothoracic surgery) violated the Teaching Physician Regulations, 42 C.F.R. §§ 415.190 and 415.192, by performing as many as three complex surgeries at the same time, failing to participate in all of the key and critical portions of those surgeries, unnecessarily inflating anesthesia times during those surgeries, and billing Medicare and other government Health Benefit Programs for those surgeries and services. In its September 2021 Complaint-in-Partial-Intervention, the government alleged that, from 2015-2021, UPMC, UPP and the surgeon submitted false claims for payment related to: (1) doubly- and triply-concurrent surgeries, during which the surgeon left a first surgery before the key and critical portions of that surgery were complete, participated in as many two other simultaneous surgeries in separate operating rooms, and caused delays and complications in some of those surgeries; (2) surgeries where the surgeon did not participate in the timeout at the outset of the procedure; (3) surgeries where the surgeon was outside the hospital facility, unlocatable for significant stretches, or otherwise not immediately available throughout the procedure; (4) unduly prolonged anesthesia services associated with the surgeon's concurrent surgeries and absences; and (5) procedures, services, and care related to otherwise avoidable complications caused by the concurrent surgeries.

In May 2023, St. Elizabeth's Hospital of the Hospital Sisters Health System in O'Fallon, Illinois, agreed to pay $12.5 million to resolve civil FCA allegations that it knowingly submitted claims to various government health care programs for emergency level services that, in fact, were urgent care services, resulting in overpayments by the government. The alleged conduct occurred between January 1, 2015, and December 31, 2021.

In May 2023, VHS of Michigan Inc., doing business as The Detroit Medical Center Inc. (DMC), Vanguard Health Systems Inc. (Vanguard), and Tenet Healthcare Corporation (Tenet), agreed to pay $29.7 million to resolve civil FCA allegations that DMC, Vanguard, and Tenet caused the submission of false or fraudulent claims to Medicare by providing kickbacks to certain referring physicians at two of its facilities in Detroit, Michigan, Sinai Grace Hospital and Harper University Hospital. The government alleged that from January 1, 2014, through December 31, 2017, Sinai Grace Hospital and Harper University Hospital provided the services of DMC-

employed mid-level practitioners to 13 physicians at no cost or below fair market value in violation of the AKS. The government further alleged that the physicians were selected because of their large number of patient referrals to Sinai Grace Hospital and Harper University Hospital and that the purpose of these arrangements was to induce the physicians to refer additional Medicare patients to DMC facilities.

In June 2023, St. Francis Physician Services, Inc., St. Francis Hospital, and Bon Secours St. Francis Health System, Inc., (collectively, St. Francis), owner and operator of the St. Francis health care system, a Section 501(c)(3) charitable organization in Greenville, South Carolina, agreed to pay $36.5 million to resolve civil FCA allegations that it violated the FCA, the Federal Stark Law, and the AKS by making payments to orthopedic surgeons that were tied to the volume or value of referrals.

Laboratory Testing

(SF) In January 2023, an owner of a clinical testing laboratory was convicted of one count of conspiracy to commit health care fraud and one count of concealing an event that affected his right to continued payments from Medicare, arising out of a scheme to operate the laboratory and submit claims to Medicare while concealing his status as an excluded person and concealing his prior health care fraud-related convictions. During the period of the conspiracy, the owner and his co-conspirator caused the laboratory to bill Medicare approximately $234 million, resulting in payments of approximately $31.7 million that Medicare would not otherwise have paid had it known the true ownership of the laboratory. The defendant was sentenced to 10 years of imprisonment in January 2024.

(SF) In January 2023, the owner of a clinical testing laboratory was convicted of one count of conspiracy to commit health care fraud for his role in a scheme to bill private insurers for laboratory tests performed at out-of-network laboratories, while falsely representing that the tests had been performed at rural hospitals with favorable in-network contracts. According to court papers, the claims were submitted through the rural hospitals and the tests were represented as having been performed there because the conspirators knew they would not have been reimbursed had they truthfully disclosed that the tests were performed at their own laboratories. The scheme resulted in the private insurers paying approximately $79 million as a result of the defendant's conduct. The defendant was sentenced to 60 months' probation in December 2023.

In April 2023, VerraLab JA d/b/a BioTap, a clinical laboratory based in Louisville, Kentucky, agreed to pay $1.5 million to resolve civil FCA allegations that it submitted false claims for court-ordered urine drug tests to Federal health care programs. The United States alleged that BioTap submitted claims for urine drug tests that were not medically necessary and were performed pursuant to court order or for other non-medical purposes from August 1, 2021, to July 27, 2022. In a related settlement agreement entered in February 2023, a licensed clinical social worker and two of his companies agreed to pay $250,000 in an ability-to-pay settlement to resolve their role in causing the submission of the same medically unnecessary urine drug testing performed by BioTap.

In July 2023, BestCare Laboratory Services LLC, (BestCare), a now defunct Texas-based company that operated a clinical laboratory, and its owner, agreed to pay $5.7 million to settle an outstanding FCA judgment. These payments are in addition to $789,652 that the United States has already collected since 2018. A judgment was entered in 2018 finding that BestCare and its owner knowingly submitted false claims to Medicare by billing for travel allowance

reimbursements that did not reflect the mileage lab technicians had actually travelled when they collected specimens from nursing home residents in Texas.

In September 2023, a Charlotte, North Carolina, man was sentenced to 200 months in prison for his role in a scheme to defraud the North Carolina Medicaid program of more than $11 million. In January 2023, a Federal jury convicted the defendant of conspiracy to commit health care fraud, multiple violations of the AKS, money laundering conspiracy, and money laundering. The defendant owned United Diagnostic Laboratories (UDL), a urine toxicology testing laboratory, and United Youth Care Services (UYCS), a company that provided mental health and substance abuse treatment services. The defendant and his co-conspirators executed a conspiracy to defraud the North Carolina Medicaid program by paying illegal kickbacks to other co-conspirators in exchange for urine samples from Medicaid-eligible beneficiaries. The beneficiaries included housing-vulnerable individuals and children eligible for housing, at-risk after school programs, and other services. Once enrolled, the beneficiaries were required to submit urine specimens for drug testing as a condition of their participation in the programs. The specimens were provided to UDL and UYCS for medically unnecessary urine drug testing. The defendant paid the recruiters a kickback from UYCS's NC Medicaid reimbursement on the drug testing and laundered the proceeds of the kickback and health care fraud conspiracy to conceal and disguise the nature and source of UYCS's illegal kickback payments for drug testing referrals. A North Carolina urine drug testing laboratory, Aspirar Medical Lab, LLC, and its owner agreed in August 2023 to pay over $1.9 million to resolve allegations that they violated the civil False Claims Act by knowingly billing North Carolina Medicaid for urine drug tests that were tainted by illegal kickbacks and medically unnecessary as part of related scheme.

Managed Care

Between December 2022 and August 2023, Santa Barbara San Luis Obispo Regional Health Authority, d/b/a CenCal Health (CenCal), a county organized health system (COHS) that contracts to arrange for the provision of health care services under California's Medicaid program (Medi-Cal) in Santa Barbara and San Luis Obispo Counties, California, and seven health care providers that contracted with CenCal agreed to pay a total of $95.5 million pursuant to seven separate settlement agreements to resolve allegations that they violated the civil FCA and the California False Claims Act by causing the submission of false claims to Medi-Cal related to Medicaid Adult Expansion under the Patient Protection and Affordable Care Act (ACA). These civil settlements resolve allegations that CenCal; Cottage Health System (Cottage), a not-for-profit hospital network operating in Santa Barbara County; Sansum Clinic (Sansum), a non-profit outpatient clinic operating in Santa Barbara County; Community Health Centers of the Central Coast (CHC), a non-profit community health center operating in Santa Barbara and San Luis Obispo Counties; Dignity Health (Dignity), a not-for-profit health system that owns and operates three hospitals and one clinic in Santa Barbara and San Luis Obispo Counties; Twin Cities Community Hospital (Twin Cities) and Sierra Vista Regional Medical Center (Sierra Vista), two acute health care facility subsidiaries of Tenet Healthcare Corporation operating in San Luis Obispo County; and Lompoc Valley Medical Center (LVMC), a California Health Care District that operates multiple health care providers, including a hospital and several clinics in Santa Barbara County, all knowingly submitted or caused the submission of false claims to Medi-Cal for enhanced services that were purportedly provided to Adult Expansion Medi-Cal members. The United States and California alleged that those enhanced services were purportedly provided by Cottage and LVMC between January 1, 2014, and June 30, 2016; by

Sansum and CHC between January 1, 2015, and June 30, 2016; by Dignity between February 1, 2015, and June 30, 2016; and by Twin Cities and Sierra Vista between January 1, 2014, and April 30, 2015. The United States and California further alleged that the payments were not allowed medical expenses permissible under the contract between California's Department of Health Care Services and CenCal; were pre-determined amounts that did not reflect the fair market value of any Enhanced Services provided; and/or the enhanced services were duplicative of services already required to be rendered. Under these settlements, the defendants agreed to pay a total of $91.4 million to the United States ($49.5 million from CenCal, $13.5 million from Dignity, $9 million from Cottage, $6.8 million from Twin Cities and Sierra Vista, $5 million from LVMC, $4.5 million from Sansum, and $3.3 million from CHC); and a total of $4.1 million to California. In connection with the settlements, CenCal, Twin Cities, and Sierra Vista entered into five-year CIAs with the HHS-OIG.

In July 2023, Martin's Point Health Care Inc. (Martin's Point), headquartered in Portland, Maine, agreed to pay $22.5 million to resolve allegations that it violated the civil FCA by submitting inaccurate diagnosis codes for its Medicare Advantage Plan enrollees to increase reimbursements from Medicare. Under the Medicare Advantage Program (MA Program), also known as Medicare Part C, Medicare beneficiaries have the option of enrolling in managed care insurance plans called Medicare Advantage Plans (MA Plans). MA Plans are paid a per-person amount to provide Medicare-covered benefits to beneficiaries who enroll in one of their plans. CMS, which oversees the Medicare program, adjusts the payments to MA Plans based on demographic information and the diagnoses of each plan beneficiary. The adjustments are commonly referred to as risk scores and, in general, high risk scores are associated with increased CMS payments to MA Plans. The United States alleged that, from 2016 to 2019, Martin's Point engaged in chart reviews of their Medicare Advantage beneficiaries to identify additional diagnosis codes that had not been submitted to Medicare. Many of the additional codes submitted, however, were not properly supported by the patients' medical records. The government alleged that Martin's Point nevertheless submitted those diagnosis codes, which resulted in higher payments from CMS.
In September 2023, national insurer The Cigna Group (Cigna) agreed to pay $172.3 million to resolve allegations that it violated the civil FCA by knowingly submitting false diagnosis data to the MA Program concerning the health of beneficiaries enrolled in its MA Plans and knowingly avoiding its obligation to repay CMS for payments it received based on the false data. Cigna owns and operates MA Organizations that offer MA Plans to Medicare beneficiaries across the country. The United States contended that, for payment years 2014 to 2019, Cigna retained coders to review patient medical records (a/k/a charts) and identify support for additional diagnosis codes that Cigna could submit to CMS to increase its risk adjustment payments. However, when the chart reviews did not substantiate certain diagnosis codes that Cigna had already submitted to CMS, Cigna did not remove those codes or reimburse CMS for the increased payments they triggered. The United States further contended that from 2012 to 2019, Cigna submitted false and invalid diagnoses of serious, complex medical conditions that were based only on the home visits to Medicare Part C beneficiaries, were not supported by the beneficiaries' medical record, could not be diagnosed without specific testing or imaging that was not performed, and were not reported to Cigna by any other health care provider who saw the beneficiary during the year in which the home visit occurred. For payment years 2016 to 2021, Cigna also allegedly knowingly submitted and/or failed to delete or withdraw inaccurate and untruthful diagnosis codes for morbid obesity to increase the payments it received from CMS for numerous beneficiaries enrolled in its MA plans, whose Body Mass Index did not

actually meet the minimum threshold required for a morbid obesity diagnosis. In connection with the settlement, Cigna entered into a five-year CIA with HHS-OIG.

Medical Devices

In October 2022, the United States secured a default judgment in the amount of $15.3 million against a chiropractor in Wichita, Kansas, along with his company, Titan Medical Compliance, LLC, for causing approximately 1,200 claims to be falsely submitted to the Federal health care programs in violation of the civil FCA. Beginning in 2014, the chiropractor promoted electro-acupuncture devices (aka P-Stim devices) as reimbursable by Medicare and other Federal health care programs and provided instructions on what codes to bill. Those codes, generating a high amount of reimbursement, were meant for legitimate, surgically implanted neurostimulators to manage chronic pain. P-Stim, on the other hand, could be applied in a few minutes in an office setting without anesthesia and by someone with minimal training. During this time, the defendants had knowledge that the P-Stim devices were not reimbursable by Federal health care programs but continued to promote the non-surgical devices anyway. This judgment is part of a national investigation into the scheme of improper billing involving P-Stim that has recovered tens of millions of dollars in the last two years. P-Stim is also branded as, among other things, ANSiStim, Stivax, NeuroStim, and NSS-2 Bridge. Federal health care programs do not reimburse for P-Stim devices, whether they are characterized as an electro-acupuncture device or as an implantable neuro-stimulator.

In December 2022, Advanced Bionics LLC, a Valencia, California, based manufacturer of cochlear implant system devices, agreed to pay more than $12 million to resolve civil FCA allegations that it misled Federal health care programs regarding the radio frequency (RF) emissions generated by some of its cochlear implant processors. The settlement resolved allegations that Advanced Bionics, in submitting pre-market approval applications to the Food FDA for Advanced Bionics' Neptune and Naida cochlear implant processors, made false claims regarding the results of its RF emissions tests. Advanced Bionics allegedly represented that its processors satisfied an internationally recognized emissions standard when, in fact, Advanced Bionics did not comply with that standard. More specifically, Advanced Bionics allegedly failed to honor the standard's requirements to test processors using worst-case configurations and improperly shielded certain emissions-generating system components during emissions testing. From January 2011 through December 2019, Advanced Bionics then allegedly sought reimbursement from Medicare, Medicaid, and other Federally funded health care programs for these devices, despite the FDA having relied on misleading statements in approving their applications. In addition to the civil settlement, Advanced Bionics entered into a five-year CIA with HHS-OIG.

In March 2023, Stimwave, LLC, (Stimwave), a medical device company based in Florida that manufactured implantable neurostimulation products, agreed to pay $8.6 million to resolve civil FCA allegations that Stimwave caused medical providers to submit false claims to Medicare by creating and selling a non-functioning dummy medical device for implantation into patients suffering from chronic pain. The government alleged that Stimwave, at the direction of its former CEO, engaged in a scheme in which Stimwave designed, created, and manufactured an inert, non-functioning component of a medical device that served no medical purpose, and instructed medical providers to surgically implant the device into patients so that medical providers could seek unlawful reimbursement payments from Medicare. The $8.6 million

payment was credited towards the $10 million monetary penalty that Stimwave was required to pay under a non-prosecution agreement.

Nursing Homes and Facilities

In November 2022, Tranquility Incorporated, d/b/a/ San Miguel Villa, a San Francisco, California, nursing home agreed to pay $2.3 million to settle allegations that it violated the civil FCA by billing the Medicare and Medi-Cal programs for grossly substandard nursing home services it provided to its residents between 2012 and 2017. The settlement resolved allegations that from 2012 to 2017, San Miguel Villa submitted, or caused to be submitted, claims to the Medicare and Medi-Cal programs for payment of its services that were grossly substandard and failed to meet minimum required standards of skilled nursing care in multiple ways. The United States alleged that nursing home residents at the facility were overmedicated with psychotropic drugs, suffered excessive falls, were exposed to resident-on-resident altercations, and experienced other mental and physical harm.

In February 2023, the landlord and several individuals and entities involved in the operation of Saratoga Center for Rehabilitation and Skilled Nursing Care (Saratoga Center), a nursing facility in Ballston Spa, New York, collectively agreed to pay more than $7.1 million to resolve allegations that they violated the civil FCA by causing the submission of false claims to the Medicaid program for worthless services provided to residents. The defendants allegedly allowed unlicensed individuals to operate Saratoga Center from February 2017 until it closed in February 2021. During that period, Saratoga Center delivered worthless services to residents, and its physical conditions deteriorated to such a degree that it violated Federal and state regulations. Specifically, the operators failed to adequately staff the home, and residents suffered medication errors, unnecessary falls, and the development of pressure ulcers. Additionally, Saratoga Center did not consistently maintain hot water throughout the facility, have an adequate linen inventory, and dispose of solid waste. In 2019, Saratoga Center was placed on the CMS Special Focus Facility list—a list of the worst-performing nursing homes in the United States. Saratoga Center remained on the list until its closure. In connection with the settlement, HHS-OIG negotiated voluntary exclusions of these individuals and entities.

In May 2023, the estate of the former owner of a skilled nursing facility in Bronx, New York, as well as the facility's former Administrator and an independent contractor, agreed to pay a total of $3.5 million to resolve civil FCA allegations that they made, or caused to be made, false claims to Medicare. The government alleged that the facility: (1) made cash payments to a supervisor at a nearby hospital for patient referrals, (2) disenrolled residents from their self-selected Medicare Advantage Plans and enrolled them in Original Medicare without their consent to increase Medicare payments, and (3) paid an independent contractor $1,000 for each resident he helped to switch to Original Medicare, and then split this fee with the former Administrator.

Pharmacies

In October 2022, a pharmacy owner and former Kentucky state representative was sentenced to 25 months in prison, followed by three years of supervised release, following a conviction for health care fraud and money laundering. In his plea agreement, the pharmacy owner admitted to a scheme in which he would bill Medicare, Kentucky Medicaid, and other health benefit programs for drug prescriptions that were never filled. Instead, the medications were placed back into the pharmacy's inventory and later resold. In addition to his prison sentence, the pharmacy owner was ordered to pay $2.7 million in restitution.

In January 2023, Walgreen Co. (Walgreens) agreed to pay $7 million to resolve allegations that it violated the civil FCA by knowingly submitting, or causing the submission of, false or fraudulent claims for payment to TennCare—the Medicaid program in Tennessee—and knowingly retaining overpayments for specialty Hepatitis C medications dispensed to TennCare enrollees who did not meet TennCare's clinical criteria for coverage and payment. The government alleged that: (1) from October 2014 to December 2016, a former pharmacist and store manager at Walgreens' specialty pharmacy in Kingsport, Tennessee falsified prior authorization requests and supporting clinical records for 65 TennCare enrollees who failed to meet clinical prior authorization requirements for Hepatitis C direct-acting antiviral (DAA) medications; (2) Walgreens improperly billed TennCare for DAAs dispensed to the TennCare enrollees based on the falsified requests; and (3) Walgreens knowingly failed to return the TennCare payments that it improperly received based on the falsified prior authorization requests, even after it became aware of its store manager's misconduct.

In April 2023, Medley Compounding Pharmacy, LLC, and others paid the United States $8 million to settle claims they improperly billed the Department of Labor, Office of Workers' Compensation Program (DOL-OWCP) in violation of the civil FCA. The United States alleged that from January 1, 2013, through December 31, 2020, the defendants knowingly submitted or caused to be submitted false claims for payment to DOL-OWCP for compounding creams, gels, and pain patches, that were neither medically necessary nor medically beneficial to the patients. In some instances, patients had never seen the prescribing physician.

(SF) In April 2023, in Miami, Florida, the beneficial owner and operator of several companies pleaded guilty to conspiracy to defraud the FDA, as well as conspiracy to commit money laundering, for his role in a scheme to illegally distribute more than $230 million in adulterated and misbranded prescription drugs that were dispensed to unsuspecting patients. The defendant illegally acquired large quantities of prescription drugs, primarily HIV medication, then created false drug labeling and other documentation to make it appear as though these high-priced drugs had been obtained legitimately. To carry out the scheme, the defendant and his co-conspirators established licensed wholesale drug distribution companies in Florida, New Jersey, Connecticut, and New York. The defendant and his co-conspirators used those companies to sell the adulterated drugs at steep discounts to other co-conspirators at wholesale pharmaceutical distributors in Mississippi, Maryland, and New York. The wholesale pharmaceutical distributors then resold the drugs to pharmacies throughout the country, which billed the drugs to health insurers, including Medicare, and dispensed the adulterated and misbranded HIV medication to unsuspecting patients. In June 2023, the defendant was sentenced to 15 years of imprisonment.

In June 2023, Smart Pharmacy, Inc., SP2, LLC, and their principal owner agreed to pay at least $7.4 million to resolve civil FCA allegations that they 1) unnecessarily added the antipsychotic drug aripiprazole to topical compounded pain creams to boost Federal reimbursement for the compounded creams, from July 2015 through December 2016; and 2) routinely waived patient copayment obligations to induce Federal health care beneficiaries to purchase compounded drugs, from January 2011 through May 2016. Aripiprazole is approved by the FDA to treat a number of psychological conditions such as schizophrenia and Tourette's disorder. The United States alleged that the defendants crushed aripiprazole pills approved for oral use and included them in compounded creams used topically for pain treatment, while knowing that there was not an adequate clinical basis to do so. The defendants allegedly included the drug in the pain creams to increase their profits on prescriptions paid for by Medicare Part D and TRICARE, the

Federal health care program for active-duty military personnel, retirees, and their families. Both Medicare Part D and TRICARE reimburse pharmacies for the individual ingredients included in compounded drugs. The defendants illegally increased their reimbursement by adding aripiprazole to the combination of drugs used in their pain creams. The government also alleged that the defendants improperly and routinely waived patient copayments to induce patients to accept the pain cream prescriptions. In connection with the settlement, the principal owner agreed to enter into a three-year integrity agreement with the HHS-OIG.

(SF) In June 2023, a pharmaceutical sales broker was convicted of charges resulting from the sale of $175 million of illegally diverted prescription HIV medication from black-market suppliers to wholesale distributors, who then sold the drugs to pharmacies with falsified product tracing documentation to make it appear that the drugs had been obtained through legitimate channels. The broker profited approximately $13 million from the scheme.

Physical Therapy

In March 2023, Physicians Primary Care (PPC), a family practice with offices located in Kentucky and Indiana, was ordered to pay a $1 million fine; the doctor owner was sentenced to 105 months of incarceration, followed by three years supervised release; and an Advance Practice Registered Nurse (APRN) was sentenced to 60 months of incarceration, followed by three years supervised release. In June 2021, after a six-and-a-half-week trial, a jury convicted PPC, the doctor owner, and the APRN of conspiracy to unlawfully distribute and dispense controlled substances. The jury also found the defendants guilty of conspiring to commit health care fraud for falsely and fraudulently billing Kentucky Medicaid, Indiana Medicaid and Medicare by submitting claims for physical therapy, counseling, and exercise services using evaluation and management codes in order to obtain higher reimbursement. The doctor and APRN were also convicted of conspiracy to commit money laundering for paying and/or receiving bonuses to incentivize the ordering of physical therapy, counseling, and exercise. Finally, the doctor owner was convicted of billing for physical therapy services using evaluation and management codes as if a physician performed a service on the patients, but in reality, a non-physician and non-physical therapist performed the service on the patients. Two other APRNs pleaded guilty, one during trial.

Physician and Other Practitioners

In April 2023, a Beverly Hills, California, plastic surgeon, along with his son, and associated medical practices and billing companies (including Tower Multi-Specialty Medical Group; Tower Wound Care Center of Santa Monica, Inc.; Tower Outpatient Surgery Center, Inc.; and Tower Medical Billing Solutions) agreed to pay $23.9 million to resolve allegations that they violated the civil FCA by submitting or causing the submission of false claims to Medicare and Medicaid concerning skin substitute products. In particular, the United States alleged that defendants manipulated the place of service code on claims for skin grafts to fraudulently maximize reimbursement from Medicare and Medicaid and billed multiple times for single-use skin substitute products, including by failing to properly dispose of unused portions of single-use skin graft materials and instead using them in later procedures involving other Medicare and Medicaid beneficiaries. The United States alleged that different aspects of this conduct occurred over various time periods between January 1, 2015, and March 21, 2021. In connection with the settlement, the plastic surgeon and his son agreed to be excluded from Federal health care programs by HHS-OIG for 15 and 3 years, respectively. Tower Multi-Specialty Medical Group agreed to be excluded for a period of 15 years as well.

In April 2023, an Arkansas doctor was sentenced to 102 months of imprisonment and ordered to pay over $4.6 million in restitution after his conviction at trial for conspiracy, wire fraud, mail fraud, violating the anti-kickback statute, lying to the FBI, falsifying/altering records, and aggravated identity theft. Marketers bribed the doctor to rubber stamp hundreds of compounded drug prescriptions for TRICARE beneficiaries whom the doctor did not know and never consulted. The doctor later attempted to obstruct the ensuing investigation by lying to the authorities, altering existing prescription slips, and creating phony medical records in response to a subpoena to make it appear his prescriptions were for bona fide patients who truly needed the drugs. The doctor's sentencing marked the end of a multi-year investigation into TRICARE-related compounding fraud that resulted in over 20 convictions in Arkansas, including three doctors, a nurse, and more than a dozen veterans of the medical sales industry.

In April 2023, a nurse practitioner in Rhode Island was sentenced to seven years in Federal prison for defrauding commercial health insurers and Medicare of nearly $12 million. The nurse practitioner had previously pleaded guilty to an eleven-count Information charging him with health care fraud, mail fraud, aggravated identity theft, and causing the introduction of misbranded drugs into interstate commerce. The nurse practitioner routinely submitted fraudulent claims for in-person patient services that he did not perform, including supposed patient visits at a ghost office in Rhode Island and at offices in Florida and New York. The nurse practitioner used seven different tax identification numbers while defrauding seven commercial insurers and Medicare out of $11.9 million.

