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Upstate New York Health Care Fraud Symposium

September 30, 2022

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WWW.ALBANYLAW.EDU/CLE

Upstate New York Health Care Fraud Symposium
September 30, 2022

10:00 a.m. – 10:15 a.m.	**Welcome and Opening Remarks** Alicia Ouellette, President and Dean, Albany Law School Hon. Carla B. Freedman, United States Attorney for the Northern District of New York
10:15 a.m. – 11:15 a.m.	**Identifying and Investigating Health Care Fraud: Government and Private Sector Perspectives** ***Moderator:*** Michael D. Gadarian, Assistant United States Attorney Northern District of New York ***Panelists:*** Lara Hodge, Special Agent, HHS-OIG Jaime Lugas, Intelligence Analyst, FBI Matthew J. Wabby, Special Agent, FBI Todd Williams, Director, Special Investigations Unit, CDPHP
11:15 a.m. – 11:30 a.m.	**Break**
11:30 a.m. – 12:30 p.m.	**Use of the False Claims in Health Care Fraud Investigations and Litigation** ***Moderator:*** Adam J. Katz, Assistant United States Attorney Northern District of New York ***Panelists:*** Erica B. Hitchings, Partner, Whistleblower Law Collaborative LLC Geoffrey R. Kaiser, Senior Counsel, Rivkin Radler LLP
12:30 p.m. – 1:30 p.m.	**Networking Lunch**
1:45 p.m. – 2:45 p.m.	**Prescription Drug Diversion** ***Moderator:*** Christopher R. Moran, Assistant United States Attorney Northern District of New York ***Panelists:*** Linda J. Clark, Partner, Barclay Damon LLP Cristina Russo, Diversion Investigator Drug Enforcement Administration
2:45 p.m.	**Closing Remarks** Elizabeth C. Coombe, First Assistant United States Attorney Northern District of New York Kelsey Shaffer, Albany Law School's Health Law Society

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Speaker Biographies

ALICIA OUELLETTE is the 18th President and Dean of Albany Law School. As a leader in legal education, Dean Ouellette has championed the value of law schools as drivers of change in communities, society, and the lives of students and graduates. As President and Dean, she has presided over Albany Law School's execution of a new strategic plan, fulfillment of an institutional affiliation with the University at Albany, expansion into online graduate programs, and completion of a record-setting fundraising campaign, *We Rise Together: The Campaign for Albany Law School*. Prior to her appointment as President and Dean, she served as Associate Dean for Academic Affairs and Intellectual Life and a Professor of Law. Before joining the law school in 2001, Dean Ouellette was an Assistant Solicitor General in the New York State Attorney General's Office and a law clerk to the Honorable Howard A. Levine at the New York Court of Appeals. As a scholar, Dean Ouellette focuses on health law, disability rights, family law, children's rights, and human reproduction. Her book, *Bioethics and Disability: Toward a Disability Conscious Bioethics*, was published in 2011 by Cambridge University Press. She has authored numerous articles published in academic journals such as the *American Journal of Law and Medicine*, *American Journal of Bioethics*, *Nevada Law Journal*, *Hastings Law Journal*, *Indiana Law Journal*, and *Oregon Law Review*. She has presented to distinguished audiences around the globe, including at the Yale School of Medicine and the United Nations in Geneva, Switzerland. In September 2020, Dean Ouellette was appointed to New York Governor's COVID-19 Vaccine Distribution and Implementation Task Force. Dean Ouellette has served in leadership positions for numerous professional and community organizations, including as chair of the Association of American Law Schools (AALS) Section for Deans, secretary and a board member for the Commission on Independent Colleges and Universities (CICU), secretary and a board member for the Burdett Birthing Center in Troy, N.Y., and a board member for the University at Albany's Institute for Health and Human Rights. An alumna of Hamilton College, Dean Ouellette graduated *magna cum laude* in 1994 from Albany Law School, where she was editor-in-chief of the *Albany Law Review*.

HON. CARLA B. FREEDMAN, ESQ. is the United States Attorney for the Northern District of New York. Ms. Freedman is the first woman confirmed for this position. Ms. Freedman previously served as an Assistant U.S. Attorney in the Syracuse office of the Northern District of New York from 2007 through 2021. She was a Supervisory Assistant U.S. Attorney and the Narcotics Chief from February 2018 through 2021. She also served as Deputy Narcotics Chief from 2016 through 2018. Before joining the U.S. Attorney's Office, Ms. Freedman was an Assistant District Attorney in the Manhattan District Attorney's Office for 16 years. She was the Chief of the Asian Gang Unit from 1997 through 2004.

LINDA J. CLARK, ESQ. is an attorney and partner at Barclay Damon, LLP, where she leads the Health Care Controversies Team. A nationally recognized litigator and health care lawyer with over 30 years of experience, she serves as lead counsel as well as national, regional, and local counsel in regulatory and compliance matters and the prosecution and defense of claims brought in state and federal courts on behalf of large groups of businesses and institutional clients in various settings and venues. Ms. Clark is a trusted advisor to health care providers, pharmaceutical companies, and pharmacies nationwide in resolving high-stakes disputes and government investigations and regulatory proceedings. She represents health care professionals and entities in all types of civil, criminal, and administrative proceedings, hearings, and appeals before various federal and state regulatory agencies, including the NYS Office of the Medicaid Inspector General (OMIG), the NYS Attorney General's Office (OAG), the NYS Department of Health (DOH), and their federal counterparts, including the Office of Inspector General (OIG) and the United States Department of Justice (DOJ), among others. In addition to her role at Barclay Damon, for over 20 years, Linda served as court-appointed defense liaison counsel for three jurisdictions in New York State in asbestos litigation, working with hundreds of defense firms and the judiciary in the administration of these cases. She currently serves as a court appointee to several high-profile administrative committees for the New York State and federal court systems. Linda also serves as a judicial hearing officer, hearing cases involving alleged judicial misconduct by the judiciary. She received her JD *cum laude* from Albany Law School and her BA *magna cum laude* from Siena College. She is admitted to practice in New York, Massachusetts, the U.S. District Courts for the Northern, Southern, Western Districts of New York and the US District Court for the District of Massachusetts and the US Supreme Court.

ELIZABETH C. COOMBE, ESQ. has been the First Assistant U.S. Attorney in the Northern District of New York since 2018. She became an Assistant United States Attorney in the District of Columbia in 1998, serving in the Appellate, Misdemeanor, General Felony, and Grand Jury Sections before being assigned to the Fraud and Public Corruption section. She transferred to the Northern District of New York in 2003. She has also served as the Criminal Chief, the Deputy Criminal Chief, and the Plattsburgh Branch Chief. Before becoming an Assistant U.S. Attorney, Ms. Coombe worked as a trial attorney in the Court of Claims and Federal Circuit Section of the Department of Justice. She also worked as a staff attorney for the Enforcement Division of the Securities and Exchange Commission and clerked for Judge Diana E. Murphy when she was the Chief Judge for the District of Minnesota. Ms. Coombe graduated from the University of Michigan Law School cum laude in 1992 and Hamilton College summa cum laude in 1989.

MICHAEL D. GADARIAN, ESQ. is an Assistant United States Attorney for the Northern District of New York. He serves as the Health Care Fraud Coordinator for the Criminal Division and has prosecuted a wide variety of matters including white-collar fraud, child exploitation, and drug offenses. Prior to joining the Criminal Division, Mr. Gadarian was a member of the Civil Division where he focused on affirmative civil enforcement under the False Claims Act and resolved several significant health care fraud investigations

resulting in multi-million-dollar settlements. He received his undergraduate degree from Rutgers College at Rutgers University in 2002 and his juris doctor from Yale Law School in 2005. After law school, Mr. Gadarian clerked for federal judges on the United States Court of Appeals for the Third Circuit, the United States District Court for the Eastern District of Pennsylvania, and the United States District Court for the Northern District of California. He also has spent time in private practice, handling primarily commercial litigation matters both as an associate and as a partner.

ERICA BLACHMAN HITCHINGS, ESQ. became a member of the Whistleblower Law Collaborative LLC (WLC) after nearly nine years in the U.S. Department of Justice (DOJ) where she successfully investigated, litigated, and settled a wide range of False Claims Act cases, including numerous health care fraud matters. At the DOJ, Erica first served as a Trial Attorney in the Civil Fraud section in Washington, D.C. and then as an Assistant U.S. Attorney in the Northern District of California. Erica's practice at WLC is devoted to representing clients nationwide in bringing actions under the federal and state whistleblower laws and programs, False Claims Acts and other whistleblower programs. Ms. Hitchings is a frequent speaker on topics of health care fraud and False Claims Act developments and teaches Health Care Fraud and Abuse at Boston University School of Law.

LARA HODGE, Special Agent Lara Hodge began her federal government career in 1999 with the U.S. Department of Justice, Immigration and Naturalization Service (INS). In 2007, she joined the U.S. Department of Health and Human Services, Office of Inspector General (HHS-OIG). Special Agent Hodge spent seven years in the HHS-OIG New York Regional Office (NYRO) located in New York City before transferring to the Albany Field Office (AFO). While at the NYRO, Special Agent Hodge was assigned to the newly formed Medicare Strike Force out of the Eastern District of New York (EDNY), which consisted of investigators from several federal, state, and local agencies, to include the Federal Bureau of Investigation (FBI) and the New York State Attorney General's Office Medicaid Fraud Control Unit (MFCU). As part of the Strike Force, she conducted numerous criminal investigations and participated in law enforcement operations throughout the country. Special Agent Hodge also conducted civil health care fraud investigations and investigations of other matters not related to health care in both the EDNY and the Southern District of New York (SDNY). Since transferring to the AFO, she has worked closely with the U.S. Attorney's Office in the Northern District of New York (NDNY), the FBI, and other federal, state, and local law enforcement partners on both criminal and civil health care fraud investigations.

GEOFFREY (JEFF) R. KAISER, ESQ. is Senior Counsel at Rivkin Radler, LLP. Mr. Kaiser has extensive experience in enforcement matters affecting the healthcare industry, concentrates his legal practice on healthcare fraud and regulatory compliance issues, white collar criminal defense, False Claims Act litigation, integrity monitoring, and internal investigations. As head of the Compliance, Investigations, and White-Collar Practice Group, and senior counsel in the Health Services Practice Group, he is frequently called upon to handle matters implicating a range of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute. The Health

Services Practice Group at Rivkin Radler has been listed in the prestigious Legal 500. The practice is also recognized as “notable” by Chambers USA. Before joining Rivkin Radler, Mr. Kaiser served for nearly 10 years in the Criminal Divisions of the U.S. Attorney’s Office for the Eastern District of New York and the U.S. Attorney’s Office for the Southern District of New York. While at the Justice Department, he directed many white-collar investigations and prosecutions, including with respect to healthcare fraud, securities fraud, mortgage fraud, mail and wire fraud, and bank fraud. As Chief of Health Care Fraud Prosecutions and Deputy Chief of Public Integrity in the Eastern District U.S. Attorney’s Office, he directed investigations against individuals and corporations facing health care fraud allegations under a variety of criminal and civil statutes. In many instances, those investigations were rooted in allegations brought by whistleblowers under the False Claims Act. He also exercised oversight responsibilities within the Public Integrity Section for all healthcare fraud cases within the Eastern District of New York. He received many recognitions and honors for his efforts as a federal prosecutor. After leaving the Justice Department, Mr. Kaiser served as a managing director with Navigant Consulting, Inc., a global expert services firm, in two of its practice groups: Disputes and Investigations and Healthcare Disputes, Compliance and Investigations. While at Navigant, he led teams performing internal investigations and integrity monitorships of individuals and organizations in the healthcare, construction, and transportation industries, and supervised a major forensic review of mortgage servicing practices by a national mortgage servicer. He also oversaw the implementation of anti-counterfeiting/brand protection strategies on behalf of global brand owners. Jeff worked as a civil litigator for more than a decade, handling commercial litigation matters involving an assortment of business disputes. He developed particular experience in the investigation and prosecution of complex civil frauds under multiple common law and statutory grounds, including the federal Racketeer Influenced and Corrupt Organizations Act (RICO). In addition, Mr. Kaiser has acted as advisor to a global conglomerate in the area of anti-counterfeiting and brand protection. He received his B.A. with Honors from the University of Virginia, where he also graduated Phi Beta Kappa. He earned a J.D. from New York University School of Law, where he served on the Moot Court Board. After graduating from law school, he served for two years as law clerk to the Hon. Fritz W. Alexander II, an associate judge on New York State’s highest court, the New York Court of Appeals. A frequent writer and speaker on a range of legal topics, particularly in the areas of healthcare fraud and compliance, Mr. Kaiser was named a Super Lawyer in the Metro New York area, 2012-2021. He is an adjunct professor of law at St. John’s University School of Law, where he teaches Health Care Fraud. The prestigious Chambers and Partners named him a “Ranked Lawyer” in Band 5 in 2022. The Health Services Practice also has been recognized in the Chambers USA

ADAM J. KATZ, ESQ. is an Assistant United States Attorney for the Northern District of New York, where he serves as the district’s Affirmative Civil Enforcement and Civil Health Care Fraud Coordinator. In this role, Mr. Katz has led dozens of complex financial fraud investigations that, cumulatively, have led to the recovery of well over $100 million for federal taxpayers. Prior to joining the United States Attorney’s Office in 2012, he served as a trial attorney with the Department of Justice, as an associate for a large law firm, and as a staff attorney to the United States Court of

Appeals for the Second Circuit. He received his undergraduate degree from the University of Maryland in 2001, his juris doctor from Syracuse University College of Law in 2004, and his a master of public administration from the Maxwell School of Citizenship and Public Affairs in 2004. Mr. Katz currently serves as an adjunct professor at Albany Law School, where he developed and now teaches courses on the False Claims Act and health care compliance.

JAIME LUGAS has worked with the Federal Bureau of Investigation (FBI) as an Intelligence Analyst (IA) since 2016, working at the FBI Headquarters for several years before transferring to the Albany Division. Prior to joining the FBI, IA Lugas worked in various research and data analyst roles at public and private sector institutions, most recently in public higher education analyzing student success and institutional effectiveness.

CHRISTOPHER MORAN, ESQ. is an Assistant United States Attorney for the Northern District of New York and primarily handles Affirmative Civil Enforcement matters. His cases involve complex investigations of fraud against the federal government and civil violations of the Controlled Substances Act. Prior to joining the United States Attorney's Office, Mr. Moran served as a trial attorney with the Department of Justice Tax Division in Washington, D.C., and as an attorney with the IRS Office of Chief Counsel, Small Business/Self Employed Division in the Washington, D.C. field office. He graduated *cum laude* from the University at Buffalo law school in 2011. He graduated from the College of the Holy Cross in 2004 with a B.A. in political science. Between college and law school, Mr. Moran served in the United States Navy.

CRISTINA RUSSO is Diversion Investigator (DI) at the U.S. Drug Enforcement Administration (DEA). She graduated from the DEA Academy, Basic Diversion Investigator Program in October 2009. She received approximately twelve (12) weeks of specialized controlled substance related training, Subsequent to the initial training, she attended numerous trainings regarding drug conspiracy, complex investigations, controlled substances identification, drug investigative techniques, interview and interrogation, federal drug prosecution, surveillance and electronic monitoring. She began her career with the DEA in the New York Division, Albany District Office and has remained there. She was assigned to the Tactical Diversion Squad (TDS) from 2011 to 2021, where she led criminal investigations, resulting in the arrests of individuals who illegally manufacture, distribute or dispense controlled substances such as doctors and pharmacies. DI Russo is currently assigned to the DEA Albany Diversion Group where she conducts regulatory investigations, registration assignments, criminal investigations and continues to assist the Albany TDS whenever possible. DI Russo's role is to prevent, detect and investigate the diversion of controlled substances and listed chemicals and monitor the tracking and distribution of them. DI Russo investigates the supply of drugs to legitimate and illegitimate sources and reviews registrant's compliance with federal regulations. DI Russo works with other federal, state and local law enforcement agencies and entities for criminal cases and collaborates with other regulatory entities.

KELSEY SHAFFER is a third-year student at Albany Law School and the current Vice President of the Health Law Society. In 2020, Ms. Shaffer graduated from Ithaca College with a B.A. in Legal Studies and a dual minor in Psychology and Health Policy. She plans to work in the private sector after law school. Over the past two years, Ms. Shaffer has worked with the Health Law Society and Albany Medical Center's Physicians for Human Rights Group to plan informative events focused on legal issues in the healthcare system. The Health Law Society hopes to have many more events with the Albany community.

MATTHEW J. WABBY is Special Agent at the Federal Bureau of Investigation (FBI) field office in Albany, NY. He investigates corruption, fraud, money laundering, and related crimes. He was previously assigned to FBI's Plattsburgh Resident Agency, where he investigated a variety of crimes, including corruption of federal officers, drug trafficking organizations, money laundering, financial crimes, and violent crimes. Before he joined the FBI, SA Wabby spent approximately seven years in public accounting. He is a licensed Certified Public Accountant (CPA) and Certified Fraud Examiner (CFE).

TODD WILLIAMS currently serves as Director of the Special Investigations Unit (SIU) at Capital District Physicians' Health Plan, Inc. (CDPHP®). With more than 25 years of health insurance and leadership experience, Mr. Williams is responsible for the development and oversight of enterprise-wide initiatives, functions, and compliance related to fraud, waste, and abuse. Prior to joining the SIU team, he held various positions at CDPHP, including leadership positions in finance, as well as various roles in physician and hospital contracting. Mr. Williams led the development of the CDPHP cost avoidance and overpayment recovery department and payment integrity functions. He earned an MBA with an advanced certificate in health care administration from SUNY Empire State College, as well as a Bachelor of Arts in psychology from the State University of New York at Oswego.

Identifying and Investigating Health Care Fraud: Government and Private Sector Perspectives

Moderator:
Michael D. Gadarian

Panelists:
Lara Hodge
Jaime Lugas
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Todd Williams

18 U.S.C.A. § 669

§ 669. Theft or embezzlement in connection with health care

Effective: August 21, 1996
Currentness

(a) Whoever knowingly and willfully embezzles, steals, or otherwise without authority converts to the use of any person other than the rightful owner, or intentionally misapplies any of the moneys, funds, securities, premiums, credits, property, or other assets of a health care benefit program, shall be fined under this title or imprisoned not more than 10 years, or both; but if the value of such property does not exceed the sum of $100 the defendant shall be fined under this title or imprisoned not more than one year, or both.

(b) As used in this section, the term "health care benefit program" has the meaning given such term in section 24(b) of this title.

CREDIT(S)

(Added Pub.L. 104-191, Title II, § 243(a), Aug. 21, 1996, 110 Stat. 2017.)

Notes of Decisions (6)

18 U.S.C.A. § 669, 18 USCA § 669
Current through P.L. 117-167. Some statute sections may be more current, see credits for details.

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18 U.S.C.A. § 1035

§ 1035. False statements relating to health care matters

Effective: August 21, 1996
Currentness

(a) Whoever, in any matter involving a health care benefit program, knowingly and willfully--

(1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; or

(2) makes any materially false, fictitious, or fraudulent statements or representations, or makes or uses any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry,

in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 5 years, or both.

(b) As used in this section, the term "health care benefit program" has the meaning given such term in section 24(b) of this title.

CREDIT(S)

(Added Pub.L. 104-191, Title II, § 244(a), Aug. 21, 1996, 110 Stat. 2017.)

Notes of Decisions (28)

18 U.S.C.A. § 1035, 18 USCA § 1035
Current through P.L. 117-167. Some statute sections may be more current, see credits for details.

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KeyCite Yellow Flag - Negative Treatment
Enacted Legislation Note in PL 117-169, August 16, 2022, 136 Stat 1818,

KeyCite Yellow Flag - Negative Treatment
Unconstitutional or Preempted

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

42 U.S.C.A. § 1320a-7b

§ 1320a-7b. Criminal penalties for acts involving Federal health care programs

Effective: February 9, 2018
Currentness

(a) Making or causing to be made false statements or representations

Whoever--

(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program (as defined in subsection (f)),

(2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment,

(3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized,

(4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person,

(5) presents or causes to be presented a claim for a physician's service for which payment may be made under a Federal health care program and knows that the individual who furnished the service was not licensed as a physician, or

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(6) for a fee knowingly and willfully counsels or assists an individual to dispose of assets (including by any transfer in trust) in order for the individual to become eligible for medical assistance under a State plan under subchapter XIX, if disposing of the assets results in the imposition of a period of ineligibility for such assistance under section 1396p(c) of this title,

shall (i) in the case of such a statement, representation, concealment, failure, or conversion by any person in connection with the furnishing (by that person) of items or services for which payment is or may be made under the program, be guilty of a felony and upon conviction thereof fined not more than $100,000 or imprisoned for not more than 10 years or both, or (ii) in the case of such a statement, representation, concealment, failure, conversion, or provision of counsel or assistance by any other person, be guilty of a misdemeanor and upon conviction thereof fined not more than $20,000 or imprisoned for not more than one year, or both. In addition, in any case where an individual who is otherwise eligible for assistance under a Federal health care program is convicted of an offense under the preceding provisions of this subsection, the administrator of such program may at its option (notwithstanding any other provision of such program) limit, restrict, or suspend the eligibility of that individual for such period (not exceeding one year) as it deems appropriate; but the imposition of a limitation, restriction, or suspension with respect to the eligibility of any individual under this sentence shall not affect the eligibility of any other person for assistance under the plan, regardless of the relationship between that individual and such other person.

(b) Illegal remunerations

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(3) Paragraphs (1) and (2) shall not apply to--

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(A) a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program;

(B) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services;

(C) any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program if--

(i) the person has a written contract, with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract, and

(ii) in the case of an entity that is a provider of services (as defined in section 1395x(u) of this title), the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity;

(D) a waiver of any coinsurance under part B of subchapter XVIII by a Federally qualified health care center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Service Act;

(E) any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 or in regulations under section 1395w-104(e)(6) of this title;

(F) any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1395mm of this title or if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide;

(G) the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under part D of subchapter XVIII, if the conditions described in clauses (i) through (iii) of section 1320a-7a(i)(6)(A) of this title are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1395w-114(a)(3) of this title), section 1320a-7a(i)(6)(A) of this title shall be applied without regard to clauses (ii) and (iii) of that section);

(H) any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in section 1395w-23(a)(4) of this title;

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(I) any remuneration between a health center entity described under clause (i) or (ii) of section 1396d(l)(2)(B) of this title and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity;

(J) a discount in the price of an applicable drug (as defined in paragraph (2) of section 1395w-114a(g) of this title) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1395w-114a of this title; and

(K) an incentive payment made to a Medicare fee-for-service beneficiary by an ACO under an ACO Beneficiary Incentive Program established under subsection (m) of section 1395jjj of this title, if the payment is made in accordance with the requirements of such subsection and meets such other conditions as the Secretary may establish.

(4) Whoever without lawful authority knowingly and willfully purchases, sells or distributes, or arranges for the purchase, sale, or distribution of a beneficiary identification number or unique health identifier for a health care provider under subchapter XVIII, subchapter XIX, or subchapter XXI shall be imprisoned for not more than 10 years or fined not more than $500,000 ($1,000,000 in the case of a corporation), or both.

(c) False statements or representations with respect to condition or operation of institutions

Whoever knowingly and willfully makes or causes to be made, or induces or seeks to induce the making of, any false statement or representation of a material fact with respect to the conditions or operation of any institution, facility, or entity in order that such institution, facility, or entity may qualify (either upon initial certification or upon recertification) as a hospital, critical access hospital, skilled nursing facility, nursing facility, intermediate care facility for the mentally retarded, home health agency, or other entity (including an eligible organization under section 1395mm(b) of this title) for which certification is required under subchapter XVIII or a State health care program (as defined in section 1320a-7(h) of this title), or with respect to information required to be provided under section 1320a-3a of this title, shall be guilty of a felony and upon conviction thereof shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(d) Illegal patient admittance and retention practices

Whoever knowingly and willfully--

(1) charges, for any service provided to a patient under a State plan approved under subchapter XIX, money or other consideration at a rate in excess of the rates established by the State (or, in the case of services provided to an individual enrolled with a medicaid managed care organization under subchapter XIX under a contract under section 1396b(m) of this title or under a contractual, referral, or other arrangement under such contract, at a rate in excess of the rate permitted under such contract), or

(2) charges, solicits, accepts, or receives, in addition to any amount otherwise required to be paid under a State plan approved under subchapter XIX, any gift, money, donation, or other consideration (other than a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to the patient)--

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(A) as a precondition of admitting a patient to a hospital, nursing facility, or intermediate care facility for the mentally retarded, or

(B) as a requirement for the patient's continued stay in such a facility,

when the cost of the services provided therein to the patient is paid for (in whole or in part) under the State plan,

shall be guilty of a felony and upon conviction thereof shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(e) Violation of assignment terms

Whoever accepts assignments described in section 1395u(b)(3)(B)(ii) of this title or agrees to be a participating physician or supplier under section 1395u(h)(1) of this title and knowingly, willfully, and repeatedly violates the term of such assignments or agreement, shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than $4,000 or imprisoned for not more than six months, or both.

(f) "Federal health care program" defined

For purposes of this section, the term "Federal health care program" means--

(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of Title 5); or

(2) any State health care program, as defined in section 1320a-7(h) of this title.

(g) Liability under subchapter III of chapter 37 of Title 31

In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31.

(h) Actual knowledge or specific intent not required

With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.

CREDIT(S)

(Aug. 14, 1935, c. 531, Title XI, § 1128B, formerly Title XVIII, § 1877(d), and Title XIX, § 1909, as added and amended Pub.L. 92-603, Title II, §§ 242(c), 278(b)(9), Oct. 30, 1972, 86 Stat. 1419, 1454; Pub.L. 95-142, § 4(a), (b), Oct. 25, 1977, 91

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Stat. 1179, 1181; Pub.L. 96-499, Title IX, § 917, Dec. 5, 1980, 94 Stat. 2625; Pub.L. 98-369, Div. B, Title III, § 2306(f)(2), July 18, 1984, 98 Stat. 1073; renumbered Title XI, § 1128B and amended Pub.L. 100-93, §§ 4(a) to (d), 14(b), Aug. 18, 1987, 101 Stat. 688, 689, 697; Pub.L. 100-203, Title IV, §§ 4039(a), 4211(h)(7), Dec. 22, 1987, 101 Stat. 1330-81, 1330-206; Pub.L. 100-360, Title IV, § 411(a)(3)(A), (B)(i), July 1, 1988, 102 Stat. 768; Pub.L. 101-239, Title VI, § 6003(g)(3)(D)(ii), Dec. 19, 1989, 103 Stat. 2153; Pub.L. 101-508, Title IV, §§ 4161(a)(4), 4164(b)(2), Nov. 5, 1990, 104 Stat. 1388-94, 1388-102; Pub.L. 103-432, Title I, § 133(a)(2), Oct. 31, 1994, 108 Stat. 4421; Pub.L. 104-191, Title II, §§ 204(a), 216(a), 217, Aug. 21, 1996, 110 Stat. 1999, 2007, 2008; Pub.L. 105-33, Title IV, §§ 4201(c)(1), 4704(b), 4734, Aug. 5, 1997, 111 Stat. 373, 498, 522; Pub.L. 108-173, Title I, § 101(e)(2), (8)(A), Title II, § 237(d), Title IV, § 431(a), Dec. 8, 2003, 117 Stat. 2150, 2152, 2213, 2287; Pub.L. 111-148, Title III, § 3301(d)(1), Title VI, § 6402(f), Mar. 23, 2010, 124 Stat. 468, 759; Pub.L. 114-115, § 8, Dec. 28, 2015, 129 Stat. 3134; Pub.L. 115-123, Div. E, Title III, § 50341(b), Title IV, § 50412(a)(2), (b), Feb. 9, 2018, 132 Stat. 208, 220.)

EXECUTIVE ORDERS

EXECUTIVE ORDER NO. 13939

<July 24, 2020, 85 F.R. 45759>

Lowering Prices for Patients by Eliminating Kickbacks to Middlemen

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Purpose. One of the reasons pharmaceutical drug prices in the United States are so high is because of the complex mix of payers and negotiators that often separates the consumer from the manufacturer in the drug-purchasing process. The result is that the prices patients see at the point-of-sale do not reflect the prices that the patient's insurance companies, and middlemen hired by the insurance companies, actually pay for drugs. Instead, these middlemen health plan sponsors and pharmacy benefit managers (PBMs) negotiate significant discounts off of the list prices, sometimes up to 50 percent of the cost of the drug. Medicare patients, whose cost sharing is typically based on list prices, pay more than they should for drugs while the middlemen collect large “rebate” checks. These rebates are the functional equivalent of kickbacks, and erode savings that could otherwise go to the Medicare patients taking those drugs. Yet currently, Federal regulations create a safe harbor for such discounts and preclude treating them as kickbacks under the law.

Fixing this problem could save Medicare patients billions of dollars. The Office of the Inspector General at the Department of Health and Human Services has found that patients in the catastrophic phase of the Medicare Part D program saw their out-of-pocket costs for high-price drugs increase by 47 percent from 2010 to 2015, from $175 per month to $257 per month. Narrowing the safe harbor for these discounts under the anti-kickback statute will allow tens of billions in dollars of rebates on prescription drugs in the Medicare Part D program to go directly to patients, saving many patients hundreds or thousands of dollars per year at the pharmacy counter.

Sec. 2. Policy. It is the policy of the United States that discounts offered on prescription drugs should be passed on to patients.

Sec. 3. Directing Drug Rebates to Patients Instead of Middlemen. The Secretary of Health and Human Services shall complete the rulemaking process he commenced seeking to:

(a) exclude from safe harbor protections under the anti-kickback statute, section 1128B(b) of the Social Security Act, 42 U.S.C. 1320a-7b, certain retrospective reductions in price that are not applied at the point-of-sale or other remuneration that drug manufacturers provide to health plan sponsors, pharmacies, or PBMs in operating the Medicare Part D program; and

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(b) establish new safe harbors that would permit health plan sponsors, pharmacies, and PBMs to apply discounts at the patient's point-of-sale in order to lower the patient's out-of-pocket costs, and that would permit the use of certain bona fide PBM service fees.

Sec. 4. Protecting Low Premiums. Prior to taking action under section 3 of this order, the Secretary of Health and Human Services shall confirm and make public such confirmation that the action is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs.

Sec. 5. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP

Notes of Decisions (276)

42 U.S.C.A. § 1320a-7b, 42 USCA § 1320a-7b
Current through P.L. 117-167. Some statute sections may be more current, see credits for details.

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KeyCite Yellow Flag - Negative Treatment
Unconstitutional or Preempted Limited on Constitutional Grounds by U.S. v. Saathoff, S.D.Cal., Apr. 06, 2010

United States Code Annotated
Title 18. Crimes and Criminal Procedure (Refs & Annos)
Part I. Crimes (Refs & Annos)
Chapter 63. Mail Fraud and Other Fraud Offenses (Refs & Annos)

18 U.S.C.A. § 1343

§ 1343. Fraud by wire, radio, or television

Effective: January 7, 2008
Currentness

Whoever, having devised or intending to devise any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises, transmits or causes to be transmitted by means of wire, radio, or television communication in interstate or foreign commerce, any writings, signs, signals, pictures, or sounds for the purpose of executing such scheme or artifice, shall be fined under this title or imprisoned not more than 20 years, or both. If the violation occurs in relation to, or involving any benefit authorized, transported, transmitted, transferred, disbursed, or paid in connection with, a presidentially declared major disaster or emergency (as those terms are defined in section 102 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5122)), or affects a financial institution, such person shall be fined not more than $1,000,000 or imprisoned not more than 30 years, or both.

CREDIT(S)

(Added July 16, 1952, c. 879, § 18(a), 66 Stat. 722; amended July 11, 1956, c. 561, 70 Stat. 523; Pub.L. 101-73, Title IX, § 961(j), Aug. 9, 1989, 103 Stat. 500; Pub.L. 101-647, Title XXV, § 2504(i), Nov. 29, 1990, 104 Stat. 4861; Pub.L. 103-322, Title XXXIII, § 330016(1)(H), Sept. 13, 1994, 108 Stat. 2147; Pub.L. 107-204, Title IX, § 903(b), July 30, 2002, 116 Stat. 805; Pub.L. 110-179, § 3, Jan. 7, 2008, 121 Stat. 2557.)

Notes of Decisions (1404)

18 U.S.C.A. § 1343, 18 USCA § 1343
Current through P.L. 117-167. Some statute sections may be more current, see credits for details.

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KeyCite Yellow Flag - Negative Treatment
Unconstitutional or Preempted Negative Treatment Reconsidered by Florida ex rel. Atty. Gen. v. U.S. Dept. of Health and Human Services, 11th Cir.(Fla.), Aug. 12, 2011

United States Code Annotated
Title 18. Crimes and Criminal Procedure (Refs & Annos)
Part I. Crimes (Refs & Annos)
Chapter 63. Mail Fraud and Other Fraud Offenses (Refs & Annos)

18 U.S.C.A. § 1347

§ 1347. Health care fraud

Effective: March 23, 2010
Currentness

(a) Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice--

(1) to defraud any health care benefit program; or

(2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program,

in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 10 years, or both. If the violation results in serious bodily injury (as defined in section 1365 of this title), such person shall be fined under this title or imprisoned not more than 20 years, or both; and if the violation results in death, such person shall be fined under this title, or imprisoned for any term of years or for life, or both.

(b) With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.

CREDIT(S)

(Added Pub.L. 104-191, Title II, § 242(a)(1), Aug. 21, 1996, 110 Stat. 2016; amended Pub.L. 111-148, Title X, § 10606(b), Mar. 23, 2010, 124 Stat. 1008.)

Notes of Decisions (182)

18 U.S.C.A. § 1347, 18 USCA § 1347
Current through P.L. 117-167. Some statute sections may be more current, see credits for details.

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18 U.S.C.A. § 1518

§ 1518. Obstruction of criminal investigations of health care offenses

Effective: August 21, 1996
Currentness

(a) Whoever willfully prevents, obstructs, misleads, delays or attempts to prevent, obstruct, mislead, or delay the communication of information or records relating to a violation of a Federal health care offense to a criminal investigator shall be fined under this title or imprisoned not more than 5 years, or both.

(b) As used in this section the term "criminal investigator" means any individual duly authorized by a department, agency, or armed force of the United States to conduct or engage in investigations for prosecutions for violations of health care offenses.

CREDIT(S)

(Added Pub.L. 104-191, Title II, § 245(a), Aug. 21, 1996, 110 Stat. 2017.)

Notes of Decisions (4)

18 U.S.C.A. § 1518, 18 USCA § 1518
Current through P.L. 117-167. Some statute sections may be more current, see credits for details.