In May 2023, a vascular surgeon from Bay City, Michigan, was sentenced to 80 months in prison for orchestrating a multimillion-dollar scheme to defraud health care programs by submitting claims for the placement of vascular stents and for thrombectomies that he did not perform, and he was ordered to pay $19.5 million in restitution collectively to Medicare, Medicaid, and Blue Cross/Blue Shield of Michigan (BCBSM). Additionally, the doctor agreed to pay the United States up to $43.4 million to resolve related civil allegations that his fraudulent billings to Federal health care programs violated the civil FCA. The doctor's scheme to defraud health insurers began as early as 2009. The plea agreement notes that he billed for the placement of multiple vascular stents in the same blood vessel and prepared medical records purporting to document the medical necessity justifying that billing. In fact, however, the doctor did not place those stents and admitted to billing for services never rendered while preparing materially inaccurate medical records to justify the fraudulent billings. The doctor also billed for arterial thrombectomies and created medical records that stated he encountered occluded arteries that would justify the performance of the procedures. However, he admitted that he often encountered no such occlusions, performed no such thrombectomies, and thus billed insurers for services never rendered while preparing false medical records to justify the fraudulent claims. The doctor's fraudulent practices resulted in $14.5 million in damages to the Federal Government, and a total of $19.5 million across Medicare, Medicaid, and BCBSM, which he agreed to repay as restitution as part of his plea agreement.

In June 2023, an Ear, Nose, and Throat physician operating in Raleigh, Lumberton, and Rockingham, North Carolina, was sentenced to 25 years in prison following her conviction on 20 criminal counts, including falsifying Medicare audits, paying kickbacks, stealing patient identities, adulterating medical devices, and conspiracy. The defendant was a top-paid Medicare provider for a procedure known as balloon sinuplasty. The defendant billed Medicare more than $46 million for the procedures between 2014 and 2018. In that time, she netted more than

$4.8 million from Medicare for these surgeries. Evidence presented at the trial demonstrated that the defendant, through her employees, marketed balloon sinuplasty, an in-office procedure to treat chronic sinusitis, as a sinus spa, and encouraged patients to come to the office for a free sinus spa, which was a treatment that they may not have needed. The defendant falsified medical records to justify the billing of balloon sinuplasty surgeries to Medicare auditors. The evidence also showed that between 2011 and the end of 2017, the defendant performed 1,555 balloon sinuplasty surgeries on 919 Medicare beneficiary patients, using the FDA-approved Entellus XprESS device. However, instead of using the device only once and only on one patient, as required by FDA guidelines, the defendant reused the devices on multiple patients. Between 2012 and 2017, the physician obtained 36 new Entellus devices, at most. The defendant failed to inform patients that they were receiving a procedure with an adulterated device. During the trial, the defendant admitted that she had sufficient money to buy every patient a new device but chose not to do so. A jury ordered the defendant to forfeit $4.8 million in proceeds from the crimes.

In June 2023, a dermatologist and his practice, Skin Cancer and Cosmetic Dermatology Center, P.C. (SCCDC), which operates 13 dermatology clinics located throughout southeast Tennessee and north Georgia, agreed to pay $6.6 million to resolve allegations that they violated the civil FCA by submitting, or causing the submission of, false or fraudulent claims for Mohs Micrographic Surgeries and other dermatological procedures. The government alleged that: (1) from January 2010 through December 2020, SCCDC knowingly billed for Mohs procedures as if the surgery and pathology portions of the procedures were performed by a single physician when in fact they were not; (2) SCCDC regularly billed Medicare for multiple procedures, performed on the same patient on the same day, in a manner that improperly circumvented Medicare's multiple procedure reduction rule; and (3) the owner of SCCDC fraudulently billed government payors under his NPI number for services performed by nurse practitioners and physician assistants who were ineligible to bill the government for the services at issue.

Prescription Drugs and Opioids

In December 2022, an Atlantic County, New Jersey, man was sentenced to 37 months in prison for his role in defrauding New Jersey state and local health benefits programs and other insurers by submitting fraudulent claims for medically unnecessary prescriptions. The individual was part of a criminal conspiracy in which state and local government employees were recruited and compensated to receive medically unnecessary compound prescription medications. He and his conspirators defrauded New Jersey health benefits programs and other insurers of more than $50 million. The individual directly caused the pharmacy benefits administrator to pay more than $1.4 million for medically unnecessary compound prescription medications for individuals he recruited into the scheme, and he received more than $430,000 in the conspiracy. In addition to the prison term, he was sentenced to three years of supervised release and ordered to pay restitution of more than $1.4 million and forfeit $437,604.

In December 2022, five defendants were sentenced for running a pill mill operation through multiple facilities in the West Texas border area. The primary defendant, a medical doctor, had previously pleaded guilty to conspiracy to distribute controlled substances and admitted that he had unlawfully prescribed Schedule II controlled substances by conducting minimal in-person examination and allowing his staff to use pre-signed prescription pads to distribute pills without him seeing the patient. The doctor received a sentence of 121 months in prison, a $10,000 fine, and agreed to pay $127,421.76 in restitution to the Texas Medicaid program. His office manager pleaded guilty to health care fraud and admitted that she had billed Medicaid for thousands of in-

person examinations from the doctor, when in fact they were conducted by mid-level practitioners. She was sentenced to 30 months in prison, as well as $127,421.76 in restitution. Three mid-level practitioners pleaded guilty to unlawful distribution of controlled substances and received sentences of 24 months, 18 months, and 12 months, respectively. All the medical practitioners involved also forfeited their licenses and DEA registrations.

In January 2023, an Iowa nurse was sentenced to 60 months of incarceration, followed by three years of supervised release, and ordered to pay $6,000 in restitution to the state. The nurse pleaded guilty in three separate Federal criminal cases to five felonies including tampering with a consumer product, false statements relating to health care matters, violating the Health Insurance Portability and Accountability Act, obtaining a controlled substance by fraud, and theft of government funds. The nurse worked at three hospitals and accessed patient records to identify patients with pain medication. The nurse then secretly acquired the patients pain medication and replaced the stolen medication with saline to be dispersed to the patients. The court noted this was one of the worst cases of narcotics theft by a health care professional it had seen.

In January 2023, a Michigan physician was sentenced to 16.5 years in prison for his role in a health care fraud scheme that resulted in over $250 million in false and fraudulent claims being submitted to Medicare, Medicaid, and other health insurance programs. The physician exploited patients suffering from addiction by administering unnecessary injections, illegally distributed over 6.6 million doses of medically unnecessary opioids, and engaged in money laundering. In September 2021, the physician was convicted at trial of conspiracy to commit health care fraud and wire fraud, health care fraud, conspiracy to defraud the United States and pay and receive health care kickbacks, conspiracy to commit money laundering, and money laundering. The physician joins 21 other defendants who were previously sentenced for participating in the same scheme. The physician owned multiple medical practices and clinical laboratories in Michigan and played a critical role in developing and implementing a "shots-for-pills" protocol at several pain clinics, whereby patients were required to receive unnecessary back injections in exchange for prescriptions of dangerous and high doses of medically unnecessary and addictive opioids. The physician excessively prescribed highly addictive opioids to his patients. In exchange for opioids, these patients would receive—or be billed as if they had received—facet joint or nerve block injections, both lucrative spinal injections. Although these spinal injections were purportedly intended to treat chronic pain, the physician injected the patients without regard to medical necessity. Evidence also revealed that if patients refused to accept the injections, he would withhold their prescriptions for opioids. From January 2012 through July 2017, the physician billed Medicare for more of these injections than any other provider in the country.

In March 2023, an Alabama doctor and his wife were each sentenced to 20 years of incarceration, followed by 120 months of supervised release. The doctor and his wife were convicted in March 2022 of drug distribution conspiracy, health care fraud, and kickback crimes. Between 2012 and 2017, the couple had run a two-location pain management practice that routinely distributed opioid prescriptions outside the course of practice to patients the doctor did not see. They also participated in health care fraud schemes, including billing for doctor office visits when the doctor was not present, and ordering tens of millions of dollars in unnecessary drug tests, topical pain cream prescriptions, braces, and nerve conduction tests. The defendants were ordered to pay more than $52 million in restitution.

In April 2023, a Bingham Farms, Michigan, physician was sentenced to 20 years in prison based on his conviction following a jury trial of thirty charges related to the unlawful distribution of prescription drugs and for health care fraud. He was also ordered to forfeit over $35 million, which represented the proceeds of drug-trafficking, property that facilitated the commission of the offense, and proceeds of the health care fraud conspiracy. In addition, the doctor was ordered to pay restitution to Medicare in the amount $5.2 million. The doctor wrote medically unnecessary prescriptions for drugs including Oxycontin, Oxycodone, morphine, hydrocodone, and Xanax and prescribed controlled substances after receiving cash from patient recruiters who brought their own patients to his practice. Trial testimony demonstrated that the doctor issued or authorized the issuance of more than 1 million opioid pills to individuals outside the course of professional medical practice and for no legitimate medical purpose in exchange for compensation. He also submitted fraudulent claims to Medicare for the office visits associated with the issuance of the controlled substance prescriptions. The doctor also sent out an unlicensed medical school graduate to perform home visits to Medicare beneficiaries and issue them prescriptions for controlled substances which had been pre-signed by him. The doctor, who was not present during the visit, directed that the fraudulent claims to Medicare be submitted as if he had performed the service.

(SF) In May 2023, a physician pleaded guilty in Texas to conspiracy to distribute and dispense controlled substances without a legitimate medical purpose and outside the usual course of professional practice for his role as supervising physician and medical director at two Houston, Texas, area cash-only, pill-mill clinics. According to court documents, from approximately May 2018 through August 2019, the defendant and his coconspirators hired nurse practitioners to see purported patients, issue prescriptions for pain medications oxycodone and hydrocodone—both Schedule II controlled substances—and document the visit as if a full evaluation had been done. In reality, patient visits were either extremely cursory or nonexistent, and the patient files were created to maintain an air of legitimacy at the clinics. During the conspiracy, the defendant resided in another state, and, in his absence, he took measures to allow the clinic staff to issue prescription on his behalf, including by pre-signing prescription pads and sharing his e-scribing credentials. In total, defendant knowingly and intentionally distributed and dispensed tens of thousands of oxycodone 30mg and hydrocodone 10-325 mg. The defendant was charged with 11 co-defendants, 10 of whom pleaded guilty, and one who was convicted at trial. The defendant and several of his codefendants await sentencing.

In May 2023, a Niles, Ohio, physician was sentenced to 72 months in prison after he pleaded guilty to illegally prescribing opioids and other controlled substances, illegally distributing controlled substances and health care fraud. The physician was also sentenced to three years of supervised release, a $5,200 special assessment, a $20,000 fine, and restitution of $148,870. According to court documents, from January 2015 through January 2022, the physician knowingly prescribed medically unnecessary controlled substances to patients outside of the usual course of professional practice and without legitimate medical purpose. In doing so, the physician fraudulently billed health care benefit programs for office visits and the controlled substances illegally dispensed. The physician also admitted to engaging in sexual acts with patients to whom he directly prescribed controlled substances, including during office visits. He also admitted to delivering dozens of oxycodone pills to one of his patients with whom he was engaged in a relationship, outside the course of treatment and without a valid prescription.

Psychiatric and Psychological Testing and Services

(SF) In January 2023, the CEO of a Federally Qualified Health Center located in Louisiana was sentenced to 82 months in prison, three years supervised release, and ordered to pay $1.8 million in restitution after being convicted of one count of conspiracy to commit health care fraud in violation of Title 18 U.S.C. § 1349 and five counts of health care fraud in violation of Title 18 U.S.C. § 1347. Additionally, the CEO was ordered to pay a fine in the amount of $30,000. The investigation revealed that the CEO's Health Clinic operated satellite clinics inside local elementary and high schools to provide routine medical services. At the CEO's direction, the clinics also taught a life skills program to classrooms of students and billed them to Medicaid as Group Psychotherapy. The investigation further revealed that to facilitate the fraudulent scheme, the CEO directed his practitioners to falsely diagnose students, including children as young as kindergartners, with serious mental health disorders. Between 2011 and 2015, his health center billed the Louisiana Medicaid program for over $1.8 Million in fraudulent claims for purported group psychotherapy services.

In February 2023, Houston, Texas, companies known as Psychiatric Solutions P.C., Longview Psychiatric Center PLLC, Longview Psychiatric Center LP, and their owner paid the United States $3 million to settle allegations that, from January 2015 through December 2021, they violated the civil FCA when they knowingly and willfully submitted, or caused the submission of, false claims to Medicare. The physician owner and the clinics allegedly submitted claims for payment to Medicare for Transcranial Magnetic Stimulation (TMS) procedures that were not performed, routinely administered TMS treatments unnecessarily and absent a valid medical purpose, and improperly billed Medicare for reimbursement of those treatments. They also billed Medicare for physician assessments when the physician did not see the patient or supervise the TMS session. The settled claims included intentionally pressuring patients to accept unnecessary medical treatments and billing for those treatments, falsifying treatment records, and billing Medicare for worthless services and services not provided.

Substance Use Treatment Centers

(SF) In October 2022, in the largest addiction treatment fraud case ever prosecuted by the DOJ, a doctor pled guilty to one count of conspiracy to commit health care fraud and wire fraud for authorizing fraudulent urine drug tests and other bogus procedures for vulnerable addiction treatment patients at over 50 treatment centers and sober homes in South Florida as the Medical Director for these facilities, in exchange for having these desperate patients sent to his own clinic where he often billed for purportedly providing them the same bogus tests. As a result of this almost 10-year scheme, private insurers were billed over $746 million and paid over $127 million for these medically unnecessary tests and services that were often procured by kickbacks, in violation of the Eliminating Kickbacks in Recovery Act. In January 2023, the owner was sentenced to 20 years in prison.

In December 2022, Camden Treatment Associates LLC, (CTA), an opioid abuse treatment facility in Camden, New Jersey, agreed to pay a total of $3.2 million to resolve criminal and civil claims that it caused kickbacks, obstructed a Federal audit, and fraudulently billed Medicaid. As part of the resolution, a criminal information was filed in Camden Federal court charging CTA with this conduct. CTA entered into a three-year deferred prosecution agreement (DPA) that requires it to abide by certain measures to avoid conviction. CTA also entered into a civil settlement agreement to pay $1.7 million to the United States to resolve claims that it violated the civil FCA by submitting fraudulent claims to Medicaid.

In March 2023, the Eastern District of Wisconsin District Court entered a default judgment against a doctor and his clinic, Healing Corner, LLC, in the amount of $2.4 million for violations of the civil FCA. Healing Corner and the doctor caused the submission of false claims to the Wisconsin Medicaid Program by ordering excess Vivitrol, a medication used to treat alcohol dependance and prevent relapse to opioid dependance. Vivitrol is administered by a health care professional to patients monthly and reimbursed by Wisconsin Medicaid at approximately $1,600 per injection. Despite prescribing, requesting refills, and receiving delivery of prescription Vivitrol from a specialty pharmacy, Healing Corner routinely did not administer the Vivitrol to the patient for whom it was prescribed. This practice generated a stockpile of excess Vivitrol, which Healing Corner administered to non-Medicaid patients for cash—often receiving over $1,000 from patients for each injection. Healing Corner also administered free samples of Vivitrol to Medicaid patients but still submitted claims to Medicaid for reimbursement.

Telemedicine Exploitation and Fraud

(SF) In October 2022, two owners and one employee of a Canadian marketing company pleaded guilty to conspiracy to defraud the United States and to pay and receive illegal kickbacks. The owners and their co-conspirators received at least $16 million in illegal kickbacks and bribes in exchange for arranging for the ordering of DME, cancer genetic testing, and other items and services that were medically unnecessary and not ordered by the patients' treating physician. The owners caused the submission of at least $32 million in fraudulent claims to Medicare as a result. One defendant was sentenced in October 2023 to 48 months of imprisonment, and another was sentenced to 27 months of imprisonment in February 2024. The remaining defendant is scheduled to be sentenced in May 2024.

(SF) In December 2022, a Valatie, New York, medical doctor was convicted of two counts of making false statements relating to health care matters in connection with false certifications of medical necessity that she signed for purported telemedicine companies. At times, the defendant did not interact with patients at all prior to signing the pre-populated prescriptions and orders for braces, pain creams, and genetic tests, which resulted in over $17 million in claims to Medicare, of which $6.4 million was paid. In May 2023, the defendant was sentenced to five years of probation, to pay $6.4 million in restitution, to forfeit $175,196 in proceeds, and to perform 2,000 hours of community service.

(SF) In April 2023, the Palm Beach County, Florida owner of a telemedicine company pled guilty to one count of conspiracy to defraud the United States and to pay and receive health care kickbacks for his role in a genetic testing scheme in which Medicare was billed at least $90 million and paid over $61 million for genetic testing orders that were medically unnecessary and procured by kickbacks. In June 2023, the owner was sentenced to 60 months in prison.

(SF) In August 2023, a physician from Ashland, Tennessee, pled guilty to conspiracy to commit health care fraud. The physician worked for a number of telemedicine companies that arranged for physicians to prescribe not medically necessary durable medical equipment, topical creams, and cancer genomic testing for individuals, including Medicare beneficiaries. He signed doctors' orders and prescriptions for these items based on brief telephonic conversations, or often no conversation at all, and without establishing a doctor-patient relationship, without seeing or physically examining the beneficiaries, and without regard to medical necessity. As a result of the orders and prescriptions the physician signed, Medicare was billed more than $41 million.

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 (5 U.S.C. App §12), 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 2023, the Secretary and the Attorney General jointly allotted $224.8 million to HHS-OIG. HHS-OIG was allocated an additional $23.3 million in HCFAC mandatory funds from the Secretary. Additionally, Congress appropriated $105.1 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.[12]

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 2023, HHS-OIG investigations resulted in 651 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid, as well as 733 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 2023 HHS-OIG excluded a total of 2,112 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 2023, 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 $1.362 billion—of which $821.4 million was in Medicare savings and $541 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 $3.35 billion, which resulted in an ROI of about $10.00 to $1.00[13]

[12] https://oig.hhs.gov/coronavirus/index.asp

[13]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.

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 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.

Strike Force Operations

In FY 2023, 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; 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 April 2023, the Strike Force announced criminal charges against 18 defendants in nine Federal districts across the United States for their alleged participation in various fraud schemes involving health care services that exploited the COVID-19 pandemic and allegedly resulted in over $490 million in COVID-19 related false billings to Federal programs and theft from Federally funded pandemic programs. In connection with the enforcement action, the department seized over $16 million in cash and other fraud proceeds. The Center for Program Integrity of the Centers for Medicare & Medicaid Services (CPI/CMS) separately announced that it took adverse administrative actions in the last year against 28 medical providers for their alleged involvement in COVID-19 schemes.

In June 2023, the Strike Force announced a strategically coordinated, two-week nationwide law enforcement action that resulted in criminal charges against 78 defendants for their alleged participation in health care fraud and opioid abuse schemes that included over $2.5 billion in alleged fraud. The defendants allegedly defrauded programs entrusted for the care of the elderly and disabled, and, in some cases, used the proceeds of the schemes to purchase luxury items, including exotic automobiles, jewelry, and yachts. In connection with the enforcement action, the Department seized or restrained millions of dollars in cash, automobiles, and real estate.

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 2023 HHS-OIG excluded 387 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 is also responsible for reinstating providers who apply and have met the requirements of their exclusions.

In FY 2023, HHS-OIG excluded a total of 2,112 individuals and entities. In addition to those mentioned in the Enforcement Actions section above, exclusion actions by HHS-OIG included:

- On March 20, 2023, OIG excluded a California neurologist for a minimum period of 55 years based on a conviction for committing non-consensual sexual acts upon multiple female patients under the guise of conducting medical exams. A jury found this individual guilty of all 63 charges related to sexual offenses to patients occurring between 2010 and 2018, including sexual battery by restraint, sexual exploitation of a patient, false imprisonment by violence, and elder or dependent adult abuse, among other charges. In addition, the court sentenced the neurologist to 332 months in prison, and the Medical Board of California revoked the individual's license to practice medicine as a physician and surgeon.
- On May 18, 2023, OIG excluded a pharmacy owner in Michigan for a minimum period of 35 years based on a conviction for conspiracy to commit wire and mail fraud related to a scheme to defraud pharmaceutical manufacturers. Specifically, this individual and co-conspirators worked together to defraud private pharmaceutical manufacturers by submitting false co-pay assistance reimbursement claims for medications that were neither prescribed nor dispensed. The court also sentenced this business owner to 72 months of incarceration and ordered that $11,916,283 in restitution be paid to multiple companies.
- On May 18, 2023, OIG excluded a Georgia pharmacist for a minimum period of 20 years due to a conviction by a jury verdict finding the individual guilty of 70 counts related to illegal dispensing and distributing controlled substances from a pill-mill pharmacy operation and one count of refusing an administrative inspection warrant. The court sentenced this individual to 188 months of incarceration, and the Nevada Board of Pharmacy revoked the professional's pharmacy license. (The individual's license in the State of Georgia lapsed and has not been renewed.)
- On May 18, 2023, OIG excluded a licensed pharmacy technician in Florida for a minimum period of 61 years based on a conviction for participating in a multi-million-dollar conspiracy to defraud the United States and pay health care kickbacks through a South Florida compounding pharmacy. Specifically, between July of 2014 and March of 2016, this individual conspired with others to pay kickbacks to patient recruiters in exchange for their referring prescriptions for unnecessary and expensive therapies to the conspirators' compounding pharmacy. These fraudulent prescriptions were issued to the Department of Defense and Department of Veterans Affairs' health care benefit

programs, resulting in approximately $88 million in financial losses to the government. The court sentenced this pharmacy technician to 60 months incarceration and ordered that approximately $75.1 million in restitution be paid.

- On June 20, 2023, OIG excluded the owner of a hospice company in California for a minimum period of eight years due to a conviction for theft of government property after the individual accepted payments under the Provider Relief Fund despite failing to meet eligibility requirements. Congress made these funds available under the CARES Act to provide emergency assistance to support health care providers that were financially impacted by the cost and care of patients infected by Covid-19. Despite attesting to compliance with the terms and conditions required for retaining these funds, this individual violated those terms by withdrawing payments for his personal use and transferring payments to another family member. The court sentenced the business owner to nine months of incarceration.
- On September 20, 2023, OIG imposed a minimum exclusion period of 24 years on a business owner convicted of perpetrating a scheme to defraud the New York Medicaid program. Specifically, the owner and business offered housing assistance to Medicaid recipients who were then required to provide their Medicaid identification numbers and submit to medically unnecessary examinations to qualify for the purported housing assistance program. Instead of providing the promised housing assistance, the owner and business used the Medicaid numbers without the recipients' consent to submit for reimbursement from the New York Medicaid program for medically unnecessary and expensive devices (e.g., custom-molded back braces) that were not provided. The court sentenced this individual to prison for a term of three to nine years and ordered that approximately $4.1 million in restitution be paid to the New York Medicaid program. The owner was also excluded by the New York Medicaid program.

Civil Monetary Penalties Law

HHS-OIG has the authority to seek CMPs, assessments, and exclusions under the Civil Monetary Penalties Law (CMPL) against a person 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 Health Care Fraud Self-Disclosure Protocol. In FY 2023, HHS-OIG concluded cases involving more than $82.9 million in CMPs and assessments.

False Claims and Kickback Affirmative Enforcement

HHS-OIG may seek a CMP or exclusion against a person that, among other things, presents a claim to Federal health care programs that the person knows or should know is false or fraudulent. HHS-OIG may also seek a CMP or exclusion against a person that knowingly and willfully violates the AKS. In FY 2023, HHS-OIG recovered more than $8.9 million and excluded 34 individuals and entities in false claims and kickback affirmative enforcement actions. Affirmative case examples include:

- In November 2022, an ambulance company entered into a $1,060,513.82 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.

- In February 2023, a physician entered into a $132,078.00 settlement agreement with HHS-OIG. The settlement agreement resolved allegations that the physician solicited and received remuneration from telemedicine and staffing companies in the form of monetary payments related to telemedicine consultations and for ordering medically unnecessary durable medical equipment and medications for Medicare beneficiaries with whom he had no physician-patient relationship and never examined.
- In June 2023, a home attendant company entered into a $866,339.25 settlement agreement with HHS-OIG. The settlement agreement resolved allegations that the company employed a personal assistant who was excluded from the New York Medicaid program and provided items or services that were billed to New York Medicaid.

Patient Dumping

HHS-OIG may also seek a CMP against any Medicare-participating hospital that 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 2023, HHS-OIG recovered more than $300,000 in cases under the EMTALA statute. EMTALA case examples follow:

- In February 2023, HHS-OIG entered into a $104,942 settlement agreement with a 271-bed acute care hospital. The settlement agreement resolved allegations that the hospital violated EMTALA. A patient presented to the Emergency Department (ED) via Emergency Medical Services (EMS) with nausea and vomiting. The patient was brought to an ED hallway. While waiting in the hallway, the patient had multiple seizures prior to any examination by the hospital. Approximately 45 minutes after arrival, ED staff moved the patient to a hospital room and began resuscitation efforts and, an hour later, the patient was pronounced deceased. Prior to these resuscitation efforts, the patient was not triaged by ED staff and had not received a medical screening examination.
- In June 2023, HHS-OIG entered into an $80,000 settlement agreement with a 157-bed acute care hospital. The settlement agreement resolved allegations that the hospital violated EMTALA. A friend brought the patient to the hospital's ED with chest pain and seizures. The friend parked in the lot across from the ED entrance. The friend ran into the ED and requested assistance getting the patient from the car. The ED registrar instructed the friend to pull around to the ambulance entrance. After returning to the vehicle, the friend managed to assist the patient out of the vehicle, but struggled to get the patient through the parking lot to the ED entrance. Right outside the ED doors, the patient collapsed, appearing to lose consciousness. Seconds later, a physician assistant walked by without acknowledgement or offering assistance. A bystander brought a wheelchair out of the ED and assisted the friend in lifting the patient into a wheelchair. The friend attempted to push the wheelchair into the ED, but the patient's legs were caught in the foot pedals. While in front of the ED entrance, the friend was waving his arms for help. The friend managed to wheel the patient into the ED and the patient was triaged. An electrocardiogram revealed that the patient had suffered a heart attack. The patient was taken to the heart catheterization lab, stopped breathing, and shortly thereafter was pronounced dead.