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KeyCite Yellow Flag - Negative Treatment
Distinguished by United States v. Spivack, E.D.Pa., September 6, 2022

142 S.Ct. 2370
Supreme Court of the United States.

Xiulu **RUAN**, Petitioner
v.
UNITED STATES
Shakeel Kahn, Petitioner
v.
United States

Nos. 20-1410 and 21-5261
|
Argued March 1, 2022
|
Decided June 27, 2022

Synopsis
Background: Defendant medical doctors were convicted in the United States District Court for the Southern District of Alabama, No. 1:15-cr-00088-CG-B-2, Callie V. S. Granade, Senior District Judge, of violating the Controlled Substances Act by dispensing Schedule II drugs, fentanyl, and Schedule III drugs outside usual course of professional practice and without legitimate medical purpose, as well as other crimes. Defendants appealed, and the United States Court of Appeals for the Eleventh Circuit, L. Scott Coogler, United States District Judge for the Northern District of Alabama, sitting by designation, 966 F.3d 1101, affirmed in part, reversed in part, and remanded. The United States Supreme Court granted certiorari review. In a second case, defendants were convicted in the United States District Court for the District of Wyoming, Alan B. Johnson, J., 2019 WL 3977355, of drug trafficking and money laundering. Defendants appealed, and the United States Court of Appeals for the Tenth Circuit, Briscoe, Circuit Judge, 989 F.3d 806, affirmed. The United States Supreme Court granted certiorari review, and cases were consolidated.

[Holding:] The Supreme Court, Justice Breyer, held that in a prosecution under the Comprehensive Drug Abuse Prevention and Control Act for "knowingly or intentionally" distributing a controlled substance "except as authorized," once a defendant meets the burden of producing evidence that his or her conduct was "authorized," the Government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner.

Vacated and remanded.

Justice Alito concurred in the judgment with opinion in which Justice Thomas joined and in which Justice Barrett joined in part.

Procedural Posture(s): Appellate Review; Trial or Guilt Phase Motion or Objection.

West Headnotes (8)

[1] **Controlled Substances** Knowledge and intent
Controlled Substances Presumptions and burden of proof
Controlled Substances Sale, distribution, delivery, transfer or trafficking

In a prosecution under the Comprehensive Drug Abuse Prevention and Control Act for "knowingly or intentionally" distributing a controlled substance "except as authorized," the "knowingly or intentionally" mens rea applies to the "except as authorized" clause; thus, once a defendant meets the burden of producing evidence that his or her conduct was "authorized," the Government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841.

9 Cases that cite this headnote

[2] **Criminal Law** Criminal Intent and Malice

As a general matter, the criminal law seeks to punish the "vicious will."

[3] **Criminal Law** Criminal Intent and Malice

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With few exceptions, wrongdoing must be conscious to be criminal.

[4] **Criminal Law** Acts prohibited by statute

When the Court interprets criminal statutes, it normally starts from a longstanding presumption, traceable to the common law, that Congress intends to require a defendant to possess a culpable mental state.

4 Cases that cite this headnote

[5] **Criminal Law** Criminal Intent and Malice

"Scienter" means the degree of knowledge necessary to make a person criminally responsible for his or her acts.

2 Cases that cite this headnote

[6] **Criminal Law** Acts prohibited by statute

When a statute is not silent as to mens rea but instead includes a general scienter provision, the presumption that Congress intends to require a defendant to possess a culpable mental state applies with equal or greater force to the scope of that provision.

3 Cases that cite this headnote

[7] **Controlled Substances** Presumptions and burden of proof

In a prosecution under the Comprehensive Drug Abuse Prevention and Control Act for knowingly or intentionally distributing a controlled substance "except as authorized," once the defendant satisfies the initial burden of production by producing evidence of authorization, the burden of proving a lack of authorization shifts back to the Government. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841.

4 Cases that cite this headnote

[8] **Controlled Substances** Sale, distribution, delivery, transfer or trafficking

In a prosecution under the Comprehensive Drug Abuse Prevention and Control Act for knowingly or intentionally distributing a controlled substance "except as authorized," the government can prove knowledge of a lack of authorization through circumstantial evidence. Comprehensive Drug Abuse Prevention and Control Act of 1970 § 401, 21 U.S.C.A. § 841.

5 Cases that cite this headnote

***2371** *Syllabus* *

Petitioners Xiulu Ruan and Shakeel Kahn are medical doctors licensed to prescribe controlled substances. Each was tried for violating 21 U.S.C. § 841, which makes it a federal crime, "[e]xcept as authorized[,] ... for any person knowingly or intentionally ... to manufacture, distribute, or dispense ... a controlled substance." A federal regulation authorizes registered doctors to dispense controlled substances via prescription, but only if the prescription is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). At issue in Ruan's and Kahn's trials was the *mens rea* required to convict under § 841 for distributing controlled substances not "as authorized." Ruan and Kahn each contested the jury instructions pertaining to *mens rea* given at their trials, and each was ultimately convicted under § 841 for prescribing in an unauthorized manner. Their convictions were separately affirmed by the Courts of Appeals.

Held: Section 841's "knowingly or intentionally" *mens rea* applies to the statute's "except as authorized" clause. Once a defendant meets the burden of producing evidence that his or her conduct was "authorized," the Government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner. Pp. 2376 – 2382.

(a) Criminal law generally seeks to punish conscious wrongdoing. Thus, when interpreting criminal statutes, the Court "start[s] from a longstanding presumption ... that Congress intends to require a defendant to possess a culpable

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mental state." *Rehaif v. United States*, 588 U. S. ——, ——, 139 S.Ct. 2191, 2195, 204 L.Ed.2d 594. This culpable mental state, known as scienter, refers to the degree of knowledge necessary to make a person criminally responsible for his or her acts. See *ibid.* The presumption of scienter applies even when a statute does not include a scienter provision, and when a statute *does* "includ[e] a general scienter provision," "the presumption applies with equal or greater force" to the scope of that provision. *Ibid.* The Court has accordingly held that a word such as "knowingly" modifies not only the words directly following it, but also those other statutory terms that "separate wrongful from innocent acts." *Id.,* at ——, 139 S.Ct., at 2197.

Here, § 841 contains a general scienter provision —"knowingly or intentionally." And in § 841 prosecutions, authorization plays a "crucial" role in separating innocent conduct from wrongful conduct. *United States v. X-Citement Video, Inc.*, 513 U.S. 64, 73, 115 S.Ct. 464, 130 L.Ed.2d 372. Moreover, the regulatory language defining an authorized prescription is "ambiguous" and "open to varying constructions," *Gonzales v. Oregon*, 546 U.S. 243, 258, 126 S.Ct. 904, 163 L.Ed.2d 748, meaning that prohibited conduct (issuing invalid prescriptions) is "often difficult to distinguish" from acceptable conduct (issuing valid prescriptions). *United States v. United States Gypsum Co.*, 438 U.S. 422, 441, 98 S.Ct. 2864, 57 L.Ed.2d 854. A strong scienter requirement helps reduce the risk of "overdeterrence," *i.e.,* punishing conduct that lies close to, but on the permissible side of, the criminal line. *Ibid.*

The statutory provisions at issue here are also not the kind to which the Court has held the presumption of scienter does not apply. Section 841 does not define a regulatory or public welfare offense that carries only minor penalties. Cf. *Rehaif*, 588 U. S., at ——, 139 S.Ct., at 2197; *Staples v. United States*, 511 U.S. 600, 618–619, 114 S.Ct. 1793, 128 L.Ed.2d 608. Nor is the "except as authorized" clause a jurisdictional provision. Cf. *Rehaif,* 588 U. S., at ——, 139 S.Ct., at 2195 – 2196. Pp. 2376 – 2378.

(b) Analogous precedent reinforces the Court's conclusion here. In *Liparota v. United States*, 471 U.S. 419, 105 S.Ct. 2084, 85 L.Ed.2d 434, *United States v. X-Citement Video*, 513 U.S. 64, 115 S.Ct. 464, 130 L.Ed.2d 372, and *Rehaif v. United States*, 588 U. S. ——, 139 S.Ct. 2191, 204 L.Ed.2d 594, the Court interpreted statutes containing a general scienter provision ("knowingly"), and considered what mental state applied to a statutory clause that did not immediately follow the "knowingly" provision. In all three cases, the Court held that "knowingly" modified the statutory clause in question because that clause played a critical role in separating a defendant's wrongful from innocent conduct. See *Liparota*, 471 U.S. at 426, 105 S.Ct. 2084; *X-Citement Video*, 513 U.S. at 72–73, 115 S.Ct. 464; *Rehaif*, 588 U. S., at ——, 139 S.Ct., at 2196. As in those cases, the Court today concludes that § 841's *mens rea* applies to the "[e]xcept as authorized" clause, which serves to separate a defendant's wrongful from proper conduct. Pp. 2378 – 2379.

(c) Neither the Government's nor the concurrence's contrary arguments are convincing. First, the Government and the concurrence correctly note that the statutory clauses in the cases just described set forth *elements* of an offense. Here, the Government and the concurrence say, § 841's "[e]xcept as authorized" clause does not set forth an element of the offense. In support, they point to a separate statutory provision —§ 885. Section 885 says that the Government need not "negative any exemption or exception ... in any complaint, information, indictment, or other pleading or in any trial," and that "the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit," not upon the prosecution. But even assuming that lack of authorization is unlike an element in these two ways, § 885 has little or nothing to do with scienter requirements. Section 885 simply absolves the Government of having to allege, in an indictment, the inapplicability of every statutory exception in each Controlled Substances Act prosecution. Section 885 also shifts the burden of production—but not the burden of persuasion —regarding statutory exceptions to the defendant, thereby relieving the Government of having to disprove, at the outset of every prosecution, the inapplicability of all exceptions.

Section 885 thus does not provide a basis for inferring that Congress intended to do away with, or weaken, ordinary and longstanding scienter requirements. At the same time, the factors discussed above—the language of § 841; the crucial role authorization plays in distinguishing morally blameworthy conduct from socially necessary conduct; the

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serious nature of the crime and its penalties; and the vague, highly general regulatory language defining the scope of prescribing authority—all support applying normal scienter principles to the "except as authorized" clause. And the Government does not deny that, once a defendant satisfies his burden of production under § 885 by invoking the authorization exception, the Government must then prove lack of authorization by satisfying the ordinary criminal law burden of proof—beyond a reasonable doubt.

The Government also offers a substitute *mens rea* standard. Instead of applying the statute's "knowingly or intentionally" language to the authorization clause, the Government instead asserts that the statute implicitly contains an "objectively reasonable good-faith effort" or "objective honest-effort standard." Brief for United States 16–17. But § 841 uses the words "knowingly or intentionally," not "good faith," "objectively," "reasonable," or "honest effort." And the Government's standard would turn a defendant's criminal liability on the mental state of a hypothetical "reasonable" doctor, rather than on the mental state of the defendant himself or herself. The Court has rejected analogous suggestions in other criminal contexts. See *Elonis v. United States*, 575 U.S. 723, 135 S.Ct. 2001, 192 L.Ed.2d 1. And the Government is wrong to assert that the Court effectively endorsed its honest-effort standard in *United States v. Moore*, 423 U.S. 122, 96 S.Ct. 335, 46 L.Ed.2d 333, as that case did not address *mens rea* at all. Nor does *United States v. Yermian*, 468 U.S. 63, 104 S.Ct. 2936, 82 L.Ed.2d 53, support the Government here, as that case dealt with a jurisdictional clause, to which the presumption of scienter does not apply.

Finally, the Government argues that requiring it to prove that a doctor knowingly or intentionally acted not "as authorized" will allow bad-apple doctors to escape liability by claiming idiosyncratic views about their prescribing authority. But the Court has often rejected this kind of argument, see, *e.g.*, *Rehaif*, 588 U. S., at ——, 139 S.Ct., at ——, and does so again here. Pp. 2378 – 2382.

(d) The Court of Appeals in both cases evaluated the jury instructions relating to *mens rea* under an incorrect understanding of § 841's scienter requirements. On remand, those courts may address whether the instructions complied with the *mens rea* standard set forth here, as well as whether any instructional error was harmless. P. 2382.

966 F.3d 1101 and 989 F.3d 806, vacated and remanded.

BREYER, J. delivered the opinion of the Court, in which ROBERTS, C. J., and SOTOMAYOR, KAGAN, GORSUCH, and KAVANAUGH, JJ., joined. ALITO, J., filed an opinion concurring in the judgment, in which THOMAS, J., joined, and in which BARRETT, J., joined as to Parts I–A, I–B, and II.

Attorneys and Law Firms

Lawrence S. Robbins, for petitioner in No. 20–1410.

Beau B. Brindley, Chicago, IL, for petitioner in No. 21–5261.

General Eric J. Feigin, Deputy Solicitor, for respondent.

Lawrence S. Robbins, Counsel of Record, William J. Trunk, Jeffrey C. Thalhofer, Carolyn M. Forstein, Leslie C. Esbrook, Robbins, Russell, Englert, Orseck & Untereiner LLP, Washington, DC, for Petitioner in No. 20–1410.

Elizabeth B. Prelogar, Solicitor General, Counsel of Record, Kenneth A. Polite, Jr., Assistant Attorney General, Eric J. Feigin, Deputy Solicitor General, Nicole Frazer Reaves, Assistant to the Solicitor General, Joshua K. Handell, David M. Lieberman, Attorneys, Department of Justice, Washington, DC, for Respondent.

Beau B. Brindley, Counsel of Record, Blair T. Westover, Law Offices of Beau B. Brindley, Chicago, IL, for Petitioner in No. 21-5261.

Opinion

Justice BREYER delivered the opinion of the Court.

***2374** A provision of the Controlled Substances Act, codified at 21 U.S.C. § 841, makes it a federal crime, "*[e]xcept as authorized*[,] ... for any person knowingly or intentionally ... to manufacture, distribute, or dispense ***2375** ... a controlled substance," such as opioids. 84 Stat. 1260, 21 U.S.C. § 841(a) (emphasis added). Registered doctors may prescribe these substances to their patients. But, as provided by regulation, a prescription is only authorized when a doctor issues it "for a legitimate medical purpose ... acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a) (2021).

In each of these two consolidated cases, a doctor was convicted under § 841 for dispensing controlled substances not "as authorized." The question before us concerns the state of mind that the Government must prove to convict these doctors of violating the statute. We hold that the statute's "knowingly or intentionally" *mens rea* applies to authorization. After a defendant produces evidence that he or she was authorized to dispense controlled substances, the Government must prove beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner, or intended to do so.

I

The question we face concerns § 841's exception from the general prohibition on dispensing controlled substances contained in the phrase "[e]xcept as authorized." In particular, the question concerns the defendant's state of mind. To prove that a doctor's dispensation of drugs via prescription falls within the statute's prohibition and outside the authorization exception, is it sufficient for the Government to prove that a prescription was *in fact* not authorized, or must the Government prove that the doctor *knew* or *intended* that the prescription was unauthorized?

Petitioners Xiulu Ruan and Shakeel Kahn are both doctors who actively practiced medicine. They both possessed licenses permitting them to prescribe controlled substances. The Government separately charged them with unlawfully dispensing and distributing drugs in violation of § 841. Each proceeded to a jury trial, and each was convicted of the charges.

At their separate trials, Ruan and Kahn argued that their dispensation of drugs was lawful because the drugs were dispensed pursuant to valid prescriptions. As noted above, a regulation provides that, "to be effective," a prescription "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). We assume, as did the courts below and the parties here, that a prescription is "authorized" and therefore lawful if it satisfies this standard. At Ruan's and Kahn's trials, the Government argued that the doctors' prescriptions failed to comply with this standard. The doctors argued that their prescriptions did comply, and that, even if not, the doctors did not knowingly deviate or intentionally deviate from the standard.

Ruan, for example, asked for a jury instruction that would have required the Government to prove that he *subjectively knew* that his prescriptions fell outside the scope of his prescribing authority. The District Court, however, rejected this request. The court instead set forth a more objective standard, instructing the jury that a doctor acts lawfully when he prescribes "in good faith as part of his medical treatment of a patient in accordance with the standard of medical practice generally recognized and accepted in the United States." App. to Pet. for Cert. in No. 20–410, p. 139a. The court further instructed the jury that a doctor violates § 841 when "the doctor's actions were either not for a legitimate medical purpose or were outside the usual course of professional medical practice." *Ibid.* The jury convicted Ruan, and the trial court sentenced him to over ***2376** 20 years in prison and ordered him to pay millions of dollars in restitution and forfeiture.

The Eleventh Circuit affirmed Ruan's convictions. See 966 F.3d 1101, 1120, 1166–1167 (C.A.11 2020). The appeals court held that a doctor's "subjectiv[e] belie[f] that he is meeting a patient's medical needs by prescribing a controlled substance" is not a "complete defense" to a § 841 prosecution. *Id.*, at 1167. Rather, the court said, " '[w]hether a defendant acts in the usual course of his professional practice must be evaluated based on an *objective* standard, not a subjective standard.' " *Id.*, at 1166 (quoting *United States v. Joseph*, 709 F.3d 1082, 1097 (C.A.11 2013); emphasis added; alteration in original).

Kahn's trial contained similar disagreements over the proper *mens rea* instructions. Ultimately, the District Court instructed the jury that it should not convict if it found that Kahn acted in "good faith," defined as "an attempt to act in accordance with what a reasonable physician should believe to be proper medical practice." App. 486. The court added that to find "good faith," the jury must conclude that Kahn "acted in an honest effort to prescribe for patients' medical conditions in accordance with generally recognized and accepted standards of practice." *Ibid.* The court also told the jury that "good faith" was a "complete defense" because it "would be inconsistent with knowingly and intentionally distributing and/or dispensing controlled substances outside the usual course of professional practice and without a legitimate medical purpose." *Ibid.* The jury convicted Kahn

of the § 841 charges, and he was sentenced to 25 years in prison.

The Tenth Circuit affirmed Kahn's convictions. See 989 F.3d 806, 812, 824–826 (C.A.10 2021). In doing so, the court held that to convict under § 841, the Government must prove that a doctor "either: (1) subjectively knew a prescription was issued not for a legitimate medical purpose; or (2) issued a prescription that was objectively not in the usual course of professional practice." *Id.*, at 825.

Both Ruan and Kahn filed petitions for certiorari. We granted the petitions and consolidated the cases to consider what *mens rea* applies to § 841's authorization exception.

II

[1] As we have said, § 841 makes it unlawful, "[e]xcept as authorized[,] ... for any person knowingly or intentionally ... to manufacture, distribute, or dispense ... a controlled substance." We now hold that § 841's "knowingly or intentionally" *mens rea* applies to the "except as authorized" clause. This means that once a defendant meets the burden of producing evidence that his or her conduct was "authorized," the Government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner. Our conclusion rests upon several considerations.

A

[2] **[3]** First, as a general matter, our criminal law seeks to punish the " 'vicious will.' " *Morissette v. United States*, 342 U.S. 246, 251, 72 S.Ct. 240, 96 L.Ed. 288 (1952); see also *id.*, at 250, n. 4, 72 S.Ct. 240 (quoting F. Sayre, Cases on Criminal Law, p. xxxvi (R. Pound ed. 1927)). With few exceptions, " 'wrongdoing must be conscious to be criminal.' " *Elonis v. United States*, 575 U.S. 723, 734, 135 S.Ct. 2001, 192 L.Ed.2d 1 (2015) (quoting *Morissette*, 342 U.S. at 252, 72 S.Ct. 240). Indeed, we have said that consciousness of wrongdoing is a principle "as universal and persistent in mature systems of [criminal] law as belief in freedom of the human will and a ***2377** consequent ability and duty of the normal individual to choose between good and evil." *Id.*, at 250, 72 S.Ct. 240.

[4] **[5]** Consequently, when we interpret criminal statutes, we normally "start from a longstanding presumption, traceable to the common law, that Congress intends to require a defendant to possess a culpable mental state." *Rehaif v. United States*, 588 U. S. ——, ——, 139 S.Ct. 2191, 2195, 204 L.Ed.2d 594 (2019). We have referred to this culpable mental state as "scienter," which means the degree of knowledge necessary to make a person criminally responsible for his or her acts. See *ibid.*; Black's Law Dictionary 1613 (11th ed. 2019); *Morissette*, 342 U.S. at 250–252, 72 S.Ct. 240.

Applying the presumption of scienter, we have read into criminal statutes that are "*silent* on the required mental state"—meaning statutes that contain no *mens rea* provision whatsoever—" 'that *mens rea* which is necessary to separate wrongful conduct from "otherwise innocent conduct." ' " *Elonis*, 575 U.S. at 736, 135 S.Ct. 2001 (quoting *Carter v. United States*, 530 U.S. 255, 269, 120 S.Ct. 2159, 147 L.Ed.2d 203 (2000); emphasis added). Unsurprisingly, given the meaning of scienter, the *mens rea* we have read into such statutes is often that of knowledge or intent. See, *e.g.*, *Staples v. United States*, 511 U.S. 600, 619, 114 S.Ct. 1793, 128 L.Ed.2d 608 (1994); *United States v. United States Gypsum Co.*, 438 U.S. 422, 444–446, 98 S.Ct. 2864, 57 L.Ed.2d 854 (1978).

[6] And when a statute is not silent as to *mens rea* but instead "*includes* a general scienter provision," "the presumption applies with equal or greater force" to the scope of that provision. *Rehaif*, 588 U. S., at ——, 139 S.Ct., at 2195 (emphasis added). We have accordingly held that a word such as "knowingly" modifies not only the words directly following it, but also those other statutory terms that "separate wrongful from innocent acts." *Id.*, at ——, 139 S.Ct., at 2197; see, *e.g.*, *ibid.*; *United States v. X-Citement Video*, Inc., 513 U.S. 64, 72, 115 S.Ct. 464 (1994); *Liparota v. United States*, 471 U.S. 419, 426, 105 S.Ct. 2084, 85 L.Ed.2d 434 (1985).

Section 841 contains a general scienter provision —"knowingly or intentionally." And in § 841 prosecutions, a lack of authorization is often what separates wrongfulness from innocence. Defendants who produce evidence that they are "authorized" to dispense controlled substances are often doctors dispensing drugs via prescription. We normally would not view such dispensations as inherently illegitimate; we expect, and indeed usually want, doctors to prescribe the medications that their patients need. In § 841 prosecutions, then, it is the fact that the doctor issued an *unauthorized* prescription that renders his or her conduct wrongful, not the fact of the dispensation itself. In other words, authorization plays a "crucial" role in separating innocent conduct—and, in the case of doctors, socially beneficial conduct—from wrongful conduct. *X-Citement Video*, 513 U.S. at 73, 115 S.Ct. 464. Applying § 841's "knowingly or intentionally" *mens rea* to the authorization clause thus "helps advance the purpose of scienter, for it helps to separate wrongful from innocent acts." *Rehaif*, 588 U. S., at ——, 139 S.Ct., at 2197; see also *X-Citement Video*, 513 U.S. at 72–73, 115 S.Ct. 464.

In addition, the regulatory language defining an authorized prescription is, we have said, "ambiguous," written in "generalit[ies], susceptible to more precise definition and open to varying constructions." *Gonzales v. Oregon*, 546 U.S. 243, 258, 126 S.Ct. 904, 163 L.Ed.2d 748 (2006); see *id.*, at 257, 126 S.Ct. 904 (regulation "gives little or no instruction on" major questions); see also 21 C.F.R. § 1306.04(a) (regulation defining "effective" prescription ***2378** as one "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice"). The conduct prohibited by such language (issuing invalid prescriptions) is thus "often difficult to distinguish from the gray zone of socially acceptable ... conduct" (issuing valid prescriptions). *United States Gypsum*, 438 U.S. at 441, 98 S.Ct. 2864. A strong scienter requirement helps to diminish the risk of "overdeterrence," *i.e.*, punishing acceptable and beneficial conduct that lies close to, but on the permissible side of, the criminal line. *Ibid.*

The statutory provisions at issue here are also not the kind that we have held fall outside the scope of ordinary scienter requirements. Section 841 does not define a regulatory or public welfare offense that carries only minor penalties. Cf. *Rehaif*, 588 U. S., at ——, 139 S.Ct. at 2196-2197; *Staples*, 511 U.S. at 606, 114 S.Ct. 1793. Rather, § 841 imposes severe penalties upon those who violate it, including life imprisonment and fines up to $1 million. See § 841(b)(1)(C); see generally § 841(b). Such severe penalties counsel in favor of a strong scienter requirement. See *Staples*, 511 U.S. at 618–619, 114 S.Ct. 1793 (noting that "a severe penalty is a further factor tending to suggest that ... the usual presumption that a defendant must know the facts that make his conduct illegal should apply"); *United States Gypsum*, 438 U.S. at 442, n. 18, 98 S.Ct. 2864.

Nor is the "except as authorized" clause a jurisdictional provision, to which the presumption of scienter would not apply. Cf. *Rehaif*, 588 U. S., at ——, 139 S.Ct., at 2195-2196; *United States v. Yermian*, 468 U.S. 63, 68–69, 104 S.Ct. 2936, 82 L.Ed.2d 53 (1984). To the contrary, and as we have explained, a lack of authorization is often the critical thing distinguishing wrongful from proper conduct.

B

Analogous precedent reinforces our conclusion. In *Liparota*, we interpreted a statute penalizing anyone who " 'knowingly uses [food stamps] in any manner not authorized by' " statute. 471 U.S. at 420, 105 S.Ct. 2084. We held that "knowingly" modified both the "use" of food stamps element and the element that the use be "not authorized." *Id.*, at 423, 433, 105 S.Ct. 2084. We applied "knowingly" to the authorization language even though Congress had not "explicitly and unambiguously" indicated that it should so apply. *Id.*, at 426, 105 S.Ct. 2084. But if knowingly did not modify the fact of nonauthorization, we explained, the statute "would ... criminalize a broad range of apparently innocent conduct." *Ibid.*

Similarly, in *X-Citement Video*, we interpreted a statute penalizing anyone who " 'knowingly transports' " or " 'knowingly receives' " videos " 'involv[ing] the use of a minor engaging in sexually explicit conduct.' " 513 U.S. at

68, 115 S.Ct. 464. We held that "knowingly" applied not only to the element of transporting or receiving videos but also to the elemental fact that the videos involve "the use of a minor." *Id.*, at 66, 115 S.Ct. 464. We recognized that this was not "the most grammatical reading of the statute." *Id.*, at 70, 115 S.Ct. 464. But, we explained, "the age of the performers is the crucial element separating legal innocence from wrongful conduct," for possessing sexually explicit videos involving *nonminors* is protected First Amendment activity. *Id.*, at 72–73, 115 S.Ct. 464.

Finally, in *Rehaif*, we interpreted a statutory scheme in which one statutory subsection provided penalties for anyone who "knowingly violates" a separate subsection. 588 U. S., at —— – ——, 139 S.Ct., at 2195-2196. This latter subsection made it "unlawful" for people with certain statuses ***2379** (*i.e.*, being a felon or being in the country unlawfully) to possess a gun. *Ibid.* We held that the first subsection's "knowingly" language applied to the status element in the second subsection. *Id.,* at ——, 139 S.Ct., at 2196. To convict under the statute, then, the Government had to prove that a defendant knew he had one of the listed statuses. *Ibid.* "Without knowledge of that status," we reasoned, "the defendant may well lack the intent needed to make his behavior wrongful," because "[a]ssuming compliance with ordinary licensing requirements, the possession of a gun can be entirely innocent." *Id.*, at ——, 139 S.Ct., at 2197.

Like the statutes at issue in these cases, the statute here contains a scienter provision. Section 841 states: "Except as authorized by this subchapter, it shall be unlawful for any person *knowingly or intentionally* ... to manufacture, distribute, or dispense ... a controlled substance." (Emphasis added.) Like those three cases, the question here concerns the mental state that applies to a statutory clause ("[e]xcept as authorized") that does not immediately follow the scienter provision. Like the three cases, the statutory clause in question plays a critical role in separating a defendant's wrongful from innocent conduct. And, like the Court in those cases, we conclude that the statute's *mens rea* applies to that critical clause.

III

We are not convinced by the Government's arguments to the contrary. First, the Government correctly points out, and the concurrence emphasizes, that the statutory language at issue in the cases we have just described set forth *elements* of the offense. Here, the Government and the concurrence say, the "except as authorized" clause does not set forth an element. See, *e.g., post,* at 2384 – 2386 (ALITO, J., concurring in judgment).

The Government and the concurrence point to two ways in which the "except as authorized" clause is unlike an element, both of which rely on a different provision of the Controlled Substances Act—§ 885. Section 885 says that the Government need not "negative"—*i.e.,* refute—"any exemption or exception ... in any complaint, information, indictment, or other pleading." This means that, in a prosecution under the Controlled Substances Act, the Government need not refer to a lack of authorization (or any other exemption or exception) in the criminal indictment. Cf. *United States v. Resendiz-Ponce*, 549 U.S. 102, 108, 127 S.Ct. 782, 166 L.Ed.2d 591 (2007) (criminal indictment must set forth all elements of the charged crime). Section 885 also says that the Government need not "negative any exemption or exception ... in any trial," and that "the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit," not upon the prosecution. Cf. *Patterson v. New York*, 432 U.S. 197, 210, 97 S.Ct. 2319, 53 L.Ed.2d 281 (1977) (Government bears burden of proving all elements of charged offense).

But even assuming that lack of authorization is unlike an element for the two purposes that § 885 sets forth, those two purposes have little or nothing to do with scienter requirements. The first has to do with the indictment. It simply says that the Government need not set forth in an indictment a lack of authorization, or otherwise allege that a defendant does not fall within the many exceptions and exemptions that the Controlled Substances Act contains. The Act excepts, for example, licensed professionals such as dentists, veterinarians, scientific investigators, and pharmacists from the prohibition on dispensing ***2380** controlled substances. See 21 U.S.C. § 802(21). The Act also excepts employees of drug manufacturers, common carriers, and people with sick family members or pets from the prohibition on possessing controlled substances. See §§ 802(27), 822(c). Section 885 merely absolves the Government of having to allege, in an indictment, the inapplicability of every statutory exception in each Controlled Substances Act prosecution.

[7] Section 885's second purpose refers only to "the burden of going forward with the evidence," *i.e.,* the burden of *production*. See Black's Law Dictionary, at 244. It says nothing regarding the distinct issue of the burden of *persuasion—i.e.,* the burden of proving a lack of authorization. Cf. *Director, Office of Workers' Compensation Programs v. Greenwich Collieries*, 512 U.S. 267, 274, 114 S.Ct. 2251, 129 L.Ed.2d 221 (1994) ("our opinions consistently distinguis[h] between burden of proof, which we defined as burden of persuasion, and ... the burden of production or the burden of going forward with the evidence"); see also *Schaffer v. Weast*, 546 U.S. 49, 56, 126 S.Ct. 528, 163 L.Ed.2d 387 (2005). Section 885 can thus be understood as providing a presumptive device, akin to others we have recognized in the criminal context, which "merely shift[s] the burden of production to the defendant, following the satisfaction of which the ultimate burden of persuasion returns to the prosecution." *County Court of Ulster Cty. v. Allen*, 442 U.S. 140, 157–158, n. 16, 99 S.Ct. 2213, 60 L.Ed.2d 777 (1979); see *Parker v. Matthews*, 567 U.S. 37, 42, n. 1, 132 S.Ct. 2148, 183 L.Ed.2d 32 (2012) (*per curiam*). Contrary to the concurrence's assertion, see *post,* at 2387 – 2388, the differences between these two burdens and the use of procedural mechanisms to shift one burden but not the other are well established. See, *e.g.,* 29 Am. Jur. 2d Evidence § 207, p. 246 (2019) ("due process does not prohibit the use of a ... procedural device that shifts to a defendant the burden of producing some evidence contesting a fact that may otherwise be inferred, provided the prosecution retains the ultimate burden of proof "); 1 W. LaFave, Substantive Criminal Law § 1.8(a), p. 102 (3d ed. 2018) (similar). In a § 841 prosecution, then, once the defendant satisfies the initial burden of production by producing evidence of authorization, the burden of proving a lack of authorization shifts back to the Government. And, as with § 885's indictment-related purpose, § 885's burden-related purpose simply relieves the Government from having to disprove, at the outset of every Controlled Substances Act prosecution, every exception in the statutory scheme.

Section 885 thus does not provide a basis for inferring that Congress intended to do away with, or weaken, ordinary and longstanding scienter requirements. At the same time, the language of § 841 (which explicitly includes a "knowingly or intentionally" provision); the crucial role authorization (or lack thereof) plays in distinguishing morally blameworthy conduct from socially necessary conduct; the serious nature of the crime and its penalties; and the vague, highly general language of the regulation defining the bounds of prescribing authority all support applying normal scienter principles to the "except as authorized" clause. That statutory requirement, while differing from an element in some respects, is sufficiently like an element in respect to the matter at issue here as to warrant similar legal treatment.

And the Government does not deny that, once a defendant claims that he or she falls within the authorization exception and the burden shifts back to the Government, the Government must prove a lack of authorization by satisfying the ordinary criminal law burden of proof—beyond a reasonable ***2381** doubt. See Brief for United States 26; Tr. of Oral Arg. 50–51; see also *id.,* at 62–65. But see *post,* at 2387 – 2388 (concurrence suggesting, contrary to the position advanced by all parties to these cases, that the Government need only prove lack of authorization by a preponderance of the evidence). Once the defendant meets his or her burden of production, then, the Government must prove lack of authorization beyond a reasonable doubt.

Resisting the "knowingly or intentionally" standard, the Government instead offers a substitute *mens rea* standard. The Government says that rather than simply apply the statute's "knowingly or intentionally" language to the authorization clause, we should read the statute as implicitly containing an "objectively reasonable good-faith effort" or "objective honest-effort standard." Brief for United States 16–17; cf. *post,* at 2389 (concurrence arguing that doctors can defend against a § 841 prosecution by proving that they have "act[ed] in subjective good faith in prescribing drugs"). That is to say, once a defendant meets his or her burden of production, the Government can convict "by proving beyond a reasonable doubt that [the defendant] did not even make an objectively reasonable attempt to ascertain and act within the bounds of professional medicine." Brief for United States 16.

We are not convinced. For one thing, § 841, like many criminal statutes, uses the familiar *mens rea* words "knowingly or intentionally." It nowhere uses words such as "good faith," "objectively," "reasonable," or "honest effort."

For another, the Government's standard would turn a defendant's criminal liability on the mental state of a hypothetical "reasonable" doctor, not on the mental state of the defendant himself or herself. Cf. *id.*, at 24 (Government

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arguing that "a physician can violate Section 841(a) when he makes no objectively reasonable attempt to conform his conduct to something *that his fellow doctors would view* as medical care" (emphasis added)).

We have rejected analogous suggestions in other criminal contexts. In *Elonis*, for example, we considered the mental state applicable to a statute that criminalized threatening communications but contained no explicit *mens rea* requirement. 575 U.S. at 732, 135 S.Ct. 2001. The Government argued that the statute required proof that a *reasonable person* would find the communications threatening. *Id.*, at 738–739, 135 S.Ct. 2001. But, we said, "[h]aving liability turn on whether a 'reasonable person' regards the communication as a threat—regardless of what the defendant thinks—reduces culpability on the all-important element of the crime to negligence." *Id.*, at 738, 135 S.Ct. 2001 (some internal quotation marks omitted). "[A]nd," we emphasized, "we 'have long been reluctant to infer that a negligence standard was intended in criminal statutes.' " *Ibid.* (quoting *Rogers v. United States*, 422 U.S. 35, 47, 95 S.Ct. 2091, 45 L.Ed.2d 1 (1975) (Marshall, J., concurring)). We believe the same of the Government's proposed standard here.

The Government asserts that we held to the contrary, and "effectively endorsed" its honest-effort standard, in *United States v. Moore*, 423 U.S. 122, 96 S.Ct. 335, 46 L.Ed.2d 333 (1975). Brief for United States 26. But the question in *Moore* was whether doctors could *ever* be held criminally liable under § 841. 423 U.S. at 124, 96 S.Ct. 335. *Moore* did not directly address the issue before us here regarding the *mens rea* required to convict under the statute.

Further, the Government, citing *Yermian*, notes that the authorization clause precedes the words "knowingly or intentionally." And, the Government argues, grammatically speaking, that fact prevents the latter *mens rea* provision from modifying ***2382** the former clause. See Brief for United States 24–25. But *Yermian* based its holding on the fact that the clause preceding the *mens rea* provision set forth a jurisdictional criteria, which is typically not subject to a scienter requirement. 468 U.S. at 68–69, 104 S.Ct. 2936; see also *Rehaif*, 588 U. S., at ——, 139 S.Ct., at 2195-2196. *Yermian* did not base its holding on the grammatical positioning of the statutory language.

Finally, the Government argues that requiring it to prove that a doctor knowingly or intentionally acted not as authorized will allow bad-apple doctors to escape liability by claiming idiosyncratic views about their prescribing authority. See, *e.g.,* Brief for United States 33. This kind of argument, however, can be made in many cases imposing scienter requirements, and we have often rejected it on bases similar to those we have set forth in Part II of this opinion. See, *e.g.*, *Rehaif*, 588 U. S., at ——, 139 S.Ct., at 2198; *Liparota*, 471 U.S. at 433–434, 105 S.Ct. 2084.

[8] We do the same here. The Government, of course, can prove knowledge of a lack of authorization through circumstantial evidence. See *ibid.* And the regulation defining the scope of a doctor's prescribing authority does so by reference to objective criteria such as "legitimate medical purpose" and "usual course" of "professional practice." 21 C.F.R. § 1306.04(a); see *Gonzales*, 546 U.S. at 285, 126 S.Ct. 904 (Scalia, J., dissenting) ("The use of the word 'legitimate' connotes an *objective* standard of 'medicine' "); *Moore*, 423 U.S. at 141–142, 96 S.Ct. 335 (describing Congress' intent "to confine authorized medical practice within *accepted* limits" (emphasis added)). As we have said before, "the more unreasonable" a defendant's "asserted beliefs or misunderstandings are," especially as measured against objective criteria, "the more likely the jury ... will find that the Government has carried its burden of proving knowledge." *Cheek v. United States*, 498 U.S. 192, 203–204, 111 S.Ct. 604, 112 L.Ed.2d 617 (1991). But the Government must still carry this burden. And for purposes of a criminal conviction under § 841, this requires proving that a defendant knew or intended that his or her conduct was unauthorized.

IV

The Government argues that we should affirm Ruan's and Kahn's convictions because the jury instructions at their trials conveyed the requisite *mens rea*. Alternatively, the Government argues that any instructional error was harmless. But the Court of Appeals in both cases evaluated the jury

instructions under an incorrect understanding of § 841's scienter requirements. We decline to decide in the first instance whether the instructions complied with the standard we have set forth today. Cf. *Rehaif*, 588 U. S., at ——, 139 S.Ct., at 2199-2200. We leave that and any harmlessness questions for the courts to address on remand.

* * *

We conclude that § 841's "knowingly or intentionally" *mens rea* applies to the "except as authorized" clause. This means that in a § 841 prosecution in which a defendant meets his burden of production under § 885, the Government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner. We vacate the judgments of the Courts of Appeals below and remand the cases for further proceedings consistent with this opinion.

It is so ordered.

Justice ALITO, with whom Justice THOMAS joins, and with whom Justice BARRETT joins as to Parts I–A, I–B, and II, concurring in the judgment.

In criminal law, the distinction between the elements of an offense and an affirmative ***2383** defense is well-known and important. In these cases, however, the Court recognizes a new hybrid that has some characteristics of an element and some characteristics of an affirmative defense. The consequences of this innovation are hard to foresee, but the result may well be confusion and disruption. That risk is entirely unnecessary.

We granted certiorari in these cases to decide whether a physician may be convicted of dispensing or distributing drugs by prescription under a provision of the Controlled Substances Act of 1970 (CSA), 21 U.S.C. § 841(a), if he or she believed in good faith that the prescription was within the course of professional practice. In my view, there is a straightforward answer to this question. The CSA contains an exception for prescriptions issued in the course of professional practice, and this exception is a carry-over from the CSA's predecessor, the Harrison Narcotics Act of 1914, 38 Stat. 785. In interpreting the Harrison Act, this Court held that a registered physician acts "in the course of his professional practice" when the physician writes prescriptions "in good faith." *Linder v. United States*, 268 U.S. 5, 17–18, 45 S.Ct. 446, 69 L.Ed. 819 (1925). I would hold that this rule applies under the CSA and would therefore vacate the judgments below and remand for further proceedings.

The Court declines to adopt this approach and instead takes a radical new course. It holds that the mental state expressed by the terms "knowingly or intentionally" in § 841(a) applies to the provision's "[e]xcept as authorized" proviso. It bases this conclusion not on anything in the language of the CSA, but instead on the "presumption, traceable to the common law, that Congress intends to require a defendant to possess a culpable mental state." *Rehaif v. United States*, 588 U. S. ——, ——, 139 S.Ct. 2191, 2195, 204 L.Ed.2d 594 (2019).

The Court's analysis rests on an obvious conceptual mistake. A culpable mental state—or, to use the traditional Latin term, "*mens rea*"—is the mental state an accused must have in relation to the *elements* of an offense. But the authorizations in the CSA that excuse acts that are otherwise unlawful under § 841(a) are not elements of the offenses created by that provision. They are *affirmative defenses*. The presumption that elements must be accompanied by a culpable mental state—which I will call "the *mens rea* canon"—provides no guidance on what a defendant must prove to establish an affirmative defense. And for that reason, that canon does not help to decide whether there is a good-faith defense in § 841(a) prosecutions of physicians.

The Court does not claim that the "[e]xcept as authorized" proviso actually constitutes an element of dispensing or distributing a controlled substance. But it concludes, based on a vague four-part test, that the proviso is "sufficiently like an element in respect to the matter at issue here as to warrant similar treatment." *Ante*, at 2380. How many other affirmative defenses might warrant similar treatment, the Court does not say. It leaves prosecutors, defense attorneys, and the lower courts in the dark. I cannot accept this cavalier treatment of an important question.

Nor can I accept the Court's conclusion that once a defendant produces evidence that his or her conduct was "authorized," "the Government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner." *Ante*, at 2376. We did not grant certiorari on the question of the burden of proof applicable to authorizations to dispense or distribute controlled ***2384**

substances. No party has briefed this issue, and its resolution is not essential to our decision in these cases. In keeping with our normal practice, I would not address this question. But because the Court volunteers its own answer, I will offer one as well. As I see it, the text of the CSA does not show that Congress intended to deviate from the common-law rule that the burden of proving "affirmative defenses—indeed, 'all ... circumstances of justification, excuse or alleviation'—rest[s] on the defendant." *Patterson v. New York*, 432 U.S. 197, 202, 97 S.Ct. 2319, 53 L.Ed.2d 281 (1977) (quoting 4 W. Blackstone Commentaries *201). And absolutely nothing in the text of the statute indicates that Congress intended to impose a burden on the Government to disprove all assertions of authorization beyond a reasonable doubt.

I

A

As relevant here, § 841(a)(1) provides that "except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally ... to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, ... a controlled substance." According to the Court's reasoning, the terms "knowingly or intentionally" in § 841(a)(1) apply to the "except as authorized" proviso at the beginning of the provision. But it is hard to see how this could be true.

As a matter of elementary syntax, the adverbs "knowingly" and "intentionally" are most naturally understood to modify the verbs that follow, *i.e.*, "manufacture," "distribute," *etc.*, and not the introductory phrase "except as authorized." That phrase, in turn, clearly modifies the term "unlawful."

The Court does not suggest otherwise. It does not claim that "knowingly or "intentionally" *modifies* the introductory proviso in a grammatical sense. (If it did, the introductory phrase would clearly be an element, and for reasons that I will explain, *infra*, at 2385 – 2386, 21 U.S.C. § 885 unmistakably rules that out.) Instead, the Court pointedly uses different terminology. It repeatedly says that the phrase "knowingly or intentionally" "*applies*" to the introductory phrase, *ante*, at 2375, 2376, 2377, 2378 – 2379, 2382 (emphasis added). And it reaches this conclusion based on grounds that have nothing to do with grammar or syntax.

Specifically, the Court relies on a substantive canon of interpretation—the *mens rea* canon. Under this canon, the Court interprets criminal statutes to require a *mens rea* for each element of an offense "even where 'the most grammatical reading of the statute' does not support" that interpretation. *Rehaif*, 588 U. S., at ——, 139 S.Ct., at 2197 (quoting *United States v. X-Citement Video, Inc.*, 513 U.S. 64, 70, 115 S.Ct. 464, 130 L.Ed.2d 372 (1994)). * ***2385** But until today, this canon has been applied only to elements, and the "except as authorized" introductory phrase in § 841(a)(1) is plainly not an element.

"The definition of the elements of a criminal offense is entrusted to the legislature, particularly in the case of federal crimes, which are solely creatures of statute." *Liparota v. United States*, 471 U.S. 419, 424, 105 S.Ct. 2084, 85 L.Ed.2d 434 (1985). See also *Dixon v. United States*, 548 U.S. 1, 7, 126 S.Ct. 2437, 165 L.Ed.2d 299 (2006). But authorization to dispense or distribute a controlled substance lacks the most basic features of an element of an offense. For one thing, it is black-letter law that an indictment must allege "the elements of the offense charged." *Hamling v. United States*, 418 U.S. 87, 117, 94 S.Ct. 2887, 41 L.Ed.2d 590 (1974). So if lack of authorization were an element, it would be necessary to allege that in every § 841(a)(1) indictment. But § 885 says that it is not "necessary for the United States to negative any exemption or exception set forth in [the relevant subchapter] in any ... indictment." Beyond that, the prosecution bears the burden of producing evidence with respect to every element of a crime. *Patterson*, 432 U.S. at 215, 97 S.Ct. 2319. But § 885(a)(1) also provides that "the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit." It could hardly be more obvious that Congress did not cast the "except as authorized" introductory proviso as an element of distributing or dispensing a controlled substance.

Instead, that proviso clearly creates an affirmative defense —that is, a "justification or excuse which is a bar to the imposition of criminal liability" on conduct that satisfies the elements of an offense. 1 W. LaFave, Substantive Criminal Law § 1.8(c) (3d ed. 2018). Section 841(a)(1) has two main parts: a principal clause generally prohibiting "knowingly or intentionally" doing certain things with respect to controlled

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substances (*i.e.*, manufacturing them, distributing them, etc.), and a proviso indicating that these acts are unlawful "except as authorized" by other statutory provisions. As we have long held, the default rule for interpreting provisions with this structure is that " 'an exception made by a proviso or other distinct clause' " designates an affirmative defense that the Government has no duty to " 'negative.' " *Dixon*, 548 U.S. at 13, 126 S.Ct. 2437 (quoting *McKelvey v. United States*, 260 U.S. 353, 357, 43 S.Ct. 132, 67 L.Ed. 301 (1922)); see also *United States v. Dickson*, 15 Pet. 141, 165, 10 L.Ed. 689 (1841) (calling this "the general rule of law which has always prevailed"). When this rule applies, it is " 'incumbent on one who relies on such an exception to set it up and establish it.' " *Dixon*, 548 U.S. at 13, 126 S.Ct. 2437 (quoting *McKelvey*, 260 U.S. at 357, 43 S.Ct. 132).

The CSA explicitly incorporates this default rule. As noted, § 885(a)(1) provides that the prosecution need not "*negative any exemption or exception set forth in this subchapter* in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding." (Emphasis added.) Short of using the words "affirmative defense," there is no ***2386** clearer way of indicating that authorization constitutes an affirmative defense.

On the most natural reading, then, § 841(a)(1) creates an offense that has as its elements (1) knowingly or intentionally (2) distributing or dispensing (3) a controlled substance. The "[e]xcept as authorized" proviso recognizes an affirmative defense that excuses or justifies conduct that otherwise would fall within § 841(a)(1)'s general prohibition. The *mens rea* canon does not speak to the constituents of that defense.

B

While the Court does not claim that the "[e]xcept as authorized" proviso is an element of a § 841(a)(1) offense, the Court argues that the proviso is "sufficiently like an element in respect to the matter at issue here" for the *mens rea* canon to apply, *ante*, at 2380 – 2381. The Court provides four reasons for this conclusion: "[T]he language of § 841 (which explicitly includes a 'knowingly or intentionally' provision); the crucial role authorization (or lack thereof) plays in distinguishing morally blameworthy conduct from socially necessary conduct; the serious nature of the crime and its penalties; and the vague, highly general language of the regulation defining the bounds of prescribing authority." *Ibid.* Not one of these reasons withstands scrutiny.

"[T]he language of § 841." The Court notes that this provision expressly sets out a *mens rea* that applies to the elements of the offense, *ante,* at 2381, but the vast majority of criminal statutes share this characteristic. Therefore, this feature does not set § 841 apart.

"[T]he crucial role authorization (or lack thereof) plays in distinguishing morally blameworthy conduct from socially necessary conduct." The Court claims that authorization separates out morally blameworthy innocent conduct; but something very similar may be said about most, if not all, affirmative defenses. Take the common-law defense of duress. Duress "excuse[s] criminal conduct where the actor was under an unlawful threat of imminent death or serious bodily injury" and the "threat caused the actor to engage in conduct violating the literal terms of the criminal law." *United States v. Bailey*, 444 U.S. 394, 409, 100 S.Ct. 624, 62 L.Ed.2d 575 (1980). But a person who acts under duress is not "morally blameworthy"—that is part of what it means to say that duress excuses otherwise-criminal conduct. Similarly, individuals who kill or wound another person in self-defense to prevent their own death or serious injury are not considered morally blameworthy. No one supposes that these defenses are hybrids, or that the *mens rea* canon is a guide to their content.

It is unclear why the Court thinks that § 841(a)'s affirmative defense is different. There are hints in the Court's opinion that it has crafted a special rule for doctors—for example, the Court describes their conduct in writing prescriptions as not just "innocent," but "socially beneficial" and "socially necessary." *Ante*, at 2377, 2380 – 2381. But § 841(a) is not a doctor-specific provision. Section 841(a)'s proviso presumably applies in the same way for all § 841(a) defendants—whether they are drug dealers accused of selling heroin or are physicians charged with abusing their authority to prescribe painkillers.

"[T]he serious nature of the crime and its penalties." The Court also suggests that authorization is "like an element" because dispensing or distributing a controlled substance is

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a felony that carries a substantial sentence. But would all felonies qualify? If not, where would the Court draw the line? The Court provides no answers.

***2387** *"[T]he vague, highly general language of the regulation defining prescribing authority."* As the Court explains, the regulation defining the authority of physicians to prescribe controlled substances allows them to issue a prescription "for a legitimate medical purpose ... in the usual course of ... professional practice." 21 C.F.R. § 1306.04(a) (2021). But § 841(a) applies to many other types of violations and many other categories of defendants. Is the proviso a hybrid element/defense only for doctors? Would its status change if the regulation were reframed in more specific terms? How can the status of a phrase in a statute depend upon an implementing regulation? The Court provides no answer to these or any other questions naturally raised by its *ipse dixit* that the exception in § 841(a) is "sufficiently like" an element to require that it be treated as such in some respects but not others.

C

The Court also errs in holding that, if a § 841(a)(1) defendant "meets the burden of producing evidence that his or her conduct was 'authorized,' " the Government has the burden to "prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner," *ante*, at 2376. As noted, the common-law rule was that the defendant had the burden of production and persuasion on any affirmative defense. And the Court has held that when Congress does not address the burden of proof in the text of a statute, "we presume that Congress intended to preserve the common-law rule." *Smith v. United States*, 568 U.S. 106, 112, 133 S.Ct. 714, 184 L.Ed.2d 570 (2013); see also *Dixon*, 548 U.S. at 13–14, 126 S.Ct. 2437.

The Court identifies one and only one reason for deviating from this background rule—the fact that § 885(a)(1) states that "the burden of going forward with the evidence with respect to any ... exemption or exception shall be upon the person claiming its benefit." Because this provision does not say expressly that a defendant also has the burden of persuasion, the Court infers that Congress meant to allocate that burden to the prosecution. That inference is unwarranted. Section 885(a)(1) explicitly relieves the Government of the burden of "negativ[ing]" exceptions "in any trial." And it is hard to see how the Government does not have the burden to "negative" exceptions if it must affirmatively disprove a prima facie case of authorization any time a defendant satisfies the initial burden of production.

But even if one credits the majority's assumption that the CSA partly deviates from the common-law rule by shifting the burden of persuasion to the Government, the majority's further holding that the Government must carry that burden with proof "beyond a reasonable doubt" comes out of thin air. The usual rule is that affirmative defenses must be proved "by a preponderance of the evidence." *Id.*, at 17, 126 S.Ct. 2437. But the majority does not identify a single word in §§ 841(a)(1), 885(a)(1), or any other provision of the CSA that even suggests that the statute imposes a burden of disproving authorization defenses beyond a reasonable doubt.

The only thing that could conceivably justify reading a reasonable-doubt requirement into a statute that says nothing on the subject is the principle that an ambiguous statute must be interpreted, when possible, to avoid unconstitutionality. See A. Scalia & B. Garner, Reading Law: The Interpretation of Legal Texts 247–251 (2012). But the Court does not claim that it would be unconstitutional for Congress to require the Government to prove lack of authorization by only a preponderance of the evidence. Indeed, the Court does not ***2388** even claim that it would be unconstitutional to shift the burden of persuasion to the defendant. Nor could it. Our precedents establish that governments are "foreclosed from shifting the burden of proof to the defendant only 'when an affirmative defense ... negate[s] an element of the crime.' " *Smith*, 568 U.S. at 110, 133 S.Ct. 714 (quoting *Martin v. Ohio*, 480 U.S. 228, 237, 107 S.Ct. 1098, 94 L.Ed.2d 267 (1987) (Powell, J., dissenting)). And we have held that when an affirmative defense instead justifies or " 'excuse[s] conduct that would otherwise be punishable,' " the "Government has no constitutional duty to overcome the defense beyond a reasonable doubt." 568 U.S. at 110, 133 S.Ct. 714 (quoting *Dixon*, 548 U.S. at 6, 126 S.Ct. 2437).

The authorization defense made available to prescribing physicians by the CSA plainly does not negate any of the defining elements of dispensing or distributing a controlled substance in violation of § 841(a)(1). As a result, the Court has no basis for reading a requirement to disprove authorization into the CSA. And at a minimum, even if the

Government must bear the ultimate burden of persuasion once the burden of production is satisfied, the CSA should be read to preserve a traditional preponderance-of-the-evidence standard for authorization defenses.

II

My analysis thus far establishes that authorization is an affirmative defense to liability under § 841(a)(1), and the constituents of that defense cannot be identified through brute-force application of a canon designed to identify the elements of an offense. In my view, the contours of that defense can be elucidated only by examining the text, structure, and history of the provisions of the CSA that define it. I turn to that task now.

The authorization relied on by the petitioners in these cases permits physicians registered with the federal Drug Enforcement Administration to prescribe controlled substances to patients by prescription. §§ 822(b), 823(f), 829(a). As we have previously interpreted it, this authorization does not allow physicians to dispense controlled substances by prescription for any reason they choose; instead, the authorization "is limited to the dispensing and use of drugs 'in the course of professional practice or research.' " *United States v. Moore*, 423 U.S. 122, 141, 96 S.Ct. 335, 46 L.Ed.2d 333 (1975) (quoting § 802(20) (1970 ed.)).

The notion of action taken "in the course of professional practice" is not defined in the CSA, but our precedents hold that when Congress employs a term of art "obviously transplanted from another legal source," it "brings the old soil with it." *George v. McDonough*, 596 U. S. ——, ——, 119 S.Ct. 1953, ——, —— L.Ed.2d —— (2022) (quoting *Taggart v. Lorenzen*, 587 U. S. ——, ——, 139 S.Ct. 1795, 1801, ——, 204 L.Ed.2d 129 (2019); internal quotation marks omitted). And the notion that a prescription is authorized if it is issued in the course of professional practice is directly traceable to the Harrison Act, which prohibited "any person" from distributing or dispensing coca leaves or opium "except in pursuance of a written order" issued by a practitioner "in the course of his professional practice only." § 2, 38 Stat. 786. Arguably, the phrase "in the course of ... professional practice" could have been read to refer only to conduct that conforms to the standards of medical practice as a purely objective matter. But our Harrison Act precedents interpreted that phrase to refer to "*bona fide* medical practice," which meant that any prescription issued "in good faith" qualified as an authorized act of dispensing one of the drugs proscribed by the statute. ***2389** *Linder*, 268 U.S. at 17–18, 45 S.Ct. 446; see also *Boyd v. United States*, 271 U.S. 104, 107, 46 S.Ct. 442, 70 L.Ed. 857 (1926); *Webb v. United States*, 249 U.S. 96, 99, 39 S.Ct. 217, 63 L.Ed. 497 (1919).

Nothing in the CSA suggests that Congress intended to depart from the preexisting understanding of action "in the course of professional practice." We have previously held that the CSA incorporates settled understandings of "the exemption given to doctors" to dispense controlled substances " 'in the course of ... professional practice' " under the Harrison Act. *Moore*, 423 U.S. at 139–140, 96 S.Ct. 335 (quoting 38 Stat. 786). And the language of the CSA supports the same conclusions that we previously reached about the Harrison Act. As our CSA precedents have explained, to act "in the course of professional practice" is to engage in the practice of medicine—or, as we have put it, to "act 'as a physician.' " *Moore*, 423 U.S. at 141, 96 S.Ct. 335. For a practitioner to "practice medicine," he or she must act for a medical purpose—which means aiming to prevent, cure, or alleviate the symptoms of a disease or injury—and must believe that the treatment is a medically legitimate means of treating the relevant disease or injury.

But acting "as a physician" does not invariably mean acting as a *good* physician, as an objective understanding of the "in the course of professional practice" standard would suggest. A doctor who makes negligent or even reckless mistakes in prescribing drugs is still "acting as a doctor"—he or she is simply acting as a *bad doctor*. The same cannot be said, however, when a doctor knowingly or purposefully issues a prescription to facilitate "addiction and recreational abuse," *Gonzales v. Oregon*, 546 U.S. 243, 274, 126 S.Ct. 904, 163 L.Ed.2d 748 (2006). Objectives of that kind are alien to medical practice, and a doctor who prescribes drugs for those purposes is not "acting as a physician" in any meaningful sense.

I would thus hold that a doctor who acts in subjective good faith in prescribing drugs is entitled to invoke the CSA's authorization defense. Under the correct understanding of that defense, a doctor acts "in the course of professional practice" in issuing a prescription under the CSA if—but only if—he or she believes in good faith that the prescription is a valid means

of pursuing a medical purpose. A doctor who knows that he or she is acting for a purpose foreign to medicine—such as facilitating addiction or recreational drug abuse—is not protected by the CSA's authorization to distribute controlled substances by prescription. Such doctors may be convicted of unlawfully distributing or dispensing a controlled substance under § 841(a)(1).

Based on this holding, I would vacate the judgments of the Courts of Appeals below. And like the Court, I would leave it to those courts to determine on remand whether the instructions provided in petitioners' respective trials adequately described the good-faith defense and whether any errors in the instructions were harmless.

All Citations

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Footnotes

* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.*, 200 U.S. 321, 337, 26 S.Ct. 282, 50 L.Ed. 499.

* Why we have held that the *mens rea* canon allows courts to ignore obvious textual evidence of congressional intent is not obvious. In our constitutional system, it is Congress that has the power to define the elements of criminal offenses, not the federal courts. *Liparota v. United States*, 471 U.S. 419, 424, 105 S.Ct. 2084, 85 L.Ed.2d 434 (1985); see also *United States v. Davis*, 588 U. S. ——, ——, 139 S.Ct. 2319, 2325, 204 L.Ed.2d 757 (2019) ("Only the people's elected representatives in the legislature are authorized to 'make an act a crime' " (quoting *United States v. Hudson*, 7 Cranch 32, 34, 3 L.Ed. 259 (1812))). The *mens rea* canon is legitimate when it is used to determine what elements Congress *intended* to include in the definition of an offense. See, *e.g.*, *Staples v. United States*, 511 U.S. 600, 605, 114 S.Ct. 1793, 128 L.Ed.2d 608 (1994) (explaining that the canon is founded on an inference of congressional intent). But applying that canon to *override* the intentions of Congress would be inconsistent with the Constitution's separation of powers. Federal courts have no constitutional authority to re-write the statutes Congress has passed based on judicial views about what constitutes "sound" or "just" criminal law. Cf. *X-Citement Video*, 513 U.S. at 80–82, 115 S.Ct. 464 (Scalia, J., dissenting) (criticizing our *mens rea* canon precedents for "convert[ing a] rule of interpretation into a rule of law" binding on Congress).

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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 2021

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

Health Care Fraud and Abuse Control Program
Annual Report for Fiscal Year 2021

July 2022

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GENERAL NOTE

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

EXECUTIVE SUMMARY

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a national Health Care Fraud and Abuse Control Program (HCFAC or the Program) under the joint direction of the Attorney General and the Secretary of the Department of Health and Human Services (HHS),[1] acting through the Inspector General, designed to coordinate federal, state, and local law enforcement activities with respect to health care fraud and abuse. In its 25th 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) 2021, the Federal Government won or negotiated more than $5.0 billion in health care fraud judgments and settlements,[2] in addition to other health care administrative impositions. Because of these efforts, as well as those of preceding years, almost $1.9 billion was returned to the Federal Government or paid to private persons in FY 2021. Of this $1.9 billion, the Medicare Trust Funds[3] received transfers of approximately $1.2 billion during this period, in addition to the almost $98.7 million in Federal Medicaid money that was similarly transferred separately to the Centers for Medicare & Medicaid Services due to these efforts.

Enforcement Actions

In FY 2021, the Department of Justice (DOJ) opened 831 new criminal health care fraud investigations. Federal prosecutors filed criminal charges in 462 cases involving 741 defendants. A total of 312 defendants were convicted of health care fraud related crimes during the year. Also, in FY 2021, DOJ opened 805 new civil health care fraud investigations and had 1,432 civil health care fraud matters pending at the end of the fiscal year. Federal Bureau of Investigation (FBI) investigative efforts resulted in over 559 operational disruptions of criminal fraud organizations and the dismantlement of the criminal hierarchy of more than 107 health care fraud criminal enterprises.

In FY 2021, investigations conducted by HHS's Office of Inspector General (HHS-OIG) resulted in 504 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid, and 669 civil actions, which include false claims and unjust-enrichment lawsuits filed in federal district court, and civil monetary penalty (CMP) settlements. HHS-OIG also excluded 1,689 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 (569) or to other health care programs (267), for beneficiary abuse or neglect (145), and as a result of state health care licensure revocations (536).

[1] Hereafter, referred to as the Secretary.
[2] The amount reported as won or negotiated only reflects the federal settlements and judgments and therefore does not reflect state Medicaid monies won or negotiated as part of any global federal-state settlements.
[3] The Medicare Trust Funds is the collective term for the Medicare Hospital Insurance (Part A) Trust Fund and the Supplemental Medical Insurance (Part B) Trust Fund.

Sequestration Impact

Sequestration of mandatory funding generally results in DOJ, FBI, HHS, and HHS-OIG having fewer resources to fight fraud and abuse of Medicare, Medicaid, and other health care programs. Due to sequester suspension, no funds were sequestered from the HCFAC program in FY 2021.[4] However, a combined total of $150.6 million in mandatory funds have been sequestered in the past nine years. Including funds sequestered from the FBI ($70.0 million in the past nine years), $220.6 million has been sequestered from mandatory HCFAC funds since FY 2013.

[4] Section 3709 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Public Law (P.L.) 116-136) suspended Medicare sequestration from May 1, 2020, through December 31, 2020; the Consolidated Appropriations Act, 2021 (P.L. 116-260) extended this suspension to March 31, 2021; the Medicare sequester moratorium included in P.L. 117-7 extended the suspension again until December 31, 2021. This sequester adjustment was meant to provide an economic boost to Medicare providers treating patients during the COVID-19 public health emergency (PHE) and has resulted in additional funding for the HCFAC program. The three bills overlap to cover the entirety of FY 2021. The FY 2022 sequester amount will reflect a pro-rated period from October 1, 2021, to December 31, 2021.

STATUTORY BACKGROUND

The Annual Report of the Attorney General and the Secretary detailing expenditures and revenues under the Health Care Fraud and Abuse Control Program for FY 2021 is provided as required by Section 1817(k)(5) of the Social Security Act.

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

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

The Act appropriates monies from the Medicare Hospital Insurance Trust Fund to an expenditure account, called the Health Care Fraud and Abuse Control Account (the Account), in amounts that the Secretary and Attorney General jointly certify as necessary to finance anti-fraud activities. The maximum amounts available for certification are specified in the Act. Certain portions of these sums are to be used only for activities of the HHS-OIG, with respect to the Medicare and Medicaid programs. In FY 2006, the Tax Relief and Health Care Act (TRHCA) (P.L 109-432, §303) amended the Act so that funds allotted from the Account are "available until expended." TRHCA also allowed for yearly increases to the Account based on the change in the consumer price index for all urban consumers (all items, United States city average) (CPI-U) over the previous fiscal year for fiscal years 2007 through 2010.[5] In FY 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act (P.L. 111-148, ACA) extended permanently the yearly increases to the Account based upon the change in the consumer price index for all urban consumers, or CPI-U.

In FY 2021, the Secretary and the Attorney General certified $321.6 million in mandatory funding to the Account. (This reflects sequester suspension per footnote four.) Additionally, Congress appropriated $807.0 million in discretionary funding. A detailed breakdown of the allocation of these funds is set forth later in this report. HCFAC appropriations generally supplement the direct appropriations of HHS that are devoted to health care fraud enforcement and have supported almost three-fourths of DOJ's health care fraud funding and over three-fourths of HHS-OIG's appropriated budget in FY 2021. (Separately, the FBI, which is discussed in the Appendix, received $152.4 million from HIPAA, after accounting for sequester suspension). Under the joint direction of the Attorney General and the Secretary, the Program's goals are:

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

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

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

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

(4) To provide education and guidance regarding complying with current health care law.

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

(1) The amounts appropriated to the Trust Funds for the previous fiscal year under various categories and the source of such amounts; and

(2) The amounts appropriated from the Trust Funds for such year for use by the Attorney General and the Secretary and the justification for the expenditure of such amounts.

This annual report fulfills the above statutory requirements.

Finally, this report fulfills the requirement in the annual discretionary HCFAC appropriation (P.L.116-260, Consolidated Appropriations Act, 2021) 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 2021, about $1.9 billion was deposited with the Department of the Treasury (Treasury) and Centers for Medicare & Medicaid Services (CMS), transferred to other federal agencies administering health care programs, or paid to private persons during the fiscal year. Monetary results from these transfers and deposits are provided in the table below:

Monetary Results: Total Transfers / Deposits by Recipient FY 2021	
Department of the Treasury	
Deposits to the Medicare Trust Fund, as required by HIPAA:	
Gifts and Bequests	$176
Amount Equal to Criminal Fines	67,452,798
Civil Monetary Penalties	69,317,338
Asset Forfeiture	134,782,877
Penalties and Multiple Damages	385,310,565
Subtotal	**$656,863,753**
Centers for Medicare & Medicaid Services	
HHS/OIG Audit Disallowances: Recovered–Medicare	68,794,312
Restitution/Compensatory Damages*	482,322,344
Subtotal	**$551,116,656**
Total Transferred to the Medicare Trust Funds	**$1,207,980,409**
Restitution/Compensatory Damages to Federal Agencies	
TRICARE	$39,348,018
HHS/OIG	10,345,715
Office of Personnel Management	9,638,816
U.S Postal Service	1,518,076
DOJ/Drug Enforcement Administration	875,324
Other Agencies	1,731,350
Subtotal	**$63,457,299**
Centers for Medicare & Medicaid Services	
Federal Share of Medicaid	98,664,671
HHS/OIG Audit Disallowances: Recovered–Medicaid	295,874,233
Subtotal	**$394,538,904**
Total	**$457,996,203**
Relators' Payments**	**$193,043,816**
GRAND TOTAL MONETARY RESULTS***	**$1,859,020,428**

*Restitution, compensatory damages, and recovered audit disallowances include returns to both the Medicare Hospital Insurance (Part A) Trust Fund and the Supplemental Medical Insurance (Part B) Trust Fund.
**These are funds awarded to private persons who file suits on behalf of the Federal Government under the qui tam (whistleblower) provisions of the False Claims Act, 31 U.S.C. § 3730(b).
***State funds are also collected on behalf of state Medicaid programs; only the federal share of Medicaid funds transferred to CMS are represented here.

The above transfers include certain collections, or amounts equal to certain collections, required by HIPAA to be deposited directly into the Medicare Trust Funds. These amounts include:

(1) Gifts and bequests made unconditionally to the Trust Funds, for the benefit of the Account or any activity financed through the Account;

(2) Criminal fines recovered in cases involving a federal health care offense, including collections under section 24(a) of Title 18, United States Code (relating to health care fraud);

(3) Civil monetary penalties in cases involving a federal health care offense;

(4) Amounts resulting from the forfeiture of property by reason of a federal health care offense, including collections under section 982(a)(7) of Title 18, United States Code; and

(5) Penalties and damages obtained and otherwise creditable to miscellaneous receipts of the general fund of the Treasury obtained under sections 3729 through 3733 of Title 31, United States Code (known as the False Claims Act, or FCA), in cases involving claims related to the provision of health care items and services (other than funds awarded to a relator, for restitution, or otherwise authorized by law).