- In July 2023, HHS-OIG entered into a settlement agreement for $50,000 with a 53-bed acute care hospital. The settlement agreement resolved allegations that the hospital violated EMTALA. A patient who was physically disabled, bed bound, and ventilator dependent, presented to the ED via EMS after the patient's tracheostomy tube had been dislodged with profuse bleeding and continuous airway obstruction. The hospital instructed EMS to take the patient to a different facility. The hospital did not provide a medical screening examination or any stabilizing treatment for the patient's obstructed airway. EMS left with the patient. The patient went into cardiac arrest just minutes after leaving the hospital's ED and was pronounced dead upon arrival at a second hospital.

Self-Disclosure Protocol

HHS-OIG maintains the Health Fraud Care Self-Disclosure Protocol (the Protocol) whereby providers and others may voluntarily disclose instances of potential fraud involving Federal health care programs to HHS-OIG. Under the Protocol, HHS-OIG resolves these instances under the CMPL for reduced penalties and other benefits compared to affirmative cases brought by HHS-OIG or DOJ for similar conduct. HHS-OIG collected $71.9 million under the Protocol in FY 2023. Self-disclosure examples include:

- In December 2022, a Washington State based acute care hospital self-disclosed conduct to HHS-OIG and paid $14,351,283.06 for allegedly violating the Civil Monetary Penalties Law. HHS-OIG alleged that the hospital submitted claims to Medicare Part A for inpatient rehabilitation stays that did not meet Medicare coverage criteria. This self-disclosure was based on conduct hospital identified after a related audit by HHS-OIG's Office of Audit Services.
- In April 2023, an Illinois based audiology practice self-disclosed conduct to HHS-OIG and paid $4,015,227.04 for allegedly violating the Civil Monetary Penalties Law. HHS-OIG alleged that the practice submitted claims to Medicaid for audiology services billed under CPT code 92585 that were not provided as claimed because audiologists did not read, interpret, or sign automated test results.
- In May 2023, a Colorado based acute care hospital self-disclosed conduct to HHS-OIG and paid $3,093,850.47 for allegedly violating the Civil Monetary Penalties Law. HHS-OIG alleged that the hospital received payment from Federal health care programs for hyperbaric oxygen services and wound care that were not performed or supervised as claimed.
- In May 2023, a New York based acute care hospital self-disclosed conduct to HHS-OIG and paid $2,702,944.61 for allegedly violating the Civil Monetary Penalties Law. HHS-OIG alleged that the hospital paid remuneration to employees and their family members who were Federal health care program beneficiaries in the form of: (1) discounts, reduced deductibles, and cost sharing on certain items and services; (2) complimentary local telephone and television services, valet parking, and cafeteria privileges; and (3) room upgrades.
- In July, a Michigan based rehabilitation company self-disclosed conduct to HHS-OIG and paid $12,256,518.14 for allegedly violating the Civil Monetary Penalties Law. HHS-OIG alleged that the company improperly billed certain Medicare Part C plans for time-based physical therapy services and physical therapy re-evaluations.

Corporate Integrity Agreements and Enforcement

Many defendants in health care fraud cases elect to settle their cases before litigation. As part of

the settlements, defendants often agree to enter into CIAs with HHS-OIG to avoid exclusion from Federal health care programs. Under a CIA, a person commits to maintaining a structured compliance program to ensure future compliance with Federal health care program rules and disclose probable violations of law to OIG. HHS-OIG monitors providers' compliance with these agreements and imposes stipulated penalties for violations. HHS-OIG collected more than $1.5 million through disclosures under CIAs in FY 2023. An example includes:

- In June 2023, after disclosing conduct to HHS-OIG under its CIA, an Illinois-based psychiatric hospital agreed to pay $735,671.64 for allegedly violating the CMPL. HHS-OIG alleged that the hospital employed an individual that it knew or should have known was excluded from participation in the Illinois Medicaid program and that no Illinois Medicaid payments could be made for items or services the individual furnished.

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 2023, HHS-OIG issued 127 audit reports and 42 evaluations, resulting in 464 new recommendations issued to HHS operating divisions, HHS grantees, and other entities. During this same period, 493 HHS-OIG recommendations were implemented.

Select examples of HHS-OIG's audit and evaluation findings in FY 2023 are listed below and organized by reports that: (1) minimize risks to people served by HHS programs, and (2) safeguard programs from improper payments and fraud.

<u>Minimize Risks to People Served by HHS Programs</u>

Nursing Homes Reported Wide-Ranging Challenges Preparing for Public Health Emergencies and Natural Disasters. In June 2022, an estimated 77 percent of nursing homes located in areas at greater risk for natural disasters reported challenges with emergency preparedness activities intended to ensure that resident care needs are met during an emergency. Nursing homes reported concerns across seven topic areas, with preparedness activities related to ensuring proper staffing during emergencies and transporting residents during evacuations being the most problematic. Of the nursing homes that reported a challenge, only about a quarter received a deficiency for emergency preparedness in their most recent compliance survey by the Centers for Medicare & Medicaid Services (CMS). The findings in this report align with prior OIG work and highlight the vulnerabilities in nursing homes' preparedness efforts that may not always be identified during CMS's compliance surveys. CMS's efforts to implement existing OIG recommendations will help address some of the emergency preparedness challenges identified in this report. This data brief contained no recommendations. (OEI-06-22-00100).

Home Health Agencies Failed To Report Over Half of Falls With Major Injury and Hospitalization Among Their Medicare Patients. Among Medicare home health patients

hospitalized for falls with major injury, over half of the falls were not reported on Outcome Assessment Information Set (OASIS) assessments by home health agencies (HHAs) as required. HHAs with the lowest Care Compare major injury fall rates reported falls less often than HHAs with higher Care Compare fall rates. For many falls, there was no OASIS assessment at all associated with the hospitalization. These findings indicate that the Care Compare home health major injury falls quality measure provides the public with inaccurate information. CMS concurred with all of our recommendations, which were for it to: (1) take steps to ensure the completeness and accuracy of the HHA-reported OASIS data used to calculate the falls with major injury quality measure; (2) use data sources, in addition to OASIS assessments, to improve the accuracy of the quality measure related to falls with major injury; (3) ensure that HHAs submit required OASIS assessments when their patients are hospitalized; and (4) explore whether improvements to the quality measure related to falls can also be used to improve the accuracy of other home health measures. (OEI-05-22-00290).

One Quarter of Medicaid Enrollees with HIV May Not Have Received Critical Services in 2021. In 2021, over a quarter of Medicaid enrollees with Human Immunodeficiency Virus (HIV) did not have evidence in their claims data of receiving one or more critical services—medical visits, viral load tests, and antiretroviral therapy (ART) prescriptions. These findings demonstrate that further action is needed to ensure that enrollees are receiving appropriate HIV care. Of particular concern, over 11,000 enrollees did not have evidence of receiving any of the three services we reviewed. These services are recommended by the Department of Health and Human Services (HHS) for all people with HIV and are vital to their overall health as well as the prevention of HIV transmission within the general population. This report data brief contained no recommendations. (OEI-05-22-00240).

The Risk of Misuse and Diversion of Buprenorphine for Opioid Use Disorder Appears to Be Low in Medicare Part D. Almost all Medicare Part D enrollees who received buprenorphine to treat their opioid use disorder received the recommended amounts in 2021; a very small number either received very high average daily dosages of buprenorphine or received buprenorphine at the same time as they received high amounts of opioids indicated for pain. Most prescribers ordered buprenorphine for a limited number of Part D enrollees; very few had patterns that raise concern. CMS concurred with our recommendations for it to: (1) inform providers about buprenorphine use and the low risk of diversion to encourage providers to treat more Part D enrollees who have opioid use disorder; (2) take steps to inform providers about the availability of buprenorphine combination products in Part D, which can minimize the risk of misuse and diversion; and (3) follow up on the prescribers with concerning patterns identified in this report. While CMS did not indicate whether it concurred with our recommendation for it to monitor the use of buprenorphine and share information, as appropriate, with Departmental partners, it did indicate ongoing activity it felt was responsive. (OEI-02-22-00160).

Home Health Agencies Used Multiple Strategies To Respond to the COVID-19 Pandemic, Although Some Challenges Persist. Home health agencies (HHAs) used their own strategies to help address challenges that the COVID-19 pandemic presented related to staffing and infection control, and HHAs benefited from CMS support such as regulatory flexibilities and expanded telehealth allowances, but challenges with staffing and telehealth persist. Our findings can help CMS identify how to help HHAs prepare for and respond to future emergencies, as well as to evaluate how changes to the home health landscape can better serve patients. CMS concurred with our recommendations that CMS: (1) evaluate how HHAs are using telehealth—specifically,

the types of services and the characteristics of patients who benefit from these services; (2) inform decision making and evaluate how the regulatory flexibilities it has offered in response to the COVID-19 Public Health Emergency affect the quality of home health care; and (3) in collaboration with the Administration for Strategic Preparedness and Response's (ASPR's) Technical Resources, Assistance Center, and Information Exchange, apply lessons learned from the COVID-19 pandemic to update and/or develop emergency preparedness trainings and materials for HHAs on responding to infectious disease outbreaks. (OEI-01-21-00110)

Long-Term Trends of Psychotropic Drug Use in Nursing Homes. Overall, psychotropic drug use in nursing homes was relatively constant from 2011 through 2019; about 80 percent of Medicare's long-stay nursing home residents were prescribed a psychotropic drug. While CMS focused its efforts on reducing the use of antipsychotics, the use of anticonvulsants increased. Additionally, over time the number of unsupported schizophrenia diagnoses increased and, in 2019, these diagnoses were concentrated in relatively few nursing homes. Our findings identified ways that CMS can enhance its monitoring of the use of psychotropic drugs in nursing homes. CMS concurred with our recommendations that CMS: (1) evaluate the use of psychotropic drugs among nursing home residents to determine whether additional action is needed to ensure that use among residents is appropriate and (2) use data to identify nursing homes or nursing home characteristics that are associated with a higher use of psychotropic drugs and focus oversight on nursing homes in which trends may signal inappropriate use. CMS did not concur with our recommendation for CMS to expand the required data elements on Medicare Part D claims to include a diagnosis code. (OEI-07-20-00500)

More Than a Thousand Nursing Homes Reached Infection Rates of 75 Percent or More in the First Year of the COVID-19 Pandemic; Better Protections Are Needed for Future Emergencies. Nursing homes had an initial surge of COVID-19 cases during the spring of 2020 and then a greater surge during the fall of that year, well after they were known to be vulnerable. More than 1,300 nursing homes had extremely high infection rates during these surges. In each of these nursing homes, 75 percent or more of the Medicare beneficiaries were diagnosed with COVID-19 or likely COVID-19 during the 2-month surge periods. These nursing homes were more common and geographically widespread during the second surge than the first, even though they were known to be vulnerable. Facilities with these extremely high infection rates experienced an average overall mortality rate approaching 20 percent—roughly double that of other nursing homes. Our findings indicate that significant changes are needed to protect residents and better prepare for current and future health emergencies. Moreover, our findings lend urgency to the Biden administration's recent initiative to improve safety and quality care in nursing homes. CMS concurred with our recommendations that CMS: (1) re-examine current nursing staff requirements and revise them as necessary and (2) target nursing homes in most need of infection control intervention and provide enhanced oversight and technical assistance to these facilities as appropriate. CMS neither concurred nor nonconcurred with our recommendation to improve how surveys identify infection control risks to nursing home residents and strengthen guidance on assessing the scope and severity of those risks. (OEI-02-20-00491)

For Medicaid-Enrolled Children Diagnosed With Lead Toxicity in Five States, Documentation Reviewed for Diagnoses and Treatment Services Raises Concerns. In five States, most of the medical records that our study reviewed for children with a lead toxicity diagnosis in their Medicaid claims lacked adequate information to confirm a diagnosis of lead toxicity, and among children for whom there was sufficient medical record documentation to confirm their diagnosis,

many did not receive comprehensive follow-up testing and treatment services, as recommended, for their identified blood lead level. Our findings can help CMS address concerns related to oversight of the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program and ensure that Medicaid-enrolled children with lead toxicity are given the best possible health care. CMS concurred with our recommendations that CMS: (1) explore the discrepancy between Medicaid claims data and medical documentation for lead toxicity and implement solutions to ensure better oversight of the EPSDT program and (2) issue guidance to reiterate State obligations under the EPSDT benefit to ensure access to services to correct or ameliorate confirmed blood lead levels identified during screenings. (OEI-07-18-00370)

Keystone First Should Improve Its Procedures for Reviewing Service Requests That Require Prior Authorization. Keystone First did not comply with Federal and State requirements when denying 76 of the sampled denied service requests. Specifically, Keystone First should not have denied the overnight care portion of 10 denied sampled pediatric skilled nursing service requests on the basis that it had not received work or school verification documentation for the caregiver. For 72 denied service requests, Keystone First's denial letter, based on Pennsylvania's required form, did not inform beneficiaries of their right to request a State fair hearing after exhausting the Managed Care Organization's (MCO's) appeals process. Denying overnight care that should be approved could place the health and safety of the beneficiary at risk. If beneficiaries do not receive information about their right to request a State fair hearing, they may not have the information needed to enable them to understand the totality of the appeals process and their rights and options within that process. Both Keystone First and CMS concurred with our recommendations that Keystone First coordinate with Pennsylvania to: (1) update Keystone First's administrative process to require that medical directors assess whether overnight care requests meet the medical necessity requirement, even if some documentation is missing; (2) review all pediatric skilled nursing service requests for which overnight care was completely denied and determine whether overnight care requests meet the medical necessity requirement; and (3) implement a revised initial denial notice to explain that a beneficiary has the right to request a State fair hearing after exhausting the MCO's appeals process.(A-03-20-00201)

Georgia Did Not Comply With Federal Waiver and State Requirements at All 20 Adult Day Health Care Facilities Reviewed. Georgia did not fully comply with Federal waiver and State requirements in overseeing providers that serve vulnerable adults receiving adult day health care services through the program. Of the 20 providers that we reviewed, 19 did not comply with 1 or more health and safety requirements, and 18 did not comply with 1 or more administrative requirements. We found 312 instances of provider noncompliance, including 126 instances of noncompliance with health and safety requirements. The remaining 186 instances related to administrative requirements, some of which could significantly affect health and safety. Georgia did not fully comply with Federal waiver and State requirements because its inspections of facilities were insufficient to ensure a continuously safe and nonhazardous environment. Georgia concurred with our recommendations that it ensure that providers correct the 312 instances of provider noncompliance identified in this report; improve its oversight and monitoring of providers; and work with providers to improve their facilities, staffing, and training. (A-04-22-00134)

CMS Did Not Accurately Report on Care Compare One or More Deficiencies Related to Health, Fire Safety, and Emergency Preparedness for an Estimated Two-Thirds of Nursing Homes. For 67 of the 100 sampled nursing homes, CMS did not accurately report on Care Compare 1 or

more deficiencies that surveyors identified during yearly and complaint inspections. The deficiencies consisted of health deficiencies for 34 nursing homes, fire safety deficiencies for 52 nursing homes, and emergency preparedness deficiencies for 2 nursing homes. In addition, for 42 of the 100 sampled nursing homes, CMS did not report on Care Compare the results of all yearly fire safety and emergency preparedness inspections. Based on our sample results, we estimated that 10,303 nursing homes had 1 or more deficiencies identified during inspections that were not accurately reported on Care Compare. Specifically, we estimated that 5,228 nursing homes had health deficiencies, 7,996 nursing homes had fire safety deficiencies, and 308 nursing homes had emergency preparedness deficiencies that were not accurately reported on Care Compare. In addition, we estimated that for 6,458 nursing homes CMS did not report on Care Compare the results of all yearly fire safety and emergency preparedness inspections. CMS partially concurred with our recommendations that it: (1) correct the inaccurately reported deficiencies that we identified for the sampled nursing homes; and (2) strengthen its processes for reviewing inspection results reported on Care Compare by requiring State survey agencies to verify the deficiencies reported, providing technical assistance and additional training to State survey agencies, and verifying that nursing home inspection results are accurately reported. (A-09-20-02007)

New York Did Not Ensure That a Managed Care Organization Complied With Requirements for Denying Prior Authorization Requests. For 35 of 70 sampled denials, New York's oversight of Centers Plan for Healthy Living (CPHL) ensured that CPHL complied with Federal and State requirements when it initially denied prior authorization requests for services and items. These denials were overturned by the State Department of Financial Services or State Office of Temporary and Disability Assistance based on additional information provided during the appeal process. However, for the remaining 35 sampled denials, we determined that CPHL justified the denials by citing incorrect information in denial notices issued to the associated Medicaid enrollees. Ultimately, the enrollees' access to requested services associated with these sampled claims were delayed a median of 75 days and, in one case, as many as 282 days, which may have significantly impacted the health and safety of Medicaid enrollees. We determined that New York's monitoring was not effective to ensure that CPHL complied with requirements for denying prior authorization requests. New York did not—and was not required to—regularly obtain and review information related to Managed Care Organizations' (MCOs) initial denials and internal appeals of prior authorization requests. Rather, New York relied on its retrospective review of a sample of prior authorization denials during its biennial operational surveys and other data. Without obtaining and reviewing information related to MCOs' initial denials and internal appeals, New York had limited ability to conduct effective oversight of CPHL's prior authorization practices. New York did not indicate concurrence or nonconcurrence with our recommendation that New York: (1) use the finding in this report to determine whether CPHL was noncompliant and determine whether a corrective action plan or other sanctions are appropriate, (2) review CPHL's appeal process and ensure that CPHL makes any necessary changes to comply with requirements for denying services, and (3) implement procedures to obtain and review information related to MCOs' initial denials and internal appeals. (A-02-21-01016)

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

CMS Should Strengthen Requirements for State Oversight and External Medical Reviews of Prior Authorization Denials in Medicaid Managed Care. Overall, the Managed Care

Organizations (MCOs) included in our review denied one out of every eight requests for the prior authorization of services in 2019, and some MCOs denied prior authorizations at rates greater than 25 percent. Despite the high number of denials, most State Medicaid agencies reported limited oversight of denials and did not offer external medical reviews of denied prior authorization requests. More action is needed to improve the oversight of denials in Medicaid managed care and the safeguards to ensure that enrollees have access to all medically necessary and covered services. CMS concurred with our recommendation for it to work with States to identify and address MCOs that may be issuing inappropriate prior authorization denials. CMS did not indicate whether it concurred with our recommendations to: (1) require States to review the appropriateness of a sample of MCO prior authorization denials regularly; (2) require States to collect data on MCO prior authorization decisions; (3) issue guidance to States on the use of MCO prior authorization data for oversight; and (4) require States to implement automatic external medical reviews of upheld MCO prior authorization denials. (OEI-09-19-00350).

Toolkit: Analyzing Telehealth Claims to Assess Program Integrity Risks. This toolkit provides detailed information on methods to analyze telehealth claims to identify program integrity risks associated with telehealth services. It is based on the methodology that the OIG developed for the report Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks (OEI-02-20-00720), which identified Medicare providers whose billing for telehealth services poses a high risk to Medicare. This toolkit is intended to assist public and private sector partners—such as Medicare Advantage plan sponsors, private health plans, State Medicaid Fraud Control Units, and other Federal health care agencies—in analyzing their own telehealth claims data to assess program integrity risks in their programs. (OEI-02-20-00723).

Labs With Questionably High Billing for Additional Tests Alongside COVID-19 Tests Warrant Further Scrutiny. In 2020, 378 labs billed Medicare Part B for questionably high levels of add-on tests alongside COVID-19 tests. These outlier labs consisted of labs for which: (1) add-on tests constituted a high proportion of each lab's total number of tests and/or (2) add-on tests constituted a high proportion of each lab's total payments for tests. Some outlier labs often billed for add-on tests in combinations that had little if any variation across patients. The add-on tests significantly increased the per-claim amounts that Medicare Part B paid to these labs. Such high levels of billing for add-on tests raise concern about potential waste or fraud, suggesting a need for further scrutiny of billing by these labs. OIG has referred these labs to CMS for further review. This report contained no recommendations. (OEI-09-20-00510)

Medicare Part B Spending on Lab Tests Increased in 2021, Driven By Higher Volume of COVID-19 Tests, Genetic Tests, and Chemistry Tests. Medicare Part B spent $9.3 billion on laboratory tests in 2021, a 17-percent increase from 2020. The increase in spending was driven by increased volume in three test categories: COVID-19 tests, genetic tests, and chemistry tests. Genetic tests exceeded pre-pandemic spending levels, while chemistry tests increased from 2020 but did not fully return to pre-pandemic spending levels. However, the decline between pre-pandemic levels for chemistry tests and the 2020 and 2021 levels could indicate that people are not seeking the routine or preventive care appointments where these tests are ordered. The second year in a row of low volume for chemistry tests raises questions about the pandemic's long-term impact on Medicare enrollee health. The data brief contained no recommendations. (OEI-09-22-00400)

The Inability To Identify Denied Claims in Medicare Advantage Hinders Fraud Oversight. Detailed data about the services provided to enrollees are essential for combating fraud and abuse in Medicare and Medicaid. We found that there is no definitive method to identify denied claims in the Medicare Advantage encounter data, and the lack of a denied-claim indicator in these data hinders program integrity oversight. Oversight entities—including CMS program integrity staff, OIG investigators and analysts, and DOJ health care fraud staff—reported that a denied-claim indicator in the Medicare Advantage encounter data would enhance the efficiency, scope, and accuracy of their efforts to combat fraud, waste, and abuse. However, CMS does not require Medicare Advantage organizations (MAOs) to submit a denied-claim indicator because CMS's Medicare Plan Payment Group does not need this indicator to determine payments to MAOs. To strengthen Medicare Advantage program oversight and combat fraud, we recommend that CMS require MAOs to definitively indicate on Medicare Advantage encounter data records when they have denied payment for a service on a claim. CMS did not concur or nonconcur with our recommendation. (OEI-03-21-00380)

CMS Should Bolster Its Oversight of Manufacturer-Submitted Average Sales Price Data To Ensure Accurate Part B Drug Payments. While CMS has some oversight procedures in place to review data on ASPs for Medicare Part B drugs, gaps exist in its oversight that allowed inaccurate data to impact Part B payment amounts. Because of invalid or missing ASP data, CMS could not calculate an ASP-based payment amount for 8 percent of drug codes at least once between 2016 and 2020. In total, we found that 24 percent of drug codes were missing ASP data for one or more specific drugs within that code in at least one quarter between 2016 and 2020. In addition, CMS reported that late ASP data submissions from manufacturers substantially hindered its ability to conduct effective oversight. CMS concurred with our recommendation that CMS build a strategy to strengthen its internal controls for ensuring the accuracy of Part B drug payments. (OEI-03-21-00390)

Manufacturers May Need Additional Guidance To Ensure Consistent Calculations of Average Sales Prices. We identified a small number of inconsistencies in how ASPs for Medicare Part B drugs are calculated and nine specific areas for which manufacturers believe additional CMS guidance may be needed to ensure more accurate ASP calculations. The manufacturers we surveyed also expressed concerns that CMS has published comparatively fewer regulations and less overall guidance regarding the calculation of the ASPs used in Medicare compared to the average manufacturer prices and best prices used in Medicaid. As a result, manufacturers say they must rely on reasonable assumptions to a much greater extent when calculating ASP than they do with these other payment benchmarks. CMS concurred with our recommendation that CMS actively review current guidance related to the nine areas identified in our report and determine whether additional guidance would ensure more accurate and consistent ASP calculations. (OEI-BL-21-00330)

Technical Assistance Brief: Implementation of Inflation-Indexed Rebates for Part B Drugs. On the basis of our prior oversight work, we anticipate that unless CMS takes action to remedy several administrative issues, it will face the following challenges in implementing inflation-indexed rebates for Part B drugs: (1) identifying products subject to Part B rebates, and (2) excluding claims from Part B rebate calculations that were already subject to rebates under the Medicaid Drug Rebate Program and to discounts under the 340B Drug Discount Program. We propose potential solutions to mitigate each administrative issue. This technical assistance brief contained no recommendations. (OEI-BL-23-00170)

Medicaid Fraud Control Units Fiscal Year 2022 Annual Report. This annual report provides statistics that highlight the accomplishments of the 53 MFCUs during FY 2022. In FY 2022, MFCUs reported 1,327 convictions (946 convictions for fraud; 381 convictions for patient abuse or neglect). Fraud convictions involved more personal care attendants than any other provider type. Nurse's aides and nurses/physician assistants had the highest numbers of convictions for patient abuse or neglect. Criminal recoveries from convictions totaled $416 million. MFCUs reported 553 civil settlements and judgments. Pharmaceutical manufacturers accounted for more civil settlements and judgments than any other provider type. MFCUs reported civil recoveries of $641 million. Combined recoveries from criminal and civil cases totaled nearly $1.1 billion. MFCUs achieved a return of $3.08 for each dollar spent. The report appendix summarizes beneficial practices that may be useful to other MFCUs. This report contained no recommendations. (OEI-09-23-00190)

Medicare Paid Independent Organ Procurement Organizations Over Half a Million Dollars for Professional and Public Education Overhead Costs That Did Not Meet Medicare Requirements. Our objective was to determine whether independent Organ Procurement Organizations' (OPOs) professional and public education overhead costs met Medicare requirements. Based on our sample results and additional findings we identified during our reconciliation, we estimated that $664,295 (consisting of an estimated $598,510 based on our sample results and $65,785 for our reconciliation findings) of the $50.9 million paid for professional and public education overhead costs was unallowable. The OPOs reported unallowable costs because: (1) they misunderstood Medicare requirements and (2) their staff made administrative errors or were not aware that costs did not meet Medicare requirements. We recommended that CMS: (1) instruct the Medicare administrative contractor (MAC) to recover $72,208 in unallowable Medicare payments by adjusting the applicable OPOs' Medicare cost reports to correct the $148,750 of unallowable professional and public education overhead costs reported, consistent with relevant laws and the agency's policies and procedures; and (2) update applicable Medicare requirements to clarify which types of professional and public education overhead costs are unallowable, which could have saved Medicare an estimated $664,295 for professional and public education overhead costs during our audit period. CMS concurred with our recommendations. (A-09-21-03020)