Expenditures

In the 25th year of operation, the Secretary and the Attorney General certified $321.6 million in mandatory funding as necessary for the Program, after accounting for mandatory sequester suspension as required by Public Law (P.L.) 116-136, P.L. 116-260, and P.L. 117-7. In addition, Congress appropriated $807.0 million in discretionary funding. Allocation by recipient is below:

FY 2021 ALLOCATION OF HCFAC APPROPRIATION				
	Mandatory Allocation[6]	**Discretionary Allocation**	**Funds Sequestered**[7]	**Total Allocation**
Department of Health and Human Services				
Office of Inspector General	$236,181,692	$99,000,000	$0	$335,181,692
Office of the General Counsel	7,427,491	0	0	7,427,491
Administration for Community Living	2,000,000	20,000,000	0	22,000,000
Food and Drug Administration	6,185,790	0	0	6,185,790
Centers for Medicare & Medicaid Services	0	596,000,000	0	596,000,000
Assistant Secretary for Planning and Evaluation	3,000,000	0	0	3,000,000
Unallocated Funding	0	0	0	0
Subtotal	**$254,794,973**	**$715,000,000**	**$0**	**$969,794,973**
Department of Justice				
United States Attorneys	$32,425,000	$31,064,440	$0	$63,489,440
Civil Division[8]	18,308,481	27,203,412	0	45,511,893
Criminal Division	12,534,604	21,860,434	0	34,395,038
Civil Rights Division	3,200,000	3,656,817	0	6,856,817
Justice Management Division	313,200	0	0	313,200
Federal Bureau of Investigation	0	6,824,172	0	6,824,172
Office of the Inspector General	0	1,390,725	0	1,390,725
Unallocated Funding	0	0	0	0
Subtotal	**$66,781,285**	**$92,000,000**	**$0**	**$158,781,285**
TOTAL	**$321,576,258**	**$807,000,000**	**$0**	**$1,128,576,258**

[6] As of FY 2007, mandatory funds are available until expended. Discretionary funds are available for two years.
[7] No funds were sequestered in FY 2021 due to mandatory sequester suspension.
[8] The Elder Justice Initiative, managed by the Civil Division, is included in the Civil Division figures.

Overall Settlements, Judgments, and Recoveries

During the fiscal year, the Federal Government won or negotiated more than $5.0 billion in judgments and settlements and attained additional administrative impositions in health care fraud cases and proceedings.[9] Because of these efforts, as well as those of preceding years, almost $1.9 billion was returned to the Federal Government or private persons. Of this $1.9 billion, the Medicare Trust Funds received transfers of approximately $1.2 billion during this period; approximately $98.7 million in federal Medicaid money was transferred to the Centers for Medicare & Medicaid Services separately due to these efforts.[10]

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

The return on investment (ROI) for the HCFAC program over the last three years (2019–2021) is $4.00 returned for every $1.00 expended. Because the annual ROI can vary from year to year depending on the number and type of cases that are settled or adjudicated during that year, DOJ and HHS use a three-year rolling average ROI for results contained in the report. Additional information on how the ROI is calculated may be found in the Appendix.

It is important to note that the ROI does not capture the full impact of the results of the Program. Civil and criminal enforcement that stops ongoing fraud saves the Program from future losses. Even actions that do not result in recoveries, for example, a search warrant, an indictment, or an arrest, may prevent the defendant from continuing to defraud federal health care programs. Therefore, this ROI calculation relies on actual recoveries and collections, and does not represent the effect of preventing future fraudulent payments. Further, the threat of oversight alone can have a sentinel impact that deters future bad actors from defrauding Medicaid, Medicare, and other federal health care benefit programs.

Strike Force

Health Care Fraud Strike Force Teams (Strike Force) harness data analytics and the combined resources of federal, state, and local law enforcement entities to prosecute complex health care fraud matters and prescription opioid distribution and diversion schemes. The Strike Force is comprised of inter-agency teams made up of investigators and prosecutors that focus on the worst offenders in regions with the highest known concentration of fraudulent activities. The Strike Force uses advanced data analysis techniques to identify aberrant billing levels in health 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.

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[9] The amount reported as won or negotiated 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.

[10] Note that some of the judgments, settlements, and administrative actions that occurred in FY 2021 will result in transfers in future years, just as some of the transfers in FY 2021 are attributable to actions from prior years.

First established in March 2007, Strike Force teams currently operate in 24 districts across the United States, including, but not limited to: Los Angeles, California; Miami and Tampa/Orlando, Florida; Chicago, Illinois; Ft. Mitchell, Kentucky; Baton Rouge and New Orleans, Louisiana; Detroit, Michigan; Brooklyn, New York; Newark, New Jersey / Philadelphia, Pennsylvania; Nashville, Tennessee; and Houston, San Antonio, and Dallas, Texas; along with the National Rapid Response Strike Force (NRRSF) located in Washington, D.C.

The NRRSF was established in September 2020. 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 Criminal Division, Fraud Section's Health Care Fraud Unit's (HCF Unit) nationwide initiatives involving billions of dollars of fraud and pressing national priorities, including the telemedicine and sober homes components of the 2020 National Health Care Fraud Takedown and the 2021 National Health Care Fraud Enforcement Action.

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 Working Group, which is chaired by the Criminal Division's HCF Unit, and comprised of leadership from over 10 key government agencies, including Food and Drug Administration (FDA), HHS, CMS, the Small Business Administration (SBA), the Department of Veterans Affairs (VA), FBI, the Drug Enforcement Administration (DEA), and Homeland Security Investigations (HSI), among others. The purpose of the Working Group is to identify, investigate, and prosecute COVID-19 health care fraud schemes, and enable coordination, deconfliction, and efficient staffing of COVID-19 health care fraud investigations. One example is the 2021 COVID-19 Health Care Fraud Enforcement Action, which resulted in charges against 14 defendants in seven federal districts across the United States for their alleged participation in various health care fraud schemes that exploited the COVID-19 pandemic and resulted in over $143.0 million in false billings.

Each Strike Force team brings the investigative and analytic resources of the FBI, HHS-OIG, the CMS Center for Program Integrity (CMS-CPI), the Defense Criminal Investigative Service (DCIS), the Federal Deposit Insurance Corporation Office of the Inspector General (FDIC-OIG), the Internal Revenue Service (IRS), and other agencies, together with the prosecutorial resources of the Criminal Division's Fraud Section and the U.S. Attorneys' Offices (USAOs) to bring cases in federal district court. During FY 2021, Strike Force accomplishments in the areas noted above, as well as USAO accomplishments included:[11]

- Filing 281 indictments, criminal informations and complaints involving charges against 444 defendants who allegedly collectively billed federal health care programs and private insurers approximately $1.7 billion[12];
- Obtaining 288 guilty pleas and litigating 23 jury trials, with guilty verdicts against 21 defendants; and

[11] The summary statistics in this document exclude sealed cases.
[12] This alleged loss amount figure only reflects the amounts of alleged loss in cases handled by the Criminal Division, Fraud Section.

- Securing imprisonment for 175 defendants sentenced, with an average sentence of over 49 months.

Since its inception, Strike Force prosecutors and USAOs in Strike Force districts filed more than 2,400 cases charging more than 5,000 defendants who collectively billed federal health care programs and private insurers approximately $24.7 billion, more than 3,300 defendants pled guilty and over 400 others were convicted in jury trials, and more than 400 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.

On September 17, 2021, the Criminal Division's Health Care Fraud Unit coordinated the Health Care Fraud National Enforcement Action, in collaboration with USAOs, HHS-OIG, FBI, the DEA, and other federal and state partners. Assistant Attorney General Kenneth A. Polite Jr. announced criminal charges against 138 defendants, including 42 doctors, nurses, and other licensed medical professionals, charged between August 1 and September 17, 2021, in 31 federal districts across the United States, for their alleged participation in various health care fraud schemes that resulted in approximately $1.4 billion in alleged losses. The charges targeted approximately $1.1 billion in fraud committed using telemedicine (the use of telecommunications technology to provide health care services remotely), $29.0 million in COVID-19 health care fraud, $133.0 million connected to substance use treatment facilities, or "sober homes," and $160.0 million connected to other health care fraud and illegal opioid distribution schemes across the country. The charges announced as part of the 2021 National Enforcement Action continued to send a clear deterrent message about the Department's ongoing commitment to ensuring the safety of patients and the integrity of health care benefit programs, even amid the continued COVID-19 pandemic.

In an initial April 2019 surge, and a second takedown in September 2019, Trial Attorneys in the Fraud Section, in conjunction with Assistant United States Attorneys (AUSAs) in more than 10 federal districts,[13] charged 73 individuals, including 64 medical professionals, with opioid-related crimes. Another 10 defendants were charged in FY 2021, including six medical professionals. As of September 30, 2021, 55 of the Appalachian Regional Prescription Opioid Strike Force (ARPO) defendants have entered guilty pleas, with more pleas scheduled. Four additional defendants have been convicted at trial, including one two-week trial in West Virginia that took place during the continued COVID-19 pandemic in May 2021. Twenty-one ARPO defendants were sentenced in FY 2021.

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 2021, OFAD AUSAs handled a variety of investigations and prosecutions involving medical professionals. OFAD attorneys filed 37

[13] Two non-ARPO districts also participated in the 2019 surge, bringing the district total to 12.

cases, against 90 defendants, alleging various charges including health care fraud, drug trafficking, and money laundering.

Health Care Fraud Prevention and Enforcement Action Team (HEAT)

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

- **To marshal significant resources across government to prevent waste, fraud and abuse in the Medicare and Medicaid programs** and crack down on the fraud perpetrators who are abusing the system and costing the government billions of dollars.
- **To reduce health care costs and improve the quality of care** by ridding the system of perpetrators who are preying on Medicare and Medicaid beneficiaries.
- **To target doctors and physicians who prescribe opioids outside the scope of legitimate medical practice** and often charge Medicare and/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, eight MFCUs participated in the National Health Care Fraud Enforcement Action in September 2021.

The DOJ and HHS have expanded data-sharing and improved information-sharing procedures in order to get critical data and information into the hands of law enforcement to track patterns of fraud and abuse and increase efficiency in investigating and prosecuting complex health care fraud cases. This expanded data sharing enables the DOJ and HHS to efficiently identify and target the worst actors in the system. The Departments established a cross-government health care fraud data intelligence sharing workgroup to share fraud trends, new initiatives, ideas, and success stories to improve awareness across issues relating to health care fraud.

Both Departments also have developed training programs to prevent honest mistakes and help stop potential fraud before it happens. This includes CMS compliance training for providers, HHS-OIG compliance program guidance documents and trainings for providers, ongoing meetings at USAOs with the public and private sector, and increased efforts by HHS to educate specific groups—including elderly and immigrant communities—to help protect them. Moreover, HHS-OIG offers a Compliance Resource Portal on its website, which includes special fraud alerts, videos, and other resources directed at various segments of the health care industry. In addition, DOJ conducts, with the support of HHS, a Health Care Fraud training program designed to teach the Strike Force concept and case model to prosecutors, law enforcement agents, and administrative support teams.

Health Care Fraud Prevention Partnership (HFPP)

The HFPP is a voluntary public-private partnership among the Federal Government, state agencies, law enforcement, private health insurance plans, employer organizations, and health care anti-fraud associations. The purpose of the partnership is to exchange data and information between the partners to help improve capabilities to fight fraud, waste, and abuse in the health care industry. The number of participants has increased to 222 public, private, and state partner organizations at the end of FY 2021. Collectively, these organizations represent more than 218 million covered lives, equivalent to more than three in four insured Americans. Sixty-six of the current partners are actively submitting claim level data representing more than 104 million individuals, or more than one in three insured Americans.

The HFPP commenced or completed studies using multiple partners' data to address fraud, waste, and abuse in FY 2021, providing partners with detailed results that can be used for corrective actions within their organizations. The HFPP continued its efforts to foster collaboration among partners by hosting virtual information-sharing sessions (due to the Public Health Emergency) and initiating a new Executive Board which will meet quarterly. 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. See the CMS HFPP section for more information on HFPP activities.

COVID-19 Pandemic-Related Enforcement

Since the start of the COVID-19 Public Health Emergency (PHE) in March 2020, CMS has examined how the PHE—and more specifically, the waivers and flexibilities offered by the Agency—may create new fraud risks in federal health programs. CMS has developed a robust fraud risk assessment process, using principles outlined in the Government Accountability Office Fraud Risk Management Framework, to identify potential risks and vulnerabilities associated with PHE and potential unintended consequences of the waivers and flexibilities. Fraud, waste, and abuse mitigation strategies include data analyses and studies, targeted investigations, development of Fraud Prevention System (FPS) models and edits, and implementation of new policies. CMS, DOJ, HHS-OIG, and other law enforcement agency partners are working

together to investigate and prosecute frauds from identified risks and related schemes. Examples of potential risks and vulnerabilities include:

- Additional, unnecessary services: Offering COVID-19 tests to Medicare beneficiaries in exchange for personal details, including Medicare information, when the services are unapproved and illegitimate. Fraudsters are targeting beneficiaries in a number of ways, including telehealth for Evaluation and Management up-coding or services not rendered, telemarketing calls, text messages, social media platforms, and door-to-door visits. These scammers exploit the pandemic to benefit themselves, and beneficiaries face potential harms. Telemedicine–using telecommunications technology to provide care remotely–has been used to facilitate fraud schemes for unnecessary services. The personal information collected can be used to fraudulently bill federal health care programs and commit medical identity theft. If Medicare or Medicaid denies the claim for an unapproved test, the beneficiary could be responsible for the cost.

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

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

- Fraudulently obtaining COVID-19 health care relief funds: Filing false claims and applications for federal relief funds, such as those provided under the Coronavirus Aid, Relief, and Economic Security (CARES) Act's Provider Relief Fund, the Paycheck Protection Program and Health Care Enhancement Act, or the Economic Impact Disaster Loan (EIDL) program.

Highlights of Significant Criminal and Civil Investigations

Our respective Departments successfully pursued Strike Force matters, as well as other criminal and civil investigations in a wide range of areas. Cases are organized by type and presented in chronological order. **Strike Force cases are denoted by *(SF)* before the lead sentence**.

Ambulance and Transportation Services

In December 2020, the owner of a New York based ambulance company (owner) was sentenced to 24 months of prison, followed by 24 months' probation, and ordered to pay restitution in the amount of $10,650,670. The owner pled guilty to one count of conspiracy to offer and pay health care kickbacks, and one count of conspiracy to defraud the lawful functions of the Internal Revenue Service. The owner and his father paid more than $8.6 million in kickbacks to co-conspirator companies not enrolled in the state's Medicaid program for the referral of beneficiaries recruited by those co-conspirators, so that the ambulance company (company) could falsely bill Medicaid as if the company had transported those beneficiaries to various clinics in Brooklyn and Queens. The defendants then falsely reported to the IRS that the illegal kickback payments were legitimate business expenses, thereby under-reporting business income and claiming false deductions.

Clinics

In October 2020, after a two-day sentencing hearing, the owner of multiple health care clinics and medical research companies in Richland, Washington, was sentenced to 340 months imprisonment, over $1.9 million in restitution, and over $5.6 million in criminal forfeiture. The sentencing followed a three-week jury trial in November 2019 in which the defendant was convicted on 47 counts of fraud, conspiracy, and controlled substance offenses in connection with his falsification of human clinical research trial data and fraudulent obtaining and dispensing of opioids, including hydrocodone and morphine. Evidence during trial and at sentencing demonstrated that the defendant not only falsified data from dozens of studies of experimental medications designed to treat diabetes, heart disease, drug addiction, and other medical conditions, but falsely posed as a medical doctor in order to convince real patients to participate in his fraudulent trials, putting them at significant risk because their participation was not being appropriately monitored by a licensed medical professional. The evidence at trial and at sentencing further demonstrated that the defendant waged a campaign of threats, retaliation, intimidation, and harassment in order to keep his scheme from coming to light, and that the defendant and his companies, which were also convicted, received over $5.6 million from the fraud. In sentencing the defendant to the longest-ever sentence for health care fraud in the Eastern District of Washington, the court noted the serious risk of grave harm to the public created by the defendant, both to his research patients as well as to the general public, given that the fraudulent and corrupted research data was intended to be submitted to the U.S. Food and Drug Administration to make approval decisions about experimental medications.

In October 2020, a pain clinic co-owner who operated several pill mills in Tennessee and Florida was sentenced to more than 33 years and ordered to forfeit $3.6 million in the Eastern District of

Tennessee. Then in December 2020, three pain clinic nurse practitioners were sentenced to prison terms ranging from 30 to 42 months for maintaining a drug-involved premises. The clinic co-owner and the three nurse practitioners had been convicted following a three-month trial for their roles in the operation of four separate pain clinics. The trial evidence showed that they operated the pain clinics as pill mills inviting abuse by providers, employees, customers, and drug traffickers with awareness that patients travelled long distances to illegally obtain controlled substances and requested prescriptions for large quantities of Schedule II Controlled Substances. The clinics distributed over 11 million tablets of oxycodone, oxymorphone, and morphine that generated over $21.0 million in clinic revenue, with a street value of $360.0 million.

(*SF*) In May 2021, the owner and operator of a purported medical clinic (clinic) in Texas was sentenced to 25 years in prison and ordered to pay $250,000 in restitution for participating in an $11.0 million Medicare fraud scheme in which fraudulent medical documents were sold to home-health agencies in and around Houston. According to the evidence presented at trial, from October 2012 through August 2015, the owner and others conspired to defraud Medicare by selling Plans of Care and other medical documents signed by a doctor, through the clinic to various home-health services, resulting in approximately $11.0 million in false and fraudulent claims for home-health services billed to Medicare. The evidence at trial showed that home-health agencies billed Medicare for home health services that were not medically necessary and, in many instances, not provided.

Diagnostic Testing

In July 2021, national electroencephalography (EEG) testing company Alliance Family of Companies LLC (Alliance) and private investment company Ancor Holdings LP (Ancor), both based in Texas, agreed to pay more than $14.8 million combined to resolve civil FCA allegations that kickbacks and other misconduct resulted in the submission of false claims to federal health care programs. The settlement resolved allegations that Alliance induced physicians to order the company's EEG testing by providing kickbacks in the form of free EEG test-interpretation reports, thereby enabling primary care physicians who were not neurologists to bill the government as if they had interpreted the tests, and that Alliance used an inaccurate billing code for certain EEG testing to generate higher reimbursements and billed for a specialized digital analysis that it did not actually perform. The settlement also resolved allegations that Ancor learned of the kickbacks based on due diligence it performed prior to investing in Alliance and then caused false claims by allowing that conduct to continue once it entered into an agreement to manage Alliance. In addition to the federal recovery, Alliance and Ancor agreed to pay more than $540,000 combined to resolve state Medicaid claims. In connection with the settlement, Alliance entered into a five-year Corporate Integrity Agreement (CIA) with HHS-OIG.

Drug Companies

In October 2020, certain individual members of the Sackler family who were shareholders and board members of opioid manufacturer Purdue Pharma LP (Purdue) agreed to pay $225.0 million to resolve civil FCA allegations that from 2013 to 2018, the individuals caused false and/or fraudulent claims for its opioid products OxyContin and Hysingla to be submitted to federal

health care programs. The settlement resolved allegations that, in 2012, the individuals knew that the legitimate market for Purdue's opioids had contracted, but they nevertheless requested that Purdue executives recapture lost sales and increase Purdue's share of the opioid market. As part of this strategy, shortly after the end of Purdue's CIA in 2013, the individuals approved a new marketing program through which Purdue sales representatives intensified their marketing of OxyContin to extreme, high-volume prescribers, causing health care providers to prescribe opioids for uses that were unsafe, ineffective, and medically unnecessary, and that often led to abuse and diversion. The settlement further resolved allegations that from approximately 2008 to 2018, at the individual family members' request, Purdue transferred assets into family holding companies and trusts that were made to hinder future creditors, and/or were otherwise voidable as fraudulent transfers.

In November 2020, opioid company Purdue Pharma LP pled guilty in the District of New Jersey to three felony offenses: one count of a dual-object conspiracy to defraud the United States and to violate the Food, Drug and Cosmetic Act (FDCA), and two counts of conspiracy to violate the Federal Anti-Kickback Statute (AKS). With respect to the first count, Purdue admitted that it conspired to defraud the United States by impeding the lawful function of the DEA by representing that Purdue maintained an effective anti-diversion program when, in fact, Purdue continued to market its opioid products to health care providers whom the company had good reason to believe were diverting opioids, and by reporting misleading information to the DEA to boost Purdue's manufacturing quotas. With respect to the AKS counts, Purdue admitted that between June 2009 and March 2017, Purdue made payments to two doctors through Purdue's speaker program to induce those doctors to write more prescriptions, and from April 2016 through December 2016, Purdue paid electronic health records developer Practice Fusion Inc. nearly $1.0 million in exchange for creating and installing a prompt in its software with the intent to cause doctors to refer, recommend, and arrange for the ordering of Purdue's opioid products. In connection with the Purdue investigation, the District of Vermont additionally prosecuted and convicted Practice Fusion's Director of National Accounts with attempting to obstruct a grand jury investigation. Purdue agreed to the imposition of an allowed, unsubordinated, general unsecured bankruptcy claim for a criminal fine of more than $3.5 billion and an additional $2.0 billion in criminal forfeiture, up to approximately $1.8 billion of which the DOJ agreed to credit against recoveries by state and local government creditors in the Purdue bankruptcy. As part of the same resolution, in October 2020, Purdue agreed to an allowed, unsubordinated, general unsecured bankruptcy claim for $2.8 billion to resolve civil FCA allegations that Purdue promoted its opioid drugs to health care providers it knew were prescribing opioids for uses that were unsafe, ineffective, and medically unnecessary, and that often led to abuse and diversion, and to resolve allegations that Purdue paid kickbacks to doctors, Practice Fusion, and certain specialty pharmacies to induce prescriptions. Purdue incorporated the criminal and civil settlements into its plan of reorganization. The district court subsequently reversed a bankruptcy court order confirming the plan and litigation over the plan continues.

In November 2020, Indivior Solutions (Indivior) was sentenced to pay $289.0 million in criminal penalties after pleading guilty to a one-count felony information in connection with the marketing of the opioid-addiction-treatment drug Suboxone, which is a formulation of buprenorphine. In connection with its guilty plea, Indivior admitted to making false statements

to promote the film version of Suboxone (Suboxone Film) to the Massachusetts Medicaid program (MassHealth) relating to the safety of Suboxone Film around children. Under the civil settlement, Indivior Inc. and Indivior plc agreed to pay an additional $300.0 million ($209.3 million to the Federal Government and $90.7 million to the states) to resolve allegations that from 2010 through 2015, Indivior companies knowingly: (a) promoted the sale and use of Suboxone to physicians who were writing prescriptions that were not for a medically accepted indication and that lacked a legitimate medical purpose, were issued without any counseling or psychosocial support, were for uses that were unsafe, ineffective, and medically unnecessary, and were often diverted; (b) promoted the sale or use of Suboxone Film to physicians and state Medicaid agencies using false and misleading claims that Suboxone Film was less susceptible to diversion and abuse than other buprenorphine products and that Suboxone Film was less susceptible to accidental pediatric exposure than tablets; and (c) took steps to delay the entry of generic competition for Suboxone to improperly control pricing of Suboxone. In connection with the criminal and civil resolutions, Indivior Inc. executed a five-year CIA with HHS-OIG. In addition, Indivior Inc. agreed to pay $10.0 million to resolve claims that it engaged in unfair methods of competition in violation of the Federal Trade Commission Act. Further, Indivior plc's former CEO and former medical director each pled guilty to a one-count misdemeanor information related to Indivior's misrepresentations to MassHealth, with the former receiving a six-month term of incarceration and $600,000 in fines and forfeiture, and the latter receiving a six-month term of home detention, 100 hours of community service, and a $100,000 fine.

In December 2020, pharmaceutical company Biogen, Inc. (Biogen), based in Cambridge, Massachusetts, agreed to pay $22.0 million to resolve civil FCA allegations that it illegally used foundations as a conduit to pay the copays of Medicare patients taking Biogen's multiple sclerosis drugs Avonex and Tysabri. The settlement resolved allegations that Biogen engaged in a prohibited kickback scheme by using two foundations, which claim 501(c)(3) status for tax purposes, as conduits to pay the copay obligations of Medicare patients to induce patients to purchase Medicare-reimbursed Avonex and Tysabri prescriptions. The government alleged that as part of the scheme, Biogen identified for its vendor certain patients in Biogen's Avonex or Tysabri free drug program, and then worked with the vendor to transfer these patients to the foundations, which received contemporaneous payments from Biogen and covered the costs of Medicare copays for most or all of these patients, while Medicare paid the remaining portion of the patients' Avonex or Tysabri claims. The government alleged that Biogen engaged in this conduct in the first quarter of 2011 for certain Avonex patients, and in the second and third quarters of 2012 and 2013 for certain Tysabri patients.

In April 2021, Bristol-Myers Squibb (BMS) agreed to pay the United States and participating states a total of $75.0 million to resolve civil FCA allegations that it knowingly underpaid rebates owed under the Medicaid Drug Rebate Program, under which drug manufacturers are required to pay quarterly rebates to state Medicaid programs in exchange for Medicaid's coverage of the manufacturers' drugs. The settlement resolved allegations that BMS underreported Average Manufacturer Prices (AMPs) for some of its drugs by improperly reducing the reported AMPs for service fees paid to wholesalers, and by improperly excluding from the reported AMPs additional value it received pursuant to price appreciation provisions in its contracts with wholesalers, thereby underpaying quarterly rebates owed to the states and

causing the United States to be overcharged for its payments to the states for the Medicaid program. BMS agreed to pay more than $41.3 million to the United States pursuant to the settlement, and the remainder to states participating in the settlement.

In September 2021, generic pharmaceutical manufacturers Taro Pharmaceuticals USA, Inc. (Taro), Sandoz Inc. (Sandoz), and Apotex Corporation (Apotex), respectively headquartered in New York, New Jersey, and Florida, agreed to pay a total of $447.2 million pursuant to three separate settlements to resolve civil FCA allegations that they participated in conspiracies to fix the price of various generic drugs that resulted in higher drug prices for federal health care programs and beneficiaries. The settlements resolved allegations that between 2013 and 2015, the three companies paid and received compensation prohibited by AKS through arrangements on price, supply, and allocation of customers with other pharmaceutical manufacturers for certain generic drugs manufactured by the companies. Under the settlements, Taro agreed to pay $213.2 million, Sandoz agreed to pay $185.0 million, and Apotex agreed to pay $49.0 million. In connection with the settlements, each company also entered a five-year CIA with HHS-OIG. The CIAs include unique internal monitoring and price transparency provisions and require the companies to implement compliance measures. All three companies previously entered into deferred prosecution agreements to resolve related criminal charges. Under the deferred prosecution agreements, Taro paid a criminal penalty of $205.6 million and admitted to conspiring with two other generic drug companies to fix prices on certain generic drugs, Sandoz paid a criminal penalty of $195.0 million and admitted to conspiring with four other generic drug companies to fix prices on certain generic drugs, and Apotex paid a criminal penalty of $24.1 million and admitted to conspiring to increase and maintain the price on pravastatin. The civil settlement payments were in addition to the criminal penalties paid by the companies.

Durable Medical Equipment (DME)

(SF) In October 2020, the owner of a telemarketing company was convicted of one count of conspiracy to pay and receive for her role in an illegal kickback scheme involving medically unnecessary DME and cancer genetic testing in which Medicare was billed at least $20.2 million and paid $6.9 million for kickback-tainted orthotic braces. In September 2021, the owner was sentenced to 36 months imprisonment.

In December 2020, DME provider Apria Healthcare Group, Inc. and its affiliate Apria Healthcare LLC (collectively Apria), based in New York, agreed to pay $40.5 million to resolve civil FCA allegations that it submitted false claims to federal health programs, including Medicare and Medicaid, by seeking reimbursement for the rental of costly, medically unnecessary non-invasive ventilators (NIVs) to program beneficiaries and improperly waiving patient co-insurance payments. The settlement resolved allegations that Apria routinely billed Medicare and other programs when it did not know whether NIVs were still being used by patients, which would have supported medical necessity, and that even when Apria had information indicating that patients were no longer using their NIVs, it often continued to bill the federal health programs. In connection with the settlement, the company also entered into a CIA with HHS-OIG.

(SF) In March 2021, the president of a purported telemedicine company pled guilty to conspiracy to commit health care fraud and wire fraud, for his role in a conspiracy to defraud Medicare through the submission of false and fraudulent orthotic brace orders. This individual admitted that he solicited illegal kickbacks and bribes in exchange for medically unnecessary orders for orthotic braces and caused the submission of over $56.0 million in false and fraudulent claims for which the suppliers of durable medical equipment were paid over $10.0 million.

(SF) In June 2021, a jury convicted the owners of two DME supplier companies in Texas of charges resulting from their involvement in a scheme to defraud Medicare. According to court documents, from approximately March 2016 through January 2019, the defendants paid kickbacks and bribes in exchange for signed doctors' orders for orthotic braces that were not medically necessary. To conceal the kickbacks and bribes, the defendants and their co-conspirators executed sham contracts and created fake invoices appearing to be for legitimate "marketing" or "business process outsourcing" services. The defendants' DME companies collectively billed Medicare Parts B and C over $59.0 million. On December 15, 2021, the defendants were each sentenced to 151 months in prison, three years' supervised release, and ordered to pay $27,104,359 in restitution.

In June 2021, a nurse practitioner in Florida was sentenced to 12 months and 1 day in prison, two years supervised release, and ordered to pay $23,880,678 in restitution. The defendant pled guilty on October 13, 2020 to one count of conspiring to solicit and receive illegal kickbacks and one count of executing a health care fraud scheme. Between 2017 and 2019, the defendant received illegal kickbacks from telemedicine and other companies to sign orders and prescriptions for medically unnecessary DME, genetic testing and prescription medications for patients identified through mass marketing. Telemarketers in the United States and elsewhere solicited patients through media ads and cold calls and then contacted the patients to obtain their insurance information. Although the telemarketers were not health care professionals, they completed order forms and sometimes encouraged patients to exaggerate the extent of their pain or need for braces and pain creams. The orders were then sent to telemedicine doctors or nurse practitioners, who were typically paid $30-$50 for each patient for whom they signed orders and prescriptions. The defendant did not have a prior doctor-patient relationship with the patients for which she signed orders and prescriptions, did not evaluate or assess the patients' needs for the items, and in most cases had no contact with the patients, who lived in states distant from her. The defendant received numerous complaints from patients, indicating that they had not requested and did not want or need the DME. Between 2017 and 2019, the defendant was paid $681,114 for signing orders and prescriptions for patients for whom she never determined a medical need for the ordered items and services. Federal health care benefit programs paid $23,880,678 for the false and fraudulent orders and prescriptions signed by the defendant.

In July 2021, a doctor in Florida was sentenced to 74 months of incarceration, followed by three years of supervised release. The doctor had previously pled guilty to one count of conspiracy to commit healthcare fraud. The doctor was involved in the Operation Brace Yourself takedown that occurred in April 2019. The doctor owned and operated several DME companies, many of which were operating in nominee owner names, that submitted high volumes of claims to Medicare for DME orthotics. The doctor purchased pre-signed doctors' orders from purported

"marketing" companies who paid bribes and kickbacks to telemedicine companies/physicians in exchange for authorizing medically unnecessary equipment. The doctors' orders were purchased at a "price per brace" in violation of the AKS. In total, the doctor caused over $20.0 million dollars in false claims to be submitted, of which about $10.7 million was paid.

In July 2021, Arriva Medical LLC (Arriva), a mail-order diabetic testing supply company based in Coral Springs, Florida until it ceased business operations in December 2017, and its parent, Alere Inc. (Alere), a medical device company now based in Abbott Park, Illinois, agreed to pay $160.0 million to resolve civil FCA allegations that Arriva, with Alere's approval, made, or caused, claims to Medicare that were false because kickbacks were paid to Medicare beneficiaries, patients were ineligible to receive diabetic testing meters, or patients were deceased. The government alleged that: (1) from April 2010 until the end of 2016, Arriva, with Alere's approval, paid kickbacks to Medicare beneficiaries by providing them "free" or "no cost" meters and by routinely waiving, or not collecting, their copayments for meters and diabetic testing supplies; (2) Arriva, with Alere's approval, systematically provided to all of its new patients, and billed Medicare for, a meter without regard to the patients' eligibility for one; and (3) Arriva submitted false claims to Medicare on behalf of deceased beneficiaries.

(SF) In August 2021, a DME company owner pled guilty to his role orchestrating a large health care fraud and money laundering scheme involving a series of bogus durable medical equipment companies that billed Medicare, a state Medicaid agency and private health insurers more than $48.0 million for medical supplies the companies never purchased and never provided. As part of its investigation, federal agents executed a search warrant on this individual's residence on March 11, 2021. During execution of that warrant, agents discovered more than $2.5 million in cash hidden in PVC piping and buried under the closet flooring in one of the bedrooms, a large amount of expensive jewelry, and another $280,000 in cash that was hidden in a safe at a separate location. On April 5, 2021, agents seized another $1.2 million from a bank account associated with one of this individual's fraudulent entities.

Electronic Health Records

In January 2021, athenahealth Inc. (Athena), an electronic health records (EHR) technology vendor based in Watertown, Massachusetts, agreed to pay more than $18.2 million to resolve civil FCA allegations that it paid unlawful kickbacks to generate sales of its EHR product. The settlement resolved allegations that Athena violated the FCA and the AKS through three marketing programs by which Athena: (1) invited prospective and existing customers to sporting, entertainment, and recreational events, providing free tickets and amenities; (2) paid kickbacks to its existing customers under a program designed to identify and refer new prospective clients to Athena; and (3) entered into deals with competing vendors that were discontinuing their EHR technology offerings to refer their clients to Athena such that Athena paid remuneration to the competitor based on the value and volume of practices that were successfully converted into Athena clients.

In April 2021, EHR software developer CareCloud, Health, Inc. f/k/a CareCloud Corporation (CareCloud) of Miami, Florida agreed to pay $3.8 million to resolve civil FCA allegations that it

paid unlawful kickbacks through its marketing referral program to generate sales of its EHR products. The settlement resolved allegations that CareCloud violated the FCA and the AKS between January 2012 and March 2017 by offering and providing its existing clients cash equivalent credits, cash bonuses, and percentage success payments to recommend CareCloud's EHR products to prospective clients; by requiring existing clients who participated in the marketing referral program to execute written agreements prohibiting them from providing negative information about CareCloud's EHR products to prospective CareCloud clients; and by failing to disclose to prospective CareCloud clients this referral-kickback arrangement or that participants in the marketing referral program were contractually prohibited from sharing negative company information with them.

Genetic Testing/RPP Testing Paired with COVID-19 Testing

(SF) In October 2020 and January 2021, two individuals who worked together as marketers were charged by information for their roles in a scheme to pay and receive kickbacks in connection with providing a laboratory with DNA swabs that could be used to perform and bill for cancer genetic tests ("CGx") and pharmacogenetic tests ("PGx"). The marketers admitted that they and others acting at their direction solicited Medicare and Medicaid beneficiaries to provide DNA samples, and paid kickbacks to a nurse practitioner who was not treating the beneficiaries in exchange for signing orders that were provided to the laboratory. They also admitted that they received kickbacks from the owners and operators of the laboratory in exchange for providing the samples and the signed orders, including providing sham contracts and invoices to conceal the kickback payments. The scheme resulted in the submission of approximately $12.0 million in claims for CGx and PGx tests that were medically unnecessary, ineligible for reimbursement by the payors, and not provided as represented.