Payments Made to Providers Under the Covid-19 Accelerated and Advance Payments Program Were Generally in Compliance with the CARES Act and Other Federal Requirements. Our objective was to determine whether COVID-19 Accelerated and Advanced Payments (CAAP) Program payments were made to providers in compliance with the CARES Act and other Federal requirements. Our audit covered $103.1 billion in total CAAP Program payments made to 46,373 providers. We found CMS generally made CAAP Program payments to providers in compliance with the CARES Act and other Federal requirements. Of the 109 providers in our sample, CMS appropriately made CAAP Program payments to all 100 providers that we randomly selected. For the nine providers under bankruptcy, CMS did not send a CAAP Program payment to six of the providers; however, CMS did make a CAAP program payment to three of the providers. Based on our sample, we found that CMS and its MACs generally made CAAP Program payments to providers in compliance with the CARES Act and other Federal requirements. Although the MACs erroneously approved CAAP Program payments to nine providers under bankruptcy, the MACs immediately identified their errors, stopped payments to six providers, and recovered improper payments made to the other three providers. We did not have any recommendations. (A-05-20-00053)

CMS Can Use OIG Audit Reports To Improve Its Oversight of Hospital Compliance. Of the 387 improperly paid claims identified in our previous 12 hospital compliance audits, 333 were inpatient claims that resulted in $5,260,147 in net overpayments, and 54 were outpatient claims that resulted in $53,729 in net overpayments. Of these 387 improperly paid claims, 229 were appealed at the first level; 22 were overturned. In addition, 126 claims were appealed at the second level; 6 were overturned. As a result, 359 overpayment determinations totaling $5,041,721 remained. After considering the results of the first and second levels of appeal, we determined that the total overpayments received by the 12 hospitals was $82 million. CMS has taken some actions to ensure that the recommendations in our previous 12 audits were implemented. However, CMS provided us with insufficient information regarding our recommendations to repay funds, and we could not determine whether it had implemented our recommendations. In addition, CMS provided us with insufficient information regarding our recommendations to follow the 60-day rule; therefore, we could not ensure that our recommendations were implemented. With respect to our recommendations to strengthen internal controls, CMS acted on most but not all of these recommendations. We made several recommendations, including that CMS: (1) continue to follow up on the overpayment recovery recommendations contained in the 12 audits and (2) improve tracking and responding on the status of claims identified in our reports as they proceed through the appeals process. CMS concurred with three of our recommendations but requested we remove two others. (A-04-21-08084)

Medicare Could Have Saved Up To $128 Million Over 5 Years if CMS Had Implemented Controls To Address Duplicate Payments for Services Provided to Individuals With Medicare and Veterans Health Administration Benefits. We found that Medicare paid providers for medical services that were authorized and paid for by VA's community care programs during our audit period, resulting in duplicate payments of up to $128 million. VHA is solely responsible for paying providers for medical services that it authorized. These duplicate payments occurred because CMS did not implement controls to address duplicate payments for services provided to individuals with Medicare and VHA benefits. Specifically, CMS did not establish a data-sharing agreement with VHA for the ongoing sharing of data between the two agencies and did not develop an interagency process to include VHA enrollment, claims, and payment data in CMS's data repository. Inclusion of these data, which is required by Federal law, would have allowed CMS to compare VHA claims data with existing Medicare claims data to identify duplicate claims paid for by both Medicare and VHA. Because CMS did not develop an interagency process, CMS did not establish an internal process (such as claims processing system edits) to address duplicate payments for medical services authorized and paid for by VHA. Furthermore, CMS guidance to providers on VA's responsibility to pay for medical services did not clarify that a provider should not bill Medicare for a medical service that was authorized by VHA. We recommended that CMS: (1) establish a comprehensive data-sharing agreement with VHA for the ongoing sharing of data; (2) establish an interagency process to integrate VHA enrollment, claims, and payment data into the CMS Integrated Data Repository to identify potential fraud, waste, and abuse under the Medicare program; (3) establish an internal process (such as system edits) to address duplicate payments made by Medicare for medical services authorized and paid for by VHA, which could have saved Medicare up to $128 million during our audit period; and (4) issue guidance to providers on not billing Medicare for a medical service that was authorized by VHA. CMS concurred with all of our recommendations and described actions that it had

taken or planned to take to address our recommendations, including working to develop processes to address duplicate payments for services authorized and paid for by VHA. (A-09-22-03004)

Medicare Improperly Paid Acute-Care Hospitals for Inpatient Claims Subject to the Post-Acute-Care Transfer Policy Over a 4-Year Period, but CMS's System Edits Were Effective in Reducing Improper Payments by the End of the Period. From 2019 through 2022, Medicare improperly paid $41.4 million to acute-care hospitals for inpatient claims subject to the post-acute-care transfer policy. These hospitals improperly billed these claims by using the incorrect discharge status codes. Specifically, they coded these claims as discharges to home or to certain types of health care institutions rather than as transfers to post-acute care. Medicare makes the full Medicare Severity Diagnosis-Related Group (MS DRG) payment to an acute care hospital that discharges an inpatient to home or certain types of health care institutions, but pays an acute-care hospital that transfers an enrollee to post-acute care a per diem rate for each day of the enrollee's stay in the hospital. The overpayment of $41.4 million represented the difference between the amount of the full MS-DRG payments and the amount that would have been paid if the per diem rates had been applied. These improper payments were made because CMS's system edits were not effective in detecting inpatient claims subject to the transfer policy in October and November 2019 and from October 2020 through March 2022. However, after CMS fixed the edits in April 2022, improper payments significantly decreased through the end of the audit period. We recommend that CMS: (1) direct the Medicare contractors to recover from acute-care hospitals the portion of the $41.4 million in identified overpayments for our audit period that are within the 4-year reopening period and (2) instruct the Medicare contractors to notify appropriate providers so that the providers can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule. CMS concurred with our recommendations. (A-09-23-03016)

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS. HHS-OIG found that HumanaChoice, with respect to seven 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 157 of the sampled 210 enrollee-years, diagnosis codes that HumanaChoice submitted to CMS but were not supported in the medical records. As a result, we estimated that HumanaChoice received at least $27.3 million in net overpayments for 2015 and 2016. (A-05-19-00013)

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS. HHS-OIG found that Excellus, with respect to seven 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 202 of the sampled 210 enrollee-years, diagnosis codes that Excellus submitted to CMS but were not supported in the medical records. As a result, we estimated that Excellus received at least $5.4 million in net overpayments for 2017 and 2018. Because of Federal regulations that limited the use of extrapolation for recovery purposes, we recommended a refund of $3.1 million. (A-07-20-01202)

Medicare Improperly Paid Physicians for Epidural Steroid Injection Sessions. Medicare did not always pay physicians for epidural steroid injection sessions in accordance with Medicare

requirements. For our audit period, Medicare improperly paid physicians $3.6 million on behalf of beneficiaries who received more epidural steroid injection sessions than were permitted by the coverage limitations in the applicable local coverage determinations. These improper payments occurred because neither CMS's oversight nor the Medicare Administrative Contractors' (MACs) oversight was adequate to prevent or detect improper payments for epidural steroid injection sessions. After our audit period, all 12 MAC jurisdictions updated their Local Coverage Determinations (LCDs) with revised coverage limitations that were specific to epidural steroid injections. (A-07-21-00618)

Medicare Improperly Paid Physicians an Estimated $30 Million for Spinal Facet-Joint Interventions. Medicare did not pay physicians for some spinal facet-joint interventions in accordance with Medicare requirements and guidance. Of the 120 sampled sessions, 66 sessions did not comply with 1 or more of the requirements. As a result, Medicare made improper payments to physicians in the amount of $18,084. Based on sample results, we estimated that Medicare improperly paid physicians $29.6 million for facet-joint interventions for our audit period. In addition, of the 120 sampled sessions, 43 had claim lines that were billed for at least 1 therapeutic facet-joint injection. Of these 43 sessions, 33 sessions did not meet Medicare guidance, i.e., had claim lines that should have been billed for diagnostic instead of therapeutic facet-joint injections. This improper billing did not result in improper payments because Medicare pays the same amount for diagnostic and therapeutic facet-joint injections. The MACs education of physicians and their billing staff varied across their jurisdictions and was not always sufficient to ensure compliance with Medicare requirements and guidance. (A-09-22-03006)

Telehealth During 2020 Helped Ensure End-Stage Renal Disease Patients Received Care, But Limited Information Related to Telehealth Was Documented. Providers documented limited information related to telehealth services in the medical records, but the end-stage renal disease (ESRD)-related telehealth service claim lines generally met certain Medicare requirements. Most medical records for sampled claim lines included documentation identifying that the service was provided via telehealth but did not include documentation that would allow us to determine whether the services were provided using 1) audiovisual interactive technology and 2) technology that was non-public-facing. Although OIG did not make any recommendations, we believe it would be beneficial for the medical records to document the type of telecommunications system used to perform the telehealth visit. This information may be beneficial to CMS and Office for Civil Rights (OCR) when considering future oversight mechanisms or changes regarding remote communication products.

CMS does not oversee or enforce whether the telecommunications systems used to provide telehealth services are non-public-facing; the Health and Human Service's Office for Civil Rights (OCR) has responsibility for oversight of this requirement. Any information in this report regarding non-public-facing telecommunications systems used is for informational purposes only. (A-05-22-00015)

CMS's Oversight of Medicare Payments for the Highest Paid Molecular Pathology Genetic Test Was Not Adequate To Reduce the Risk of up to $888.2 Million in Improper Payments. CMS and the MACs oversight of Medicare payments for CPT code 81408 did not: (1) ensure that all Medicare enrollees had established relationships with ordering providers; (2) ensure that Medicare payments for CPT code 81408 were related to diseases associated with genes that would generally be tested and billed under that CPT code; and (3) include adequate monitoring

of the number of tests billed under CPT code 81408, a Tier 2 molecular pathology procedure (MPP) code, to determine whether that number exceeded the number of tests billed under Tier 1 MPP codes. (Tier 2 MPPs are generally performed in lower volumes than Tier 1 MPPs because the diseases being tested for are rare.) In addition, not all MACs could identify the specific gene tested by laboratories billing CPT code 81408. Finally, although five of the seven MACs had Local Coverage Article guidance that prohibited or limited use of CPT code 81408, two MACs' Local Coverage Articles did not limit its use. Although CMS officials stated that CMS conducts data analysis (e.g., to identify high-risk providers), CMS did not ensure that the MACs provided sufficient oversight over billing of and payments for CPT code 81408. Two of the MACs' payments made up 97 percent of the total payments for CPT code 81408 for our audit period. Because there were no longer payments for this CPT code by the end of our audit period (December 31, 2021), we consider the issues identified by this audit corrected. However, based on the results of our audit, up to $888.2 million in Medicare payments made for CPT code 81408 claims that we identified for our audit period were at risk of improper payment. (A-09-22-03010)

Medicare Paid Millions More for Physician Services at Higher Nonfacility Rates Rather Than at Lower Facility Rates While Enrollees Were Inpatients of Facilities. Medicare sometimes paid higher nonfacility rates rather than lower facility rates for physician services while enrollees were Part A skilled nursing facility (SNF) or hospital inpatients. During the 2-year audit period, Medicare made overpayments of $22.5 million for 1,130,182 claim lines by paying the nonfacility rate for services coded as furnished in a nursing facility or SNF setting without Part A coverage while enrollees were a Part A SNF inpatients. CMS did not have Common Working File (CWF) system edits to detect these coding errors. Similarly, while enrollees were Part A SNF or hospital inpatients, Medicare paid an additional $22.1 million for 1,012,203 physician service claim lines coded as furnished in a nonfacility setting. CMS has expressed reluctance to take enforcement action for these claim lines because neither statute nor CMS's regulation specifically addresses situations in which a SNF or hospital inpatient leaves to receive a physician service in a nonfacility setting. (A-04-21-04084)

Medicare Improperly Paid Providers for Some Psychotherapy Services, Including Those Provided via Telehealth, During the First Year of the COVID-19 Public Health Emergency
Providers did not meet Medicare requirements and guidance when billing for some psychotherapy services, including services provided via telehealth. For 128 sampled enrollee days, providers did not meet these requirements (e.g., psychotherapy time was not documented). In addition, for 54 sampled enrollee days, providers did not meet Medicare guidance (e.g., providers' signatures were missing). (We did not review 4 sampled enrollee days and treated them as non-errors because they were already part of other OIG reviews.) Based on our sample results, we estimated that of the $1 billion that Medicare paid for psychotherapy services, providers received $580 million in improper payments for services that did not comply with Medicare requirements, consisting of $348 million for telehealth services and $232 million for non-telehealth services. We also present the information we obtained on providers' experience with providing telehealth services during the PHE for the sampled enrollee days. CMS may be able to use this information when making decisions about how telehealth can be best used to meet the needs of Medicare enrollees in the future. We found that some providers reported challenges in furnishing telehealth services and most providers used approved communication technology to provide those services. (A-09-21-03021)

Medicare Could Have Saved up to $216 Million Over 5 Years if Program Safeguards Had Prevented At-Risk Payments for Definitive Drug Testing Services. For the 5-year audit period, Medicare paid $704.2 million for definitive drug testing services that were at risk for noncompliance with Medicare requirements. Specifically, these payments were for the definitive drug testing service with the highest reimbursement amount (procedure code G0483). These payments were made to 1,062 at-risk providers that routinely billed procedure code G0483 and may not have been reasonable and necessary. We determined that presumptive drug testing preceded most definitive drug testing services billed by both the at-risk and other providers. However, the at-risk providers may not have always used presumptive testing to determine the number of drug classes that needed to be tested using definitive drug testing, because they routinely billed for testing 22 or more drug classes using G0483 and the other providers did not. Although the at-risk providers billed a significantly higher percentage of definitive drug testing services using G0483 than the other providers, the at-risk and other providers had similar characteristics (such as the types of patients they tested and the frequency of testing). This suggests that the at-risk providers may have been able to bill for definitive drug testing services using primarily procedure codes with lower reimbursement amounts, as the other providers did. If CMS's program safeguards had focused on at-risk payments to at-risk providers for procedure code G0483, Medicare could have saved up to $215.8 million for our audit period. (A-09-21-03006)

Noridian Healthcare Solutions, LLC, Made $8.8 Million in Improper Capitation Payments to Physicians and Qualified Nonphysician Practitioners in Jurisdiction E for Certain Services Related to End-Stage Renal Disease. Noridian did not make some monthly capitation payments (MCPs) to physicians and qualified nonphysician practitioners in Jurisdiction E for certain end-stage renal disease (ESRD)-related services in accordance with Medicare requirements and guidance. Of the sampled 100 enrollee-months, 26 enrollee-months did not meet 1 or more of the requirements. As a result, Noridian made improper MCPs of $4,663 to physicians and qualified nonphysician practitioners. Enrollees were responsible for $1,162 in coinsurance related to the improper payments. These improper payments occurred because Noridian's oversight was not sufficient to ensure that physicians and qualified nonphysician practitioners met Medicare billing requirements for ESRD-related services. Based on our sample results, we estimated that for our audit period Noridian made approximately $8.8 million in improper MCPs to physicians and qualified nonphysician practitioners for ESRD-related services. We also estimated that Medicare enrollees paid approximately $2.2 million in coinsurance for the improperly paid ESRD-related services. (A-09-21-03016)

Medicare Providers Did Not Always Comply With Federal Requirements When Billing for Advance Care Planning. Medicare providers that billed for advanced care planning (ACP) services in an office setting did not always comply with Federal requirements. Specifically, of the 691 ACP services associated with our sample, providers did not comply with Federal requirements for 466 services totaling $33,332. Based on our sample results, we estimated that Medicare providers in an office setting were paid approximately $42.3 million for ACP services that did not comply with Federal requirements. These payments occurred because the providers did not understand the Federal requirements for billing ACP services. We also identified questionable claims associated with 12 sampled beneficiaries for whom 15 or more ACP services were received. Although the billing of these ACP services did not reflect noncompliance with Medicare requirements, the billings do not align with guidance contained in CMS's Frequently

Asked Questions. (A-06-20-04008)

Medicare Improperly Paid Physicians for Co-Surgery and Assistant-at-Surgery Services That Were Billed Without the Appropriate Payment Modifiers. From our 100 statistically sampled services, we found that 69 did not comply with Federal requirements. Specifically, these statistically sampled services included 49 that were incorrectly billed without the co-surgery modifier, 14 that were incorrectly billed without an assistant-at-surgery modifier, and 6 that were incorrectly billed as duplicate services. These statistically sampled service errors resulted in overpayments of $31,545. Based on the results of our statistical sample, we estimated that Medicare made $4.9 million in improper payments for physician surgical services during our audit period. In addition to the statistically sampled services, based on our review of the 127 corresponding services, we further found that 62 of these corresponding services did not comply with Federal requirements. These corresponding service errors resulted in overpayments of $24,471. Altogether, these statistically sampled and corresponding service errors occurred primarily because CMS did not have adequate system controls to identify and prevent such payments. (A-01-20-00503)

The Number of Beneficiaries Who Received Medicare Part B Clinical Laboratory Tests Decreased During the First 10 Months of the COVID-19 Pandemic. During the pandemic period, the number of beneficiaries who received Medicare Part B lab tests decreased for: (1) all lab tests and (2) lab tests associated with certain chronic medical conditions (i.e., diabetes, kidney disease, and heart disease) common among Medicare beneficiaries. From March through December in 2016, 2017, and 2018, and for the pre-pandemic period (in 2019), the number of beneficiaries who received lab tests paid for by Medicare decreased by one percent or less in each year. However, for the pandemic period (in 2020), the number of beneficiaries who received lab tests decreased by about 9 percent compared with the pre-pandemic period. Our comparison of the numbers of beneficiaries who received lab tests during the pandemic and pre-pandemic periods identified the following trends: (1) The number of beneficiaries who received lab tests had the highest percentage decreases during the first 3 months of the pandemic period when compared with the same months during the pre-pandemic period; (2) for almost 90 percent of lab tests for which the number of tests performed had decreased during the pandemic period, the number of beneficiaries who received those tests decreased by more than 10 percent; (3) for the gender and residential location (i.e., rural or urban) demographics, during the pandemic period the number of beneficiaries who received lab tests had similar percentage decreases for each category within the corresponding demographic (e.g., the female and male genders had similar percentage decreases); (4) for the race or ethnicity group demographic, during the pandemic period there was more variation in the percentage decreases in the number of beneficiaries who received lab tests for each category (e.g., the Hispanic or Latino category had a higher percentage decrease than the White category); and (5) the number of beneficiaries with diabetes, kidney disease, and heart disease who received common lab tests for those conditions decreased during the pandemic period. The results of our data analysis suggest that the COVID-19 pandemic contributed to these decreases. Lab tests are important for beneficiaries with chronic medical conditions, which are associated with hospitalizations, billions of dollars in Medicare costs, and deaths. (A-09-21-03004)

Medicare Made $17.8 Million in Potentially Improper Payments for Opioid-Use-Disorder Treatment Services Furnished by Opioid Treatment Programs. Payments made to opioid treatment programs (OTPs) for opioid use disorder (OUD) treatment services may not have

complied with Medicare requirements. Specifically, Medicare made up to $17.8 million in potentially improper payments to OTPs, consisting of the following payments: $10.4 million for claims for which a bundled payment was made for a weekly episode of care (i.e., a weekly bundle) that was covered by a payment for another weekly bundle for the same enrollee at the same OTP; $5.1 million for take-home supplies of medication (i.e., methadone or buprenorphine) that were covered by other payments for take-home supplies of medication or by payments for weekly bundles that included medication; $1.3 million for OUD treatment services that were claimed without an OUD diagnosis; and $1 million in payments for intake activities that occurred a total of 14 or more times for the same enrollee during our audit period. These potentially improper payments occurred because, among other causes, CMS did not instruct MACs to implement system edits to prevent OTPs from being paid for OUD treatment services covered by other Medicare payments for the same enrollee at the same OTP. (A-09-22-03005)

Medicare Paid $30 Million for Accumulated Repair Costs That Exceeded the Federally Recommended Cost Limit for Wheelchairs During Their 5-Year Reasonable Useful Lifetime. The accumulated costs of repairs paid by Medicare for some enrollee-owned wheelchairs that were within their 5-year RUL exceeded the federally recommended cost limit. For 504,794 of the 688,948 repairs (73 percent) that we reviewed, Medicare paid suppliers before the accumulated costs of repairing 77,200 wheelchairs had exceeded the federally recommended cost limit. However, the remaining 184,154 repairs (27 percent) were paid after the accumulated costs of repairing 16,962 wheelchairs had exceeded the federally recommended cost limit, resulting in $30.1 million in potentially unallowable Medicare payments. Enrollee coinsurance associated with the potentially unallowable payments totaled $7.6 million. Suppliers' billing of these wheelchair repairs may reflect noncompliance with Medicare requirements. Specifically, the excessive costs for repairing these wheelchairs may indicate that the repairs were not reasonable or that enrollees were furnished substandard wheelchairs that would not remain serviceable for their entire 5-year RUL. CMS concurred with all of our recommendations and described its corrective actions for addressing our recommendations, including exploring opportunities to strengthen Medicare requirements and notifying DME MACs of our audit so that they may evaluate the risk associated with claims for wheelchair repairs. (A-09-22-03003)

CMS Generally Ensured That Medicare Part C and Part D Sponsors Did Not Pay Ineligible Providers for Services to Medicare Beneficiaries. CMS generally ensured that sponsors complied with Federal requirements for preventing payments for Medicare services to ineligible providers. However, some sponsors submitted encounter and prescription drug event (PDE) data to CMS indicating that ineligible providers rendered services and wrote prescriptions for Medicare beneficiaries. We identified 136 Part C sponsors and 62 Part D sponsors that may have paid claims for health care services associated with ineligible providers. The ineligible providers were able to submit these claims to plan sponsors because some sponsors may not have had effective compliance programs in place to prevent, detect, and correct noncompliance with CMS's program requirements. Although Part D regulations expressly require Part D sponsors to reject (or Part D sponsors to require their pharmacy benefit managers (PBMs) to reject) pharmacy claims unless they contain active and valid provider identification numbers of the prescriber who prescribed the drug, CMS does not have similar requirements for claims submitted to Part C sponsors. Additionally, CMS system edits did not properly work to identify all ineligible providers after sponsors submitted their encounter and PDE data to CMS. As a result, CMS used data from services associated with ineligible providers in its risk adjustment of

capitation payments to the sponsors. The HHS-OIG makes a series of recommendations for CMS to direct Part C and Part D sponsors to ensure that only eligible providers receive payments for Medicare services. We also recommend that CMS strengthen its oversight of sponsors and provider identifiers to prevent deactivated and deceased providers from receiving payments for Medicare services. (A-02-20-01027)

Medicare Part D Plan Sponsors and CMS Did Not Ensure That Transmucosal Immediate-Release Fentanyl Drugs Were Dispensed Only to Beneficiaries Who Had a Cancer Diagnosis. Medicare Part D plan sponsors and CMS did not ensure that all transmucosal immediate-release fentanyl (TIRF) drugs were dispensed in accordance with Medicare requirements. Medicare requires that TIRF drugs be dispensed only for the medically accepted indication of breakthrough cancer pain. For 7,552 prescription drug events (PDEs), plan sponsors approved TIRF drugs dispensed to 810 beneficiaries who did not have a cancer diagnosis in their Medicare claims history to support a medically accepted indication for use of these drugs. As a result, plan sponsors paid $86.2 million in unallowable Part D total costs. Plan sponsors also approved 2,023 PDEs totaling $19.7 million for TIRF drugs for 176 beneficiaries whose most recent cancer diagnosis in their Medicare claims history was more than 1 year before the drugs were dispensed. Although we did not determine these PDEs to be unallowable, they were at high risk of being unallowable. We recommend that CMS work with its plan sponsors to: (1) delete the PDEs related to the $86.2 million of unallowable Medicare Part D total costs and determine after reconciliation the impact to the Federal Government and (2) identify and delete any unallowable PDEs related to the $19.7 million of Part D total costs for beneficiaries whose most recent Medicare claim with a cancer diagnosis was for services provided more than 1 year before the TIRF drugs were dispensed, and determine the impact to the Federal Government. The report contains three other recommendations. CMS did not concur with four of our five recommendations and did not explicitly state whether it concurred with our fifth recommendation. (A-09-20-03033)

Mississippi Did Not Always Invoice Rebates to Manufacturers for Physician Administered Drugs. Mississippi did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Mississippi did not invoice for or collect from manufacturers rebates associated with $2.2 million (Federal share) in physician-administered drugs. Of this amount, $820,732 (Federal share) was for single-source drugs and $395,621 (Federal share) was for top-20 multiple-source drugs. Further, we were unable to determine whether Mississippi was required to invoice for rebates associated with $1 million (Federal share) for other multiple-source physician-administered drug claims. In addition, Mississippi did not invoice for or collect from manufacturers $35.6 million (Federal share) in rebates for physician administered drugs invoiced on crossover claims, for which beneficiaries are eligible for both Medicare and Medicaid. Mississippi's internal controls did not always ensure that the drug utilization data it collected were used to invoice manufacturers and collect rebates. (A-07-21-06101)

North Carolina Did Not Always Invoice Rebates to Manufacturers for Physician Administered Drugs. North Carolina did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. North Carolina did not invoice for or collect from manufacturers rebates associated with $3.1 million (Federal share) in physician-administered drugs. Of this amount, $2.3 million (Federal share) was for single-source drugs and $734,000 (Federal share) was for top-20 multiple-source drugs. Further, we were unable to

determine whether, in some cases, North Carolina was required to invoice for rebates for other multiple-source physician-administered drug claims. North Carolina did not invoice the manufacturers for rebates associated with claims totaling $685,000 (Federal share) for these multiple-source drugs. (A-07-21-07002)

Kentucky Did Not Always Invoice Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations. Kentucky did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees. Kentucky did not invoice for, and collect from manufacturers, rebates totaling $21.6 million ($15.5 million Federal share) for physician-administered drugs dispensed to MCO enrollees. Of this amount, $15.6 million ($11.2 million Federal share) was for drugs that were required to be rebated. In addition, Kentucky did not invoice for rebates associated with $6 million ($4.3 million Federal share) in other multiple-source physician-administered drugs that were eligible for rebates. (A-04-22-07102)

Alabama Did Not Always Invoice Rebates to Manufacturers for Pharmacy and Physician-Administered Drugs. Alabama did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for pharmacy and physician-administered drugs. Alabama did not invoice for, and collect from manufacturers, rebates associated with $21 million ($14.9 million Federal share) in single-source and $62,043 ($43,981 Federal share) in top-20 multiple-source physician-administered drug claims. Further, we were unable to determine whether, in some cases, Alabama was required to invoice for rebates for other multiple-source physician-administered drug claims. Alabama did not invoice the manufacturers for rebates associated with the claims totaling $410,454 ($290,455 Federal share) for these multiple-source drugs. Lastly, the OIG identified $6,568 ($4,719 Federal share) in single-source and $219,220 ($157,395 Federal share) in multiple-source pharmacy drug claims where Alabama did not collect a rebate from manufacturers. (A-04-21-08090)

The District of Columbia Has Taken Significant Steps To Ensure Accountability Over Amounts Managed Care Organizations Paid to Pharmacy Benefit Managers. The District of Columbia provided some oversight of its Managed Care Organization (MCOs) with the intent of ensuring adequate accountability over amounts paid for prescription benefits to its pharmacy benefit managers (PBMs). This oversight consisted of guidance requiring MCOs to report spread pricing. However, the amounts reported were aggregated with other amounts and as a result did not provide transparency over the amount of the funds that was attributable to spread pricing. We found that PBMs kept $23.3 million in spread pricing during our audit period. Spread pricing may increase the cost of Medicaid prescriptions for both the MCO and the Medicaid program and, if not correctly accounted for, inflate the cost of the drugs. Limiting spread pricing may decrease Federal and State spending through lower payments to MCOs. We recommend that the District develop policies and procedures for validating MCO, PBM, and pharmacy transactions on a periodic basis to ensure transparency of costs associated with the prescription drug program. The District concurred with our recommendation and asked for clarification and guidance regarding the amounts or percentages that are deemed appropriate for PBMs to retain under the practice of spread pricing. (A-03-20-00200)

States With Separate Children's Health Insurance Programs Could Have Collected an Estimated $641 Million Annually If States Were Required To Obtain Rebates Through the Medicaid Drug Rebate Program. Under current Federal requirements for the Medicaid Drug Rebate Program

(MDRP), States must obtain drug rebates for Medicaid-covered outpatient prescription drugs that are provided through Medicaid or an expansion of its Medicaid program (Medicaid expansion). However, for separate Children's Health Insurance Program (CHIP) drugs, those Federal Medicaid drug rebate requirements do not apply. As of the preparation of this Data Brief, 40 States operate separate CHIPs, whether in combination with Medicaid expansion or on a stand-alone basis. Separate CHIP is a program under which a state receives Federal funding to provide child health assistance to uninsured, low-income children and which meets the requirements of section 2103 of the Social Security Act. We identified the total drug rebates that states could have collected under their separate CHIPs if states had been required to obtain those rebates through the MDRP. If Federal law were to require States to obtain rebates under the MDRP for separate CHIP drugs, the 40 States that operated separate CHIPs could, according to our estimates, have invoiced, collected, and directly received $641.2 million from the drug manufacturers for calendar year 2020. These estimated rebates totaled $125.5 million for the States and $515.7 million for the Federal Government. Because this Data Brief contains no recommendations, CMS did not provide written comments on our draft Data Brief but did furnish technical comments, which we addressed as appropriate. (A-07-22-06106)

New York Improved Its Monitoring of Medicaid Community Rehabilitation Services But Still Claimed Improper Federal Medicaid Reimbursement Totaling $20 Million. New York generally complied with Medicaid requirements for claiming Federal reimbursement for community rehabilitation services. For 111 of the 120 sampled claims, New York properly claimed Medicaid reimbursement for all community rehabilitation services. However, New York claimed reimbursement for some unallowable community rehabilitation services for the remaining 9 sampled claims. Specifically, services were provided although service plans were not timely signed or maintained, claims did not meet Medicaid reimbursement standards, and services were not appropriately authorized. Based on sample results, we estimated that New York improperly claimed at least $19.9 million in Federal Medicaid reimbursement for community rehabilitation services that did not comply with Medicaid requirements. Although we commend New York for its efforts in improving some aspects of its monitoring of providers, its overall monitoring activities were still not adequate to ensure that providers complied with Medicaid requirements. New York partially concurred with our recommendations that it refund $19.9 million to the Federal Government. We also recommend that New York improve its monitoring activities by increasing the number of case files reviewed when conducting monitoring visits at providers, and by providing formal guidance or training to providers to clarify Medicaid requirements related to providing community rehabilitation services. (A-02-22-01011)

Virginia Made Capitation Payments to Medicaid Managed Care Organizations After Enrollees' Deaths. The State agency made unallowable capitation payments after enrollees' deaths. For 67 of the 100 capitation payments in our sample, Virginia made unallowable capitation payments totaling $76,939 ($51,062 Federal share). For 30 of the remaining capitation payments in our sample, Virginia adjusted the capitation payments before our audit. We could not fully confirm that the remaining 3 enrollees associated with 3 of the 100 capitation payments were deceased. Based on our sample results, we estimated that Virginia made unallowable capitation payments totaling at least $21.8 million ($15.7 million Federal share) to Managed Care Organizations (MCOs) on behalf of 12,054 deceased enrollees during our audit period. Virginia made unallowable capitation payments on behalf of deceased enrollees because it did not have

adequate controls in place to enable it to identify all deceased enrollees and properly cancel their enrollment. Virginia did not specifically indicate it concurred with our recommendations that it: (1) refund $15.7 million to the Federal Government; (2) identify and recover unallowable capitation payments, which we estimate to be at least $21.8 million, made to MCOs during our audit period on behalf of deceased enrollees; and (3) identify and recover unallowable capitation payments made on behalf of deceased enrollees in 2018 and 2022 and repay the Federal share of amounts recovered. We also recommended that Virginia continue to pursue development and implementation of an automated matching and eligibility update process and implement additional supervisory review. (A-03-22-00203)

California Made Almost $16 Million in Unallowable Capitation Payments for Beneficiaries With Multiple Client Index Numbers. California made unallowable capitation payments on behalf of beneficiaries with multiple Client Index Numbers (CINs). Of the 100 beneficiary matches in our sample, California correctly made capitation payments on behalf of individuals associated with 24 beneficiary matches. However, it incorrectly made capitation payments that totaled $657,057 ($328,529 Federal share) on behalf of individuals associated with the remaining 76 beneficiary matches. The unallowable capitation payments occurred because the associated beneficiaries had multiple CINs. According to California, human error caused it to assign multiple CINs to these beneficiaries. Specifically, during the file clearance process, California county staff made data entry errors that included misspelling beneficiaries' names. Also, staff transposed Social Security numbers, failed to identify and link multiple records, and did not always identify and resolve variations in beneficiaries' names. In addition, the algorithm that California used to create the Beneficiary Name and Date of Birth (DOB) Match Report was too broad and, thus, not effective. Further, California did not require county staff to review training materials. Based on our sample results, we estimated that California made unallowable capitation payments totaling approximately $31.4 million ($15.7 million Federal share) on behalf of beneficiaries with multiple CINs during our audit period. California concurred with our recommendations that it: (1) refund to the Federal Government approximately $15.7 million in unallowable payments, (2) review capitation payments that fell outside of our audit period and refund any unallowable payments, (3) ensure that the algorithm used to create its revised Beneficiary Name and DOB Match Reports is effective at detecting individuals with multiple records, (4) require county staff to review training materials on the prevention of issuing multiple CINs, and (5) enhance its controls to ensure that no beneficiary is issued multiple CINs. (A-04-21-07097)

Florida Did Not Refund $106 Million Federal Share of Medicaid Managed Care Rebates It Received for Calendar Years 2015 Through 2020. Florida calculated and received the required Managed Care Organization (MCO) rebates totaling $448,891,916 ($292,485,420 Federal share) for our audit period in accordance with Florida statutes and the terms of the Medicaid MCO contracts. However, Florida did not properly refund the Federal share of MCO rebates in accordance with Federal requirements. Florida reported only calendar year 2020 rebates on the CMS-64, which totaled $274,856,893 ($186,332,359 Federal share), but it did not report rebates for calendar years 2015 through 2019 totaling $174,035,023 ($106,153,061 Federal share). Florida did not report the rebates it received from the MCOs for calendar years 2015 through 2019 on the CMS-64 because Florida officials erroneously believed that they were not required to do so before the Centers for Medicare & Medicaid Services (CMS) added the January 15, 2021, provision to the special terms and conditions (STCs) specifically requiring Florida to refund the Federal share of rebates. As a result, before January 15, 2021, Florida did not include

a step in its written instructions for preparing the quarterly CMS-64 to report the rebates and refund the Federal share to the Federal Government. Florida did not concur with our recommendation that it refund $106,153,061 to the Federal Government, representing the Federal share of rebates for calendar years 2015 through 2019 that Florida did not refund. (A-04-22-04089)

Missouri Claimed Federal Medicaid Reimbursement for Tens of Millions in Consumer-Directed Personal Care Assistance Services That Did Not Comply With Federal and State Requirements. Missouri did not always ensure that the consumer directed personal care assistance (PCA) services for which it claimed Federal Medicaid reimbursement during FYs 2018 and 2019 complied with Federal and State requirements. Specifically, 17 of the 150 sampled items were at least partially unallowable because of errors related to: timesheets that could not be provided or that lacked detail; units of service charged that exceeded the number authorized; lack of documentation that attendants were registered, screened, and employable; and recipients with plans of care that were not signed. Based on our sample results, we estimated that Missouri claimed at least $52.5 million ($34.2 million Federal share) for unallowable consumer directed PCA services during FYs 2018 and 2019. In addition, timesheets for 46 of the 150 sampled items did not identify the specific services that were performed in accordance with the plans of care. We are setting aside, for Centers for Medicare & Medicaid Services (CMS) resolution, an estimated $133.8 million ($87 million Federal share) associated with these 46 items. For our second objective, Missouri did not have established and implemented pandemic emergency preparedness standards and protocols within the consumer directed PCA program. Most providers for the sampled items did not have any emergency preparedness documentation for a pandemic response. Missouri did not concur with our recommendation that it refund the $34.2 million (Federal share) in overpayments to the Federal Government and work with CMS to determine the allowability of the $87 million (Federal share) and refund any amount that is determined to be unallowable. (A-07-20-03243)

Four States Reviewed Received Increased Medicaid COVID-19 Funding Even Though They Terminated Some Enrollees' Coverage for Unallowable or Potentially Unallowable Reasons. The four States we reviewed did not meet all the requirements to receive the increased COVID-19 Federal medical assistance percentage (FMAP). All four States terminated Medicaid enrollees' coverage for unallowable or potentially unallowable reasons. Two States (Texas and Minnesota) terminated Medicaid coverage for 26,915 total enrollees for unallowable reasons, and three States (New York, Florida, and Minnesota) terminated Medicaid coverage for 220,113 total enrollees for potentially unallowable reasons due to a lack of support or documentation. Additionally, Minnesota may have inappropriately charged some enrollees cost-sharing for COVID-19 testing, services, and treatment. Minnesota could not determine whether Medicaid enrollees were responsible for any cost-sharing, and enrollees may have been charged up to $951,202 for COVID-19-related testing, services, and treatment. CMS concurred with our recommendations that CMS: (1) work with the four States to determine what amount, if any, of the funding they received because of the increased COVID-19 FMAP should be refunded to the Federal Government; and (2) work with Minnesota to determine whether Medicaid enrollees were responsible for any cost-sharing for COVID-19 testing, services, or treatments and, if any cost-sharing is identified, work with Minnesota to ensure that enrollees are reimbursed for any out-of-pocket expenses incurred. (A-06-21-09002)

Other HHS-OIG Fraud and Abuse Prevention Activities

Data Analytics

HCFAC funding supports the work of HHS-OIG's Chief Data Office (CDO) to provide OIG auditors, evaluators, investigators, and legal staff with the data and analytics needed to support OIG's mission of fighting fraud, waste, and abuse in HHS programs. CDO provides advanced data analytics to expand its portfolio of self-service tools for Medicare and Medicaid oversight, and customized analytics with artificial intelligence (AI) and machine learning (ML) to:

- proactively monitor and target agency oversight of high-risk HHS programs and health care providers;
- identify trends, outliers, and potential investigative and audit targets;
- enhance decision-making;
- optimize HHS-OIG operational processes; and
- support mission-critical work.

HHS-OIG's team of highly trained data analysts, data scientists, statisticians, and data engineers partner closely with OIG investigators, auditors, attorneys, and evaluators to identify HHS's most significant risks and better target fraud, waste, and abuse, especially in support of OIG priority outcomes focus areas of managed care and nursing homes. HHS-OIG applies predictive and geospatial analytics, customized dashboards, AI and ML capabilities including neural networks and text mining to identify and support prosecutions of sophisticated fraud schemes; as well as audits and evaluations by utilizing high-value health care, grant, contract, law enforcement, and operational data. More than 850 unique staff members used HHS-OIG analytic tools for mission-focused work to generate provider-specific reports and claims exports, page views, and other analytic insights, and drove a 25 percent increase in self-service tools usage actions 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 informed 10 audits and 5 evaluations related to pandemic oversight during the fiscal year. Collectively, this body of work identified more than $580 million in improper payments for services that did not comply with Medicare requirements as well as questionable billings for COVID-19 testing, other add-on tests, and improper billing for patients with health insurance by pandemic relief programs. Examples of high impact reports supported by OIG analytics involving pandemic oversight from fiscal year 2023 include:

- *Medicare Improperly Paid Providers for Some Psychotherapy Services, Including Those Provided via Telehealth, During the First Year of the COVID-19 Public Health Emergency* (A-09-21-03021);
- *Labs With Questionably High Billing for Additional Tests Alongside COVID-19 Tests Warrant Further Scrutiny* (OEI-09-20-00510);
- *Medicare Part B Spending on Lab Tests Increased in 2021, Driven By Higher Volume of COVID-19 Tests, Genetic Tests, and Chemistry Tests* (OEI-09-22-00400); and
- *More Than a Thousand Nursing Homes Reached Infection Rates of 75 Percent or More in the First Year of the COVID-19 Pandemic; Better Protections are Needed for Future Emergencies* (OEI-02-20-00491).

In support of OIG's Managed Care priority outcome, CDO analytics staff also supported 11 Medicare Advantage audits which collectively identified $78 million in overpayments to MA

plans, and six Medicaid managed care audits to identify more than $49 million in overpayments to MCOs for deceased beneficiaries, concurrent enrollments in multiple states, and up to $23 million in questioned costs claimed by pharmacies.

HHS-OIG analytics supported agency investigative actions that led to criminal charges filed in U.S. courts targeting fraudulent telemedicine, orthotic braces, pain medication, and pharmacy and other health care schemes totaling more than $2.1 billion in false claims and a nationwide coordinated law enforcement action announced by DOJ and HHS in June 2023. Furthermore, HHS-OIG's data analytics supported law enforcement actions targeting fraudulent respiratory pathogen panel (RPP) billings and other fraudulent claims to Medicare and pandemic programs exceeding $470 million in April 2023. OIG analytics also continue to identify and support cases filed as part of the ARPO and the NEPO Strike Force efforts.

Overall, OIG analytics staff supported 55 audits, and 23 evaluations completed during the fiscal year, and 161 criminal investigations across the Medicare and Medicaid portfolios as of September 30, 2023.

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 2023, HHS-OIG, in consultation with DOJ, issued 9 advisory opinions and modified one advisory opinion. During the 27 years of the HCFAC program, HHS-OIG has issued more than 400 advisory opinions, modified 25 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

HHS-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. At the end of FY 2023, these trainings had reached a total of over 9,400 audience members.

Centers for Medicare & Medicaid Services

In FY 2023, Congress appropriated CMS $665.6 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 2023, Congress continued to direct HHS to fund the Administration for Community Living's (ACL) Senior Medicare Patrol (SMP) Program; therefore, $35.0 million of CMS's $665.6 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.[14]

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. The UPICs conduct 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. Various UPIC administrative actions result in Medicare savings, including automated edit claim denials, non-automated review claim denials, provider

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

revocations and deactivations, overpayment recoveries, and law enforcement referrals. CMS publishes savings from UPIC activities in annual Medicare and Medicaid Integrity Programs Report to Congress.

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 (P.L. 111-240). FPS analyzes Medicare FFS and Medicaid (Transformed Medicaid Statistical Information System (T-MSIS)) 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 administrative actions, including claim denials, payment suspensions, Medicare billing privilege revocations, and law enforcement referrals.

During FY 2023, the FPS provided information for 1,137 new and 1,994 existing leads or investigations opened by program integrity contractors.[15] The program integrity contractors reported initiating FPS-attributable actions against 1,095 providers in FY 2023.

Integrated Data Repository and One Program Integrity (One PI)

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. CMS has integrated 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

CMS conducts Medicare Major Case Coordination (MCC) activities with HHS-OIG and DOJ. This process provides an opportunity for policy experts, law enforcement officials, clinicians, and fraud investigators to collaborate before, during, and after the development of fraud leads. This level of collaboration has contributed to several successful coordinated law enforcement actions and helped CMS to better identify national fraud trends and program vulnerabilities.

As a result of the MCC, there has been a marked increase in the number and quality of law enforcement referrals from CMS. Since implementation of the MCC, there have been over 5,000 cases reviewed at MCC, and law enforcement partners have made over 3,100 requests for CMS

[15] CMS quantifies leads and investigations to describe how FPS contributes to program integrity investigative activities. As additional context, CMS notes that more than one FPS alert may inform a lead/investigation, and there may be more than one lead/investigation on the same provider if, for example, multiple complaints are received about that provider.

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 2023, CMS reviewed 1,106 cases at MCC meetings, and law enforcement partners made 538 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 2023 include:

- On April 20, 2023, the DOJ announced criminal charges against 18 defendants in nine Federal districts across the U.S. for their alleged participation in various fraud schemes that exploited the COVID-19 pandemic, including shipping unsolicited COVID-19 over-the-counter tests. DOJ seized more than $16 million in cash and other fraud proceeds, with CMS assisting in the investigation. The same day, CMS announced its administrative actions against 28 medical providers for their alleged involvement in COVID-19 schemes.[16]
- On June 28, 2023, the DOJ, together with Federal and state law enforcement partners, announced a strategically coordinated, two-week nationwide law enforcement action that resulted in criminal charges against 78 defendants for their alleged participation in health care fraud and opioid abuse schemes that included over $2.5 billion in alleged fraud. The action included charges against 11 defendants in connection with the submission of over $2 billion in fraudulent claims resulting from telemedicine schemes.[17] On that day, CMS separately announced that it had taken adverse administrative actions during the previous six months against 90 medical providers for their alleged involvement in health care fraud.

In FY 2020, CMS expanded the MCC process to Medicaid, meeting with individual States and law enforcement partners. The level of collaboration resulting from the Medicaid MCC has helped CMS better identify national trends and program vulnerabilities that can lead to fraud and other improper payments.

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 can help CMS complete more accuracy reviews and provide additional analysis to CMS.

- Medicare Fee-for-Service Prior Authorization
  In FY 2023, CMS continued nationwide prior authorization of 46 power mobility device

[16] https://www.justice.gov/opa/pr/justice-department-announces-nationwide-coordinated-law-enforcement-action-combat-covid-19
[17] https://www.justice.gov/opa/pr/national-enforcement-action-results-78-individuals-charged-25b-health-care-fraud

(PMD) codes, five pressure reducing support surface codes, six lower limb prosthetic codes, and five lower limb orthoses codes. Additionally, on March 20, 2023, CMS implemented a voluntary prior authorization program for 53 PMD accessories. As noted in the 2019 ESRD and DMEPOS final rule (84 Fed. Reg. 60648 (November 8, 2019)), suppliers are permitted to voluntarily submit prior authorization requests for certain DMEPOS accessories on the same prior authorization request as a DMEPOS item on the Required Prior Authorization List. The DME MACs review requests for prior authorization for the noted items, communicate decisions with suppliers and physicians, and other Medicare practitioners, and provide ongoing education and customer service.

In FY 2023, 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. Additionally, on November 23, 2022, CMS finalized the addition of Facet Joint Interventions to the nationwide prior authorization process for hospital outpatient department services, in the Calendar Year 2023 Outpatient Prospective Payment System/Ambulatory Surgical Center Final Rule (CMS-1772-FC)[18], for services furnished on or after July 1, 2023. 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 to that of their peers and educate recipients about Medicare coding, billing, and coverage guidelines and strategies for implementing self-audit processes into their practices, where appropriate. A CBR does not necessarily indicate improper billing and/or prescribing by the recipient, and only in select instances are providers and suppliers referred for additional review or education. Typically, CBRs are sent to a 5,000 outlier providers per topic based on data analysis for a defined period. In FY 2023, CMS issued a total of ten CBRs on ten unique topic areas, including nursing home visits, chiropractic manipulative treatment (CMT), urinalysis, hospice, and subsequent annual wellness visits (AWV).

Outreach and Education

CMS's provider education and outreach helps reduce the Medicare improper payment rate by giving Medicare providers 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. One of those strategies is the Targeted Probe and Educate (TPE) program, in which contractors conduct a small number of reviews and provide individualized education to the provider. This program identifies potentially problematic providers and attempts to educate them on correct

[18] https://www.govinfo.gov/content/pkg/FR-2022-11-23/pdf/2022-23918.pdf

documentation and billing. In May 2023, CMS hosted a provider focus group to address medical review and prior authorization updates.

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.

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 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. Through provider screening and enrollment, CMS continues to prevent and reduce fraud, waste, and abuse in the Medicare program and support the states with 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 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 the requirements in the limited and moderate screening levels. In FY 2023, CMS continued FCBCs, and denied approximately 757 enrollments and revoked 27 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 2023, APS utilization resulted in more than 10 million screenings. These screenings generated more than 700 criminal alerts for potentially fraudulent providers and suppliers for further review by CMS. APS review resulted in approximately 237 revocations based on a felony conviction, 284 revocations based on a state medical license action, and 23,064 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 2023, this work resulted in about 275 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 2023, CMS deactivated approximately 227,000 enrollments and revoked 3,300 enrollments. Site visits, revalidation, and other initiatives have contributed to the deactivation[19] and revocation[20] of more than one and half 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.

In FY 2023, CMS made significant changes to PECOS to simplify access, improve usability, and enhance the security of the system, including the following changes:

- Added new functionality to PECOS for providers to generate a PDF report containing copies of all submitted enrollment application information, including copies of accompanying documents.
- Implemented necessary enhancements to ensure providers/suppliers are scrolling through all legal documents and confirming the submitted information before they have electronically signed the application.
- Added new Rural Emergency Hospital (REH) as a Provider Type in PECOS and added relevant functionality for enrollment of REH providers.
- Implemented changes to PECOS to support the two new national provider enrollment contractors for DME supplier enrollments.
- Updated PECOS to increase the screening level of skilled nursing facilities to high to ensure they are properly screened.
- Reconciled enrollment Ownership control across records at the Entity level to improve ownership data accuracy in PECOS.

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 is an initiative called the Medicaid and CHIP Business Information Solution (MACBIS). MACBIS 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, and evaluation and to assess program integrity of the overall Medicaid and CHIP programs. MACBIS provides operational, financial, pharmacy,

[19] 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.

[20] Revocation means the provider's or supplier's billing privileges are terminated. See 42 CFR § 424.535.

quality, and business performance data through products and services such as T-MSIS, Medicaid and CHIP Program (MACPro), Medicaid and CHIP Financial (MACFin), and the Medicaid Drug Programs to assist in preventing fraud, waste, and abuse.

State Audit Compliance and Financial Management Oversight

The State Audit Compliance and Financial Management Oversight projects began in September 2020. To support these projects, CMS acquired contractor assistance for two separate efforts. The first is to assist CMS with review of data reported by states to support payments to health care providers, and also perform data analysis, collection, and evaluation, including review of states' use of statistical sampling techniques to determine if Medicaid claims submitted by states for Federal financial participation (FFP) are allowable under Federal guidelines. 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. The second effort develops, implements, and aligns measures that improve CMS's approach to the annual OMB single state agency (SSA) audit and identifies opportunities to optimize the compliance supplement that guides single state auditors as they review state Medicaid and CHIP programs. This project also improves 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 initiatives and anticipates continued contractor engagement in these areas through FYs 2024-2025.

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, claims processing, pharmacy management, etc. These systems work in concert with one another and must adhere to Federal regulation[21] and guidance, including the Medicaid Information Technology Architecture (MITA) framework, several standards and conditions,[22] 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, data quality, 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 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

[21] Mechanized Claims Processing and Information Retrieval Systems (90/10) Final Rule available at https://www.Federalregister.gov/documents/2015/12/04/2015-30591/medicaid-program-mechanized-claims-processing-and-information-retrieval-systems-9010

[22] https://www.medicaid.gov/medicaid/data-and-systems/mita/index.html

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. CMS has updated the Medicaid Enterprise Systems certification process to ensure more comprehensive analysis of CMS funded State Medicaid systems. 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.[23] 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. CMS annually reports Medicaid and CHIP improper payment estimates in the HHS Agency Financial Report. The Medicaid program and CHIP have been identified as being at risk for significant improper payments. CMS estimates improper payment rates in Medicaid and CHIP through the 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.

The reporting year (RY) 2023 national Medicaid improper payment rate was 8.58 percent, representing $50.33 billion in gross Federal improper payments. The RY 2023 national Medicaid improper payment rates by component are 6.90 percent for Medicaid FFS, 0.00 percent for Medicaid managed care, and 5.95 percent for Medicaid eligibility. The RY 2023 national CHIP improper payment rate was 12.81 percent, representing $2.14 billion in gross Federal improper payments. The RY 2023 national CHIP improper payment rates by component are 7.09 percent for CHIP FFS, 0.59 percent for CHIP managed care, and 10.86 percent for CHIP eligibility.

The areas driving the RY 2023 Medicaid and CHIP improper payment estimates are as follows:

- **Insufficient Documentation:** Represents situations where there is insufficient information to determine if a payment was proper in accordance with the program requirements. Insufficient documentation accounted for 81.84 percent, or $41.19 billion, of total errors cited in Medicaid FFS, Medicaid managed care, and Medicaid eligibility in

[23] https://www.medicaid.gov/Federal-policy-guidance/downloads/smd22001.pdf

RY 2023 and 68.05 percent, or $1.45 billion, of total errors cited in CHIP FFS, CHIP managed care, and CHIP eligibility in RY 2023.