(SF) In January 2021, at the conclusion of a one-week trial, a patient recruiter was found guilty of conspiracy to commit health care fraud, health care fraud, conspiracy to pay and receive kickbacks, and the receipt of kickbacks for his role in in a fraud scheme with losses of approximately $3.3 million in billed claims. The trial evidence showed that this individual was a patient recruiter who was integral to the execution of a cancer genetic testing scheme by recruiting Medicare beneficiaries, and obtaining buccal swabs from them, for genetic testing that was not medically necessary and not covered by Medicare. The trial evidence further showed that this individual was responsible for paying telemedicine doctors kickback payments in order to obtain doctor's orders authorizing the genetic testing. The individual and his co-conspirators would then send the buccal swabs and the doctor's orders to laboratories that would subsequently bill Medicare for the genetic testing. In April 2021, the patient recruiter was sentenced to 10 years in prison for his part in leading the scheme. This was the first cancer genetic testing case and the first case charging payments to telemedicine companies as a kickback to go to trial.

(SF) Between January 2021 and September 2021 four defendants pled guilty in connection with the submission of over $70.0 million in false and fraudulent claims for allergy and COVID-19 testing. The charges relate to false and fraudulent statements about the existence, regulatory status, and accuracy of a COVID-19 test that was purportedly offered by the Arrayit Corporation. The conspiracy allegedly sought to induce the ordering of the Arrayit COVID-19

test and to bundle, i.e., require combination with the COVID-19 test and Arrayit's medically unnecessary allergy test. The COVID-19 test results were not provided in a timely fashion and were not reliable in detecting COVID-19. To date, the Arrayit Vice President of Marketing, Arrayit Medical Director, a physician, and an executive of an Arizona marketing organization have entered pleas of guilty in connection with the scheme.

Home Health Providers

(SF) In November 2020, a physician-owner was sentenced to 5 years in prison and ordered to pay $9.5 million in restitution after conviction for a conspiracy to commit healthcare fraud, conspiracy to solicit and receive healthcare kickbacks, and making false statements in a healthcare matter as part of a multi-million-dollar home healthcare fraud scheme. The September 2019 trial evidence showed that the physician-owner conspired with others to defraud Medicare by signing false and fraudulent home healthcare paperwork that was used to submit fraudulent claims to Medicare. The physician-owner required home healthcare agencies to pay an illegal kickback, which she disguised as a "co-pay," in exchange for certifying and recertifying patients for home healthcare services. The evidence showed she would not release the home healthcare paperwork until the home healthcare companies or their marketers paid her the kickback.

(SF) In November 2020 and early 2021, four defendants were sentenced for their roles in a $80.4 million home health care fraud, wire fraud, and money laundering scheme that took place in the Southern District of Florida. In November 2020, the group's money mule received a sentence of approximately 8 years. In January 2021, the first kingpin and his lieutenant were sentenced to 17.5 years and 10 years, respectively. In May 2021, the second kingpin was also sentenced to 17.5 years. These individuals operated three sham home health agencies that never treated a single patient, yet billed Medicare for over $80.0 million in fraudulent claims, of which they received approximately $50.0 million. They laundered the proceeds through dozens of shell companies. They evaded law enforcement detection for years by requiring nominee owners of the home health agencies and shell companies to permanently flee to Cuba upon the conclusion of their involvement in the scheme, beyond the jurisdiction of the United States.

In August 2021, a residential care company based in Oregon, At Home Care LLC, doing business as At Home Care Group (AHCG), and its owner agreed to pay $2.9 million to resolve civil FCA allegations that between March 2013 and September 2018, it billed the Oregon Medicaid program for services not provided. The settlement resolved allegations that AHCG altered caregiver scheduling calendars and billed the Oregon Medicaid program for hours of in-home care not actually provided. Under the settlement, AHCG and its owner will pay more than $1.8 million to the United States and more than $1.0 million to Oregon. As part of the settlement, AHCG's owner was required to divest ownership in the company and enter a state court guilty plea for two counts of False Claims for Health Care Payment, and AHCG and its owner agreed to be excluded from all federal health payors for 15 years and 8 years, respectively.

In September 2021, a Las Vegas resident was sentenced to 144 months in federal prison and ordered to pay $4,321,590.39 in restitution to the North Carolina Medicaid Program. In May

2021, his wife was sentenced to 14 years in federal prison for her role in the fraud. The two conspired to defraud the North Carolina Medicaid Program of over $10.0 million between 2017 and 2019 alone. The husband admitted that he and his wife carried out the fraud by exploiting an eligibility tool that was entrusted only to North Carolina Medicaid providers. Specifically, the defendants searched publicly available sources, such as obituary postings on the internet by North Carolina funeral homes, to locate recently deceased North Carolinians and extract certain personal information for the deceased, including their name, date of birth, and date of death. Using the extracted information, the defendants queried the North Carolina Medicaid eligibility tool to determine whether the deceased individual had a Medicaid Identification Number and was otherwise eligible for Medicaid coverage during their life. If so, the defendants used that individual's identity to "back-bill" North Carolina Medicaid for up to one year of fictitious home health services that were allegedly rendered prior to the death of the individual. The husband admitted that he and his wife carried out the fraud via the internet from locations around the globe, including their corporate office building in Las Vegas, their penthouse condominium in Las Vegas, a corporate office in North Carolina, and from various hotels and luxury resorts in and outside of the United States. The husband further pled guilty to conspiring with his wife to launder the proceeds of the fraud into various luxury items. These expenses included a $900,000 wire for the purchase of a British Aerospace Bae 125-800A private jet, hundreds of thousands of dollars in Tiffany & Co. and Brioni clothing and jewelry, thousands of dollars in Eastern North Carolina business properties, and thousands of dollars in gym equipment.

In September 2021, BAYADA, BAYADA Home Health Care Inc., BAYADA Health LLC, and BAYADA Home Care (collectively, the BAYADA Companies), headquartered in New Jersey, agreed to pay $17.0 million to resolve civil FCA allegations that they violated the AKS by paying a kickback to a retirement home operator by purchasing two of its home health agencies located in Arizona. The settlement resolved allegations that the BAYADA Companies bought the two home health agencies to induce referrals to BAYADA of Medicare beneficiaries from retirement communities operated by the seller throughout the United States, and that from January 2014 through October 2020, the BAYADA Companies submitted false claims for payment to Medicare for services provided to beneficiaries referred to BAYADA as a result of the kickback transaction.

Hospice Care

(SF) In November 2020, the administrator of a Southern California hospice was convicted of charges resulting from his involvement in a conspiracy to defraud Medicare. According to court documents, from 2011 to 2018, the administrator, along with his co-conspirators, paid illegal kickbacks to patient recruiters for the referral of hospice beneficiaries and, when clinical staff at the hospice determined that beneficiary referrals did not qualify to receive hospice services, the administrator overruled those determinations and nonetheless caused the beneficiaries to be put on hospice services. The administrator was personally responsible for $4,769,982 in false and fraudulent claims to Medicare, resulting in Medicare paying the hospice $2,984,914 for medically unnecessary hospice services for beneficiaries, many of whom had been recruited

through illegal kickbacks. The owner pled guilty to conspiracy to commit health care fraud and was sentenced to 30 months in prison and restitution of over $2.1 million.

In January 2021, Allstate Hospice LLC (Allstate) and Verge Home Care LLC (Verge) and their two founders, all located in Texas, agreed to jointly pay over $1.8 million to resolve civil FCA allegations that they submitted claims to Medicare that resulted from unlawful referrals, in violation of the Stark Law and the AKS. The settlement resolved allegations that the founders offered compensation to physicians in exchange for referrals to both Allstate and Verge, which included providing monthly payments pursuant to medical directorships that were in excess of fair market value for the hours worked by the physicians. The settlement also resolved allegations that the founders sold interests in Allstate to five different physicians, who were referral sources for both Allstate and Verge, which ultimately netted those physicians substantial quarterly dividends.

(SF) In February 2021, the CEO of a Texas-based group of hospice and home health entities, was sentenced to 15 years in prison in connection with an over $150.0 million fraud scheme that was one of the first criminal hospice fraud cases tried to a verdict. During the scheme, the defendants enrolled patients in expensive hospice services who were not expected to die within six months, as is required for eligibility for hospice, billed for fraudulent services, and manufactured false and fictitious records and produced them to a federal grand jury. Further, the defendants laundered proceeds generated from the scheme to purchase luxury vehicles, including a Porsche, clothing from high end retailers such as Louis Vuitton, premium season tickets to see the San Antonio Spurs, and exclusive real estate. Finally, the defendants misled the FBI, directed others to lie to the FBI, and took steps to cover up illegal kickbacks that a co-conspirator was receiving in connection with the scheme. The CEO's co-conspirator, the owner of the hospice and home health entities, was also convicted following the November 2019 trial. He was sentenced to 20 years in prison in December 2020. Two other co-conspirators have pled guilty and are awaiting sentencing.

Hospitals and Health Systems

In April 2021, four executives of a Texas based healthcare company and its various health centers were ordered to federal prison for a massive scam perpetrated in the Houston area. The four executives were part of the executive team for a company that owned a hospital, as well as community mental health centers in the Houston area known by their locations. Each location operated a partial hospitalization program (PHP). The PHP was supposed to be a treatment program for individuals with mental illness, intended to closely resemble a highly structured, short-term hospital inpatient program. However, while it was a distinct and organized intensive treatment program, it offered less than 24-hour daily care. The four men were responsible for the day-to-day operation of the company and the hospital and were involved in the implementation of the various kickback programs. Numerous people were referred for treatment in exchange for payment. However, the vast majority did not qualify for PHP services, because they were not experiencing an acute psychotic episode or were actually suffering from intellectual disability, dementia, or Alzheimer's. In total, the company billed Medicare approximately $189.0 million in total for fraudulent PHP services and the Texas Medicaid program paid approximately $66.0

million on those clams. As a result, Executive 1 was sentenced to 120 months in prison and ordered to pay $21,359,798 in restitution. Executive 2 was sentenced to 48 months in prison and ordered to pay $21,359,798 in restitution. Executive 3 was sentenced to 30 months in prison and ordered to pay $19,533,806 in restitution. Finally, Executive 4 was sentenced to 30 months in prison and ordered to pay $1,500,000 in restitution.

In July 2021, Akron General Health System (AGHS), a regional hospital system based in Akron, Ohio that was acquired at the end of 2015 by the Cleveland Clinic Foundation, agreed to pay more than $21.2 million to resolve civil FCA allegations of improper relationships with certain referring physicians that resulted in the submission of false claims to the Medicare program. The settlement resolved allegations that between August 2010 and March 2016, AGHS paid compensation substantially in excess of fair market value to area physician groups to secure their referrals of patients, in violation of the AKS and the Stark Law, and then submitted claims for services provided to these illegally referred patients, in violation of the FCA.

In August 2021, San Mateo County Medical Center and San Mateo County (collectively SMMC), located in California, agreed to pay approximately $11.4 million to resolve civil FCA allegations that SMMC submitted or caused the submission of claims to Medicare for non-covered inpatient admissions. The settlement resolved allegations that from January 2013 through February 2017, SMMC admitted certain patients for whom inpatient care was not medically reasonable or necessary, including patients who were admitted for reasons other than medical status, and then billed Medicare for such patients despite SMMC's knowledge that the costs for admitting them were not reimbursable by Medicare. In connection with the settlement, SMMC entered into a five-year CIA with HHS-OIG.

Laboratory Testing

In May 2021, the Florida-based University of Miami (UM) agreed to pay $22.0 million to resolve civil FCA allegations that it ordered medically unnecessary laboratory tests and submitted false claims through its laboratory and off campus hospital-based facilities (UM Hospital Facilities). The settlement resolved allegations that UM: (1) knowingly engaged in improper billing relating to its UM Hospital Facilities by converting multiple physician offices to UM Hospital Facilities and then seeking payment at higher rates without providing beneficiaries the required notice; (2) billed federal health care programs for medically unnecessary laboratory tests for patients who received kidney transplants at the Miami Transplant Institute (MTI), a transplant program operated by UM and Jackson Memorial Hospital (JMH); and (3) caused JMH to submit inflated claims for reimbursement for pre-transplant laboratory testing conducted at the MTI, in violation of related party regulations, by controlling JMH's decision to purchase pre-transplant laboratory tests from UM at inflated rates in exchange for UM's surgeons and surgical department continuing to perform surgeries at JMH. In a separate agreement, JMH agreed to pay $1.1 million to resolve related civil FCA allegations. Contemporaneous with the UM settlement, UM agreed to enter into a CIA with HHS-OIG.

In September 2021, a federal district court entered default judgments on civil FCA claims for the United States totaling more than $136.0 million against pain management clinics Oaktree

Medical Centre P.C. (Oaktree), FirstChoice Healthcare P.C. (FirstChoice), Pain Management Associates of the Carolinas LLC (PMA of the Carolinas), and Pain Management Associates of North Carolina P.C. (PMA of North Carolina), and a urine drug testing laboratory, Labsource, LLC, all based in South Carolina. The government had alleged that Oaktree, FirstChoice, Labsource, PMA of the Carolinas and PMA of North Carolina provided illegal financial incentives to providers to induce their referrals of urine drug tests in violation of the Stark Law and the AKS. The district court had previously entered a default judgment in the amount of more than $4.2 million against urine drug testing laboratory ProLab LLC and substance use counseling clinic ProCare Counseling Center LLC. The government had alleged that ProCare and ProLab billed federal health care programs for unnecessary urine drug tests.

Managed Care

In August 2021, Sutter Health, a California-based health care services provider, and several affiliated entities, including Sutter Bay Medical Foundation (doing business as Palo Alto Medical Foundation, Sutter East Bay Medical Foundation, and Sutter Pacific Medical Foundation) and Sutter Valley Medical Foundation (dba Sutter Gould Medical Foundation and Sutter Medical Foundation) (collectively Sutter Health) agreed to pay $90.0 million to resolve civil FCA allegations that Sutter Health knowingly submitted inaccurate information about the health status of beneficiaries enrolled in Medicare Advantage Plans under the Medicare Part C program. The settlement resolved allegations that Sutter Health knowingly submitted unsupported diagnosis codes for certain patient encounters for beneficiaries under its care, which in turn caused inflated payments to be made to the Medicare Advantage Plans and to Sutter Health, and that once Sutter Health became aware of these unsupported diagnosis codes, it failed to take sufficient corrective action to identify and delete additional unsupported diagnosis codes. In connection with the settlement, Sutter Health, Sutter Bay Medical Foundation, and Sutter Valley Medical Foundation entered into a five-year CIA with HHS-OIG.

Medical Devices

In October 2020, medical device maker Merit Medical Systems Inc. (MMSI), of South Jordan, Utah, agreed to pay more than $15.2 million to resolve civil FCA allegations that the company paid kickbacks to health care providers to induce the use of MMSI products. The settlement resolved allegations that, for over six years, MMSI engaged in a kickback scheme to pay physicians, medical practices, and hospitals in the form of millions of dollars in free advertising assistance, practice development, practice support, and purported unrestricted "educational" grants to induce the healthcare providers to purchase and use a wide variety of MMSI products in medical procedures performed on Medicare, Medicaid, and TRICARE beneficiaries. In addition to the federal recovery, MMSI agreed to pay more than $2.7 million to resolve state Medicaid claims.

In July 2021, St. Jude Medical Inc. (St. Jude), which was acquired by Abbott Laboratories in January 2017, agreed to pay $27.0 million to settle civil FCA allegations that between November 2014 and October 2016, it knowingly sold defective heart devices to health care facilities that, in turn, implanted the devices into patients insured by federal health care programs. The settlement

resolved allegations that St. Jude failed to disclose serious adverse health events in connection with the premature depletion of the battery in certain models of its implantable defibrillators used in patients at risk of cardiac arrest due to an irregular heartbeat.

In July 2021, medical device manufacturers Alere Inc. and Alere San Diego Inc. (Alere), respectively located in Waltham, Massachusetts and San Diego, California during the relevant time period, agreed to pay more than $38.7 million to resolve civil FCA allegations for billing, or causing others to bill, Medicare for defective rapid point-of-care testing devices from 2008 to 2016. The settlement resolved allegations by the United States that Alere knowingly sold defective blood coagulation monitors used by Medicare beneficiaries taking anticoagulant drugs, and that despite awareness that those systems were linked to over a dozen deaths and hundreds of injuries, including intra-cerebral hemorrhaging and cardiovascular events following bleeding episodes, Alere concealed the defect for years and billed Medicare for the use of the defective devices.

Nursing Homes and Facilities

In March 2021, the last of five defendants, all paid caregivers at a residential facility in Fulton, Missouri, was sentenced to probation on one count of health care fraud. The facility contracted to provide housing and care for developmentally disabled persons through a Missouri Department of Health Initiative. The case involved the death of a developmentally disabled Medicaid beneficiary, C.D. From 2014-16, Defendant 1 was aware that C.D. was in declining health, but she did not seek medical care for him because she did not want to be blamed for mistreating him. In approximately September-October 2016, when the beneficiary's health continued to decline and he was obviously very ill, she took him and his roommate to her home and kept them in its unfinished basement. The beneficiary experienced an acute medical emergency in the presence of Defendant 1 and her husband, Defendant 2. Both observed the beneficiary's physical distress and obvious medical need but did not perform CPR, call for an ambulance, or otherwise seek medical care because they did not want to be blamed for his poor health. The beneficiary died in their presence at their home. In April 2017, Defendant 1 reported to the Fulton Police Department that C.D. was missing, leading to a week-long search by law enforcement, volunteers, dogs, and drones. After a fruitless search, the beneficiary's body was found in a trash bin encased in concrete enclosed in a crate in Defendant 1's storage unit in Fulton. Defendant 2 provided the crate in which the beneficiary's body was encased in concrete, and he helped haul it to the storage unit. Defendants 1 and 2 each pled to one count of violating the beneficiary's civil rights by willfully failing to provide him necessary medical care. Defendant 1 also pled to one count of health care fraud because she was involved in submitting claims to Medicaid for the beneficiary's care after he died to hide the fact that he died. She was sentenced to 210 months and Defendant 2 was sentenced to 188 months in prison. Defendants 1 and 2's two adult children, who also worked at the facility, each pled guilty to one count of knowingly falsifying a document with the intent to impede, obstruct, or influence the investigation into the beneficiary's death, and were sentenced to twelve months in prison and probation, respectively. The fifth defendant pled guilty to falsely completing and signing the beneficiary's Community RN Monthly Health Summary every month from at least September 2016 (the time of the beneficiary's death) through March 2017 (shortly before the beneficiary's

body was discovered), falsely stating that she had performed a face-to-face assessment of the beneficiary and had provided the other services she was required to do as a Community Registered Nurse.

In May 2021, SavaSeniorCare, LLC and related entities (Sava), based in Georgia, agreed to pay more than $11.2 million to the government and certain states to resolve civil FCA allegations that Sava caused its skilled nursing facilities (SNFs) to bill the Medicare program for rehabilitation therapy services that were not reasonable, necessary or skilled, and that Sava billed the Medicare and Medicaid programs for grossly substandard skilled nursing services. The settlement resolved allegations that between October 2008 and September 2012, Sava knowingly submitted false claims for rehabilitation therapy services as a result of a systematic effort to increase its Medicare billings through corporate-wide policies and practices that exerted significant pressure on its SNFs to meet unrealistic financial goals. The settlement also resolved allegations that between October 2008 and September 2012, Sava knowingly submitted false claims to certain states' Medicaid programs for coinsurance amounts for rehabilitation therapy services for beneficiaries eligible for both Medicare and Medicaid and for whom Sava also allegedly submitted or caused the submission of false claims to Medicare for those services. The settlement further resolved allegations that between January 2008 and December 2018, Sava knowingly submitted false claims for payment to Medicare and certain states' Medicaid programs for grossly and materially substandard and/or worthless skilled nursing services. In connection with the settlement, Sava entered into a five-year chain-wide CIA with HHS-OIG.

In May 2021, Care Initiatives, a Texas corporation with a home office in West Des Moines, Iowa, agreed to repay the United States $214,200 to resolve claims the United States was entitled to restitution for the federal share of Medicaid funds the facility received for an approximately 10-week period while residents at Dubuque Specialty Care, a Care Initiatives facility, were suffering from or testing positive for COVID-19. The settlement resolved allegations that repayment of these funds was warranted due to Dubuque Specialty Care's practices surrounding COVID-19 infections, including the facility's allegedly deficient procedures and criteria for screening symptomatic employees.

In July 2021, Select Medical Corporation, the prior parent company of Select Medical Rehabilitation Services Inc. (SMRS), and Encore GC Acquisition LLC, the successor-in-interest to SMRS, agreed to pay $8.4 million to resolve civil FCA allegations that SMRS knowingly caused 12 SNFs in New York and New Jersey to submit false claims to Medicare for rehabilitation therapy services that were not reasonable, necessary, or skilled. The settlement resolved allegations that at various times between January 2010 through March 2016, SMRS's corporate policies and practices encouraged and resulted in the provision of medically unnecessary, unreasonable, and unskilled therapy services being provided to patients at the 12 SNFs.

Pharmacies

(SF) In December 2020, an owner and operator of a marketing company in Colleyville, Texas, pled guilty to one count of conspiracy to commit healthcare fraud. The charges resulted from the defendant's role in an over $2.0 million conspiracy in which the defendant offered and paid

kickbacks and bribes to his co-defendants, a Texas-state licensed physician and a marketer in exchange for signed prescription of medically unnecessary compounding medications, i.e., pain creams, for TRICARE beneficiaries that the beneficiaries did not need or use. The compounding medications were filled by a boutique compounding pharmacy located in Fort Worth, Texas. The defendant received a percentage of the compounding pharmacy's net profits, i.e., the TRICARE reimbursement amounts minus the medication costs as determined by the pharmacy. The court sentenced the defendant to a term of imprisonment of 51-months and restitution of over $2.0 million. In May 2021, the Texas-licensed physician, pled guilty to one count of conspiracy to commit healthcare fraud, and the marketer pled guilty to one count of obstructing a federal audit. The marketer defendant was sentenced to a term of imprisonment of 18-months. The physician defendant awaits sentencing.

(SF) In January 2021, a licensed pharmacist pled guilty to one count of conspiracy to commit health care fraud. The charge stemmed from a scheme in which the defendant and at least five Detroit-based pharmacies caused the submission of more than $6.8 million in false and fraudulent claims to Medicare, Medicaid, and Blue Cross Blue Shield of Michigan. The false and fraudulent claims consisted of prescriptions that were submitted as claims through drug plan sponsors as if they were dispensed to beneficiaries, but in fact were never dispensed. The pharmacist personally profited from his participation in the scheme by receiving fraudulent proceeds for personal use.

(SF) In April 2021, the owner of multiple pharmacies in Queens, New York, pled guilty to mail fraud, health care fraud, and conspiracy to commit health care fraud. The charges stemmed from the defendant's participation in multiple schemes to defraud health care programs, including Medicare Part D and Medicaid drug plans of more than $6.5 million, between approximately May 2015 to January 2018 and December 2018 to March 2020. According to court filings, these false and fraudulent claims included claims for reimbursement for drugs that were not dispensed, prescribed as claimed, or medically necessary, or that were purportedly dispensed during a time when one of the pharmacies was no longer licensed and registered with the State of New York. The owner agreed to pay over $6.5 million in restitution and $5.1 million in forfeiture.

In April 2021, two dozen defendants were sentenced after pleading to charges related to a vast prescription drug-billing scheme involving a Haleyville, Alabama-based pharmacy, Northside Pharmacy, which did business under the name Global Compounding Pharmacy. The defendants included company executives and managers, a prescriber, billers, and sales representatives. Another two defendants were convicted after a jury trial in March. From 2013 to 2016, this large-scale conspiracy billed insurers for massive quantities of medically unnecessary prescription drugs. The scheme involved directing employees to get medically unnecessary drugs for themselves, family members, and friends, and billing drugs without patients' knowledge. The scheme resulted in pharmacy benefit managers paying Global nearly $50.0 million in claims in just a two-year period, including more than $8.4 million for prescriptions Global employees got for themselves, and more than $13.0 million for prescriptions written by providers who got cash or whose spouses worked at Global. Those sentenced included Global's president, who received 170 months in prison; the lead compounding pharmacist, who received

102 months; and the billing manager, who received 132 months. The conspirators were collectively ordered to pay nearly $50.0 million in restitution.

In May 2021, AlixaRx, LLC, a national provider of pharmacy services to long-term care facilities, agreed to pay more than $2.7 million to resolve allegations that it violated the Controlled Substances Act (CSA) and the civil FCA by allowing opioids and other controlled substances to be dispensed without valid prescriptions. The settlement resolved allegations that between January 2014 and December 2017, AlixaRX violated the CSA by dispensing pursuant to purported "emergency prescriptions" in the absence of any true emergency and instead used these purported emergency prescriptions to effectuate simple refills of the patients' medications. In addition, the settlement resolved allegations that AlixaRx routinely failed to obtain written prescriptions within seven days after the verbal authorization, and rather than disclose these violations to the DEA as required by law, AlixaRx engaged in a nationwide scheme to cover up its violations by obtaining backdated prescriptions from the prescribing physicians, in many cases over a year after the controlled substances were dispensed. The settlement also resolved allegations that AlixaRx submitted false claims to Medicare for these invalid emergency prescriptions and billed Medicare Part D for claims that had already been reimbursed through claims paid to long-term care facilities under Medicare Part A.

Physical Therapy

In December 2020, former Georgia-based physical therapy company McLeod-Hughes and Associates, LLC and its owner agreed to pay $506,811 to resolve civil FCA allegations that it submitted bills to the Medicare and TRICARE programs for physical therapy services provided by unlicensed, uncredentialed or otherwise unapproved individuals. The settlement resolved allegations that the company submitted claims to Medicare and TRICARE for physical therapy services purportedly provided by approved providers when, in fact, athletic trainers and other unlicensed, uncredentialed, or otherwise unapproved individuals furnished the physical therapy services. In connection with the settlement, the company voluntarily agreed to be excluded as a provider from Medicare and other federal health care programs.

Physician and Other Practitioners

In December 2020, a Tallahassee, Florida doctor pled guilty to 56 counts of committing health care fraud, conspiracy to commit heath care fraud, and aggravated identity theft. From late 2015 to early 2020, the defendant committed unnecessary and invasive surgical procedures, and billed for additional procedures not performed. As part of his plea, the defendant acknowledged engaging in a wide-ranging and consistent pattern of performing two invasive diagnostic angiography procedures—one on each leg—on hundreds of his patients, whether medically indicated or not. The defendant also agreed to and the court entered a consent judgment for $30.0 million to resolve civil FCA allegations for billing for interventional angioplasty procedures that were never performed, including billing for procedures when the defendant was out of the country or otherwise not in the office. The United States separately settled with the billing company, A/R Medical Claims Recovery, LLC d/b/a Medical AR Revenue Solutions, LLC, for $150,000.

In April 2021, Doctors Care, P.A., a South Carolina urgent care provider network, and its management company, UCI Medical Affiliates of South Carolina, agreed to pay $22.5 million to resolve civil FCA allegations that from 2013 through 2018, UCI falsely certified that certain urgent care visits were performed by providers who were credentialed to bill the state's Medicaid program, Medicare, and TRICARE for medical services, while the services were performed by non-credentialed providers. The settlement resolved allegations that UCI knew that federal insurance programs would deny claims submitted with the billing number of a provider who had not yet received their billing credentials, but instead of solving its credentialing problem, submitted the claims falsely, "linking" the uncredentialed rendering providers to credentialed billing providers in order to get the claims paid. In connection with the settlement, UCI and Doctors Care entered into a CIA with HHS-OIG.

In April 2021, a chiropractor was sentenced to 108 months in prison following his guilty plea to conspiracy to commit health care fraud. From 2011 through 2017, the defendant ran a medical services corporation that provided a variety of pain management and rehabilitation services. The defendant also ran multiple additional medical corporations with nominee owners meant to disguise the defendant's and his co-conspirator's fraudulent true ownership. The defendant and his co-conspirators engaged in widespread fraud that included submitting claims to insurance providers, including Medicare, for medically unnecessary services and procedures or services that were not actually rendered. In addition, defendant and his co-conspirators engaged in double billing, altering and fabricating medical records, and obstructing and impeding audits by Medicare and other insurance companies to conceal the fraud. As part of the fraudulent scheme, defendant encouraged the continued use and billing of lucrative, high risk facet injections by a doctor who had no formal training and who taught himself by shadowing other doctors and watching YouTube videos. Defendant was involved in all aspects of the billing for these injections, even when several patients suffered serious adverse effects, with one patient dying of related complications. As part of his sentence, defendant was ordered to pay over $9.0 million in restitution, and to forfeit over $9.0 million.

In June 2021, a Houston chiropractor and her clinics, Campbell Medical Group PLLC and Johnson Medical Group PLLC dba Campbell Medical Clinic, agreed to pay $2.6 million to resolve civil FCA allegations that they submitted false claims to Medicare and TRICARE for implantable neurostimulators. The settlement resolved allegations that the chiropractor and her staff did not perform the surgeries to implant the neurostimulators, and instead nurse practitioners working for the clinic taped a small acupuncture device to patients' ears—something they learned by watching training videos on YouTube. The settlement also resolved allegations that the chiropractor was specifically warned by employees and her billing company that her practices were not compliant, including that she was committing "possible fraud." As part of the settlement, the chiropractor and her medical entities agreed to be subject to a 10-year period of exclusion from participating in any federal health care programs

In September 2021, a cardiologist based in Orlando, Florida, agreed to pay over $6.7 million to resolve civil FCA allegations that he performed medically unnecessary ablations and vein stent procedures. The settlement resolved allegations that from January 2013 to December 2019, the

cardiologist performed the ablations and stent procedures on veins that did not qualify for treatment under accepted standards of medical practice and made misrepresentations in patient medical records to justify the procedures, and that, in many instances, the ablations were performed either exclusively or primarily by one or more ultrasound technicians outside their scope of practice. In connection with the settlement, the cardiologist and Interventional Cardiology & Vascular Consultants, PLC entered into a detailed, multi-year integrity agreement with HHS-OIG.

Prescription Drugs and Opioids

In October 2020, a doctor in New York was sentenced to serve 70 months in prison and three years' supervised release and ordered to pay restitution in the amount of $344,562.65 to his victims, including Medicare. The sentence was the result of the doctor's guilty plea, entered on January 7, 2020, in which he pled guilty to one count of conspiracy to unlawfully distribute controlled substances and one count of healthcare fraud. In carrying out the conspiracy, the doctor and his employees issued more prescriptions for controlled substances annually than any other prescriber or prescribing entity in New York State, including hospitals. Specifically, the doctor and his employees carried out their conspiracy by: (1) prescribing controlled substances without conducting a physical examination and/or after conducting only a limited and inadequate physical examination; (2) prescribing controlled substances in ways that were likely to cause, and did cause, dependence and addiction, and that contributed to existing addictions; and (3) recommending a course of treatment, including the prescribing of controlled substances, which caused the death of at least six individuals, and contributed to the deaths of others.

In March 2021, the chief executive officer (CEO) of a Michigan and Ohio-based group of pain clinics and other medical providers, was sentenced to 15 years in prison for developing and approving a corporate policy to administer unnecessary back injections to patients in exchange for prescriptions of over 6.6 million doses of medically unnecessary opioids. In addition to the prison sentence, the CEO was also ordered to pay over $51.0 million in restitution to Medicare, as well as forfeiture to the United States of property traceable to proceeds of the health care fraud scheme, including over $11.5 million, commercial real estate, residential real estate, and a Detroit Pistons season ticket membership. The CEO pled guilty in 2018 to one count of conspiracy to commit health care fraud and wire fraud, and one count of money laundering. Twenty-one other defendants, including 12 physicians, have been convicted thus far, including four physicians who were convicted after a one-month trial in 2020. According to court documents, from 2008 to 2016, the CEO's clinics had a policy to offer patients, some of whom were suffering from legitimate pain and others of whom were drug dealers or opioid addicts, prescriptions of Oxycodone 30 mg, but forced the patients to submit to unnecessary back injections in exchange for the prescriptions. Patients who were addicted to opioids told the doctors that they did not want, need, or benefit from the injections, were denied medication by the defendants and their co-conspirators until they agreed to submit to the expensive and unnecessary injections.

(SF) In June 2021, a physician licensed in Tennessee and Indiana was sentenced to 36 months in prison for his unlawful prescribing of opioids to four patients. All four patients eventually

overdosed and died after receiving opioids from the defendant. The physician admitted in a guilty plea to knowingly distributing hydrocodone, a Schedule II controlled substance, to a patient who did not have any significant underlying health issues justifying such a prescription. From May 26, 2015, to November 1, 2018, the total pill count associated with the physician's charges was 587,344.

In July 2021, a New York doctor was sentenced in federal court to 121 months in prison for participating in a scheme to receive bribes and kickbacks in the form of fees for sham educational programs ("Speaker Programs") from pharmaceutical company Insys Therapeutics in exchange for prescribing millions of dollars' worth of Subsys, a potent fentanyl-based spray manufactured by Insys, among other offenses. In March 2013, a Regional Sales Manager for Insys sent an email to the doctor informing him that he would receive more Speaker Programs in the coming months because Insys wanted prescriptions of Subsys to increase and urging the doctor to put more patients on Subsys. The doctor responded, in part, "Got it," and significantly increased his Subsys prescriptions in the following months, during which he received approximately $33,600 in Speaker Program fees. The doctor was also sentenced to 210 months in prison, to run concurrently with the other sentence, for distributing oxycodone and fentanyl to a patient for no legitimate medical purpose. During the period in which the doctor was receiving kickbacks from Insys, he was also distributing powerfully addictive prescription drugs to a particular patient who died of a fentanyl overdose. In addition to the prison sentence, the doctor was sentenced to three years of supervised release, ordered to forfeit $308,600 and ordered to pay a total fine of $75,000 across the two cases.

(SF) In August 2019, a federal jury sitting in the Southern District of Texas convicted an unlicensed medical professional of distributing and dispensing schedule II opioids with no legitimate medical purpose and outside the usual course of professional practice and conspiring to do so. The charges stemmed from the defendant's role at a medical clinic in Rosenberg, Texas, where he acted as a medical doctor—though he was not licensed—to illegitimately prescribe nearly identical prescriptions for hydrocodone and carisoprodol—a dangerous combination of controlled substances. The defendant was charged alongside the clinic's owner and a medical doctor, both of whom pled guilty in advance of trial. In December 2020, a federal judge sentenced the codefendants. The clinic's owner, who is currently a fugitive in Pakistan, was sentenced to 240 months imprisonment, forfeiture, and a $500,000 fine. The medical doctor who pled guilty in advance of trial, was sentenced to 72 months imprisonment and forfeiture. The unlicensed medical professional was sentenced to 96 months imprisonment after being convicted at trial.