  - During RY 2023, CMS worked with states to independently verify certain situations where the state could not provide documentation to support state actions. This process included CMS independently accessing databases and reviewing submitted eligibility determination information that had been produced after the original claim payment or determination date, to evaluate if a provider or beneficiary would have been eligible to provide or receive goods/services. Of the 330 claims eligible for independent verification, CMS independently verified 92 claims through receipt of verification or access to system information provided by states. Of the 92 claims independently verified, CMS deemed 81 claims technically improper; the payment was to the right recipient for the correct amount, but the payment process did not comply with applicable regulations and statutes. The effect of these independent verifications is reflected as technically improper payments in the reported improper payment rates.

- **State Non-Compliance:** Represents noncompliance with Federal eligibility redetermination requirements, enrolled providers not appropriately screened by the state, 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 10.42 percent in RY 2022 to 6.90 percent in RY 2023 and the CHIP FFS component improper payment estimate decreased from 11.23 percent in RY 2022 to 7.09 percent in RY 2023.
- **Improper Determinations (CHIP-specific):** Represents situations where the beneficiary was inappropriately claimed under Title XXI (CHIP) rather than Title XIX (Medicaid). Improper Determinations accounted for approximately 21 percent, or $0.41 billion, of total errors cited in CHIP FFS, CHIP managed care, and CHIP eligibility.

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 2023 Agency Financial Report[24] and on CMS websites.[25]

Medical Loss Ratio Audits

CMS conducts audits of Medicaid managed care plans' financial reporting in selected states, focused on Medical Loss Ratio (MLR). CMS conducted a risk-based analysis to select additional states for audit beginning in FY 2021. In December 2022, CMS initiated an audit of Ohio's six Managed Care Organizations' MLR reporting for the Medicaid managed care population, and this audit is currently ongoing. In June 2023, CMS initiated an audit of Washington's six Managed Care Organizations' MLR reporting for the Medicaid managed care population, and this audit is currently ongoing.

Financial Oversight of Medicaid Managed Care

This project provides resources to accelerate oversight of Medicaid managed care, including improvements and expansion in the areas of MLR reporting compliance, risk mitigation

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

reviews, and increased oversight of state directed payment arrangements. Specific tasks include the development of project workflows as well as internal analytic tools and dashboards, policy analysis including typology development, design of reporting templates, and development of technical guides for CMS and states. The project also assists CMS with the organization and analysis of data related to "in lieu of" services and settings (ILOSs), including assisting CMS with development of standardized documentation and a tracking tool to document every ILOS approved and denied.

In addition, it provides technical assistance of state managed care claiming methodologies for capitation payments subject to an increased or reduced Federal medical assistance percentage (FMAP), including under American Rescue Plan Act of 2021 (ARP) sections 9811, 9813, 9814, 9815, 9817, and other statutory provisions that authorize an FMAP increase or reduction (e.g., FMAP reduction related to electronic visit verification under section 12006(a) of the 21st Century Cures Act). States are required to develop claiming methodologies to identify the portion of the Medicaid managed care capitation rate attributable to the expenditures for a particular population, service, or benefit. Contractor support to provide technical assistance to states and CMS on these claiming methodologies will ensure that states claim the appropriate amount of Federal funds for services and benefits subject to a differential FMAP.

HCBS Rate Reviews

The Rate Review project supports CMS in ensuring proper billing and rate reimbursement in Home and Community Based Services (HCBS) waiver and state plan programs in a fee for service delivery system and improving oversight of rate setting & financial reporting for Programs of All-inclusive Care for the Elderly (PACE). Tasks include: rate methodology and rate fiscal integrity systems review; compilation of data for benchmarking and trending analyses; technical assistance to states and CMS, and maintenance of the HCBS Rates, EVV & Quality Collaborative Tool, an internal tool that tracks state rate methodologies; and health & welfare projects including environmental scans, scorecard reports, survey & certification reports, and Quarterly Learning Collaborative Meetings for Health & Welfare.

Medicaid Drug Pricing Initiatives

This project supports a learning collaborative that develops products, toolkits, and guidance documents to support state implementation of VBP strategies in their Medicaid drug programs.

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 86 active demonstrations representing estimated Federal outlays of $168.2 billion in FY 2023. 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.

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 prescribers and 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 2023, the I-MEDIC initiated 692 investigations; submitted 65 recommendations for provider revocations; submitted 174 referrals to law enforcement, including 63 immediate advisements; and submitted 181 referrals to other entities, such as state pharmacy and medical boards, Medicare quality improvement organizations, and other Medicare contractors.[26]

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 and 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, $6.7 million was recovered from Part D sponsors during FY 2023.

Contract-Level Risk Adjustment Data Validation (RADV) Audits

RADV audits are HHS'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. HHS 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 January 2023, CMS finalized technical details regarding the RADV program, specifically codifying in regulation that CMS will extrapolate RADV audit findings beginning with payment year (PY) 2018 audits.

Overpayment Recoveries Related to Statutory Provisions

As required by Section 1128J(d) of the Social Security Act, Part C organizations are required to report and return identified overpayments. This requirement helps reduce improper payments by encouraging Part C organizations to submit accurate payment information. In FY 2023, Part C organizations reported and returned approximately $58.8 million in self-reported overpayments. That provision likewise requires Part D sponsors to report and return all identified overpayments. This requirement contributed to increased attention to data accuracy by Part D sponsors. In FY 2023, Part D sponsors self-reported and returned approximately $3 million in overpayments.

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 (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.

[26] The I-MEDIC's investigative efforts and ensuing recommendations may involve providers/suppliers participating in Medicare FFS, Medicare Part C, and/or Medicare Part D.

Program Audits

CMS conducts program audits of Parts C and D plan sponsors (including organizations offering Medicare-Medicaid Plans) and PACE organizations to evaluate select program requirements related to the delivery of health care services and medications to beneficiaries.

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

These activities 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 2023, CMS conducted nine 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 November 2022, May 2023, and September 2023; and a Part C Fraud, Waste, and Abuse webinar in March 2023. 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 and continued quarterly releases in FY 2023.

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 D program requirements, and failure to substantially meet the applicable conditions of 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 about 7,300 Part C plan benefit packages on June 5, 2023, and project to cover about 33.8 million enrollees in contract year 2024. 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 Medicare 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 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. The encounter data characterizes the context and purpose of each item and service provided to MA enrollees. CMS established and continues to maintain the Encounter Data System (EDS), which, to date, has collected over 9.7 billion encounter data records (EDRs). Among other uses, the encounter data collected by the EDS allows CMS to make accurate risk adjusted payments reflecting the predicted cost of care for MA enrollees.

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

Encounter Data Oversight and Integrity Activities

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 is designed to align with direction provided by the GAO [27]and lays out an incremental approach to assess and drive encounter data submission and quality over multiple years. Among other activities, CMS provides Part D plans with submission performance reports and technical notes to give them the opportunity to review and improve submission processes.

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 2023 (based on the 2021 payment year), the projected Part C improper payment estimate is 6.01 percent, representing $16.55 billion in improper payments.

In FY 2023, CMS implemented a revised sample allocation methodology to reallocate the sampled beneficiaries across the strata proportionally according to strata size rather than evenly. By evaluating the variances within and between strata, CMS determined the alternative sample allocation would yield a more precise overall error estimate and a more efficient sample. In FY 2021 and FY 2022, CMS implemented methodology and policy changes which established a baseline in each year. The FY 2023 error rate calculation follows those previously implemented policy changes. While FY 2023 and FY 2022 are comparable, they are not directly comparable to earlier reporting years.

To improve the Part C improper payment rate, CMS has implemented the following actions:

- Comprehensive Trainings: In March 2023, CMS held a Medicare Part C Fraud, Waste, and Abuse webinar covering the latest schemes, trends, data analysis, and investigations. The training featured presentations by law enforcement, plan sponsors, and program integrity contractors. In October 2023, an in-person training for plan sponsors addressed Medicare Part C and D schemes, trends, data analysis, and investigations. It also included a demonstration of our latest systems that aid plan sponsors in oversight and monitoring.
- Outreach: HHS maintained formal outreach to plan sponsors for incomplete or invalid documentation to address potential improper payments during the sample submission period. Furthermore, HHS sent Final Findings Reports to all Part C sponsors participating in the improper payment measurement, offering feedback on their submissions and validation results compared to all participating sponsors.

[27] https://www.gao.gov/products/gao-14-571

- Risk Adjustment Data Validation (RADV) Audits: Contract-level RADV audits are HHS's primary strategy corrective action to recoup overpayments in Medicare Part C. RADV uses medical record review to verify the accuracy of diagnoses submitted by MA organizations for risk adjusted payment. HHS expects payment recovery will have a sentinel effect on the quality of risk adjustment data 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 January 2023, CMS finalized technical details regarding the RADV program, specifically codifying in regulation that CMS will extrapolate RADV audit findings beginning with payment year (PY) 2018 audits.

The Part D gross improper payment estimate reported for FY 2023 (based on the 2021 payment year) was 3.72 percent or $3.35 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.

In FY 2023, CMS implemented methodology refinements that contributed to an increase in the FY 2023 improper payment rate estimate. The methodology was adjusted to recognize payment errors resulting from the use of incorrect benefit parameters. In those instances, Sponsors were not utilizing CMS approved parameters in the original processing of a PDE. Including improper payments due to the application of incorrect benefit parameters improves the accuracy of the simulation by incorporating those improper payments rather than suppressing those errors, as occurred in prior years' estimations. Other technical methodology changes included: improving the accuracy of the simulation by using a more appropriate sampling unit, decreasing the number of simulations to align to statistical literature, aligning the confidence interval calculation to the sample design, and improving the simulation by applying more accurate estimates when there are missing or incomplete payment parameters. Due to the methodology changes introduced in FY 2023, the rates for FY 2022 and FY 2023 are not comparable. The FY 2023 estimate is a new baseline for improper payments in Medicare Part D.

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

- Training: In FY 2023, CMS continued national training sessions on payment and data submission with detailed instructions as part of the improper payment estimation process for Part D plan sponsors. CMS conducted Opioid Education Mission webinars in November 2022 and May 2023. In September 2023, an in-person Opioid Education Mission took place at the Atlanta Regional Office.
- Outreach: CMS continued formal outreach to plan sponsors with respect to invalid or incomplete documentation to clear potential improper payments during the sample submission window. Additionally, CMS distributed Final Findings Reports to all Part D plan sponsors participating in the Part D improper payment measurement. This report provided feedback on their submission and validation results against an aggregate of all participating plan sponsors.

- Part D Audits: HHS audits Part D plan sponsors to address high-risk drugs and educate them on fraud, waste, and abuse. These audits have varying scopes but share the goal of reducing and recovering improper Part D payments. HHS conducted 11 Part D audits in FY 2023.
- Program Integrity Audits: HHS audits Part D plan sponsors to reduce improper payments and detect non-compliance with program integrity requirements. HHS conducted four Program Integrity Audits, aiming to educate plan sponsors about fraud, waste, and abuse issues.

Additional information on Medicare Part C and Part D improper payments can be found in the FY 2023 Agency Financial Report[28] and CMS website.[29]

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 2023, CMS triaged more than 73,000 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 35,000 policies met the unauthorized enrollment criteria and subsequently cancelled the policies. 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 over 80 investigations of outlier and high-risk agents and brokers, and made recommendations for administrative action, including suspension and termination of an agent's and/or broker's registration to sell policies on the FFM. CMS also performed over 800 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. Ninety-three (93) such requests were received and fulfilled to date. Last, 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 a 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 FFM and reported for the first time in the FY 2022 AFR. HHS continues to develop the improper payment measurement methodology for the SBMs and issued a final rule in April 2023 to establish the Improper Payment Pre-testing and Assessment (IPPTA) to prepare SBMs for the planned measurement of improper payments. 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. HHS will continue to update its annual financial reports with the measurement and implementation status.

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

The Exchange Improper Payment Measurement (EIPM) is an annual measurement of payment error for the FFM to estimate the extent of payments which did not satisfy regulatory requirements relating to eligibility and payment determinations. The improper payment rate and amounts estimated from this sample reflect all health insurance applications with APTC payments processed by the FFM for CY 2021. States that do not use the FFM to administer the APTC program, and instead have elected to operate independent SBMs, were not considered in the sample.

The FFM improper payment estimate for FY 2023, for measurement of CY 2021, is 0.58 percent or $271.75 million. None of the improper payment estimate is associated with missing or insufficient documentation. The estimated percentage of APTC dollars paid correctly was 99.42 percent. This means the FFM paid an estimated $46.23 billion correctly in FY 2023.

The causes of overpayments include manual administrative errors (60.71 percent of over-payments, or $158.28 million) and automated process errors (39.29 percent of overpayments, or $102.44 million) associated with determining consumer eligibility for APTC payments.

Manual administrative errors generally relate to the FFM's processing of additional documentation provided by consumers in situations where the FFM was unable to verify consumer eligibility using automated processes. Manual eligibility verifications involve complex rules and a large variety of documentation types and formats, and therefore have a heightened risk of error. The nature of manual administrative errors may vary between reporting periods. For calendar year 2021, the primary driver of manual errors related to the FFM accepting consumer-submitted documents which didn't contain elements required by policy (for example, absent company letterhead and a signature of a company official for written explanations provided by a consumer's employer).

Combined Improper Payment Data

The APTC program represents the first of two potential[30] 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 (hereafter, Net PTC). That is, total Premium Tax Credit outlays/credits are equal to APTC payments plus Net PTC claims. The Internal Revenue Service (IRS) measures improper payments associated with Net PTC claims, and for Calendar Year 2021 reported[31] Net PTC claims of $1.97 billion, improper payments of $512.71 million, and an improper payment rate of 26.04 percent. The combined APTC and Net PTC improper payment estimate is $784.46 million out of $48.47 billion total Premium Tax Credit outlays/claims, or 1.62 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 SBMs.

In the ordinary course of preparing their tax filing, a consumer may claim a total Premium Tax Credit that is less than the APTC payments made on behalf of the consumer for the respective tax year. For example, a consumer's income for the tax year may exceed what the consumer anticipated when the consumer enrolled in health insurance coverage, resulting in eligibility for a

[30] Taxpayers may elect not to benefit from APTC payments, and instead may claim the entirety of the Premium Tax Credit at the time of tax filing.

[31] Please also see the Fiscal Year 2023 U.S. Department of the Treasury's Agency Financial Report for more information.

lesser Premium Tax Credit benefit than expected. Amounts paid in APTC exceeding the total Premium Tax Credit to which a consumer is entitled are referred to as "Excess APTC." A consumer may have an obligation to repay Excess APTC amounts, and such repayments may reduce monetary losses associated with improper payments. The combined APTC and Net PTC improper payment information does not reflect any effects related to the repayment of Excess APTC.

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

- Systems Automation: HHS takes corrective actions by identifying and fixing system defects within the Exchanges, often identified through internal quality control and external reviews.
- Eligibility Support Contractor Education: Personnel undergo thorough onboarding training, annual refreshers, and quick lessons for policy or operations updates. HHS conducted extra training sessions for Data Matching Issues verifications, casework, and outreach.
- Agent/Broker Risk Model: The Marketplace Program Integrity Contractor uses a risk model to assess agents' and brokers' potential fraud or misconduct and calculates a risk score for each agent or broker based on various risk factors. Agents or brokers with the highest risk scores are investigated first. In 2023 CMS began taking administrative actions based on this model.

Additional information on FFE improper payments can be found in the FY 2023 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.

Healthcare 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.

- Leveraging HFPP resources and relationships to generate 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 2023, the HFPP reached a total membership level of 300 partner organizations, comprised of 6 Federal agencies, 80 law enforcement agencies, 15 associations, 136 private payers, and 63 state and local partners, including 50 State Medicaid Agencies.

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, consistent with all applicable privacy requirements, frequently updated data including personally identifiable information (PII) and protected health information (PHI). The HFPP is currently using professional, institutional, and pharmacy claims, and began collecting dental claims to be used in studies beginning in FY 2024.

Over 334 billion professional claim lines (professional, institutional, and pharmacy) were submitted by partners through FY 2023 for the purpose of conducting cross-payer analyses. Examples of studies initiated in FY 2023 include the identification of problematic billing in the following areas:

- COVID-19 add-on laboratory testing,
- excessive telehealth billing,
- applied behavioral analysis (ABA) therapy,
- genetic testing,
- outlier billing for members with substance use disorder (SUD), and
- evaluation and management (E/M) improbable days.

The HFPP also continued its efforts to foster collaboration among partners in FY 2023 by hosting 5 virtual information-sharing sessions, small group discussions, and quarterly Executive Board meetings. Of these sessions, one was specifically for state partners and drew 168 attendees, while the average of the other four was over 1,278 attendees per event. 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 holds various focus groups to foster open dialogue on issues and schemes, and to identify types of studies partners would like the HFPP to conduct.

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 2022 data publication (on June 30, 2023) was the second 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 that added five provider types to the Open Payments data.

For Program Year 2022 (January 1, 2022–December 31, 2022), CMS published 12.59 billion in payments[32] and ownership and investment interests that were made from reporting entities to covered recipients. This amount is comprised of 14.11 million publishable records attributable to 588,514 physicians, 271,682 non-physician practitioners,[33] and 1,240 teaching hospitals. Payments in the three major reporting categories included:

- $3.71 billion in general (i.e., non-research related) payments;
- $7.58 billion in research payments; and
- $1.29 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 80.66 million records, accounting for $68.44 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 2023, HHS allocated $35 million in HCFAC appropriations to the Administration for Community Living (ACL) to support SMP program infrastructure and provide grants to SMP projects 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 has been modified in subsequent appropriations to require a fixed amount as a funding floor for ACL. Between FY 2018 and FY 2022, the amount was increased gradually from $17.6 million to $30 million. In FY 2023, appropriations were set at no less than $35 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

[32] All Open Payments numbers above one million are rounded, which may result in the total of the individual payment categories not adding to the total published value.

[33] For the purpose of the Open Payments program, NPPs include: physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants and certified nurse midwives. The non-physician practitioner terms are defined in the Final Rule. (See 42 C.F.R. § 403.902.)

FY 2022, ACL requested and received $2 million for a one-time effort supported by wedge funding to expand efforts of the program at the national, state, and local levels to reach people in underserved communities. In FY 2023, an additional $1.3 million in wedge funding was provided. However, these funds were not to support the Senior Medicare Patrol program, but were provided instead to address misuse of Medicaid funding, supporting work between ACL and CMS involving: (1) implementation and related oversight of the Medicaid HCBS settings rule; and (2) work with CMS and others across HHS through ACL's networks to prevent the unnecessary institutionalization of people with disabilities.

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 2023, ACL held a new SMP grant competition and awarded $32.5 million in funding to 54 SMPs nationwide, all of whom were incumbent grantees. Each SMP grantee received a standard, base amount of funding to support the operation of their project, as well as an additional, variable amount of funding based on the number of Medicare beneficiaries residing in the state and rural areas of the state. SMP projects use this funding to educate and empower Medicare beneficiaries to prevent, detect, and report Medicare fraud, errors, and abuse.

COVID-19 Fraud Schemes

Fraud schemes relating to COVID-19 became prevalent beginning in March 2020 and have continued since that time. Throughout the COVID-19 public health emergency, 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. The majority of complaints received by the SMP grantees continued to relate to COVID-19 treatments, testing, vaccines, and cures, followed by complaints about other pandemic-related fraud. COVID-19 related cases increased exponentially during spring 2023. Total cases averaged 11.4 per month from 2020–2022 and grew to an average of 139.3 cases per month during the first seven months of 2023. It is anticipated that this number will decline with the end of the public health emergency in May 2023, but the SMP program has yet to see a significant dip in cases.

In addition, ACL, the HHS-OIG, and the SMP National Resource Center have continued to work 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 to warn Medicare beneficiaries and their families to take precautions. 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: 2022 Performance Data for the Senior Medicare Patrol Projects (OEI-02-23-00150)), the SMP projects conducted 525 group education events covering COVID-19 fraud issues in 2022, reaching a total of 8,791 people. In addition, they conducted 183 instances of media outreach on this topic, reaching an estimated 12.5 million people.

Genetic Testing Fraud Schemes

Genetic testing fraud continued to be a widespread issue nationally in FY 2023 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 reaction to this ongoing concern, the SMP program continued its educational outreach on fraud schemes involving genetic testing. The consumer fraud alert on genetic testing advised beneficiaries to be suspicious of strangers who offer free genetic tests. The alert also cautioned beneficiaries about sharing personal information that can be used fraudulently. In 2022, the SMP projects conducted 537 group education events covering genetic testing fraud issues in 2022; these events reached 37,286 people. In addition, they conducted 165 instances of media outreach on this topic, reaching 13.4 million people.

Hospice Fraud Schemes

The SMP program also expanded its educational outreach on fraud schemes involving hospice in FY 2023. A hospice-related consumer alert warned beneficiaries about potential fraud schemes that involve unsolicited marketing tactics to enroll beneficiaries in hospice services. It advised beneficiaries to be sure that their doctor had assessed their condition and certified that they are terminally ill and expected to live 6 months or less. The alert also advised beneficiaries never to accept gifts in return for hospice services and to be wary of too-good-to-be-true offers. In 2022, the SMP projects conducted 322 group education events covering hospice fraud issues, reaching a total of 25,535 people. In addition, they conducted 121 instances of media outreach on this topic, reaching 12.9 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 2022 (OEI-02-23-00150). In CY 2022, the SMP projects had a total of 5,365 active team members who conducted 18,274 group outreach and education events, reaching an estimated 1,240,000 people. In addition, the projects had 246,722 individual interactions with, or on behalf of, a Medicare beneficiary. For CY 2022, the SMP projects reported $153,812 in expected Medicare recoveries. Over half of these recoveries came from one project that identified a provider who billed for evaluation and management (E/M) claims when the only service rendered was the administration of the COVID-19 vaccine. The E/M claims were not supported by the medical record. The provider was ordered to pay over $86,000 to resolve their civil liability. In addition, cost avoidance in 2022 totaled $31,122, while savings to beneficiaries and others totaled $74,459 for all SMP projects.

Since the SMP program's inception, the program has received nearly 4 million inquiries from Medicare beneficiaries about preventing, detecting, and reporting billing errors, potential fraud, or other discrepancies. SMP projects have also educated more than 43.8 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 2020-2023 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 $148.8 million in savings attributable to the SMP program since its inception in 1997.

Medicare Fraud Prevention Week

In FY 2023, the second Medicare Fraud Prevention Week (MFPW) was held June 5–11, 2023, marking the SMP program's 26th 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 initial event was a true success, confirming the need for this observance to be celebrated in years to come. The event focused on the actions that everyone could take to prevent Medicare fraud, errors, and abuse. Materials 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. Goals for this second MFPW 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 final impact was measured. Highlights include:

- Facebook paid ad campaign resulted in a reach of 1,297,455 and 13,551 event landing page views;
- Google page ad campaigns resulted in 7.04 million impressions, 56,500 clicks, and 52,800 conversions (traffic to website);
- Spotify ads were used for the first time for MFPW. As a result of three ads, there was a combined reach of 991,988, 1,099,481 impressions, and 3,798 clicks to the event website.
- Smpresource.org had 35,260 page views, up from 14,988 page views last year, and 10,412 users, up from 2,992 users;
- Significant media coverage throughout the U.S., including an online article by WTOP—the largest radio station (by revenue) in the U.S. with an average of 5.8 million monthly website visitors;
- The SMPRC news release, which was distributed nationally via PR Newswire/Cision, was picked up by 403 media outlets, with an estimated reach of more than 266 million people nationwide;
- An estimated 307+ Facebook posts with an estimated reach of nearly 3 million;
- An estimated 160+ tweets with an estimated reach of 2.3 million;
- Two OHIC/ACL tweets receiving a significant number of views;
- Acl.gov/MFPW received 650 page views with an average time spent on the page of 4:37 minutes; and
- The matte article, "How to avoid becoming a victim of Medicare fraud," received 1,088 online placements with an estimated audience reach of more than 164 million people.

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 2023, the Center received a continuation award totaling $850,000. In addition, the Center received supplemental funds totaling $150,000 to focus on the continuation of previously planned grants. 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. One highlights of the SMP National Resource Center's planned work during the next five-year period includes researching, developing, and maintaining a new national SMP-focused mobile application. This mobile app will be the first of its kind by helping beneficiaries more capably identify potential fraud risks and occurrences. This app will have FISMA-level information security and is being actively built currently for hopeful launch late 2024. Additional grant highlights include 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 2023, 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)[34] and SMP National Beneficiary Satisfaction Survey contract. The goal of this contract, which entered Year 4 in FY 2023, 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

[34] The SHIP 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.

educational presentations and identify opportunities for recognition and overall network improvements.

The third 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:

- 4.57—"This Presentation provided me with useful information"
- 4.62—"Overall, I am satisfied with the presentation today"
- 4.38—"I would contact the presenter for help or information"
- 4.59—"I would recommend this presentation to others"

One-on-One Interactions:

- 4.17—"I was able to find and contact SMP in a timely fashion"
- 4.33—"The information provided to me was useful"
- 4.35—"SMP provided me with useful information"
- 4.52—"Overall, I was satisfied with my interaction with SMP"
- 4.40—"I would contact SMP again for assistance"
- 4.40—"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 2023, HHS allocated the Office of the General Counsel (OGC) $8.0 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 2023 helped the government establish approximately $881.4 million 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 2023, OGC worked collaboratively with DOJ and HHS-OIG on numerous FCA matters regarding a variety of issues such as: 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 Record (EHR) incentive programs, kickbacks and other unlawful marketing practices in connection with 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 2023 helped the Federal Government recover approximately $8.06 million.

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 2023. 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, in *Forest City Rehab & Nursing Center*, OGC successfully defended CMS's finding of immediate jeopardy based on the facility's failure to take all reasonable precautions to protect residents from foreseeable abuse and accidents. Although the facility was aware that two residents suffered from severe mental illness and had violent criminal histories, it housed them in the same room, mostly unsupervised. Shortly thereafter, following signs of discord, one of the residents was found unresponsive. He died due to strangulation by his roommate. The ALJ sustained the imposition of a $234,495 CMP, finding the facility's decision to house the two volatile residents together, "unfathomable," and, "a recipe for explosive consequences."

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 2023, OGC successfully argued that the revocation of the billing privileges of Stuart Todd Lewis, DO, and his ten-year reenrollment bar should be affirmed. The remedies were based on Dr. Lewis's conviction for conspiracy to commit wire and bank fraud, and his failure to report the adverse legal action to CMS.

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 defends CMS non-renewal or termination actions of Part C and Part D plan contracts.

Regulatory Review and Programmatic Advice

In FY 2023, 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:

- With the end of the public health emergency (PHE) related to the COVID-19 pandemic, much of the COVID-19 work has subsided; however, OGC continues to provide counsel to CMS on a wide variety of PHE-related topics in the context of Medicare, Medicaid, and CHIP. For example, OGC continued to advise CMS on issues regarding the COVID-19 vaccine rule, including providing advice on programmatic implications involving CMS and state oversight functions, and OGC advised CMS on the final rule withdrawing COVID-19 vaccination mandates for health care workers.
- OGC continues to spend extensive time on various opioid-related issues, primarily related to potential CMS monetary recoveries stemming from other parties' settlements, judgments, and bankruptcy actions.
- OGC has a significant role in advising CMS on the implementation of the drug pricing reforms in the Inflation Reduction Act of 2022. OGC is assisting and advising CMS on its development of policies for Medicare Part D Inflation Rebate Program, Medicare Part B Inflation Rebate Program, and the Medicare Drug Price Negotiation Program. Support for program-integrity aspects of these programs include counsel on the development of policies for compliance monitoring and corrective action plans as well as mechanisms for imposition of CMPs.
- OGC attorneys assisted with several important program integrity proposed and final rules. OCG advised CMS on provider enrollment riders in the annual home health, hospice, and physician fee schedule rules, and on proposed rules that would establish new disclosure requirements for nursing home ownership with a focus on private equity, codify DMEPOS requirements regarding the need for refills, and modify existing regulations regarding reporting and returning overpayments.
- OGC attorneys advised CMS's Center for Program Integrity on significant regulatory and enforcement matters pertaining to provider enrollment, payment suspension (including expedited review of payment suspensions notices related to COVID-19 test kits), local coverage determinations, overpayment recovery, pre-payment and post-payment medical review, and prior authorization.
- OGC continues to counsel the CMS Quality, Safety, and Oversight Group (QSOG) on issues related to the oversight and enforcement of certified institutional providers' compliance 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 and commented on regulations and guidance documents addressing surveys and requirements for end stage renal dialysis (ESRD) facilities, nursing homes, hospitals, and hospice programs, among others.
- OGC advised on a final rule which finalized CMS authorities with respect to extrapolation and other issues related to risk adjustment data validation audits in Medicare Part C.
- 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, the imposition of compliance actions and corrective action plans, and the implementation of Advance Investment Payments.

- OGC continues to collaborate with DOJ and the Health Resources and Services Administration (HRSA) on issues arising in connection with the Provider Relief Fund (PRF) which Congress created through the CARES Act (2020), to assist health care providers during the pandemic.

Physician Self-Referral (Stark Law)

In FY 2023, 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 2023, OGC continued to assist and advise CMS following the publication of its rule modernizing and clarifying the Stark regulations, which went into effect in 2021. 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 2023, 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.

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 a Chapter 11 bankruptcy case, *In re Americore Holdings*, OGC represented CMS's interests when the estate retained and used money that was issued, post-bankruptcy petition, in April 2020, in the initial distribution from the PRF. The estate was ineligible to retain the PRF money, however, because its hospital closed at the end of 2019. Upon the trustee's unsuccessful efforts to reopen the hospital and her sale of the assets of the defunct facility, the trustee remitted a portion of the sale proceeds to HRSA toward repayment of the PRF money. She then joined in a motion for administrative expense priority treatment of HRSA's claim for the amount outstanding. The court entered an order to that end.

State Medicaid Disallowances

Over the past several years, upon identifying an increasing number of questionable state financing schemes designed to maximize Federal payments under Medicaid, CMS has taken an increased number of Medicaid disallowances. Correspondingly, OGC continues to see a significant increase in its workload regarding proposed disallowances, requested reconsiderations, and defense against Medicaid disallowance appeals before the Departmental Appeals Board. As a result of OGC's advocacy, CMS has prevailed in matters in FY 2023 that have upheld millions of dollars in disallowances.

In summary, OGC's efforts in FY 2023 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 2023, HHS allocated $6.4 million in HCFAC funding to the FDA's 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 can prevent 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 336 criminal HCFAC investigations. In FY 2023, OCI, through its PFP, opened 11 criminal investigations, including investigations involving drug compounders, clinical trials, and foreign and domestic medical-product manufacturers.

The 11 criminal investigations opened through PFP in FY 2023 are broken down as follows:

- Three investigations involving allegations of clinical trial fraud. The first investigation involves a firm who is alleged to have conducted clinical trials and engaged in data fabrication, enrollment of subjects when not clinically appropriate, and assessment scores being changed. A second investigation involves alleged clinical trial fraud and falsification of documents among staff submitting their own blood and urine in place of ineligible patients for various drug studies. The third investigation involves alleged falsification of data, failure to report adverse events, and forging subject enrollment data.

- Three investigations involving allegations of application fraud. The first investigation involves a firm who is alleged to have intentionally misrepresented data necessary to determine safety and effectiveness to obtain Section 510(k) clearance. The second investigation involves a doctor who is alleged to have created a fictious laboratory and allegedly falsified an FDA approval letter for Individual Patient Expanded Access for a biologic clinical study. The third investigation involves a medical device manufacturer and doctor that are alleged to have omitted documentation regarding device microprocessor and software validation under previous Section 510(k) applications.
- Three investigations involving allegations of fraudulent marketing schemes. One investigation involves a firm who is alleged to have falsely reported and misrepresented to the market and public regarding FDA approval status on their company's Investigational New Drug application. The second investigation involves alleged false or misleading promotional claims by health care providers, marketers, or pharmaceutical sales representatives on the intended use of a drug, as well as health care fraud and potential kickbacks. The third investigation pertains to the alleged manufacturing of an unapproved mixture for injection.
- Two investigations involving allegations of flagrant manufacturing violations. One investigation involves a firm who is alleged to have marketed and used unapproved biological products and made false statements and misrepresentations to FDA investigators. The other investigation involves an alleged manufacturing defect in medical devices approved to monitor patient vital signs. The defect is alleged to have caused a delay of notification to medical personnel in instances where patient conditions require prompt attention.

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 2023 are as follows:

- In October 2022, in the Southern District of Florida, four defendants were sentenced who conspired to defraud clients paying for clinical trial work intended to evaluate treatments for various medical conditions, including opioid dependency, irritable bowel syndrome, and diabetic nephropathy. The defendants were ordered to pay approximately $2.1 million in restitution. In May 2023, an additional defendant who was identified as the principal investigator was found guilty of making false statements to an FDA investigator.
- In November 2022 and December 2022, in the Northern District of California, two defendants were sentenced for defrauding investors of hundreds of millions of dollars. At trial, the government demonstrated that the defendants knew that many of their representations to FDA and others regarding their company's proprietary blood analyzer were false. Yet, they conspired to convince potential investors and patients that the claims were true. The first defendant was sentenced to over 11 years in Federal prison and the second defendant was sentenced to almost 13 years in Federal prison. They were also ordered to pay approximately $452,047,268 in restitution and fines.

- In November 2022, in the District of New Jersey, a French national and executive of a pharmaceutical company was sentenced to time served and deported to France. The French national previously pled guilty for making false statements to the FDA indicating he had purchased the New Drug Application to gain control of the rights to sell a weight-loss drug in the United States.
- In March 2023, in the Northern District of Ohio, eight defendants were sentenced for conspiracy to commit mail and wire fraud. Five defendants were sentenced to approximately five years, two and a half years, two years, and a year in Federal prison while the remaining three defendants received probation. In aggregate, the defendants were ordered to pay $20,118,967 in restitution. The defendants enrolled subjects in clinical trials under fictitious names, past subjects without their knowledge, and other subjects who did not meet pre-established criteria. In addition, the defendants fabricated and falsified medical records, informed consent forms, and other documentation regarding these studies.
- In May 2023, in the Central District of California, two defendants were sentenced for their participation in a scheme to submit fraudulent claims to an insurance company for a fake clinical trial to recruit students insured by a college university. The two defendants were sentenced to three years of probation and ordered to pay approximately $667,000 in restitution and fines.
- In May 2023, in the District of Massachusetts, a medical corporation pled guilty to charges related to the receipt of misbranded drugs and was ordered to pay more than $2.5 million in fines and forfeiture. The medical corporation used foreign Botox to treat patients suffering from migraine headaches and did not disclose to these patients that it purchased the drugs from foreign sources or that the drugs were not labeled for distribution in the United States.
- In September 2023, in the Southern District of Florida, the last of four subjects was convicted of providing false statements to the FDA and falsifying data associated with a clinical trial evaluating the efficacy of a potential treatment for Clostridium difficile. One defendant was sentenced to four years of probation and ordered to pay $277,920 in restitution and fines. The remaining three defendants are scheduled to be sentenced in November 2023.

In addition to the successful prosecutions noted above, the FDA believes that various investigations already initiated under the PFP may lead to future judicial action, such as criminal prosecution and monetary recoveries. These investigations include drug manufacturers and clinical investigators under investigation for data integrity and other violations that 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. Examples of the training that occurred in FY 2023 are:

- In November 2022, OCI special agents participated in a three-day in-person conference sponsored by the National Health Care Anti-Fraud Association. The conference allowed OCI special agents to enhance their skills managing complex investigations, including negotiation techniques and interpretation of clinical trial data. Additionally, this conference allowed OCI special agents to liaise with subject matter experts and partner law enforcement agencies, thereby positioning FDA to receive new leads for

investigations under the PFP program.

- In February 2023, OCI special agents provided training on suspected fraud or misconduct in clinical trials to its external partners at the Society of Quality Assurance during the 7th Global Quality Assurance Conference. This training included clinical trial case examples, a question-and-answer session, ways to report suspected criminal activity through the appropriate channels, and an opportunity to engage with OCI representatives.
- In March 2023, OCI special agents provided training to new FDA consumer safety officers (CSOs). The training is intended to introduce new CSOs to PFP's initiatives and investigative priorities and educate them how regulatory inspections and evidence obtained during regulatory activities can help identify health care fraud.
- In April 2023, OCI special agents provided training to newly hired criminal investigators at the Federal Law Enforcement Training Center in Charleston, South Carolina. The training provided new OCI special agents with the fundamentals of health care fraud and FDA's PFP initiatives and priorities.
- In April 2023, OCI special agents provided training to newly assigned or hired CSOs in FDA's Office of Regulatory Affairs, Bioresearch Monitoring Program. The training is intended to introduce new CSOs to PFP's initiatives and investigative priorities and educate them how regulatory inspections and evidence obtained during regulatory activities can help identify potential criminal violations.

DEPARTMENT OF JUSTICE

United States Attorneys

The U.S. Attorneys were allocated $67.3 million in FY 2023 HCFAC funding for civil and criminal health care fraud enforcement efforts. These funds supported AUSAs, 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 (CSA) 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[35]

In FY 2023, USAOs opened 802 new criminal health care fraud investigations and filed criminal charges in 346 cases involving 530 defendants. During that period, 476 defendants were convicted of health care fraud-related crimes.

Civil Matters and Cases[36]

In FY 2023, USAOs opened 770 new civil health care fraud investigations and there were 1,147 civil health care fraud matters pending at the end of the fiscal year. In FY 2023, together with the Civil Division and relators, USAOs obtained settlements and judgments under the civil FCA totaling over $1.8 billion.

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.

Qui tam cases and other civil health care fraud FCA cases are either 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 CSA against defendants ranging from manufacturers down to individual licensed providers. Civil AUSAs also work to stop ongoing fraud through the use of the Anti-fraud Injunction Statute.

[35] FY 2023 numbers are actual data through the end of September 2023. This data includes all occurrences of records classified with the 03G–Health Care Fraud criminal program code.

[36] FY 2023 numbers are actual data through the end of September 2023. This data includes all occurrences of records classified with the FRHC–Health Care Fraud civil code.

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 25 districts across the country. Each Strike Force team consists of AUSAs and support personnel from the USAO, as well as attorneys and support staff from the Criminal Division and law enforcement agencies.

Since 2018, USAOs for 10 Federal districts in six states[37] have joined with Criminal Division attorneys, as well as law enforcement partners at the FBI, HHS-OIG, and DEA, to form 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, under the Opioid Fraud and Abuse Detection Unit (OFAD) program, 11 AUSAs are allocated to focus 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 March, the Associate Attorney General announced the formation of the Opioid Crisis Civil Enforcement Task Force. The U.S. Attorneys for the Districts of Colorado and Rhode Island, along with senior leadership from the Civil Division, lead the Task Force in its mission to coordinate major national litigation against pharmacies and distributors for alleged violations of the CSA and/or the FCA. Over a dozen USAOs are actively involved in this Task Force and in litigating the matters under its mandate.

In FY 2023, USAOs continued their pursuit of civil and criminal investigations for gross failure of care as part of the Elder Justice Initiative's National Nursing Home Initiative. As noted in the case discussions above, one case against a landlord and other operators of a nursing home in New York resulted in a $7 million civil FCA recovery for worthless services, as well as the exclusion of numerous individuals from Federal health care programs after the operators allowed conditions to deteriorate to the point that residents suffered medication errors, unnecessary falls, and the development of pressure ulcers.

USAOs also take an active part in nationwide criminal health care fraud enforcement actions. Nine districts participated in the April 2023 COVID-19 health care fraud enforcement action, and numerous others charged health care fraud matters during the Nationwide COVID-19 Enforcement Action led by the COVID Fraud Enforcement Task Force in August 2023. These actions include fraud related to over-the-counter COVID tests, Personal Protective Equipment, the Provider Relief Fund, and billing for unnecessary office visits or tests associated with COVID testing or vaccinations.

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. In addition to the nursing home case discussed above, USAOs prosecuted cases involving schemes that exploited or harmed:

[37] The USAOs are the Northern District of Alabama, Eastern District of Kentucky, Western District of Kentucky, Southern District of Ohio, Eastern District of Tennessee, Middle District of Tennessee, Western District of Tennessee, Northern District of West Virginia, Southern District of West Virginia, and Western District of Virginia.

- children who were recruited for unnecessary drug testing;
- 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; and
- hospital patients who were provided saline for pain because hospital employees had stolen morphine or fentanyl from the vials.

Moreover, USAOs are also handling complex, resource-intensive cases involving several complex schemes. Many of these schemes involve kickbacks, an insidious form of fraud in that it alters clinical decision-making and is often hard to detect. Kickbacks make up all or part of the wrongdoing in many of the highlighted cases this year, including:

- COVID-19 testing, genetic testing, and DME schemes;
- electronic health record fraud;
- sophisticated fraud schemes involving complex ownership structures of health care entities, including by private equity and real estate investment vehicles;
- home health and hospice fraud; and
- compounded pharmaceutical and other prescription drug fraud.

In addition to funding AUSAs, auditors, paralegals, and investigators in USAOs, HCFAC funding provides critical support for complex health care fraud investigations and litigation. Using these funds, the Executive Office for U.S. Attorneys (EOUSA) supports contract forensic investigators and auditors 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 National Health Care Anti-Fraud Association's (NHCAA) SIRIS database.

As well as managing national-level support, EOUSA provides districts with case-specific funding and litigation support for extraordinary needs. In FY 2023, HCFAC money funded more than 41 such requests from USAOs totaling more than $2 million. This support pays for consultants in highly technical areas, such as software experts in EHR cases, economic experts in Medicare Part C and opioid cases, and medical consultants in highly paid specialties, and it is essential to investigating and developing these complex cases.

To ensure a focused and coordinated approach to health care fraud enforcement, EOUSA has a national health care fraud coordinator, and each USAO has designated criminal and civil health care fraud coordinators. EOUSA coordinates policy and enforcement with HHS and other DOJ components, and also manages HCFAC program requirements such as the timely reporting of criminal fine amounts to Treasury for transfer to the Medicare Trust Fund, and the timely reporting of health care fraud convictions to HHS for inclusion in the National Provider Database. EOUSA also organizes extensive training for AUSAs, as well as paralegals, investigators, and auditors on a wide variety of health care fraud enforcement matters. EOUSA presented webinars throughout the year focused on emerging health care fraud issues. District 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.

Civil Division

The Civil Division received approximately $60.8 million in FY 2023 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 2023, civil health care fraud settlements and judgments under the False Claims Act exceeded $1.8 billion.[38]

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 a testing company paid kickbacks to physicians ostensibly supervising PET scans, in the form of hourly rates far in excess of fair market value and for certain other services never rendered (the CII matter discussed above). Moreover, the Fraud Section resolved allegations that an electronic health record company, Modernizing Medicine Inc., solicited and received kickbacks from a life sciences company in exchange for recommending and arranging for the EHR company's customers to use that company's products (the ModMed matter discussed above). The Fraud Section also resolved allegations that another EHR company paid kickbacks in the form of credits (worth up to $10,000) and entertainment or sporting events tickets to customers to induce purchases and referrals of its products the (NextGen matter discussed above). And the Fraud Section resolved matters resolving allegations of providers paying or receiving kickbacks (for example the Smart Pharmacy 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, the Fraud Section secured a $172.5 million settlement with a national insurer over submitting unsupported diagnosis codes to CMS to increase reimbursement for the insurer's Part C plans. The case involved allegations of chart reviews leading to unsubstantiated diagnosis codes and diagnosis codes classifying patients as morbidly obese, where those patients did not meet the clinical threshold for such a diagnosis (the Cigna matter discussed above). And the Fraud Section continues to investigate or litigate a number of significant matters involving alleged FCA violations concerning Medicare Part C plans or

[38]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 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.

providers, covering a large variety of allegedly fraudulent conduct resulting in inflated Federal reimbursements.

Also, the Fraud Section continued to secure settlements involving Medicaid managed care. In particular, after securing the first such settlement of its kind last year, the Fraud Section secured several other settlements involving the Medicaid Managed Care adult expansion (the Cen-Cal related matters described above). As in the past, the Fraud Section works on Medicaid Managed Care supplements, pursuing schemes also impacting traditional Medicaid (such as the Advanced Bionics and NextGen matters discussed earlier).

As it has previously, the Fraud Section also resolved a number of matters in FY 2023 in which providers billed Federal health care programs for medically unnecessary services, services not rendered as billed, or services not meeting coverage requirements. For example, the Cornerstone and BioTelemetry matters discussed earlier each involved allegations that either hospitals or other providers defrauded Medicare into paying for medically unsupported services, services not rendered, services performed by unlicensed individuals, or services actually conducted—in part—outside the United States in violation of Federal law. And the Smart Pharmacy, Tower Medical, and SCCDC matters described above resolved allegations of medically unnecessary drugs or procedures being provided to Medicare beneficiaries, to boost reimbursement or in contravention of Medicare rules designed to limit unnecessary utilization or limit single use products to use on just one patient.

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.

The Fraud Section also continues to pursue fraud schemes arising from the opioid epidemic, and as part of this work, the Fraud Section and the Northern District of Ohio filed a complaint under the FCA against Rite Aid Corporation and various subsidiaries alleging that Rite Aid knowingly filled unlawful prescriptions for controlled substances. In addition to alleging claims under the FCA, the government's complaint also alleges violations of the CSA. The government's complaint alleges that Rite Aid knowingly filled at least hundreds of thousands of unlawful prescriptions for controlled substances that lacked a legitimate medical purpose, were not for a medically accepted indication, or were not issued in the usual course of professional practice. These unlawful prescriptions included prescriptions for the dangerous and highly abused combination of drugs known as "the trinity," prescriptions for excessive quantities of opioids, such as oxycodone and fentanyl, and prescriptions issued by prescribers whom Rite Aid pharmacists had repeatedly identified internally as writing illegitimate prescriptions.

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. In investigating potential FCA violations, the

Fraud Section closely coordinates with HHS-OIG and CMS, as well as non-Federal entities, including state Attorneys General and state MFCUs, as appropriate.

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 DOJ'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 the Initiative's resources, trainings and tools can be found on the Department's Elder Justice Website (justice.gov/elderjustice). More information regarding the efforts of the Initiative can be found in the Department's annual Elder Justice Report to Congress, which can also be found on the Elder Justice Website.

The Consumer Protection Branch

The Consumer Protection Branch (CPB or the Branch) leads the Department's effort to protect consumers by investigating and prosecuting consumer fraud, deceptive practices, and enforcing product safety laws and other laws related to consumer protection. At the core of the Branch's mission is safeguarding all Americans, but especially the most vulnerable of American consumers, from dangerous, illegal, or fraudulent food, dietary supplements, drugs, medical devices, and consumer products. To this end, the Branch aggressively pursues both civil and criminal cases against those who unlawfully manufacture, distribute, or sell such products that endanger consumers and the government. CPB's growing team contributed more than 70,000 hours to these matters in FY 2023, and that number is likely to grow in the coming year.

Much of the Branch's health care work comes from its close collaboration with the FDA to investigate and prosecute matters related to the Federal Food, Drug, and Cosmetic Act, as well as its partnerships with the DEA and other law enforcement agencies to pursue a host of health care fraud cases. The Branch also routinely collaborates with the USAOs on health care investigations of all sizes, as well as with the Commercial Litigation Branch's Fraud Section to prosecute major health care fraud cases.

During the last year, the Branch continued to work to disrupt the illegal sales of opioids by expanding its active investigations of wrongdoers among pharmaceutical opioid manufacturers, wholesale distributors, pharmacies, and health care providers. CPB's robust portfolio of active investigations seeks to identify and stop wrongdoing at all levels using cutting-edge review tools and a collaborative approach to prosecution. To this end, the Branch engages partner agencies, law enforcement partners, and a large contractor staff to thwart the unlawful manufacture and distribution of opioids and to seek significant civil and criminal monetary penalties.

The Branch continued to lead the charge in the ongoing multi-component litigation effort in United States v. Walmart, Inc., et al. (D. Del.). The 2020 complaint against Walmart alleged numerous violations of the CSA related to the dispensation of opioids from the company's 5,000 pharmacies nationwide. While the Branch continues to dedicate thousands of hours of Federal attorney and contractor time each month to the Walmart matter, it is just one of several large-scale opioid investigations and ongoing litigation.

In December 2022, the Branch, along with its multi-district partners including the USAOs for the District of New Jersey, Eastern District of Pennsylvania, Eastern District of New York, and District of Colorado, filed a civil complaint against Amerisource-Bergen Corporation and two of its subsidiaries *(United States v. AmerisourceBergen Corp., et al.* (E.D. Pa.)), collectively one of the country's largest wholesale pharmaceutical distributors. The complaint alleged that the companies violated Federal law in connection with the distribution of controlled substances to pharmacies and other customers across the country. The complaint alleged that from 2014 through the present, the defendants violated the CSA by failing to report hundreds of thousands of suspicious orders of controlled substances to the DEA. Further, the complaint alleged that AmerisourceBergen employed inadequate internal programs to monitor and identify suspicious orders, and that AmerisourceBergen was aware of significant red flags indicative of diversion of prescription drugs to illicit markets. The complaint seeks both civil penalties and injunctive relief.

In partnership with USAOs, the Branch also is continuing to bring opioid enforcement cases involving local and regional clinics and pharmacies that ignore obvious red flags of diversion and abuse, which can lead to tragic overdoses and deaths. In one recent matter, the court in the Western District of Texas ordered a San Antonio pharmacy and its pharmacist to pay a $275,000 civil penalty and imposed restrictions related to the dispensing of opioids and other controlled substances. In another, the court in the Middle District of Florida ordered a Tampa-area pain management clinic to close and entered judgments against the clinic's owners and its former physician to restrict their ability to prescribe or distribute opioids. The court in the District of Maryland enjoined a Cumberland, Maryland pharmacy and its owner from dispensing controlled substances and ordered them to pay a $120,000 civil penalty. These cases and others make a difference in the local communities where the Branch helps to stem the flow of diverted prescription opioids.

The CPB's extensive FDCA enforcement work continues to protect consumers affected by FDCA violations related to food safety, pharmaceutical, dietary supplements, and medical devices. In one matter, food and ingredient manufacturing company Kerry Inc. pleaded guilty to a charge that it manufactured breakfast cereal under insanitary conditions at an Illinois facility linked to a 2018 salmonellosis outbreak. The company agreed to pay a criminal fine and forfeiture amount totalling $19.228 million, which at the time constituted the largest-ever criminal penalty following a criminal conviction in a food safety case. A Pennsylvania-based medical device distributor, Jet Medical, Inc. agreed to pay $200,000 to resolve criminal allegations relating to a migraine headache treatment, and Jet and two related companies agreed to pay another $545,000 in a civil settlement involving the same device.

Working with USAO partners, the Branch obtained an indictment against a man and business in the Western District of Wisconsin alleged to have committed numerous counts of fraud in a scheme to defraud Medicare and Medicaid by diverting funds through 24 skilled nursing

facilities and nine assisted living facilities in Wisconsin and Michigan being operated without adequate staff, supplies, or services. The indictment alleged that from January 2015 through September 2018, the defendants billed Medicare for over $189 million and received over $49 million and that they billed Medicaid for over $218 million and received over $93 million.

The Branch also continues its work to combat COVID-19 fraud schemes even as the pandemic itself abates. The CPB joined with other components to prosecute numerous cases during the Department's COVID-19 Fraud Enforcement Action from May through July 2023, a sweep of 718 civil and criminal enforcements involving over $800 million in alleged fraud. In August, the Branch announced an enforcement action against nutritional supplement company Quickwork LLC, and one of its owners for claims that their supplements could be used to treat or prevent COVID-19. The defendants were ordered to pay more than $1 million in civil penalties.