In August 2021, after a 9-day jury trial, a Wisconsin nurse practitioner and her partner, owners and operators of Clinical Pain Consultants (CPC), were convicted of conspiracy to distribute controlled substances and multiple counts of unlawful distribution of controlled substances. Between at least 2015 and 2016, the defendants ran CPC as a "pill mill," prescribing large doses of opioids outside the usual course of professional practice and not for a legitimate medical purpose. Opioids such as oxycodone, oxycontin, methadone, and fentanyl were prescribed to over 99 percent of the patients at CPC. In 2015 and 2016, the defendant was the number one prescriber of oxycodone among all Medicaid providers in the state of Wisconsin. The defendant

was also convicted of distribution of controlled substances resulting in death. Based on the conviction on the death-resulting-from charge, the nurse faces a mandatory minimum of 20 years' imprisonment.

Psychiatric and Psychological Testing and Services

In January 2021, Florida-based Oglethorpe Inc., its two Ohio inpatient psychiatric hospitals, Cambridge Behavioral Hospital (Cambridge) and Ridgeview Behavioral Hospital (Ridgeview), and its Ohio substance use treatment facility, The Woods at Parkside (Parkside) (collectively Ogelthorpe), agreed to pay more than $10.2 million to resolve civil FCA allegations of improperly providing free long-distance transportation to patients and admitting patients at Cambridge and Ridgeview who did not require inpatient psychiatric treatment, resulting in the submission of false claims to the Medicare program. The settlement resolved allegations that between August 2013 and June 2019, Ogelthorpe provided free long-distance van transportation to patients to induce them to seek treatment at the defendants' facilities, in violation of the AKS, and then submitted claims for services provided to these patients, in violation of the FCA. The settlement also resolved allegations that Oglethorpe, Cambridge, and Ridgeview submitted, or caused to be submitted, false claims to Medicare for medically unnecessary inpatient psychiatric admissions and associated services at the two hospitals. Contemporaneous with the settlement, Oglethorpe entered into a CIA with HHS-OIG.

(SF) In June 2021, a clinical social worker with a master's degree in social work pled guilty to one count of conspiracy to commit health care fraud. The charge stemmed from a scheme in which the defendant and her co-conspirators caused the submission of more than $1.4 million in false and fraudulent claims for psychotherapy services from two different Detroit-based companies to Medicare. These false and fraudulent claims included billing for individual and group psychotherapy services that were rendered by ineligible providers and for services that were not provided at all. The defendant was educated by the HHS' Office of Audit Services after being investigated for her ineligible billing practices, yet she continued to perpetuate her scheme to defraud. From 2015 to 2020, the defendant was the highest billing provider in both the state of Michigan and the Midwest region for 45-minute individual psychotherapy claims submitted to Medicare.

In August 2021, Carenow Services, LLC, a Rosswell, Georgia-based psychotherapy services provider, and its CEO agreed to pay $2.0 million to settle civil FCA allegations that they billed Medicare and Medicaid for psychotherapy sessions at nursing homes and skilled nursing facilities that were medically unnecessary, improperly documented, or billed at higher intensity levels than justified. The settlement resolved allegations that between 2012 and 2018, Carenow billed Medicare and the state's Medicaid program for psychotherapy sessions at nursing homes and skilled nursing facilities that did not have any documented medical necessity. The settlement also resolved allegations that, in those situations where the psychotherapy sessions were medically necessary, Carenow upcoded its services and billed Medicare and Medicaid at higher reimbursing procedural codes.

Substance Use Treatment Centers

In October 2020, the owner of two Florida based substance use treatment centers and a medical health clinic, was sentenced to 210 months imprisonment, and ordered to pay restitution in the amount of $ 4,231,288 following his conviction, after a six-week jury trial, of conspiracy to commit health care fraud and wire fraud, five counts of health care fraud, conspiracy to commit money laundering, and eleven counts of money laundering. As part of the scheme, the conspirators exploited vulnerable drug addicts, falsified paperwork, and entered into various kickback arrangements, all in order to receive millions of dollars of falsely and fraudulently obtained funds for their own personal use and benefit. The owner operated the three facilities from in or around June 2016 through May 2019. At trial, the Government emphasized that the defendant provided unlawful inducements to the approximately 500 patients consisting of free airline travel, housing, vapes, manicures, cash, and failure to collect patient responsibilities for copayments and deductibles. The facilities also billed for medically unnecessary therapeutic services consisting of therapy and urine analyses, the former having not been provided but billed by defendant's substance use clinics. From June 2016 through May 2019, the Government attributed approximately $38.0 million in fraudulent billing submitted by owner's clinics, which resulted in the reimbursement of over $6.0 million in payments.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

The HHS-OIG mission is to protect the integrity of HHS programs and the health and welfare of the people they serve. As established by the Inspector General Act of 1978, HHS-OIG is an independent and objective organization that fights fraud, waste, and abuse and promotes efficiency, economy, and effectiveness in HHS programs and operations.

HHS-OIG's vision is to drive positive change in HHS programs and in the lives of the people they serve. HHS-OIG pursues this vision through independent oversight of HHS programs and operations and by providing HHS and Congress with objective, reliable information for use in policymaking. HHS-OIG assesses the Department's performance, administrative operations, and financial stewardship. HHS-OIG also evaluates risks to HHS programs and recommends recovery of misspent funds and program improvements. HHS-OIG's law enforcement component investigates fraud and abuse of HHS programs and holds wrongdoers accountable for their actions. In addition to safeguarding federal funds, HHS-OIG takes oversight and enforcement action to promote the safety and quality of services delivered by HHS programs.

As the leading oversight agency specializing in health care fraud, HHS-OIG employs a multi-disciplinary approach and uses data-driven decision-making to produce outcome-focused results.

HHS-OIG strives to be a flexible and efficient organization that adapts to the needs of the times. HHS-OIG deploys resources as optimally as possible to keep pace with the fast-changing nature of health care programs and the corresponding changes in fraud, waste, and abuse. To do so, HHS-OIG leverages sophisticated data analysis to identify and target potential fraud schemes and areas of program waste and abuse and to provide quality, timely, and actionable data to frontline staff, as well as to its government and, as appropriate, private sector partners. HHS-OIG combines data analysis, field intelligence, and state-of-the-art investigative techniques to combat fraud and abuse. HHS-OIG also continues to modernize its infrastructure capacity to deliver high-quality, timely, actionable data to produce these results. HHS-OIG is focused on developing data-driven key performance indicators and has helped achieve results in priority areas and measures that further the goals of HHS-OIG's work.

With respect to HCFAC funds, HHS-OIG focuses on combating Medicare and Medicaid fraud, waste, and abuse, including in priority areas such as protecting beneficiaries from prescription drug abuse, including opioid abuse; enhancing program integrity in noninstitutional care settings, such as home health and hospice care; and strengthening Medicaid program integrity, including working with state partners to enhance the effectiveness of the MFCUs. HHS-OIG is also strengthening oversight of nursing homes, Medicare Advantage (MA) managed care plans, Medicaid managed care programs, value-based models, Medicare hospital payments efficiency, telehealth and other remote care expansion, and cybersecurity.

A certain portion of the funds appropriated under HIPAA are, by law, set aside for the Medicare and Medicaid activities of HHS-OIG. In FY 2021, the Secretary and the Attorney General jointly allotted $213.9 million to HHS-OIG. HHS-OIG was allocated an additional $20.2 million in HCFAC mandatory funds from the Secretary. Additionally, Congress appropriated $99.0 million in discretionary funding for HHS-OIG HCFAC activities.

Responding to the COVID-19 Pandemic

Responding to COVID-19 remains an unprecedented challenge for HHS and for the delivery of health care and human services to the American people. As the COVID-19 pandemic response and recovery evolves in the United States, HHS-OIG's oversight evolves as well. It will be critical to understand the efficacy of pandemic response efforts over time and the lessons learned for future pandemics and broader emergency preparedness. HHS-OIG has used innovative approaches to provide independent, objective information to decisionmakers and other stakeholders about response and recovery efforts. HHS-OIG's COVID-19 oversight work pursues the priorities consistent with our Strategic Plan: (1) protect people, (2) protect funds, (3) protect infrastructure, and (4) promote the effectiveness of HHS programs—now and into the future. HHS-OIG is using risk assessment and data analytics to identify, monitor, and target potential fraud, waste, and abuse affecting HHS programs and beneficiaries and to promote the effectiveness of HHS's COVID-19 response and recovery programs, including Medicare and Medicaid programs and beneficiaries. Oversight efforts include close coordination with key government partners, including the Pandemic Response Accountability Committee.

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

HHS-OIG Priority Outcomes

According to USA Spending, HHS in FY 2021 had some of the highest expenditures among all federal agencies at $2.8 trillion, including increased supplemental funding for the pandemic response. With such a large and diverse portfolio to oversee, HHS-OIG sets priority outcomes to achieve the greatest impact across HHS's many programs. In the FY 2022 President's Budget, HHS-OIG included its key performance indicators that align with HHS-OIG's priority outcomes. HHS-OIG's current priority outcome areas were selected based on past and ongoing work, top challenges facing HHS as identified annually by HHS-OIG, the ability to collect data, and the ability to influence outcomes. HHS-OIG's priority outcome areas fall into two broad categories:

1. **Minimize risks to beneficiaries.**
    - Protect beneficiaries from prescription drug abuse.
    - Promote patient safety and accuracy of payments in home and community settings.

2. **Safeguard programs from improper payments and fraud.**
    - Strengthen Medicaid protections against fraud and abuse.

During FY 2021, HHS-OIG leadership met to assess and revise our priority outcome approach based on our recently revised Strategic Plan. Multidisciplinary teams identified progress they plan to achieve for these important areas. These new and revised Priority Outcomes teams have been developing approaches to achieve results as well as identifying metrics that can be used to track progress. More details on the new priority outcomes will be provided in the FY 2023 HHS-OIG budget justification.

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 2021, HHS-OIG investigations resulted in 504 criminal actions against individuals or entities that engaged in crimes related to Medicare and Medicaid, as well as 669 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 2021 HHS-OIG excluded a total of 1,689 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 2021, potential savings from legislative and administrative actions that were supported by HHS-OIG recommendations were estimated by third parties, such as the Congressional Budget Office or actuaries within HHS, to be $2.7 billion—$2.2 billion in Medicare savings and $497.0 million in savings to the federal share of Medicaid. HHS-OIG's expected recoveries from its involvement in health care audits and investigations totaled more than $4.1 billion, which resulted in an ROI of about $12.00 to $1.00.[14]

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

[14] This ROI uses a 3-year average of expected recoveries, fines, penalties, and stolen and misspent funds relating to HHS-OIG's health care oversight 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.

Enforcement

HHS-OIG works with its law enforcement partners to conduct criminal and civil investigations involving the Medicare and Medicaid programs and participates in settlements of False Claims Act cases, including settlements reached through negotiations of Corporate Integrity Agreements (CIAs). HHS-OIG works with the MFCUs to address fraud and abuse in the Medicaid program. In addition to investigating criminal and civil matters, HHS-OIG imposes CMPs for a variety of health care-related offenses.

Strike Force Operations

In FY 2021, HHS-OIG continued to staff and support Strike Force operations working in conjunction with the DOJ Criminal Division's Fraud Section, local USAOs, the FBI, and state and local law enforcement agencies. HHS-OIG has assigned agents to Strike Forces in Miami and Tampa, Florida; Dallas and Houston, Texas; Los Angeles, California; Detroit, Michigan; Brooklyn, New York; Baton Rouge and New Orleans, Louisiana; Chicago, Illinois; and Newark, New Jersey/Philadelphia, Pennsylvania; along with a Corporate Strike Force in Washington, D.C. HHS-OIG supports Strike Force operations by providing investigative, analytic, and forensic resources.

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 September 2021 a nationwide enforcement action resulted in 138 charged defendants across 51 federal districts, including more than 42 doctors, nurses, and other licensed medical professionals. These defendants were collectively charged with submitting more than $1.4 billion in allegedly false and fraudulent claims to federal health care programs and private insurers, including more than $1.1 billion connected to telemedicine $29.0 million in COVID-19 health care fraud, $133.0 million connected to substance use treatment facilities or "sober homes," and $160.0 million connected to other health care fraud and illegal opioid distribution schemes across the country. 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 substantial portion of HHS-OIG's investigations. In addition to the opioid related nationwide enforcement actions, in FY 2021 HHS-OIG excluded 114 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, controlled substances, or as a result of license revocation. This list of conduct is not exhaustive but identifies the most prevalent cases underlying HHS-OIG's exclusions of individuals or entities. The effect of an HHS-OIG exclusion is that no federal health care

program payment may be made for any items or services furnished: (1) by an excluded person or (2) at the medical direction or on the prescription of an excluded person. HHS-OIG completed the deployment of a new service for MFCUs to report convictions through a central web-based portal for exclusion. HHS-OIG is also responsible for reinstating providers who apply and have met the requirements of their exclusions.

In FY 2021, HHS-OIG excluded a total of 1,689 individuals and entities. In addition to those mentioned in the Enforcement Actions section above, exclusion actions by HHS-OIG included:

- In January 2021, HHS-OIG excluded an executive of a drug company in Massachusetts for a minimum period of 28 years based on the executive's racketeering conspiracy conviction. From approximately September 2012 to about March 2015, this individual participated in a scheme that bribed and provided kickbacks to prescribers to increase sales of a liquid formulation of fentanyl. The court sentenced this individual to 12 months and 1 day of incarceration and ordered restitution of approximately $5.0 million. The action of this individual caused providers to prescribe greater quantities of a potent opioid, thus causing substantial, real, and lasting harm to the patients of the bribed providers.

- In March 2021, HHS-OIG excluded a nurse aide working at a nursing home in Texas for a minimum period of 75 years based on the aide's conviction on two counts of aggravated sexual assault of an elderly or disabled person after raping a non-verbal, elderly patient suffering from dementia. The nurse aide was sentenced to life in prison.

- In May 2021, HHS-OIG excluded a private business owner in Pennsylvania for a minimum period of 95 years based on the business owner's conviction related to theft of government property. From about 1999 to about October 2014, this individual participated in a scheme that promised to return expired drugs from the individual's business's health care client facilities (hospitals, pharmacies, long term care facilities) in exchange for a fee. The business owner then laundered the proceeds of the fraud by keeping the profits that this entity received for returning the expired drugs. More than 13,000 clients were impacted by this fraudulent activity. The court ordered the business owner to forfeit $114,832,400 and imposed a sentence of five years of incarceration.

- In July 2021, HHS-OIG excluded a medical doctor in Wyoming for a minimum period of 45 years based on the doctor's convictions related to unlawful distribution of opioids. From about January 2011 to about November 2016, the doctor prescribed addictive opioids for payments in small, rural communities located in and around Arizona, Wyoming, and the Wind River Indian Reservation, specifically targeting vulnerable addicts for opioid prescriptions. The doctor's conduct resulted in the death of an individual, and the court sentenced the doctor to 300 months of incarceration. In addition, the Arizona Board of Medicine suspended the individual's license to practice as a medical doctor.

- In August 2021, HHS-OIG excluded a pharmaceutical entity in Virginia for a minimum period of 80 years based on its conviction for knowingly and willfully making materially false statements relating to health care matters. From about December 2012 to about December 2015, this entity marketed a specific Suboxone product to physicians and health care programs using false and misleading claims. In addition, employees and agents of the entity falsely informed the Massachusetts Medicaid program (MassHealth) that the Suboxone product had a safety benefit related to unintended pediatric exposure compared to other drugs in order to persuade MassHealth to pay for the drug. This entity also failed to correct inaccurate and misleading statements. The entity caused an estimated loss of $244,165,000 based on its conduct.

Civil Monetary Penalties

HHS-OIG has the authority to seek CMPs, assessments, and exclusions under the Civil Monetary Penalties Law (CMPL) against an individual or entity based on a wide variety of prohibited conduct. HHS-OIG brings CMP cases to emphasize HHS-OIG guidance, enhance HHS-OIG work such as audits and evaluations, fill enforcement gaps, and level the playing field for compliant providers. HHS-OIG uses its CMP authorities in three common ways: (1) false claims and kickback affirmative enforcement, (2) Emergency Medical Treatment and Labor Act (EMTALA) enforcement, and (3) the Self-Disclosure Protocol. In FY 2021, HHS-OIG concluded cases involving more than $79.9 million in CMPs and assessments.

Affirmative Litigation and Exclusion

HHS-OIG may seek a CMP or exclusion against an individual or entity that presents claims to federal health care programs that the individual or entity knows or should know are for items or services that were not provided as claimed or were false or fraudulent. HHS-OIG may also seek a CMP or exclusion against an individual or entity that knowingly and willfully violates the AKS by: (1) offering or paying remuneration, directly or indirectly, to induce referrals of federal health care program business; or (2) soliciting and receiving remuneration, directly or indirectly, in return for referrals of federal health care program business. In FY 2021, HHS-OIG recovered more than $9.2 million in false claims and kickback affirmative enforcement actions. HHS-OIG also excluded 39 individuals and entities from participation in federal health care programs based on allegations of false claims and kickbacks.

Affirmative litigation examples include:

- In April 2021, HHS-OIG entered a settlement with a physician and its physicians (collectively, Respondents) in Florida for $1,082,182.50. The settlement resolved allegations that the Respondents submitted claims for comprehensive clinical pathology consultations that were for services provided: (1) by pharmacists in a hospital setting that did not meet the requirements to be billed "incident to" a physician's professional services; and (2) to hospital inpatients on consecutive days of the patient's stay where no consultation request had been made, no written narrative report by a consultant pathologist was produced, and no exercise of medical judgment by a consultant pathologist was required.

- In August 2021, HHS-OIG entered a settlement with an ambulance service entity in Massachusetts for $704,706.62 to resolve allegations that the entity presented claims to Medicare Part B for ambulance transportation to and from SNFs when such transportation was already covered by the SNF consolidated billing payment under Medicare Part A.

Patient Dumping

HHS-OIG may also seek a CMP against any hospital that negligently violates its obligations under EMTALA, known as the "patient dumping" statute, which requires a hospital to stabilize and treat, or appropriately transfer if the hospital lacks the specialized capabilities necessary to stabilize the person, anyone who presents to an emergency department with an emergency medical condition. In FY 2021, HHS-OIG recovered $125,000 in cases under the EMTALA statute. Patient dumping examples include:

- In December 2020, a regional medical center (RMC) entered into a $100,000 settlement with HHS-OIG. The settlement resolved allegations based on the following facts: On January 10, 2016, a person came to the RMC's emergency department complaining of chest pain, nausea, vomiting, and diarrhea. The RMC failed to perform an adequate screening exam, and the person waited 3 hours and 44 minutes in the waiting room while his symptoms worsened with no treatment. The person left the RMC and went to another hospital. The second hospital diagnosed the person with triple vessel disease, performed an emergency heart catheterization, and sent the person back to the RMC for an urgent, triple coronary bypass surgery. The RMC paid $100,000—the maximum penalty—to resolve these allegations.

Self-Disclosure Protocol

HHS-OIG maintains the Self-Disclosure Protocol (the Protocol) whereby providers may voluntarily identify, disclose, and resolve instances of potential fraud involving federal health care programs for resolution under the CMPL. The Protocol incentivizes persons to detect and prevent fraud internally and to bring potential fraud to HHS-OIG's attention. Under the Protocol, HHS-OIG provides these persons with speedy resolutions, reduced CMPs, and other benefits compared to affirmative cases brought by HHS-OIG or DOJ for similar conduct. HHS-OIG collected $70.5 million under the Protocol in FY 2021. Self-disclosure examples include:

- In October 2020, a Massachusetts hospital self-disclosed conduct to HHS-OIG and paid $6,952,847 for allegedly violating the CMPL. HHS-OIG alleged that the hospital failed to maintain physician certifications, recertifications, and treatment plans for inpatient psychiatry services in violation of Medicare billing requirements. The hospital retained a third-party contractor who was responsible for managing the hospital's inpatient psychiatric unit, including maintaining proper medical records for patients in the unit.

- In February 2021, a hospital located in Virginia self-disclosed conduct to OIG and paid $6,050,628 for allegedly violating the CMPL, specifically provisions applicable to physician self-referrals and kickbacks. HHS-OIG alleged that the hospital paid

remuneration to two medical groups in the form of office space, office staff, and services rendered under call coverage arrangements.

- In April 2021, a radiation therapy entity in Colorado self-disclosed conduct to HHS-OIG and paid $3,569,645.76 for allegedly violating the CMPL. HHS-OIG alleged that the entity submitted false claims for certain radiation and oncology services involving 25 different CPT codes, including radiation therapy planning and simulation services, also known as "physics and dosimetry," and evaluation and management services provided to patients undergoing radiation therapy.

Corporate Integrity Agreements and Enforcement

Many health care providers elect to settle their cases before litigation. HHS-OIG provides information on its website that identifies how it evaluates future risk to federal health care programs from providers who settle health care fraud cases (called the Fraud Risk Indicator). As part of the settlements, providers often agree to enter into CIAs with HHS-OIG to avoid exclusions from Medicare, Medicaid, and other federal health care programs.

Under a CIA, a provider commits to establishing a compliance program and taking other specified steps to ensure future compliance with federal health care program rules. The compliance programs are designed, in part, to prevent future fraud. HHS-OIG monitors providers' compliance with these agreements. Parties to CIAs are required to disclose certain "reportable events" which may implicate HHS-OIG's CMP authorities. HHS-OIG may impose penalties on entities that fail to comply with the requirements of their CIAs, as shown below. HHS-OIG collected more than $500,000 through CIA enforcement. CIA enforcement examples include:

- In September 2021, HHS-OIG excluded a prosthetics entity in Louisiana from participation in all federal health care programs based on a material breach of the entity's integrity agreement (IA) with HHS-OIG. The entity failed to submit an implementation report, retain an Independent Review Organization, and submit the claims review reports required by the IA. The entity was previously excluded in March 2021 for default of its payment obligations under its August 2020 settlement agreement with the United States.

- In April 2021, a California management corporation and a facility it manages entered into a $121,783.31 settlement with HHS-OIG. HHS-OIG alleged that the facility employed an individual who it knew or should have known had been excluded from participation in the California Medicaid program (Medi-Cal) and that no Medi-Cal 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 2021, HHS-OIG issued 162 audit reports and 46 evaluations, resulting in 506 new recommendations issued to HHS operating divisions, HHS grantees, and other entities. During this same time period, 432 OIG recommendations were implemented.

Select examples of HHS-OIG's audit and evaluation findings in FY 2021 are listed below and organized by HHS-OIG's two broad priority outcomes to: (1) minimize risks to beneficiaries, and (2) safeguard programs from improper payments and fraud.

Minimize Risks to Beneficiaries

CMS's Controls Related to Hospital Preparedness for an Emerging Infectious Disease Were Well-Designed and Implemented but Its Authority Is Not Sufficient for It To Ensure Preparedness at Accredited Hospitals. CMS's controls were well-designed and implemented, but CMS's authority is not sufficient for it to fulfill its responsibility to ensure that accredited hospitals maintained quality and safety during an emerging infectious disease emergency. In February 2019, although CMS announced that it was critical for all hospitals to plan for emerging infectious diseases, CMS will not be able to determine that all accredited hospitals had updated emergency preparedness plans to include this preparedness until 2022 due to accreditation organizations' quality and safety inspection cycles. When COVID-19 emerged in the United States, CMS requested (but could not require) accreditation organizations to perform special targeted infection control surveys to help accredited hospitals prepare for COVID-19 patients. Accreditation organizations performed no such special surveys and, as of August 17, 2020, state survey agencies had performed these surveys at only about 13 percent of accredited hospitals and had not performed any in 13 states because of CMS's limited authority over accredited hospitals. As a result of these limitations, CMS could not ensure that accredited hospitals would continue to provide quality care and operate safely during the COVID-19 PHE, and cannot ensure quality and safety at accredited hospitals when a future emerging infectious disease threatens the United States. (A-02-21-01003)

CMS's COVID-19 Data Included Required Information From the Vast Majority of Nursing Homes, but CMS Could Take Actions To Improve Completeness and Accuracy of the Data. CMS's COVID-19 data for nursing homes included the required data from the vast majority of nursing homes (e.g., the number of confirmed COVID-19 cases among residents); however, the data were not complete or accurate for some nursing homes. Specifically, for 775 of the 15,388 nursing homes (about five percent), CMS's COVID-19 data: (1) did not include all of the COVID-19 data that nursing homes were required to report, and (2) were not complete or accurate after CMS performed its quality assurance checks (e.g., the number of confirmed COVID-19 cases among residents may have been under- or over-reported). These conditions occurred in part because, CMS's quality assurance checks were not always effective in ensuring

the accuracy and completeness of the COVID-19 data for nursing homes. In addition, two areas were identified in which CMS could take additional actions to help ensure that its COVID-19 data are complete and accurate. First, CMS could provide technical assistance to all nursing homes that fail its quality assurance checks. Second, CMS could make additional efforts to ensure that: (1) CMS's and states' COVID-19 data elements (e.g., confirmed COVID-19 cases among residents) are comparable (i.e., CMS and states could use the same data elements), and (2) the reported data are not substantially different. When CMS's COVID-19 data are complete and accurate, federal and state officials and other stakeholders may be able to more effectively monitor trends in infection rates and develop public health policies when making decisions about how to ensure the health and safety of nursing home residents and staff. (A-09-20-02005)

Medicare Lacks Consistent Oversight of Cybersecurity for Networked Medical Devices in Hospitals. Medicare accreditation organizations, which derive their requirements from the Conditions of Participation, rarely use their discretion to examine the cybersecurity of networked devices during hospital surveys. Our findings can help CMS identify ways to add consistent oversight of networked medical device cybersecurity in hospitals. Subsequent to the report release, CMS concurred with the recommendation to identify and implement an appropriate way to address cybersecurity of networked medical devices in its quality oversight of hospitals, in consultation with HHS partners and others. (OEI-01-20-00220)

Onsite Surveys of Nursing Homes During the COVID-19 Pandemic: March 23-May 30, 2020. In response to the COVID-19 pandemic, CMS adjusted its oversight approach by standardizing surveys, prioritizing the most serious complaints, elevating attention on infection control, and developing a new survey tool to ensure that nursing homes implement actions to prevent the spread of COVID-19. However, these changes have resulted in less comprehensive oversight of nursing homes and residents. Our findings can help CMS enhance its approach to nursing home oversight. We recommended that CMS: (1) assess the results of infection control surveys and revise the survey as appropriate, (2) work with states to help overcome challenges with personal protective equipment (PPE) and staffing, and (3) clarify expectations for states to complete backlogs of standard surveys and high-priority complaint surveys. CMS did not explicitly concur with our first and third recommendations but stated it has already taken steps to implement those recommendations. CMS did not concur with our second recommendation. (OEI-01-20-00430)

Opioid Use in Medicare Part D During the Onset of the COVID-19 Pandemic. As the pandemic took hold, each of about 5,000 Medicare beneficiaries per month had an opioid overdose. Almost a quarter of a million beneficiaries received high amounts of opioids through Part D in the first eight months of 2020. At the same time, the number of beneficiaries receiving drugs for treatment of opioid use disorder increased slightly. It is critical to continue to monitor the use of opioids and drugs for the treatment of opioid use disorder in Part D as COVID-19 presents new challenges for beneficiaries taking these drugs. (OEI-02-20-00400)

Medicare Beneficiaries Hospitalized With COVID-19 Experienced a Wide-Range of Serious, Complex Conditions. The wide-ranging and complex conditions of Medicare beneficiaries

hospitalized with COVID-19 can create substantial challenges in meeting the needs of these patients, particularly during surges in hospitalizations. While almost all of these beneficiaries were treated for acute respiratory issues—such as viral pneumonia—many were treated for other types of serious conditions, including acute kidney failure, heart attacks, and sepsis. More than half of the beneficiaries hospitalized with COVID-19 received intensive care or mechanical ventilation. We also found that beneficiaries who were dually eligible, Black, Hispanic, or elderly were hospitalized at disproportionately higher rates than nonelderly Whites. Gaining a better understanding of Medicare beneficiaries hospitalized with COVID-19—including the conditions for which they were being treated and demographic makeup—can assist federal, state, and local efforts during the COVID-19 pandemic. (OEI-02-20-00410)

COVID-19 Had a Devastating Impact on Medicare Beneficiaries in Nursing Homes During 2020. Nursing home residents have been particularly affected by COVID-19 as they are predominantly elderly, tend to have underlying conditions, and live in close quarters. However, data on the number of nursing home residents who were diagnosed with COVID-19 or likely COVID-19, particularly data from early in the pandemic, have not been readily available. Nursing homes are not required to report cases and deaths that occurred before May 8, 2020. OIG found that two-in-five Medicare beneficiaries in nursing homes were diagnosed with either COVID-19 or likely COVID-19 in 2020. Almost 1,000 more beneficiaries died per day in April 2020 than in April 2019. Overall mortality in nursing homes increased to 22 percent in 2020 from 17 percent in 2019. About half of the Black, Hispanic, and Asian beneficiaries in nursing homes had or likely had COVID-19, and 41 percent of White beneficiaries did. Understanding the pandemic's impact on nursing home residents is necessary if tragedies like this are to be averted. (OEI-02-20-00490)

CMS Use of Data on Nursing Home Staffing: Progress and Opportunities To Do More. CMS has taken important steps to build and use a new data source for information on nursing home staffing but has opportunities to better leverage this information. HHS-OIG's findings can help CMS identify ways to better inform consumers and improve oversight of staffing in nursing homes. HHS-OIG recommended that CMS: (1) provide data to consumers on nursing staff turnover and tenure, as required by federal law; (2) ensure the accuracy of non-nurse staffing data used on Care Compare; (3) consider residents' levels of need when identifying nursing homes for weekend inspections; and (4) take additional steps to strengthen oversight of nursing home staffing. CMS concurred with all four of our recommendations. (OEI-04-18-00451)

Opioids in Medicaid: Concerns About Opioid Use Among Beneficiaries in Six Appalachian States. More than 450 of these beneficiaries were at serious risk of opioid misuse or overdose. Of the 10 million Medicaid beneficiaries in 6 Appalachian states in 2018, 1,044,558 beneficiaries (about 1 in 10) received at least 1 prescription opioid. Some 5,897 of these beneficiaries received high amounts of opioids, 463 of these beneficiaries were at serious risk of opioid misuse or overdose, and 19 prescribers had questionable opioid prescribing practices. Previous HHS-OIG work found that beneficiaries at serious risk may experience serious outcomes related to opioid use, including opioid use disorder or overdose. (OEI-05-19-00410)

CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes. CMS has taken important steps to reduce the use of antipsychotic drugs in nursing homes and could further that progress by collecting more complete data on residents' use of these drugs. HHS-OIG found that CMS's use of the Minimum Data Set (MDS) as the sole data source to count the number of nursing home residents receiving antipsychotic drugs may not always provide complete information. This means that some residents' use of antipsychotics may not have been detected by CMS's quality measure intended to monitor the use of these drugs. HHS-OIG's findings suggest that CMS could enhance the information it uses to monitor antipsychotics in nursing homes by using additional data sources in its measurements of this issue, which is complex and critical for resident health and safety. HHS-OIG recommended that CMS take additional steps to validate the information reported in MDS assessments and supplement the data it uses to monitor the use of antipsychotic drugs in nursing homes. CMS concurred with both of our recommendations. (OEI-07-19-00490)

Update on Oversight of Opioid Prescribing and Monitoring of Opioid Use: States Have Taken Action To Address the Opioid Epidemic. In July 2019, HHS-OIG issued a report summarizing and comparing information provided by eight selected states: Nebraska, Nevada, New Hampshire, Tennessee, Texas, Utah, Washington, and West Virginia. For this update to the original audit, we selected an additional three states in the Appalachian region, which is an area with high rates of opioid overdose deaths: Alabama, Kentucky, and Ohio. The selected states have created policies and procedures and passed laws and regulations related to opioids and are using opioid-related data to perform both data analytics and outreach to providers and patients. The states have implemented a number of opioid-related prevention, detection, and treatment programs and have taken many other actions to address the opioid epidemic. (A-09-20-01000)

Iowa Should Improve Its Oversight of Selected Nursing Homes' Compliance With Federal Requirements for Life Safety and Emergency Preparedness. Iowa did not ensure that selected nursing homes in the state that participated in the Medicare or Medicaid programs complied with CMS requirements for life safety and emergency preparedness. During our onsite inspections, we identified deficiencies in areas related to life safety and emergency preparedness at all 20 nursing homes we reviewed. We found 122 instances of noncompliance with life safety requirements and 133 instances of noncompliance with emergency preparedness requirements. As a result, residents at the 20 nursing homes were at increased risk of injury or death during a fire or other emergency. The identified areas of noncompliance occurred because Iowa did not have a standardized life safety training program for all staff (not currently required by CMS). In addition, Iowa did not adequately follow up on deficiencies previously cited or require nursing homes or inspection contractors to: (1) tag systems that are critical to the health and safety of nursing home residents when these systems may not work as required, and (2) notify the state. (A-07-19-03238)

New York Did Not Fully Comply With Federal and State Requirements for Reporting and Monitoring Critical Incidents Involving Medicaid Beneficiaries With Developmental Disabilities. New York did not ensure that providers fully complied with federal waiver and state requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities residing in community-based settings. Of the 30 incidents of

potential abuse and neglect in our sample, 23 incidents were properly reported and investigated; however, seven incidents were not. Because incidents of potential abuse and neglect were not properly reported or investigated, beneficiaries were put at an increased risk of harm. Of the 48 reported and substantiated incidents of abuse and neglect in our judgmental sample, we found that the associated providers complied with the critical incident reporting and monitoring requirements. (A-02-17-01026)

Safeguard Programs From Improper Payments and Fraud

Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS. HHS-OIG found that Humana did not submit some diagnosis codes to CMS for use in the risk adjustment program in accordance with federal requirements. HHS-OIG identified some diagnosis codes that Humana submitted to CMS but that were not supported in the medical records. HHS-OIG also identified diagnosis codes that were supported in the medical records that Humana should have submitted to CMS but did not. As a result, we estimated that Humana received at least $197.7 million in net overpayments for 2015. (A-07-16-01165)

Hospitals Did Not Comply With Medicare Requirements for Reporting Cardiac Device Credits. HHS-OIG found that hospitals did not comply with Medicare requirements for reporting cardiac device credits, resulting in potential Medicare overpayments. HHS-OIG found that hospitals likely did not comply with Medicare requirements associated with reporting manufacturer credits for recalled or prematurely failed cardiac medical devices. As a result, 911 hospitals received payments of $76.0 million rather than the $43.0 million they should have received, resulting in $33.0 million in potential overpayments. It was determined that Medicare contractors made these overpayments because they do not have a postpayment review process to ensure that hospitals reported manufacturer credits for cardiac medical devices. (A-01-18-00502)

CMS and Its Contractors Did Not Use Comprehensive Error Rate Testing Program Data To Identify and Focus on Error-Prone Providers. HHS-OIG found that CMS and its contractors did not use Comprehensive Error Rate Testing (CERT) data to identify and focus on error-prone providers for review and corrective action. Using CERT data, HHS-OIG identified 100 error-prone providers from 2014 through 2017. Of the $5.8 million reviewed by CERT for these providers, $3.5 million were incorrectly paid, which was an improper payment rate of 60.7 percent. We determined that during the same period, Medicare made $19.1 billion in fee-for-service (FFS) payments to these 100 error-prone providers. (A-05-17-00023)

CMS Did Not Ensure That Medicare Hospital Payments for Claims That Included Medical Device Credits Were Reduced in Accordance With Federal Regulations, Resulting in as Much as $35 Million in Overpayments. CMS did not ensure that Outpatient Prospective Payment System (OPPS) payments for claims that included medical device credits were reduced in accordance with federal regulations. These regulations require the use of the device offset amount—100 percent of the device offset amount for each without cost or full credit replacement device and 50 percent of the device offset amount for each partial credit replacement device—when calculating the reduced OPPS payment amount. By following the Medicare Claims Processing Manual (the

Manual) instructions, Medicare administrative contractors (MACs) did not comply with these regulations when calculating the claims that we reviewed. As a result, Medicare made estimated overpayments of as much as $35.4 million to hospitals for our audit period. This error occurred because as part of federal rulemaking in CY 2014, CMS announced its intention to update federal regulations in order to reduce OPPS payments for replaced medical devices. This intended update was not finalized in the text of the federal regulations. However, CMS revised the relevant language in its guidance—the Manual. (A-07-19-00560)

Medicare Advantage Organizations Are Missing Opportunities To Use Ordering Provider Identifiers To Protect Program Integrity. In MA, encounter data lack National Provider Identifiers (NPIs) for providers who order and/or refer durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); clinical laboratory services; imaging services; and home health services. (Encounter data are the detailed information that MA organizations (MAOs) submit to CMS regarding each service provided to MA beneficiaries.) Almost half of MAOs that lack ordering NPIs on at least some MA encounter records raised concerns that this hinders their data analysis for program integrity. Most MAOs that collect any ordering NPIs use them to conduct oversight activities, but one in five does not—despite having the data to do so. Furthermore, most MAOs that collect these ordering NPIs do not validate them against CMS's NPI registry. We recommended that CMS encourage MAOs to perform program integrity oversight using ordering NPIs. CMS neither concurred nor nonconcurred with our recommendation. (OEI-03-19-00432)

Trend Toward More Expensive Inpatient Hospital Stays in Medicare Emerged Before COVID-19 and Warrants Further Scrutiny. Hospitals play an essential role in our health care system; nearly one-fifth of all Medicare payments are for inpatient hospitalizations. Inpatient hospital billing in the years leading up to the pandemic indicates that some stays at the highest severity level could be susceptible to inappropriate billing. Our findings can help CMS gain a better understanding of how hospitals bill Medicare and improve its oversight of hospital billing. We recommended that CMS conduct targeted reviews of MS-DRGs and stays that are vulnerable to upcoding, as well as the hospitals that frequently bill them. CMS did not concur. (OEI-02-18-00380)

Some Medicare Advantage Companies Leveraged Chart Reviews and Health Risk Assessments To Disproportionately Drive Payments. Twenty MA companies drove a disproportionate share of the $9.2 billion in estimated risk-adjusted payments from diagnoses reported only on chart reviews and health risk assessments (HRAs), and on no other 2016 encounter records. Each company generated a share of payments from these chart reviews and HRAs that was more than 25 percent higher than the share of enrolled MA beneficiaries. Among these 20 MA companies, one company stood out in its use of chart reviews and HRAs to drive risk-adjusted payments without encounter records of any other services provided to the beneficiaries for those diagnoses. This company had 40 percent of the risk-adjusted payments from both mechanisms and yet enrolled only 22 percent of the MA beneficiaries. In addition, this company accounted for about one-third of all payments from diagnoses reported solely on chart reviews and more than half of all payments from diagnoses reported solely on HRAs. We recommended that CMS: (1) provide oversight of the 20 MA companies that had a disproportionate share of the risk-adjusted payments from chart reviews and HRAs, (2) take additional actions to determine the

appropriateness of payments and care for the one MA company that substantially drove risk-adjusted payments from chart reviews and HRAs, and (3) perform periodic monitoring to identify MA companies that had a disproportionate share of risk-adjusted payments from chart reviews and HRAs. CMS neither concurred nor nonconcurred with our recommendations. (OEI-03-17-00474)

Massachusetts Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs. Massachusetts did not always comply with federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Massachusetts did not invoice manufacturers for rebates associated with $11.4 million (federal share) in physician-administered drugs. Massachusetts did not invoice for rebates for any physician-administered drug claims identified as hospital outpatient claims. (A-06-18-04001)

Minnesota Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed Care Organizations. Minnesota did not fully comply with federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to MCO enrollees. Minnesota did not bill for and collect manufacturers' rebates that we calculated to be $6.1 million (federal share). Minnesota did not always bill for and collect manufacturers' rebates because Minnesota and its contractor did not identify all of the rebate-eligible drugs in the utilization data submitted by the MCOs. (A-05-17-00018)

New Mexico Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed Care Organizations (MCOs). New Mexico did not fully comply with federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees. New Mexico did not bill for and collect from manufacturers' rebates of $1.0 million (federal share). The errors occurred because the state agency's internal controls did not always ensure that it billed manufacturers to secure rebates and because the state agency did not always collect the utilization data necessary to bill the manufacturers. (A-06-16-00001)

Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2019 Average Sales Prices. Based on 2019 data, CMS reduced Medicare Part B reimbursements for 18 drugs, saving Medicare and its beneficiaries $6.2 million over one year. This finding highlights the success of HHS-OIG's mandated quarterly comparisons of average sales prices (ASPs) with average manufacturer prices (AMPs) and implementation of CMS's current price-substitution policy. If HHS-OIG finds that the ASP for a drug exceeds the AMP by a certain percentage—currently five percent—the ASP based payment amount is substituted with a lower calculated rate. This serves as a mechanism for monitoring market prices and limiting potentially excessive payment amounts. (OEI-03-21-00130)

Despite Savings on Many Lab Tests in 2019, Total Medicare Spending Increased Slightly Because of Increased Utilization for Certain High-Priced Tests. HHS-OIG analyzed all claims for lab tests performed in 2019 and paid for under the Medicare Part B Clinical Laboratory Fee Schedule. We identified key statistics and emerging trends for the top 25 lab tests based on Medicare spending in 2019. In the second year of the new payment system required by the

Protecting Access to Medicare Act of 2014, reduced payment rates for many lab tests resulted in savings for the Medicare program. However, total Medicare spending increased slightly because of increased utilization and spending on certain high-priced tests, such as genetic tests. (OEI-09-20-00450)

Data on Medicaid Managed Care Payments to Providers Are Incomplete and Inaccurate. Effective oversight of Medicaid requires a national system with complete and accurate data. CMS established T-MSIS for this purpose. Payment data are a critical component of T-MSIS. These data include the amounts paid, billed, and allowed for every service provided to Medicaid enrollees, including those services provided through managed care. We recommended that CMS: (1) review states' managed care payment data in T-MSIS and ensure that states have corrective action plans to improve data completeness and quality, as appropriate; (2) make public its reviews of states' managed care data; and (3) clarify and expand its initiative on payment data. CMS did not concur. (OEI-02-19-00180)

Nationwide, Almost All Medicaid Managed Care Plans Achieved Their Medical Loss Ratio Targets. Federal requirements for medical loss ratios (MLRs) were established to ensure that Medicaid managed care plans spend most of their revenue on health care services and quality improvement, thereby limiting the amount that a plan can spend on administration and keep as profit. An MLR is the percentage of revenue that a managed care plan spends on services related to the health of its enrollees. We found that 92 percent of Medicaid managed care plans (471 of 513) achieved MLRs that met or exceeded the federal 85 percent standard for MLRs. Although federal MLR regulations do not require states to set minimum MLRs, 34 states had established minimum MLRs for 434 Medicaid managed care plans. Ninety-one percent of plans met these state-set minimum MLRs. However, 39 plans failed to meet their state-set minimum MLRs for the period reviewed. Nineteen of these plans reported owing a total of $197.8 million to states that had opted to require that their plans return money to the state when the plans did not meet minimum MLRs. This data brief demonstrates that states that choose to establish minimum MLRs with requirements to return money may recoup millions of Medicaid dollars from plans that fail to meet the state-set minimum MLRs. (OEI-03-20-00230)

Medicaid Fraud Control Units FY 2020 Annual Report. This annual report provides statistics that highlight the accomplishments of the 53 MFCUs during FY 2020. MFCUs reported that the COVID-19 pandemic created significant challenges for MFCU staff, operations, and court proceedings. However, MFCUs reported taking steps to mitigate the effects of the pandemic and, despite challenges, continued to carry out their Medicaid program integrity functions in FY 2020. MFCUs reported 1,017 convictions in FY 2020. Fraud cases accounted for 76 percent of the MFCU convictions, while patient abuse or neglect was involved in 24 percent. Approximately 47 percent of the 774 MFCU fraud convictions involved personal care services attendants and agencies. MFCUs were responsible for 786 civil settlements and judgments, 33 percent of which involved pharmaceutical manufacturers. MFCUs reported $1 billion in criminal and civil recoveries. In an appendix to the report, HHS-OIG summarized beneficial practices identified by HHS-OIG in its reviews or inspections that may be useful to other MFCUs. (OEI-09-21-00120)

Risk Assessment Puerto Rico Medicaid Program. To fulfill HHS-OIG's responsibilities under P.L. No. 116-94, we conducted a high-level risk assessment of Puerto Rico Medicaid program controls and processes. Our approach included interviewing program officials from various units that administer the Puerto Rico Medicaid program and reviewing documents that they provided. We identified program integrity, beneficiary eligibility, provider enrollment, overpayment reporting, and contracting as key areas at high risk for improper Medicaid program payments. In addition, we determined that the risk of improper Medicaid program payments in Puerto Rico could be increased because there have been no recent reviews of Puerto Rico Medicaid program payments performed by CMS, and because Puerto Rico's MMIS has not been fully implemented. Finally, we identified one area (program management) at moderate risk for improper Medicaid program payments due to limitations in staff hiring and training. Based on the results of our high-level risk assessment, we determined that audits of Puerto Rico's Medicaid program are warranted to protect federal funds by identifying inaccurate program payments. We have used the results of this assessment to set priorities for performing these audits. We initiated two audits in FY 2021 related to potentially improper payments. Specifically, we will determine whether Puerto Rico improperly claimed Medicaid reimbursements for payments on behalf of deceased beneficiaries and beneficiaries who were assigned multiple Medicaid identification numbers. (A-02-20-01011)

Ohio Did Not Correctly Determine Medicaid Eligibility for Some Newly Enrolled Beneficiaries. For our sample of 150 beneficiaries, Ohio did not determine eligibility for 18 beneficiaries in accordance with federal and state requirements and did not provide supporting documentation to verify that the remaining 66 potentially ineligible beneficiaries were newly eligible. (The total exceeds 150 because three beneficiaries were found to be ineligible for one determination period and found to be potentially ineligible for another period.) These deficiencies occurred because Ohio's eligibility determination system lacked the necessary system functionality, and eligibility caseworkers made errors. In addition, Ohio did not always maintain documentation to support eligibility determinations. On the basis of our sample results, we estimated that Ohio made Medicaid payments of $77.5 million (federal share) on behalf of 51,219 ineligible beneficiaries and $746.4 million (federal share) on behalf of 241,998 potentially ineligible beneficiaries. (A-05-18-00027)

Ohio Made Capitation Payments to Managed Care Organizations for Medicaid Beneficiaries With Concurrent Eligibility in Another State. Ohio made an estimated $5.9 million in August 2018 capitation payments on behalf of beneficiaries who were concurrently eligible and residing in another state. On the basis of our sample results, we estimated that Ohio could have saved $5.9 million ($4.2 million federal share) for August 2018 capitation payments made to MCOs on behalf of beneficiaries with concurrent eligibility. (A-05-19-00023)

Kansas Made Capitation Payments to Managed Care Organizations After Beneficiaries' Deaths. Kansas made at least $17.3 million in unallowable capitation payments to MCOs on behalf of beneficiaries whose dates of death preceded the service period covered by the monthly capitation payment, for which it claimed at least $9.7 million in unallowable federal reimbursements. Specifically, 1,383 capitation payments totaling $2.7 million ($1.5 million federal share), which were made on behalf of deceased beneficiaries who had dates of death in Kansas's eligibility

system that did not always agree with the information in the Social Security Administration's Death Master File (DMF), were unallowable. Furthermore, 100 capitation payments in our stratified random sample totaling $192,991 ($108,657 federal share) and made on behalf of beneficiaries who had a date of death recorded in the DMF but who did not have a date of death in Kansas's system were unallowable. On the basis of our sample results, we estimated that Kansas made unallowable capitation payments totaling at least $14.6 million (at least $8.2 million federal share). In addition, Kansas had previously overreported capitation payments totaling more than $2.0 million ($1.2 million federal share) that were related to prior-period adjustments. (A-07-20-05125)

New York Improved Its Monitoring of Its Personal Care Services Program But Still Made Improper Medicaid Payments of More Than $54 Million. New York claimed federal reimbursement for personal care services that did not comply with certain federal and state requirements for 28 of the 100 sampled claims. Specifically, New York received reimbursements for personal care services for which there were: (1) no valid nursing or social assessment; (2) no independent medical review; (3) no valid physician's order, or the order was not timely; (4) no documentation of services provided; and (5) no plan of care. Additionally, for some claims the personal care aide who provided the associated services had not undergone a timely criminal history check or did not meet training requirements. The unallowable claims occurred because New York's monitoring of the personal care services program was not adequate to ensure that services complied with federal and state requirements. However, we noted that in 2017 New York made some improvements to its monitoring of the program. On the basis of our sample results, we estimated that New York improperly claimed at least $54.5 million in federal Medicaid reimbursement for personal care services during our audit period. In addition, the health and safety of some Medicaid beneficiaries may have been put at risk because a personal care aide had not undergone a criminal history check or did not meet training requirements. (A-02-19-01016)

About 79 Percent of Opioid Treatment Program Services Provided to Medicaid Beneficiaries in Colorado Did Not Meet Federal and State Requirements. Colorado's oversight during the audit period did not ensure that Opioid Treatment Program (OTP) services provided to Medicaid beneficiaries met federal and state requirements. Of the 100 OTP services we sampled, 21 complied with federal and state requirements but 79 did not meet applicable federal and state requirements. Colorado's oversight of OTPs consisted primarily of biennial audits conducted by the state Opioid Treatment Authority that were not sufficient in scope and depth of coverage to ensure that OTPs maintained a recordkeeping system that was adequate to document and monitor patient care, or to ensure that OTP services met federal and state requirements. The biennial audits of each OTP were performed by a single person, covered approximately 10 percent of patient charts, and took between one and two days to perform. Given all of the tasks that these audits sought to conduct, we do not believe that reviewing 10 percent of patient charts over the course of one to two days was adequate for one person to be able to thoroughly review patient charts for deficiencies and to devote sufficient time to other tasks. On the basis of our sample results, we estimated that more than 1.1 million OTP services, or about 79 percent, did not meet federal and state requirements during the audit period. (A-07-20-04118)

California Claimed at Least $2 Million in Unallowable Medicaid Reimbursement for a Selected Provider's Opioid Treatment Program Services. California did not claim Medicaid reimbursement for the selected provider's OTP services in accordance with federal and state requirements. Among the 100 sample items, one sample item was allowable but 99 sample items had services that were unallowable. On the basis of our sample results, we estimated that California claimed at least $2.4 million in unallowable federal Medicaid reimbursement for OTP services during our audit period. These deficiencies occurred because California's oversight activities did not ensure that OTP services met federal and state requirements. We also identified deficiencies in two areas in which California could improve the quality of care provided to beneficiaries receiving OTP services. (A-09-20-02001)

Massachusetts Made at Least $14.0 Million in Improper Medicaid Payments for the Nonemergency Medical Transportation Program. Massachusetts claimed federal Medicaid reimbursement for 86 of 100 sampled lines of service submitted by transportation providers that did not comply with certain federal and state requirements. The improper claims for unallowable services were made because the state's monitoring and oversight of the nonemergency medical transportation (NEMT) program did not ensure that NEMT services were for qualifying medical services and were adequately documented. In addition, for all 100 sample items, driver qualifications and vehicle inspection, registration, and maintenance policies or schedules were not adequately documented. On the basis of our sample results, we estimated that at least 758,847 Medicaid claims totaling $14,142,730 ($7,071,365 federal share) did not comply with certain federal and state regulations. (A-01-19-00004)

New York Improperly Claimed $439.0 Million In Medicaid Funds for Its School-Based Health Services Based on Certified Public Expenditures. New York claimed unallowable federal funds because it did not support that all random moments coded as health care were for Medicaid-eligible health services. New York also did not provide support that it did not double-claim for services when a student in one school district received services from another school district. In addition, New York improperly claimed excess costs for one year. Finally, New York did not follow federal random moment time study (RMTS) requirements and used an unsupported method to claim Medicaid costs. New York and its contractor developed complex methods that were difficult or impossible to correctly implement and support with documentation. As a result, New York claimed estimated unallowable federal funds totaling $98.0 million. In addition, New York claimed $32.0 million in federal funds because it did not follow federal RMTS requirements or document that CMS approved its allocation methodology, and $309.0 million in federal funds using ratios that were not supported. (A-02-18-01019)

New York's Claims for Federal Reimbursement for Payments to Health Home Providers on Behalf of Beneficiaries Diagnosed With Serious Mental Illness or Substance Use Disorder Generally Met Medicaid Requirements But It Still Made $6.0 Million in Improper Payments to Some Providers. Among the 150 payments in our random sample, New York properly claimed reimbursements for 141 payments but improperly claimed reimbursements for the remaining nine payments. Specifically, New York's health home providers did not provide a comprehensive patient-centered care plan covering the sampled date of service for enrolled beneficiaries (five payments) and did not document health home services (four payments). The

improper payments occurred because New York did not adequately monitor health home providers for compliance with certain federal and state requirements for providing, documenting, and billing services. Health home providers' failure to develop comprehensive patient-centered care plans and provide health home services could have resulted in beneficiaries not getting the services that they needed and may have put their health and safety at risk. On the basis of our sample results, we estimated that New York improperly claimed at least $6.0 million in federal Medicaid reimbursements for payments made to health home providers for services provided to beneficiaries diagnosed with serious mental illness or substance use disorder. (A-02-19-01007)

Kentucky Claimed Millions in Unallowable School-Based Medicaid Administrative Costs. Kentucky did not claim school-based Medicaid administrative costs in accordance with federal requirements. It used an invalid random moment sampling to allocate costs to Medicaid and included unallowable costs in its cost pools. In addition, Kentucky claimed these costs without promptly submitting cost allocation plan amendments to the Department of Health and Human Services, Division of Cost Allocation (DCA) for review and without obtaining DCA approval. As a result, the $58.9 million ($29.4 million federal financial participation) that it claimed in school-based Medicaid administrative costs for FY 2009 through FY 2014 were unallowable. (A-04-17-00113)

Indiana Received Over $22.0 Million in Excess Federal Funds Related to Unsupported Community Integration and Habilitation Waiver Services at 12 Selected Service Providers. Indiana did not ensure that all Community Integration and Habilitation (CIH) Waiver services were provided in accordance with federal, state, and waiver requirements. We determined that services associated with 236 claims were provided in accordance with the requirements; however, services associated with 64 claims were not. Documentation provided by CIH Waiver service providers did not support that the services associated with 39 claims were provided in accordance with the requirements. Overpayments associated with these 39 claims totaled $10,675 ($7,108 federal share). In addition, some CIH Waiver service providers were unable to provide any documentation to support 25 claims totaling $90,802 ($60,448 federal share). Therefore, overpayments associated with the 64 claims totaled $101,477 ($67,556 federal share). On the basis of our sample results, we estimated that these providers were unable to support that they provided services totaling at least $33.5 million ($22.3 million federal share) in accordance with the CIH Waiver requirements. These issues occurred because Indiana's monitoring of CIH Waiver services was not adequate to ensure that services complied with federal, state, and CIH Waiver requirements. (A-05-19-00022)

Medicare Improperly Paid Physicians for More Than Five Spinal Facet-Joint Injection Sessions During a Rolling 12-Month Period, and Noridian Healthcare Solutions, LLC, Made Improper Medicare Payments of $4.0 Million to Physicians in Jurisdiction E for Spinal Facet-Joint Injections. Medicare did not pay physicians for selected facet-joint injection sessions in accordance with federal requirements, and Noridian Healthcare Solutions, LLC (Noridian), did not pay physicians in Jurisdiction E for spinal facet-joint injections in accordance with Medicare requirements. Specifically, for selected facet-joint injections MACs in the 11 jurisdictions with a coverage limitation made improper payments of $748,555. In addition, if the remaining MAC jurisdiction had kept the coverage limitation in place during our audit period, Medicare could

have saved $513,328. Also, we estimated that Noridian improperly paid physicians $4.2 million for facet-joint injections for our audit period. (A-09-20-03003, A-09-20-03010)

Peninsula Regional Medical Center: Audit of Medicare Payments for Polysomnography Services, North Mississippi Medical Center: Audit of Medicare Payments for Polysomnography Services, and University of Michigan Health System: Audit of Medicare Payments for Polysomnography Services. Peninsula Regional Medical Center (Peninsula), North Mississippi Medical Center (North Mississippi), and the University of Michigan submitted Medicare claims for some polysomnography services that did not comply with Medicare billing requirements. Specifically on the basis of our sample results, we estimated that Peninsula received overpayments of at least $66,647 for polysomnography services provided during the audit period. The errors occurred because Peninsula's policies and procedures did not address the processing of Medicare claims for polysomnography services to ensure that services billed to Medicare were adequately documented and coded correctly. Additionally, on the basis of our sample results, we estimated that North Mississippi received overpayments of at least $67,038 for polysomnography services provided during the audit period. North Mississippi stated that the errors occurred because of a misunderstanding of the Medicare policy. Although North Mississippi had some policies and procedures in place, it did not adequately explain how to process Medicare claims for polysomnography services and ensure that services billed to Medicare were coded correctly or that technicians attending a polysomnography service had the required credentials. Furthermore, on the basis of our sample results, we estimated that the University of Michigan received overpayments of at least $12,520 for polysomnography services during our audit period. The errors occurred because University of Michigan policies and procedures did not address the processing of Medicare claims for polysomnography services to ensure that services billed to Medicare were adequately documented and coded correctly. (A-04-19-07087, A-04-19-07086, A-04-20-07088)

An Ophthalmology Clinic in California: Audit of Medicare Payments for Eye Injections of Eylea and Lucentis. An ophthalmology clinic in California (the Clinic) generally complied with Medicare requirements when billing for intravitreal injections of Eylea and Lucentis, which accounted for 88 percent of the total payments in our sample. However, the Clinic did not always comply with Medicare requirements when billing for other services provided on the same day as the intravitreal injections (e.g., injections of an anesthesia drug). For 301 services and drugs, the Clinic did not comply with the requirements; 195 services were not separately payable, and 106 services and drugs were not reasonable and necessary. Because the Clinic's medical director was unfamiliar with Medicare's billing requirements, the Clinic did not have policies and procedures to ensure that services and drugs billed to Medicare were correctly billed or reasonable and necessary. On the basis of our sample results, we estimated that at least $398,625 of the $4.3 million paid to the Clinic was unallowable for Medicare reimbursement. (A-09-19-03022)

Medicare Could Have Saved Up to $20.0 Million Over Five Years if CMS Oversight Had Been Adequate To Prevent Payments for Medically Unnecessary Cholesterol Blood Tests. Payments made to providers for direct-measurement, low-density lipoprotein (LDL) cholesterol tests (direct LDL tests) that were billed in addition to lipid panels did not comply with Medicare

requirements. Under certain circumstances, it may be medically necessary for a provider to perform both tests for the same beneficiary on the same date of service. However, CMS and Medicare contractors explained that these circumstances should happen with limited frequency. We determined that some providers billed LDL tests in addition to lipid panels for the same beneficiary on the same date of service more than 75 percent of the time. (Such providers are known as "at-risk providers.") In total, we identified $20.4 million in Medicare payments made to at-risk providers for direct LDL tests.

Two Medicare contractors' review of medical records associated with 20 judgmentally sampled claims found that all of the direct LDL tests billed in addition to lipid panels were medically unnecessary. Because the claim lines for the $20.4 million in payments to at-risk providers for direct LDL tests had characteristics similar to the claim lines in the judgmental sample, we determined that up to $20.4 million in payments were improper. If CMS had had oversight mechanisms to prevent such payments, Medicare could have saved up to $20.4 million for our audit period. (A-09-19-03027)

CMS Needs To Strengthen Regulatory Requirements for Medicare Part B Outpatient Cardiac and Pulmonary Rehabilitation Services To Ensure Providers Fully Meet Coverage Requirements. CMS regulatory requirements related to Medicare outpatient cardiac and pulmonary rehabilitation services did not contain sufficient information to ensure that claims for these services met Medicare coverage requirements. Specifically, the requirements lacked details related to what patient-specific information should be contained in a beneficiary's medical record and how this information should relate to individualized treatment. As a result, for all 100 sampled beneficiary-days, we determined that medical record documentation obtained from the selected provider did not contain sufficient evidence to support whether Medicare coverage requirements for reimbursement of cardiac and pulmonary rehabilitation services were met. On the basis of our sample results, we estimated that $2.7 million in Medicare payments made by CMS to the selected provider for outpatient cardiac and pulmonary rehabilitation services may not have met Medicare coverage requirements as intended. Furthermore, based on our review we believe that Medicare payments totaling approximately $626.0 million made by CMS to all providers for outpatient cardiac and pulmonary rehabilitation services during our audit period may not have met the requirements. (A-02-18-01026)

Sleep Management, LLC: Audit of Claims for Monthly Rentals of Noninvasive Home Ventilators. Most Medicare claims submitted by Sleep Management for the monthly rental of noninvasive home ventilators (NHVs) did not comply with Medicare requirements. Of the 100 sampled claim lines with payments totaling $75,694, 2 complied with Medicare requirements; however, 98 claim lines with payments totaling $74,288 did not comply. Based on our sample results, we estimated that Medicare made overpayments to Sleep Management of at least $29.1 million for the monthly rental of NHVs that did not comply with Medicare requirements. These overpayments occurred because Sleep Management did not follow its policies and procedures to ensure that it obtained sufficient documentation to support the medical necessity of the NHVs or discontinued service for lack of beneficiary usage. (A-04-18-04066)

Medicare Made Millions of Dollars in Overpayments for End-Stage Renal Disease Monthly Capitation Payments. CMS did not always make Medicare monthly capitation payments to physicians for monthly end-stage renal disease (ESRD)-related services provided in CY 2016 through CY 2018 in accordance with federal requirements. Specifically, 23,695 claims were for services for which physicians reported monthly ESRD-related billing codes more than once for the same beneficiary for the same month. These claims consisted of 21,763 claims that resulted in $4 million in overpayments for instances in which a different physician reported codes for services and 1,932 claims that resulted in $291,813 in overpayments for instances in which the same physician reported codes for services. Beneficiaries were responsible for up to $1.1 million in cost sharing related to these 23,695 claims. We are setting aside potential overpayments related to an additional 1,598 claims totaling $289,169 and $74,563 in beneficiary cost-sharing for CMS's review and determination. CMS did not have adequate claims processing controls in place, to include system edits, to identify and prevent these overpayments. (A-07-19-05117)

Opportunities Exist for CMS and Its Medicare Contractors To Strengthen Program Safeguards To Prevent and Detect Improper Payments for Drug Testing Services. We identified three weaknesses in the Medicare contractors' established program safeguards for preventing and detecting improper payments for drug testing services and promoting provider compliance with Medicare requirements. Specifically, the contractors did not have: (1) clear and consistent requirements or guidance for laboratories to use when determining the number of drug classes to bill for definitive drug testing services, (2) procedures for identifying or limiting the frequency of drug testing services (e.g., the number of drug tests performed per year) for each beneficiary across all Medicare jurisdictions, and (3) consistent requirements in their Local Coverage Determinations or any procedures for identifying claims for direct-to-definitive drug testing. If CMS and its contractors cannot ensure that laboratories' claims for drug testing services comply with Medicare requirements, laboratories may receive improper payments and beneficiaries with substance use disorders may receive medically unnecessary drug testing services. (A-09-20-03017)

Medicare Payments for Transitional Care Management Services Generally Complied With Federal Requirements, but Some Overpayments Were Made. Payments made to physicians for Transitional Care Management (TCM) services provided during CYs 2015 and 2016 generally complied with federal requirements, but we identified almost $1.7 million in overpayments associated with 13,577 claims (that were outside the reopening and recovery period) for instances in which multiple physicians billed for TCM services for a beneficiary's same 30-day TCM service period and for instances in which a physician billed on different dates for TCM and restricted overlapping care management services provided during the same 30-day TCM service period for the same beneficiary. These overpayments represented only 0.006 percent of the total TCM payments made during our audit period. We also identified 853 claims that were outside the reopening and recovery period, and that totaled at least $74,275 in unallowable services, for instances in which a physician submitted claims on the same date for TCM and restricted overlapping care management services that were rendered for the same beneficiary during a single 30-day TCM service period. We were not able to determine which of these claims were overpayments. CMS did not have controls in place to include claim system edits, to prevent and detect multiple TCM services provided to beneficiaries, and to identify instances of overlapping

care management. (A-07-17-05100)

Medicare Continues To Make Overpayments for Chronic Care Management Services, Costing the Program and Its Beneficiaries Millions of Dollars. Not all payments made by CMS to providers for noncomplex and complex CCM services rendered during CYs 2017 and 2018 complied with federal requirements, resulting in $1.9 million in overpayments associated with 50,192 claims. We identified 38,447 claims resulting in $1.4 million in overpayments for instances in which providers billed noncomplex or complex CCM services more than once for the same beneficiary for the same service period. We also identified 10,882 claims that resulted in $438,262 in overpayments for instances in which the same provider billed for both noncomplex or complex CCM services and overlapping care management services rendered to the same beneficiaries for the same service periods. Furthermore, we identified 863 claims that resulted in $52,086 in overpayments for incremental complex CCM services that were billed along with complex CCM services that we identified as overpayments. For these 50,192 claims, beneficiaries' cost-sharing totaled up to $540,680. These errors occurred because CMS did not have claim system edits to prevent and detect overpayments. (A-07-19-05122)

CMS Needs To Issue Regulations Related to Phlebotomy Travel Allowances. For this audit, we focused on two previous audits of phlebotomy travel allowance payments for clinical diagnostic laboratory tests made by two Medicare administrative contractors (MACs) from January 1, 2015, through December 31, 2016, and on current travel allowance guidance. In our two previous audits of MAC payments for phlebotomy travel allowances, we determined that the two MACs paid providers for phlebotomy travel allowances that did not comply with Medicare guidance. Specifically, in our two MAC audits, 93 of the 202 sampled paid claim lines we reviewed complied with Medicare guidance, but 109 paid claim lines did not comply. (Some lines did not comply for more than one reason.) Errors identified in those audits were related to incorrectly prorated mileage, incorrect payment rates, and inadequate documentation. On the basis of the sample results, we estimated that the two MACs paid providers a combined $2.7 million in phlebotomy travel allowance payments that were not in accordance with Medicare guidance. In addition, we spoke with CMS in June 2020 and, at that time, CMS had not begun the notice and comment rulemaking process necessary to clarify provider guidance related to prorating mileage on claims for phlebotomy travel allowances or to issue further guidance. (A-06-20-04000)

Other HHS-OIG Fraud and Abuse Prevention Activities

Data Analytics

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

health care, grants, law enforcement, and operational data to identify and support prosecutions of sophisticated fraud schemes as well as potential audit and evaluation findings. At least 635 unique staff members used HHS-OIG analytic tools for mission-focused work to generate more than 68,000 actions, including provider-specific reports and claims exports, among other work products and analytic insights, during the fiscal year.

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

HHS-OIG analytics staff quickly pivoted to monitor COVID-19 testing, treatment, and billings for other services such as DME, allergy, genetic, respiratory, and other testing to detect patterns of inappropriate bundling of services and billing for services not rendered. HHS-OIG also monitored changes in services delivered through telemedicine to identify inappropriate billing schemes. HHS-OIG analytics supported agency investigative actions that led to criminal charges filed in U.S. courts involving at least 23 of 42 doctors, nurses, and other licensed medical professionals, and 18 other cases against owners and operators of DME suppliers, labs, and providers, as well as marketers, patient recruiters, and PRF recipients included in the nationwide health care fraud enforcement actions announced by DOJ and HHS on September 17, 2021. Furthermore, HHS-OIG's data analytics continue to identify and support cases filed as part of the Appalachian Regional Prescription Opioid Strike Force effort.

Our data and technical experts are also partnering with HHS-OIG auditors and evaluators to provide custom data and analytics support focused on pandemic-related work. As of September 30, 2021, HHS-OIG analytics staff supported 21 audits, 24 evaluations, and 98 criminal investigations launched since the onset of the COVID-19 pandemic across the Medicare and Medicaid portfolio as well as dozens of COVID-19 related projects and exploratory work.

Outreach and Guidance

HHS-OIG strives to cultivate a culture of compliance in the health care industry through various educational and outreach efforts.

Advisory Opinions

HIPAA established an advisory opinion process through which parties may obtain binding legal guidance on the application of the federal AKS and other HHS-OIG administrative enforcement authorities to existing or proposed health care financial arrangements.

During FY 2021, HHS-OIG in consultation with DOJ issued 18 advisory opinions. During the 24 years of the HCFAC program, HHS-OIG has issued nearly 400 advisory opinions, modified 21 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.

HHS-OIG also engages with stakeholders to seek insight on how to promote compliance while encouraging innovation in the health care industry. For instance, HHS-OIG in December 2020 issued a final rule as part of HHS's broader Regulatory Sprint to Coordinated Care initiative. In this rule, HHS-OIG promulgated new and modified safe harbors to the AKS and new exceptions to the CMP provision prohibiting inducements to beneficiaries in an effort to remove barriers to arrangements that could promote greater care coordination and value-based care.[15] HHS-OIG also recently published a Request for Information seeking to identify ways that it could modernize the accessibility and usability of our publicly available information.[16] HHS-OIG will host roundtables with stakeholders in FY 2022 to further solicit feedback on this topic.