The Branch continued its work related to the safety of nicotine and tobacco products. After 23 years of litigation, the Department's longstanding civil racketeering lawsuit, *United States v. Philip Morris USA, Inc., et al.*, D.D.C., was resolved by the entry of a court order imposing the final corrective remedies ordered by the court. The order requires the defendants, the nation's largest cigarette companies, to display signs in 200,000 retail locations nationwide that sell cigarettes to protect the public's health by preventing misleading labelling and advertising by manufacturers. These signs display corrective messaging that outlines the adverse health effects of smoking, the addictiveness of smoking and nicotine, and the detrimental health effects of exposure to second-hand smoke, among other things.

Further, the Branch continued and expanded its work to protect the public from the illegal manufacture and sale of electronic nicotine delivery system (ENDS) products by filing civil suits against six companies and related individuals alleging that the defendants caused tobacco products to become adulterated and misbranded while held for sale, and that they continued to manufacture, sell, and distribute the adulterated and misbranded vaping products despite receiving warning letters from the FDA.

Through its steadfast partnership with the USAO for the Southern District of Florida, CPB continued to endeavour to combat fraud in prescription drug and medical device clinical trials and drug-approval submissions to the FDA. For example, the Branch obtained a conviction in May 2023 against a Florida physician for false representations regarding clinical trials, when no clinical trials had been performed. In another case, CPB senior trial attorneys lead the prosecution of a sham clinical trial company resulting in four convictions and more than $277,000 in restitution.

Criminal Division

The Criminal Division was allocated $43.7 million in FY 2023 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 Violent Crime and Racketeering Section (formerly the Organized Crime and Gang Section).[39]

[39] The former Organized Crime and Racketeering Section was renamed the Violent Crime and Racketeering Section at the end of FY 2023.

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 2023, the HCF Unit's Strike Force program provided attorney staffing, litigation support, and leadership and management to the Strike Forces operating in judicial districts across the United States. The Strike Forces operate 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. The NRRSF provides litigation support and partners with USAOs in jurisdictions where the Strike Force does not have a permanent location.

In 2018 and 2022, the HCF Unit created the ARPO Strike Force and New England Prescription Opioid Strike Force (NEPO), respectively, as joint efforts among 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, 2023, ARPO and NEPO have charged 123 defendants involving more than 117 million controlled substance pills. These efforts have resulted in 68 guilty pleas and 16 trial convictions.

In FY 2023, the HCF Unit achieved the following results:

- filed 146 indictments, criminal informations and complaints involving charges against defendants who allegedly collectively billed Federal health care programs and private insurers approximately $3.2 billion;
- obtained 156 guilty pleas and litigated 40 jury trials, with guilty verdicts against 35 defendants; and
- securing imprisonment for 149 defendants sentenced, with an average sentence of 50 months.

Since the Strike Force inception, prosecutors and AUSAs in Strike Force districts have filed more than 3,000 cases charging more than 5,800 defendants who collectively billed Federal health care programs and private insurers approximately $30 billion, more than 4,100 defendants pleaded guilty and over 500 others were convicted in jury trials, and more than 3,600 defendants were sentenced to imprisonment for an average term of approximately 49 months. Medicare payment trends demonstrate the positive impact of Strike Force enforcement and prevention efforts.

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 to prosecute these significant multi-jurisdictional and corporate fraud cases. Examples of the types of cases prosecuted by NRRSF involve the successful prosecutions of multiple executives of health care companies, including the prosecution of the trial conviction and eight-year sentence of the president of a Silicon Valley-based medical technology company for health care and securities fraud; the conviction and four-year sentence of the Chief Compliance Officer of a pharmacy holding company for Medicare fraud; the guilty plea by the former CEO of a publicly traded biotech company for his scheme to defraud investors by making false and misleading statements about the purported development of a new, blood-based COVID-19 test, which led to millions of dollars in investor losses; and charges against the CEO, former CEO, and VP of Business Development of purported software and services companies. NRRSF also has led the prosecutions of sober homes operators and doctors who exploited patients suffering from addiction, 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.

The HCF Unit coordinated two separate, targeted enforcement actions during FY 2023: the COVID-19 Health Care Fraud Enforcement Action and the National Health Care Fraud Enforcement Action.

In April 2023, the Strike Force announced criminal charges against 18 defendants in nine Federal districts across the United States for their alleged participation in various fraud schemes involving health care services that exploited the COVID-19 pandemic and allegedly resulted in over $490 million in COVID-19 related false billings to Federal programs and theft from Federally funded pandemic programs.

In June 2023, the Strike Force announced a strategically coordinated, two-week nationwide law enforcement action that resulted in criminal charges against 78 defendants for their alleged participation in health care fraud and opioid abuse schemes that included over $2.5 billion in alleged fraud. In connection with the enforcement action, the Department seized or restrained millions of dollars in cash, automobiles, and real estate.

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, or beneficiaries who live a great distance from the clinic they purportedly regularly attended in person.[40] For example, in one case, the data team's efforts led to the opening of an investigation and ultimate conviction of two defendants for a $455 million COVID-19 laboratory testing scheme; over $15.7 million was seized, providing an outsized return on investment for taxpayers. In FY 2023, the team also has completed approximately 2,838 requests for data analysis assistance for USAOs. 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 and that of its USAO and law enforcement partners.

The Violent Crime and Racketeering Section (VCRS)

The Criminal Division's Violent Crime and Racketeering Section (VCRS) 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 than 2.3 million such private sector health plans which cover some 135 million Americans. VCRS 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 Knoxville, Tennessee a VCRS attorney continued to assist the USAO for the Eastern District of Tennessee with the prosecution of the owner-operators of pill mill clinics which sold opioid prescriptions for cash without a legitimate medical purpose. Two investor-owners of clinics charged with RICO conspiracy were extradited from Italy. They pleaded guilty in November 2022 and were sentenced in December 2023 to imprisonment for 120 and 130 months respectively, and they agreed to forfeit more than $2.3 million. Following a 43-day trial, a jury found a co-owner of the clinics and three nurses guilty of maintaining a drug-involved premises. The co-owner was also found guilty of conspiring to distribute controlled substances, money laundering, and RICO conspiracy. In October 2020, the clinic co-owner was sentenced to more than 33 years in prison and forfeiture of $3.6 million. In December 2020, the three nurse practitioners were sentenced to prison terms ranging from 30 to 42 months for their convictions of maintaining a 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 million in clinic revenue, with a corresponding street

[40] 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.

value of $360 million. This partnership between VCRS and the Eastern District of Tennessee has resulted in the investigation and prosecution of over 140 individuals.

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

VCRS 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). VCRS is also responsible for drafting and reviewing criminal legislative proposals affecting employee health benefit plans. Finally, VCRS provides legal guidance to prosecutors and required approval in the use of the RICO statute in prosecutions of racketeering enterprises such as those involved in the distribution of illegal drugs, abuse of Medicare and Medicaid plans, and crimes against privately funded health care benefit programs.

Civil Rights Division

The Civil Rights Division was allocated $11.4 million in FY 2023 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 to combat 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 2023 Accomplishments

Key litigation and enforcement accomplishments in FY 2023 of the Civil Rights Division are:

- Number of matters in active enforcement: 23,
- Cumulative estimate of individuals with disabilities affected: 90,984, and
- Number of institutional facilities affected: 2,377.

Special Litigation Section

In FY 2023, the Section's enforcement efforts affected more than 1,400 health care facilities in eight states, and included the opening of two new investigations, the filing of three statements of interest, and monitoring compliance with seven agreements and one remedial court order impacting over 25,000 individuals with disabilities.

In October 2022 and December 2022, the Section issued findings reports concluding that there is reasonable cause to believe that Nevada and Alaska violate Title II of the ADA by failing to provide community-based behavioral health services for children. As a result, many children with behavioral health disabilities endure unnecessary and unduly long admissions to psychiatric hospitals and psychiatric residential treatment facilities. The Section determined that Nevada and Alaska can reasonably modify their service systems to prevent such unnecessary institutionalization by providing these services to the children who need them.

In January 2023, the Section entered into a consent decree with the State of Iowa to resolve the Department's claims that the State exposes Glenwood residents to unreasonable harm and serious risk of harm by subjecting them to uncontrolled and unsupervised experimentation, inadequate physical and behavioral health care, and inadequate protection from harm, including deficient safety and oversight mechanisms. The decree prohibits uncontrolled and unsupervised experiments; requires better staffing, training, and oversight for clinical care; dramatically limits the use of restraints and seclusion; and requires substantial State oversight over all aspects of Glenwood's operation. The State must also implement policies and procedures to address the underlying deficiencies that led to the alleged constitutional violations. The State of Iowa announced that it plans to close Glenwood in July 2024, and the consent decree requires the State to ensure that Glenwood residents move to the most integrated setting consistent with their informed choice, needs and preferences, with the appropriate services and supports in place. The agreement appoints an independent monitor who assesses the State's compliance with the decree's terms.

In March and June of 2023, the Section issued reports finding discrimination against people with behavioral health disabilities, in violation of Title II of the ADA, when jurisdictions rely primarily on police to be the sole responders to people experiencing behavioral health issues,

even when safety does not require a law enforcement response. The Section released its findings regarding the Louisville Metro Police Department and the Louisville/Jefferson County Metro Government in March 2023. In June 2023, the Section issued a second report making those findings about the City of Minneapolis and the Minneapolis Police Department.

In July 2023, the Section issued a findings report concluding that the South Carolina's use of adult care homes to provide services to adults with serious mental illness violates the Americans with Disabilities Act (ADA). As a result, thousands of adults with mental illness are segregated in adult care homes, often remaining in these facilities for years. The Section determined that South Carolina can reasonably modify its service system to prevent such unnecessary institutionalization by providing services to the people who need them to live in integrated settings.
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 2023, the Disability Rights Section concluded its district court litigation in the longstanding case *United States v. Florida*, No. 12-cv-60460 (S.D. Fla.). Initially filed in 2013, this case was brought on behalf of 140 children with complex medical needs unnecessarily institutionalized in nursing facilities, as well as approximately 1,800 additional children at risk of entering institutions. The amended complaint, filed in June 2022, alleged that Florida's failure to provide community-based supports and services led to the children's segregation in violation of Title II of the ADA.

A two-week bench trial was held in May 2023, during which the Section presented the testimony of more than a dozen fact witnesses as well as five expert witnesses. In July 2023, the Court issued a ruling in favor of the United States, finding Florida to be in violation of the ADA. The Court also ordered injunctive relief, including systemic changes to care coordination, discharge planning, and provision of private duty nursing. The State has filed an expedited appeal with the U.S. Court of Appeals for the Eleventh Circuit.

On September 29, 2023, the Section filed a lawsuit against the State of Colorado for unnecessarily segregating adults with physical disabilities, including older adults, in nursing facilities, in violation of Title II of the ADA. The Section previously notified Colorado of its findings of discrimination in a March 2022 letter [41] to Colorado Governor Polis. The letter of findings demanded that Colorado remedy the civil rights violations identified.

The Section also filed three statements of interest. The first was filed in *Timothy B. v. Kinsley*, No. 1:22-cv-1046 (M.D.N.C.). This case was brought on behalf of children with disabilities in the custody of North Carolina's child welfare system. Plaintiffs alleged unnecessary segregation in psychiatric residential treatment facilities (PRTFs), in violation of the ADA's integration mandate. The statement, filed in April 2023, explained that in order to state an integration mandate claim: (1) a determination by a state treatment professional is not the only way to determine appropriateness for community placement, and (2) children in state custody need not allege that their custodian affirmatively chose community-based care. The statement also

[41] United States Letter of Findings to Colorado, available at: https://www.justice.gov/d9/case-documents/attachments/2022/03/03/letter_of_finding_-_colorado.pdf

clarified plaintiffs' standing and that state court proceedings to determine that a child needs treatment in a PRTF do not collaterally estop integration mandate claims.

Two statements of interest were filed in *Marsters v. Healey*, 1:22-cv-11715-NMG (D.Mass.), in September 2023. This lawsuit claims that adults with disabilities are unnecessarily segregated in Massachusetts nursing facilities in violation of Title II of the ADA and *Olmstead.* The Section filed one statement of interest in response to the Defendant's opposition to Plaintiffs' motion for class certification. The Department's statement explains that class certification is regularly granted in *Olmstead* cases because: (1) *Olmstead* cases raise common questions concerning the defendant's systemic policies and practices and (2) single injunctive relief is appropriate to remedy the unnecessary segregation of a large group of people. The other statement of interest responded to the Defendant's partial motion to dismiss the named Plaintiffs for failing to allege an injury in fact. The Department's brief clarifies that: (1) unnecessary segregation is an injury in fact that meets Article III standing requirements and (2) plaintiffs need not request and be denied a specific service to establish standing to bring a claim under Title II of the ADA.

Educational Opportunities Section

In FY 2023, the Educational Opportunities Section continued to advance pending litigation against the State of Georgia in which 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.

In October 2022, the Section issued a letter of findings to the State of Alabama, notifying the State that it was relegating children in foster care with emotional and behavioral disabilities to unnecessarily segregated classes and unequal educational opportunities by enrolling them in psychiatric residential treatment facilities' on-site schools without regard to each student's ability to perform in local public schools.

Finally, as part of a continued enforcement effort to combat unlawful seclusion, EOS has resolved three investigations into districts that unnecessarily segregate students with disabilities and use behavior and restraint practices in violation of the ADA. The agreements —reached in December 2022, February 2023, and April 2023—are in Okaloosa, Florida; Anchorage, Alaska; and Spokane, Washington, respectively.

Office of the Inspector General

The Office of the Inspector General (DOJ-OIG) was allocated $1.2 million in FY 2023 HCFAC funding to address health care fraud as it directly impacts the DOJ operations. The DOJ spends over $1 billion a year to provide health care to inmates of the Federal Bureau of Prisons (BOP) and detainees of the U.S. Marshals Service (USMS), and expends more than $115 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. The DOJ-OIG accomplishes this through fraud monitoring, investigations, and issuance of public reports that highlight internal control risk and recommend corrective actions on issues found.

In FY 2023, the DOJ-OIG established the BOP Interdisciplinary Team to leverage the OIG's diverse talent and collective knowledge across Divisions and Offices to enhance and expand the

OIG's oversight of the BOP. The Interdisciplinary Team has one overarching goal—to enhance the OIG's oversight of the BOP by increasing intra-agency collaboration and strategic work planning. Health care fraud is a key concern of the Interdisciplinary Team and the information exchanged has led to the formulation of a number of relevant audit proposals.

During FY 2023, the Evaluations and Inspection (E&I) Division enhanced its ability to assess the quality of health care provided to BOP inmates by employing two contract health care subject matter experts (SME): a doctor and a nurse. In collaboration with E&I staff, the health care SME have conducted onsite inspections of two BOP institutions, Federal Correctional Institution (FCI) Waseca and FCI Tallahassee, during which they assessed the quality of health care provided to inmates at those institutions. The DOJ-OIG publicly issued its FCI Waseca inspection report in May 2023 and publicly issued its FCI Tallahassee inspection report in November 2023. During FY 2023, the health care SME also developed a BOP inspection quality of care assessment tool that E&I will begin using in FY 2024. It is anticipated that this tool will allow the OIG to report on a greater number of BOP quality of health care issues than it has done previously. In addition to supporting E&I's BOP inspections program, the health care subject matter experts have assessed individual inmate health care records in support of broader OIG oversight of the BOP.

In FY 2023, the DOJ-OIG Investigations Division continued to collaborate 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 maintained a secure data platform to identify anomalous billing and referred investigative leads to the Investigations Division. Because the BOP lacks a centralized system of inmate health care claims data, the DOJ-OIG ODA expends additional resources to prepare this data for fraud detection.

In FY 2023, the DOJ-OIG continued its outreach efforts, conducting 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 three health care fraud outreach sessions. During FY 2023, the Investigations Division received five health care-related complaints.

During FY 2023, the DOJ-OIG continued participating in two health care fraud working groups, as well as a cross-agency oversight committee focused specifically on Federal health care programs, 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 and trends with other organizations. From these collaborations, the DOJ-OIG conducted a data match that resulted in an investigation.

The DOJ-OIG sought refreshed health care claims data directly from the BOP Center for Medicare & Medicaid Services (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.

In FY 2022, the DOJ-OIG secured the services of a SME to review health care claims for two open and ongoing investigations. During FY 2023, the SME completed a review of BOP health care claims and subsequently provided a draft report of their findings, suggesting two health care

providers inappropriately billed the BOP for nearly all the relevant claims. The DOJ-OIG ODA provided a random sampling of claims from the two health care providers for the SME to review. 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 27 investigations connected to DOJ health care-related activities and programs.

In September 2022, the DOJ-OIG issued a multi-discipline Management Advisory Memo (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 of the 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. In FY 2023, the DOJ-OIG worked with the BOP to resolve the recommend-dations and the BOP has taken meaningful action to address the concerns raised in the MAM.

FY 2023 Accomplishments

Key oversight accomplishments in FY 2023 for the DOJ-OIG include:

- Investigations opened: 2, and
- Inspections initiated that include assessments of the provision of health care: 2.

APPENDIX

Federal Bureau of Investigation

The Federal Bureau of Investigation (FBI) was allocated $160.2 million in HCFAC Program funding in FY 2023 to support the facilitation, coordination, and accomplishment of the goals of the program. In addition, the FBI received $7.6 million in DOJ FY 2023 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 2023 was used to support a total of 855 positions (517 Agent and 338 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 2023, the FBI opened 658 new HCF investigations, and 3,440 investigations were pending at the end of FY 2023. Investigative efforts throughout the fiscal year produced 583 criminal convictions, 374 indictments, and 180 informations. In addition, investigative efforts resulted in over 620 operational disruptions of criminal fraud organizations and the dismantlement of more than 127 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, 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 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 2023, the FBI opened 286 joint investigations with task force and working group partners, more than 112 of which were opened and investigated by 17 established FBI HCF task forces. To further this initiative, FBI personnel also participate in 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, as well as the regional ARPO and NEPO. 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, New York (Brooklyn), 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.

In June 2023, DOJ announced the 2023 National Health Care Fraud and Opioid Abuse Enforcement Action in a joint statement with the FBI and its partners. In this law enforcement action, 78 individuals across the nation were charged with criminal conduct accounting for over $2.5 billion billed in various health care fraud schemes, with actual losses exceeding $1.1 billion. Of the 78 charged, 30 individuals were licensed medical professionals and/or doctors. Over two-thirds of the HCF cases included in this Action were investigations in which the FBI was involved. The defendants allegedly defrauded programs entrusted for the care of the elderly and disabled, and, in some cases, used the proceeds of the schemes to purchase luxury items, including exotic automobiles, jewelry, and yachts. In connection with the enforcement action, the Department seized or restrained millions of dollars in cash, automobiles, and real estate.

This operation was conducted jointly with HHS-OIG, DEA, CMS/CPI, State Medicaid Fraud Control Units, HSI, FDA, IRS-CI, VA-OIG, USPS-OIG, FDIC-OIG, OPM-OIG, Amtrak-OIG, and other Federal and state law enforcement agencies. 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 Major Provider and Large-Scale Conspiracies 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 June 2023, a Federal jury in the Eastern District of Kentucky convicted a dentist for unlawfully prescribing opioids, including unlawfully prescribing morphine that caused his patient's death. The dentist owned and operated dental clinics in Crescent Springs. Despite clear signs—including being told explicitly that his prescribing of controlled substances was dangerous and put his patients' lives at risk—he prescribed powerful opioids to his patients for routine dental procedures. He charged $37,000 for dental procedures and prescribed one patient medically unnecessary quantities of narcotics, including morphine. Several days later, the patient fatally overdosed on the morphine. The dentist was convicted of one count of unlawful distribution of controlled substances resulting in death and one count of unlawful distribution of controlled substances. He is scheduled to be sentenced in December 2023. He faces a mandatory minimum of 20 years in prison and a maximum penalty of life in prison on the unlawful distribution of controlled substances resulting in death count, and a maximum penalty of 20 years in prison on the unlawful distribution count. The FBI and DEA investigated the case.

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 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 CSA—including highly addictive opiates, from their lawful purpose into illicit drug traffic.

In furtherance of this initiative, FBI NY opened an investigation on allegations that a licensed physician who operated a pain-management clinic located in Midtown Manhattan serviced patients seeking oxycodone and other pain-relief medications commonly diverted for illicit purposes. In exchange for cash payments, the physician wrote thousands of prescriptions for large quantities of oxycodone to individuals who he knew did not need the pills for any legitimate medical purpose. Many of the purported patients were addicted to opioids and, in some cases, sold oxycodone pills on the street to drug users. Between in or about November 2017 and in or about September 2020, the physician prescribed more than 1.3 million oxycodone pills, and he generally dispensed these pills after conducting limited or no examination of the purported patients. The purported patients who obtained oxycodone at the clinic were often drug-addicted individuals who failed drug tests administered by the clinic. The physician nevertheless continued to prescribe large quantities of oxycodone to these patients, many of whom traveled long distances to obtain the illicit oxycodone from the clinic. With particularly vulnerable patients, the defendants solicited and, in some instances, received sex acts in exchange for oxycodone prescriptions. This case was worked jointly with HHS-OIG, and the New York Police Department (NYPD). In March 2023, the physician was sentenced to 12.5 years imprisonment and in February 2023, his coconspirator was sentenced to 10 years 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.

Stimwave is an example of a Major Provider investigation. As cited on p. 29, in March 2023, the former CEO of Stimwave, LLC, a Florida-based medical device company, was indicted for one count of conspiracy to commit wire fraud and HCF, and one count of HCF in connection with a scheme to create and sell a non-functioning dummy medical device for implantation into patients suffering from chronic pain, resulting in millions of dollars in losses to Federal health care programs. Stimwave admitted wrongdoing and entered into a Non-Prosecution Agreement requiring a $10 million monetary penalty and ongoing compliance measures.

LabSolutions, LLC, is an example of a Large-Scale Conspiracy. As noted on p. 20, between 2017 through 2019, the owner of LabSolutions enrolled his lab with the Medicare program in order to submit fraudulent claims for cancer genetic tests (CGx) and pharmacogenomic tests (PGx). In 2019, as part of DOJ's Operation Double Helix take down, the owner was indicted and arrested for a $463 million HCF scheme, one of the largest HCF indictments. He was convicted during jury trial in December 2022. This vast network of marketers and doctors caused thousands of false and fraudulent genetic tests to be billed to the Medicare program. In August 2023, the owner was sentenced to 324 months (27 years) in prison. The 27-year sentence was one of the largest sentences handed down for genetic testing subjects. The Judge commented that his decision for the lengthy sentence was due to the high loss amount to the Medicare program, the elaborate nature of the scheme, and the targeting of our vulnerable elderly population's fear of cancer. To date, the asset forfeiture for the owner and LabSolutions totals approximately $32.2 million. This was a Strike Force investigation and prosecution.

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 public, as well as with 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.

In FY 2023, HCFU engaged external partners and the FBI's Office of Public Affairs in an effort to develop a public awareness campaign to educate the public on identifying and reporting HCF activity. This campaign is intended to reach the public through various media platform outlets such as social media, television, magazines, and mailers. This campaign strategy is currently in development and will be a highly anticipated endeavor next year. Furthermore, HCFU updated the FBI.gov website with helpful HCF information such as common schemes, vulnerabilities, and tips on how to avoid becoming a victim of HCF scams. HCFU continues to work with the

CMS Administration for Community Living, Office of Healthcare Information and Counseling to educate 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 2023, the Criminal Division's Fraud Section, in coordination with the FBI and multiple Federal agencies announced the results of the 2023 National Health Care Fraud COVID-19 Law Enforcement Action. The nationwide Health Care Fraud COVID-19 Law Enforcement Action began on April 3, 2023, and focused on fraud related to the pandemic relief efforts by the Federal government. The investigations included allegations such as: false billing, billing for services not rendered, genetic testing fraud, theft from pandemic assistance programs such as the Health Resources and Service Administration (HRSA) COVID-19 Uninsured Program, fraudulent COVID-19 vaccination cards, fraud related to COVID-19 rapid test kits, and kickback schemes. The enforcement action included 18 indictments and arrests and spanned across nine Federal judicial districts. The fraudulent billing to public and private health programs during the investigations totaled approximately $490 million. Of the approximate $490 million fraudulent billing total, approximately $488 million is attributed to six FBI or joint FBI/HHS-OIG investigations. CMS identified 28 medical professionals who received administrative actions (payment suspensions) as a result of the schemes. As a result of the operation, approximately $16 million in cash and other fraud proceeds was seized. Four FBI field offices investigated cases included in the enforcement action, including three Health Care Fraud Strike Force field offices located in Brooklyn, the Gulf Coast, and Los Angeles. This operation was conducted with HHS-OIG, CMS, DOI-OIG, IRS, FDA, DOL-OIG, DCIS, 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 2023, the HCFU continued its virtual trainings to address the educational needs of FBI personnel. The virtual training platform made training more accessible to FBI personnel. In FY 2023, eight virtual training sessions were held, and over 500 FBI employees participated in the training sessions. In FY 2023, the HCFU hosted its first two in-person trainings since the

pandemic. Those two trainings were attended by 322 participants. Additionally, the HCFU sent 112 participants to trainings offered by other agencies.

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 and 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 each year (not including portions of CMS funding dedicated to the Medicare Integrity Program listed in the table on page 132).
- 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 2023, 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	**Fiscal Year 2023**
Office of Inspector General	$224,810,730
Health and Human Services Wedge[42]	42,997,744
Medicare Integrity Program[43]	1,024,714,705
MIP/Medicare (non-add)	*945,890,498*
Medi-Medi (non-add)	*78,824,207*
Department of Justice Wedge[40]	70,192,098
Federal Bureau of Investigation[44]	160,177,645
Subtotal, Mandatory HCFAC	**$1,522,892,922**

Discretionary Resources	**Fiscal Year 2023**
Office of Inspector General	$105,145,000
CMS Program Integrity	665,648,000
CMS Program Integrity (non-add)	*630,648,000*
Senior Medicare Patrols (ACL non-add)	*35,000,000*
Department of Justice	122,207,000
Subtotal, Discretionary HCFAC	**$893,000,000**
Grand Total, HCFAC	**$2,415,892,922**

[42] 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.

[43] 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.

[44] 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

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

VCRS—Violent Crime and Racketeering Section