Centers for Medicare & Medicaid Services

In FY 2021, Congress appropriated CMS $616.0 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 2021, Congress required HHS to fund the Administration for Community Living's (ACL) Senior Medicare Patrol (SMP) Program; therefore, $20.0 million of CMS's $616.0 million in discretionary funding was allocated to ACL to support the program. More information on the SMP Program activities and accomplishments are discussed in the ACL section of this report on page 84. With the HCFAC funds, CMS works to ensure that accurate payments are made to legitimate individuals and entities for allowable services or supplies provided to eligible beneficiaries of federal health care programs.

[15] HHS-OIG, Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77,684 (Dec. 2, 2020).
[16] HHS-OIG, OIG Modernization Initiative To Improve Its Publicly Available Resources—Request for Information, 86 Fed. Reg. 5,3072 (Sept. 24, 2021).

CMS also performs many program integrity activities that are beyond the scope of this report because they are not funded directly by the HCFAC Account or discretionary HCFAC funding. This includes activities such as the Recovery Audit Program and Medicare Secondary Payer. CMS's program integrity activities are discussed at length in the annual Medicare and Medicaid Integrity Programs Report to Congress, which can be found on the CMS website.[17]

Address the Full Spectrum of Fraud, Waste, and Abuse

CMS defines program integrity very simply, "pay it right." Program integrity focuses on paying the right amount, to legitimate providers and suppliers, for covered, reasonable and necessary services provided to eligible beneficiaries, while 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. The UPICs develop investigations and take actions to prevent improper payments from being made to Medicare providers and suppliers. UPICs undertake activities including provider and beneficiary interviews and site visits, initiating appropriate administrative actions (e.g., prepayment edits, payment suspensions, revocations), and performing program integrity reviews of medical records and documentation. While a variety of other contractors also perform medical review, UPIC reviews are uniquely focused on fraud detection and investigation. For example, the UPICs look for possible falsification of documents that may be associated with an attempt to defraud the Medicare and Medicaid programs. Various UPIC administrative actions result in Medicare savings, including automated edit claim denials, non-automated review claim denials, provider revocations and deactivations, overpayment recoveries, and law enforcement referrals.

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

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

Fraud Prevention System (FPS)

FPS is the predictive analytics technology required under the Small Business Jobs Act of 2010.[18] FPS analyzes FFS claims using sophisticated algorithms to target investigative resources; generate alerts for suspect claims or providers and suppliers; and provide information to facilitate and support investigations of the most egregious, suspect, or aberrant activity. CMS uses the FPS information to prevent and address improper payments using a variety of administrative actions, including claim denials, payment suspensions, Medicare billing privilege revocations, and law enforcement referrals.

During FY 2021, the FPS generated alerts that resulted in 516 new leads for program integrity contractors (PICs) and augmented information for 521 existing PIC leads or investigations. The PICs reported initiating FPS-attributable actions against 778 providers in FY 2021.

Medicare FFS and Medicaid National Correct Coding Initiative (NCCI)

NCCI promotes national correct coding methodologies and reduces improper coding that may result in inappropriate payments in Medicare FFS. NCCI Procedure-to-Procedure edits prevent inappropriate payment for billing code pairs that should not generally be reported together by the same provider for the same beneficiary and date of service, while NCCI Medically Unlikely Edits define for each HCPCS/CPT code the maximum units of service (UOS) that a provider would report under most circumstances for a single beneficiary on a single date of service. Estimated savings from Medicare NCCI edits are published in the Annual Report to Congress on the Medicare and Medicaid Integrity Programs.[19]

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

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

One PI provides CMS program integrity contractors, law enforcement personnel, HHS-OIG investigators, and other organizations a centralized single access point to analytical tools and data needed to fight Medicare and Medicaid fraud, waste, and abuse. One PI provides access to Medicare and Medicaid data from the Integrated Data Repository (IDR), which allows users to investigate improper payments, identify fraud schemes, create and enhance fraud prevention models, take administrative actions, pursue civil and criminal penalties, and more to protect Medicare and Medicaid taxpayer dollars. One PI augments the Medicare Parts A, B (including Durable Medical Equipment (DME) and home health claims), Part C encounter data, and Part D prescription drug event records, as well as beneficiary data that is available in the IDR to provide a comprehensive view of claims data, beneficiary data, and prescription drug information as well as Transformed Medicaid Statistical Information System (T-MSIS) data and Medi-Medi formats. One PI is currently working to integrate 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.

[18] Public Law 111-240.

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

The Command Center and Coordinated Program Integrity Activities

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

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

As a result of the MCC, there has been a marked increase in the number and quality of law enforcement referrals from CMS. Since implementation of the MCC, there have been over 3,200 cases reviewed at MCC, and law enforcement partners have made over 2,000 requests for CMS to refer reviewed cases. CMS program integrity activities and investigations continue to contribute to law enforcement investigations, CMS administrative actions and CMS initiatives. In FY 2021, CMS reviewed 1,029 cases at MCC meetings, and law enforcement partners made 607 requests for CMS to refer reviewed cases.

Examples of the ways in which CMS has provided support to the HHS-OIG and DOJ throughout fiscal year 2021 include:

- On May 26, 2021, DOJ announced approximately 14 law enforcement indictments of individuals involved in COVID-19 related fraud schemes in a coordinated law enforcement action with the HHS-OIG and CMS. CMS separately announced that day that it took administrative actions against over 50 DME suppliers for their involvement in health care fraud schemes relating to abuse of CMS programs during the pandemic.

- On September 17, 2021, DOJ announced criminal charges against 138 defendants, including 42 doctors, nurses, and other licensed medical professionals, in 31 federal districts across the United States for their alleged participation in various health care fraud schemes that resulted in approximately $1.4 billion in alleged losses. In addition, CMS took administrative action against 28 providers on behalf of Medicare beneficiaries and to protect the Medicare Trust Fund.

Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Initiatives

DME suppliers historically have posed a high risk of fraud and CMS has undertaken an aggressive strategy to address this risk. In FY 2021, our activities included DME investigations, which included reviews of suppliers and physicians identified as potentially suspicious or high

risk. CPI implemented a national investigative strategy and took administrative actions against referring providers associated with DOJ's 2019 national DME takedown known as Operation Brace Yourself (OBY).[20]

Outreach and Education

CMS's provider education and outreach helps reduce the Medicare improper payment rate by giving Medicare providers the timely and accurate information they need to bill correctly the first time.

The Medicare FFS claims processing contractors, known as MACs, educate Medicare providers and suppliers about Medicare policies and procedures, including local coverage policies, significant changes to the Medicare program, and issues identified through review of provider inquiries, claim submission errors, medical review data, and Comprehensive Error Rate Testing program data. The MACs use a variety of strategies and communication channels to offer Medicare providers and suppliers a broad spectrum of information about the Medicare program.

CMS continues to work with providers and suppliers, states, and others to protect CMS programs from fraud, waste, and abuse schemes. CMS is focused on safeguarding programs and protecting beneficiaries from fraud, waste, and abuse, while also working to minimize unnecessary provider burden. Providing education and training opportunities in ways that explain how to avoid improper payments and also alert stakeholders to fraud, waste and abuse schemes protect the financial security of CMS's programs by reducing improper payments and curtailing emerging fraud schemes. By offering regular in-person and virtual events and trainings, as well as clear and concise information online, CMS continues to provide needed information that is responsive to the realities of clinical practice.

Proactively Manage Provider Screening and Enrollment

Provider enrollment is the gateway to the Medicare and Medicaid programs and is the key to preventing ineligible providers and suppliers from entering either program. CMS's role in the provider and supplier enrollment process differs between the Medicare and Medicaid programs. CMS directly administers Medicare and oversees the provider enrollment and screening process for providers and suppliers participating in the Medicare FFS program. CMS uses provider and supplier enrollment information in a variety of ways, such as claims payment and fraud prevention programs. States directly oversee the provider screening and enrollment process for their Medicaid programs, and CMS provides regulatory guidance and technical assistance to states. CMS is committed to maintaining operational excellence in its provider enrollment and screening process. Through provider screening and enrollment, CMS continues to prevent and reduce fraud, waste, and abuse in the Medicare program and ensure that only eligible providers are caring for beneficiaries and receiving payment. CMS also works with states to support

[20] https://www.justice.gov/opa/pr/federal-indictments-and-law-enforcement-actions-one-largest-health-care-fraud-schemes.

proper enrollment and accurate billing practices to detect and combat fraud, waste, and abuse in their Medicaid programs.

Medicare Provider Screening and Site Visits

CMS regulations establish three levels of provider and supplier enrollment risk-based screening: "limited," "moderate," and "high," and each provider and supplier specialty category is assigned to one of these three screening levels. Providers and suppliers designated in the "limited" risk category undergo verification of licensure and a wide range of database checks to ensure compliance with all provider- or supplier-specific requirements. Providers and suppliers designated in the "moderate" risk category are subject to unannounced site visits in addition to all the requirements in the "limited" screening level, and providers and suppliers in the "high" risk category are subject to fingerprint-based criminal background checks (FCBCs) in addition to all of the requirements in the "limited" and "moderate" screening levels. In FY 2021, FCBCs were paused due to the COVID-19 public health emergency (PHE). CMS anticipates resuming FCBC in FY 2022, although the PHE remains in effect.

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 2021, APS utilization resulted in more than 7,700,000 screenings. These screenings generated more than 29,000 potential licensure alerts, and more than 3,000 criminal alerts for potentially fraudulent providers and suppliers for further review by CMS. APS review resulted in approximately 94 criminal revocations, 230 licensure revocations, and 46 licensure deactivations.

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. This work resulted in about 225 revocations due to non-operational site visit determinations for all providers and suppliers.

CMS's provider screening and enrollment initiatives in Medicare have had a significant impact on removing ineligible providers and suppliers from the program. In FY 2021, CMS deactivated approximately 123,000 enrollments and revoked 2,290 enrollments. Site visits, revalidation, and other initiatives have contributed to the deactivation[21] and revocation[22] of more than one million enrollment records since FY 2012, when CMS started implementing these screening and enrollment requirements.

Provider Enrollment, Chain and Ownership System (PECOS)

PECOS is the system of record for all Medicare Provider/Supplier enrollment data, which

[21] 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.

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

includes Part A, Part B, and DME. It is the Internet-based system that providers and suppliers use to enroll, revalidate, or update their enrollment information in the Medicare FFS program. PECOS stores all information furnished by providers and suppliers; tracks all enrollment processing and the results of MAC evaluation; and provides feeds to FFS claims payment systems, which are used in processing all claims. Medicare FFS claims processing cannot occur without provider/supplier enrollment information from PECOS. All provider/supplier updates and validations, both systematic and those performed manually by MACs, are stored and sent by PECOS. It is integrated with and supports multiple enterprise systems and CMS operations for the Merit-Based Incentive Payment System (MIPS), demonstrations and model tests, and DMEPOS competitive bidding, providing direct access to information on the relationships between individuals and organizations stored in enrollment records. PECOS is a critical part of CMS's program integrity strategy and is used along with the APS, as a data source by the FPS and many other program integrity partners, including the UPICs, Recovery Audit Program, the HHS-OIG, and state program integrity programs.

PECOS is the source for vetting CMS's Accountable Care Organization programs and models and provides information that is used as a primary factor to determine program and model eligibility. PECOS supports data transparency through interfacing with programs such as Open Payments, Physician Compare, and Nursing Home Compare and also supports CMS data management initiatives through Master Data Management (MDM), Unified Case Management (UCM), Pricing, Data Analysis and Coding (PDAC), One PI, Integrated Data Repository (IDR), Health Information Technology for Economic and Clinical Health (HITECH), and other data analysis teams. State Medicaid programs also rely on data-sharing efforts to support requirements for screening providers and suppliers. CMS is focused on transitioning PECOS to a modernized, enterprise resource that is a platform for all provider/supplier enrollments across Medicare, Medicaid, and other CMS programs. This single platform is intended to allow streamlining and consistency in user workflows and standardize interfaces with systems internal and external to CMS.

In FY 2021, CMS made significant changes to PECOS to simplify access, improve usability and enhance the security of the system, including the following changes:

- Updated PECOS to support the integration of new site visit contractor's data, including DME site visits;
- Made enhancements to the State Medicare Report to allow state Medicaid agencies to easily access Medicare screening and revalidation information;
- Implemented Home Infusion Therapy as a new supplier type and incorporated necessary extract changes related to the supplier type;
- Updated PECOS to include two new physician specialties—Micrographic Dermatologic Surgery (MDS) and Adult Congenital Heart Disease (ACHD);
- Implemented necessary changes to support provider enrollment using waivers and flexibilities during the PHE;
- Implemented the enhancements necessary to ensure all Part B CMS-588 Electronic Funds Transfer (EFT) data that flows to the claims system comes directly from PECOS;

- Continued enhancing and streamlining the PECOS interface to better assist providers with application submission and MACs in processing Medicare applications;
- Implemented enhancements to the APS and Unified Global Extract (UGE) files by adding additional data elements to serve stakeholder needs better;
- Cleaned up the Death Master File (DMF) and Medicare Exclusion Database (MED) data and implemented process improvements for data quality and fraudulent claims prevention;
- Added geolocation information for the practice location addressees to support access to care analysis for provider appeals process, and
- Established a disaster recovery process using the Disaster Recovery as a Service (DRaaS). This provides the PECOS system the ability to failover and failback for all three PECOS environments (Development, Validation, and Production).

Medicaid Screening and Enrollment

As part of its oversight role in Medicaid, CMS works closely with state Medicaid agencies (SMAs) to provide regulatory guidance, technical assistance, and other support with respect to provider screening and enrollment. SMAs can comply with federally required Medicaid screening and enrollment requirements by using CMS's Medicare screening results for dually-enrolling providers, eliminating the need and burden associated with states re-screening such applicants. States may use Medicare screening data, including site visits, payment of application fees, and FCBCs. For Medicaid-only FFS providers, SMAs must at a minimum follow the same risk-based screening procedures as required for Medicare's screening and enrollment process.

During FY 2021, CMS continued to expand its efforts to assist states with meeting Medicaid screening and enrollment requirements. These efforts include enhanced sharing of Medicare enrollment and screening data with states, enhancing the data compare service to help states identify providers for which the state is able to rely on Medicare's screening, providing technical assistance to states through individual state calls, publishing additional guidance in the Medicaid Provider Enrollment Compendium (MPEC), continuing monthly Technical Assistance Group (TAG) calls, and establishing a TAG call dedicated solely to screening and enrolling Medicaid managed care network providers.

CMS shares the Medicare provider enrollment record via the PECOS administrative interface and in bulk data extracts from PECOS. Additionally, CMS launched the PECOS States' page in January 2017, and included provider enrollment information such as Medicare enrollment status, site visit information, fingerprint results, ownership information, Medicare risk levels, and more. Since May 2016, CMS has offered the data compare service that more easily enables a state to rely on Medicare's screening, in lieu of conducting state screening. Using the data compare service, a state provides an extract of its actively enrolled provider population to CMS and then CMS returns information to the state indicating for which providers the state is able to rely on Medicare's screening. CMS has made enhancements to this service, which include tailoring the type of comparison to meet a state's specific needs (for example, supplying provider ownership information reported to Medicare, practice location information, deactivated National Provider Identifiers (NPIs) and deceased providers). In FY 2018, CMS launched the Data Exchange (DEX) system, which is used to share data among CMS and the separate Medicaid programs of

every state. This system stores all state-submitted for cause terminations as well as all Medicare revocations, and HHS-OIG exclusion data, and enhances collaboration, improves reporting, and creates transparency through this process. In FY 2021, CMS continued the Medicaid screening pilot process, that began with Iowa and Missouri, to screen Medicaid-only providers through its APS system on behalf of states and produce a report of providers with licensure issues, criminal activity, and Do Not Pay activity. CMS believes centralizing this process will improve efficiency and coordination across Medicare and Medicaid, reduce state and provider burden, and addresses one of the biggest sources of error as measured by the Payment Error Rate Measurement (PERM) program today. In 2021, CMS continued to expand the pilot to other states. Currently, Oklahoma, Nevada, North Dakota, Tennessee, Colorado, Rhode Island, Oregon, and West Virginia are participating in the pilot and CMS continues to work with other states to gauge their interest.

CMS provides ongoing guidance, education, and outreach through targeted technical assistance to states on federal requirements for Medicaid screening and enrollment. In addition, CMS continues to publish updates to the Medicaid Provider Enrollment Compendium (MPEC), which is sub-regulatory guidance designed to assist states in applying certain regulatory requirements. The latest update published in March 2021 clarified Medicaid screening and enrollment policies and procedures for the state Medicaid agencies.[23]

Medical Review

- Accuracy reviews
  CMS uses the Medical Review Accuracy Contractor (MRAC) to conduct medical reviews of claim determinations made by the Medicare Medical Review Contractors (MRCs). MRCs include the MACs, UPICs, and the Supplemental Medical Review Contractor (SMRC). In 2021, the MRAC also assisted with measuring the accuracy of medical review conducted by the RACs while a procurement for the RAC Validation Contractor (RVC) was underway. The MRAC helps CMS by measuring the accuracy rate for each contractor, to ensure the contractors are consistent in their medical review decisions, and feeds information into the Award Fee Component for the MACs to determine where policy/issues/medical review inconsistencies may be present. CMS performs a number of accuracy reviews using its own clinicians; however, the MRAC is able to complete more accuracy reviews and provides additional analysis to CMS.

- Prior Authorization
  In a final rule, CMS established an initial Master List of certain DMEPOS that are frequently subject to unnecessary utilization and established a prior authorization process for these items.

  In FY 2021, CMS continued the prior authorization of certain DMEPOS items. CMS requires prior authorization as a condition of payment on 40 power mobility device codes and five pressure reducing support service codes. Beginning on September 1, 2020, prior

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

authorization of six lower limb prosthetic codes were required in California, Michigan, Pennsylvania, and Texas. Prior authorization for these codes expanded nationwide on December 1, 2020.[24] The DME MACs review requests for prior authorization for the noted items, communicate decisions with suppliers and physicians, and provide ongoing education and customer service.

In FY 2020, CMS finalized a regulation through the Calendar Year 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS-1717-FC) establishing a nationwide prior authorization process and requirements for certain hospital outpatient services that demonstrate significant increases in volume. Beginning July 1, 2020, CMS required prior authorization for the following services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation. In FY 2021, as part of the Calendar Year 2021 Outpatient Prospective Payment System/Ambulatory Surgical Center Final Rule (CMS -1736-FC), CMS added cervical fusion with disc removal and implanted spinal neurostimulators to the prior authorization process effective July 1, 2021. This process serves as a method for controlling unnecessary increases in the volume of these services. The MACs review requests for prior authorization for the noted services, communicate decisions to providers, and provide ongoing education and customer service.

- Comparative Billing Reports
  Comparative Billing Reports (CBRs) are educational tools providers can use to support efforts to protect the Medicare Trust Fund. These reports compare an individual provider or supplier's billing and/or prescribing practices for a specific billing code, policy group, or service with the billing and/or prescribing practices of that provider's or supplier's peers in the same state and/or specialty, and national averages. CBRs inform providers about Medicare coding, billing, and coverage guidelines and strategies for implementing self-audit processes into their practices, where appropriate. Currently, CBRs are available for download by the provider or supplier on a secure electronic portal as well as mailed in full via postal mail. Since 2011, CBRs have been issued on topics such as physical therapy, opioids, and orthoses claims. Typically, CBRs are sent to approximately 5,000 outlier providers per topic based on data analysis for a defined period of time. Topics are based on Government Accountability Office (GAO) and HHS-OIG reports, Comprehensive Error Rate Testing program findings, and agency and contractor data analysis. A CBR does not necessarily indicate improper billing and/or prescribing by the provider and only in select instances are providers and suppliers referred for additional review or education. In FY 2021, CMS issued a total of eleven CBRs on nine unique topics areas including critical care, comprehensive eye examinations, chronic care management, and wound debridement.

[24] Prior authorization for these lower limb prosthetic codes was originally scheduled to begin in California, Michigan, Pennsylvania, and Texas on May 11, 2020, and nationwide on October 8, 2020; however, CMS temporarily delayed implementation due to the COVID-19 PHE.

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, the Medicaid and CHIP Business Information Solution (MACBIS) initiative will improve the ability of CMS and states to gather and analyze data that will support program integrity activities. MACBIS is a CMS enterprise-wide initiative providing products and services to modernize and transform information and data exchanges with states and other key stakeholders aimed at improving monitoring, oversight, evaluation, and inspect program integrity of the overall Medicaid and CHIP programs. MACBIS provides program, operational (such as T-MSIS), financial, pharmacy, quality, and business performance data to key stakeholders to assist in preventing fraud, waste, and abuse.

HCFAC funding also supports the preparation and dissemination of educational toolkits for states to use to enhance awareness of Medicaid fraud, waste, and abuse among providers, beneficiaries, managed care organizations, and others. States participate in and receive support and technical assistance and education from CMS through:

- Medicaid Technical Advisory Groups,
- Voluntary state assistance site visits for technical assistance and education,
- Webinars,
- Medicaid Integrity Institute (MII),
- Provider screening and enrollment strategies,
- Onsite/virtual focused program integrity reviews,
- Provider audits and investigations through the five UPICs,
- Desk reviews of state processes and procedures, and
- Payment Error Rate Measurement (PERM) corrective action plan and Medicaid Eligibility Quality Control (MEQC) oversight

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

<u>Health and Welfare Special Review Teams</u>
The Health and Welfare Special Review Teams (H&W SRT) project began in late September 2018 and has historically been performed with the assistance of a contractor. The purpose of this project is to ensure that state quality monitoring methodologies are efficiently and effectively preventing, detecting, and remediating all instances of abuse and/or neglect to beneficiaries in home and community-based settings, including group homes and assisted living programs. The H&W SRT is in the process of analyzing all statewide Home and Community-Based Services (HCBS) data available for all states to identify states to receive onsite or virtual reviews.

As of August 2021, 10 reviews had been conducted, including onsite reviews in Ohio, Massachusetts, Maryland, Oregon, the District of Columbia, California, Nebraska, West Virginia, Montana, and a virtual review for Maine. In January 2021, CMS began transitioning

these activities from the contractor to CMCS staff. As of October 2021, these activities are now performed entirely by CMS.

State Audit Compliance and Financial Management Oversight

The State Audit Compliance and Financial Management Oversight projects began in September 2020. The purpose of these projects is to acquire contractor assistance for two separate efforts. The first is to perform data analysis, collection, and evaluation, including the use of statistical sampling techniques, to review data provided by states related to payments to health care providers to determine if Medicaid claims submitted by states for federal financial participation (FFP) are allowable under federal guidelines. As a whole, this work supports the overall responsibility of CMS to ensure that all claimed expenditures meet statutory and regulatory requirements and are appropriate for the Medicaid program to provide efficient review of activities relating to the performance of Financial Management Reviews (FMRs). The second effort will develop, implement, and align measures that improve CMS' approach to the annual OMB single state agency (SSA) audit and identify opportunities to optimize the compliance supplement that guides single state auditors as they review state Medicaid and CHIP programs. This project will also improve the analysis of the findings resulting from SSA and HHS-OIG audits of state Medicaid and CHIP programs to assist CMS in better identifying high risk policy areas. CMS is actively engaged with contractors on both of these initiatives and anticipates continued contractor engagement in these areas through FY 2023.

Medicaid Enterprise System

State Medicaid agencies develop, implement, operate and maintain information technology systems to support their program operations. The systems generally include eligibility and enrollment, managed care payment, encounter data and/or claims processing, pharmacy management, etc. These systems work in concert with one another and must adhere to federal regulation[25] and guidance, including the Medicaid Information Technology Architecture (MITA) framework, several standards and conditions,[26] 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 independent technical assistance to states with respect to IT and policy requirements, including monitoring and oversight, working with state-specific system requirements, IT system builds, and associated interfaces for all states and the territories. Required technical artifacts are analyzed and tracked to assess state progress. CMS State

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

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

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 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 is working to release updated Medicaid Enterprise Systems (MES) Certification guidance to ensure a more comprehensive analysis of CMS funded state systems functionality. Moving forward, CMS is focused on increasing accountability and state flexibility by creating an outcomes-based oversight model for state systems certification. This approach will focus on producing timely and accurate claims payment results, properly screening and enrolling providers, member management, and comprehensive data analytics and reporting capabilities including timely and accurate submissions of required federal reporting such as T-MSIS.

Improper Payment Rate Measurement and Increased Accountability in Medicaid and CHIP Programs

The Payment Integrity Information Act of 2019 requires each agency to periodically review programs it administers and identify programs that may be susceptible to significant improper payments. For those programs determined to be susceptible, the agency is required to estimate the amount of improper payments, submit those estimates to Congress, and report on actions the agency is taking to reduce improper payments. The Medicaid and CHIP programs have been identified as being at risk for significant improper payments. CMS estimates improper payment rates in Medicaid and CHIP through the PERM program. The improper payment rates are based on reviews of the FFS, managed care, and eligibility components of Medicaid and CHIP in the year under review. CMS measures Medicaid and CHIP improper payment rates using a 17-state rotation so that each state is reviewed once every three years. States are required to submit corrective action plans to CMS to address the root causes of errors and deficiencies in an effort to reduce improper payments.

In the HHS FY 2021 Agency Financial Report (AFR),[27] CMS reported the national Medicaid improper payment rate based on measurements conducted in FYs 2019, 2020, and 2021. The FY 2021 national Medicaid improper payment rate was 21.69 percent, representing $98.72 billion in gross federal improper payments. The FY 2021 national Medicaid improper payment rates by component are 13.90 percent for Medicaid FFS, 0.04 percent for Medicaid managed care, and 16.62 percent for Medicaid eligibility. The FY 2021 national CHIP improper payment rate was 31.84 percent, representing $5.37 billion in gross federal improper payments. The FY 2021

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

national CHIP improper payment rates by component are 13.67 percent for CHIP FFS, 0.48 percent for CHIP managed care, and 28.71 percent for CHIP eligibility.

The majority of Medicaid and CHIP improper payments are a result of eligibility errors discovered through the reintegration of the PERM eligibility component. A federal contractor[28] conducts the eligibility measurement, allowing for consistent insight into the accuracy of Medicaid and CHIP eligibility determinations and increased oversight of identified vulnerabilities. Based on the measurement of all three cycles of states, eligibility errors are mostly due to insufficient documentation to verify eligibility or non-compliance with eligibility redetermination requirements. The majority of the insufficient documentation errors represent both situations where:

- The required verification was not done at all, and
- There is indication that the eligibility verification was initiated but there was no documentation to validate the verification process was completed.

These insufficient documentation situations are related primarily to income verification.

A smaller portion of improper payments are considered a known monetary loss to the program, which are claims where CMS has sufficient information to determine that Medicaid payment should not have occurred or should have been made in a different amount.

The CHIP improper payment rate was also driven by claims where the beneficiary was inappropriately deemed eligible for CHIP, but was eligible for Medicaid, mostly related to beneficiary income, third party insurance, or household composition/tax filer status. Additionally, state non-compliance with provider screening, revalidation, enrollment, and NPI requirements is a major contributor to the Medicaid and CHIP improper payment rates.

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

Additional information on the Medicaid and CHIP improper payments can be found in the FY 2021 Agency Financial Report[29] and CMS websites.[30]

Medical Loss Ratio Examinations

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

[28] Prior to FY 2014, the eligibility component was reviewed and self-reported by the states to CMS for national improper payment reporting.
[29] https://www.hhs.gov/about/agencies/asfr/finance/financial-policy-library/agency-financial-reports/index.html
[30] https://www.cms.gov/ImproperPayments

Medicaid managed care population, and this review is currently ongoing.

Medicaid 1115 Financial Oversight

Medicaid section 1115 demonstrations are an increasingly important vehicle for state innovation in Medicaid program development, expansion and financing. Forty-seven states and the District of Columbia operate at least one section 1115 demonstration, and there are approximately 80 active demonstrations representing estimated federal outlays of $192.8 billion in FY 2021. The Medicaid section 1115 demonstration portfolio continues to grow in number, federal outlays, and policy importance and complexity. CMS has committed additional staff and reorganized section 1115 demonstration work to develop and implement a more robust approach to monitor and oversee these demonstrations.

CMS is exploring refinements to its section 1115 demonstration budget neutrality policy to assure fiscal integrity and to better accommodate certain investments through the use of section 1115 expenditure authority to strengthen the provider safety net and make advancements in closing health disparity gaps. The goal is to develop a budget neutrality policy that can adapt to real-world factors and maintain a balance between integrity and flexibility.[31] In addition, to strengthen the review of state-submitted quarterly budget neutrality performance reports, CMS has developed and continues to maintain a standardized budget neutrality reporting tool for states that will need to be updated for any modifications to budget neutrality policy.

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

Beyond budget neutrality, CMS continues to expand and make more robust its oversight of the integrity of demonstration implementations. This has included the continued training on and implementation of standard operating procedures, as well as continuing to utilize user feedback to make updates and refinements to PMDA to strengthen internal controls and development of standardized reports that permit more efficient and meaningful review of demonstration performance relative to expectations established in the demonstration special terms and conditions. Relatedly, CMS continues to provide technical assistance to states to assure they understand and implement these more robust monitoring standards.

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

[31] https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/smd18009.pdf

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

The Rate Review and Fiscal Integrity Project improves the efficiency and effectiveness of rate setting oversight and financial reporting for the Programs of All-inclusive Care for the Elderly (PACE), and HCBS waiver and state plan programs. Project tasks include rate methodology review and analysis, data compilation, electronic visit verification system (EVV) required for personal care services and home health care services under Medicaid, and health and welfare activities to help states prevent fraud, waste and abuse monitoring and education and training for states and CMS staff. Specifically, this includes:

- Ensuring that states are compliant with the HCBS assurances as described in section 1915(c) of the Social Security Act;
- Analyzing current state section 1915(c) payment and financing trends, impacts to section 1915(c) programs resulting from the COVID-19 PHE, and waiver program updates to strengthen and enhance access to section 1915(c) waiver services;
- Providing education and training related to financial accountability, rate development, EVV systems, and incident management systems;
- Assessing state compliance with EVV implementation requirements outlined in section 12006 of the 21st Century Cures Act (Cures Act); and
- Conducting environmental scans of states' incident management systems to identify methods to detect unreported incidents and methods for monitoring the health and safety of Medicaid participants.

A new contract was executed to continue tasks within this project on September 30, 2020. From October 1, 2020, to August 15, 2021, CMS completed 137 reviews of HCBS waivers for 38 states and compiled reports with findings pertaining to the waivers' fiscal and quality components for each. Findings from fiscal and quality reviews are aggregated in an annual report each year, which helps inform technical assistance activities and guide program improvements. CMS also conducted 28 PACE reviews during this period, spanning 25 states.

Since October 1, 2020, eleven presentations have been completed and made available to state staff via technical assistance calls and web posting. They cover topics such as trends in HCBS waiver program financing, the role of family caregivers in HCBS, billing validation and oversight with EVV and findings and recommendations from the CMS survey of states' incident management systems for HCBS waivers.

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.

Plan Program Integrity Medicare Drug Integrity Contractor (PPI MEDIC) and Investigations MEDIC (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), known as

the Plan Program Integrity Medicare Drug Integrity Contractor (PPI MEDIC) and the Investigations Medicare Drug Integrity Contractor (I-MEDIC). The PPI MEDIC has a national focus related to plan oversight pertaining to the following Part C and Part D program integrity initiatives: identification of program vulnerabilities, data analysis, health plan audits, outreach/ education, and law enforcement support, which includes requests for information (RFI). As a result of the PPI MEDIC's data analysis projects and Part D plan sponsor self-audits, $8.68 million was recovered from Part D sponsors in the first nine months of FY 2021. The primary purpose of the I-MEDIC is to detect, prevent, and proactively deter fraud, waste, and abuse for high-risk prescribers/pharmacies in Medicare Part C and Part D by focusing primarily on complaint intake and response, data analysis, investigative activities, referrals to law enforcement partners, and law enforcement support, which includes RFIs. In FY 2021, the I-MEDIC initiated 764 investigations; submitted 20 recommendations for provider revocations; submitted 251 referrals to law enforcement, including 56 immediate advisements; and submitted 185 referrals to other entities, such as state pharmacy and medical boards, Medicare quality improvement organizations, and other Medicare contractors.

Medicare Parts C and D Marketing Oversight

Each year CMS analyzes Annual Notice of Change (ANOC) documents and takes compliance action against Part C Plans, also known as Medicare Advantage Organizations (MAOs), Part D Prescription Drug Plans (PDPs), Section 1876 Cost Plans, and Medicare-Medicaid Plans (MMPs) that fail to send timely and accurate ANOC documents to Medicare enrollees. The ANOC provides Medicare enrollees with vital information that can affect their ability to make informed choices concerning their Medicare health care and prescription drug options.

Program Audits

CMS conducts program audits of Parts C and D plan sponsors (including organizations offering Medicare-Medicaid Plans) and PACE organizations to evaluate their delivery of health care services and medications to beneficiaries. In order to conduct a comprehensive audit of a sponsor's operation and maximize CMS's resources, scheduled Parts C and D program audits in 2021, as well as in prior years, occur at the parent organization level, though PACE audits are conducted at the contract level.

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

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

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

Compliance and Enforcement

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

- CMPs;
- Intermediate sanctions (i.e., suspension of marketing, enrollment, payment); and
- CMS initiated contract terminations.

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

- Substantially failing to comply with program and/or contract requirements,
- Performance under a contract with CMS in a manner that is inconsistent with the efficient and effective administration of the Medicare Part C and Part D program requirements, and
- Failure to substantially meet the applicable conditions of the Medicare Part C and D program.

Part C Benefits Review Activities

Each year, CMS requires Part C organizations to submit bids and plan benefit packages detailing how their Part C plans will provide coverage to beneficiaries for the following year. MAOs submitted to CMS more than 6,900 Part C plan benefit packages on June 7, 2021 and project to cover more than 29.5 million enrollees in contract year 2022. Bid and plan benefit submissions are reviewed to ensure they do not discriminate against beneficiaries and comply with CMS regulations. Plan standards are established and communicated annually, and the following reviews are performed:

- Low Enrollment Plans—CMS evaluates existing Part C plans that have low total enrollment to make sure these plans are sustainable over time and protect beneficiaries from selecting a potentially unsustainable plan.

- Total Beneficiary Cost (TBC)—CMS evaluates increases in beneficiary cost sharing or decreases in plan benefits from one year to the next. This evaluation ensures beneficiaries receive value in their benefit package selection and protects them from large increases in out-of-pocket costs.

- Maximum Out of Pocket Costs (MOOP)—CMS conducts this review to examine the maximum out-of-pocket costs for enrollees in Part C and protect beneficiaries from very high out of pocket medical costs.

- Service Category Cost-Sharing Standards—CMS evaluates the cost-sharing that plans include in their bids and plan benefit packages to ensure the plans do not exceed established limits and are not discriminatory.

- Actuarial Equivalence—CMS reviews bids to make certain the estimated cost sharing presented in the bid is actuarially equivalent to the cost-sharing levels under FFS. CMS currently examines four categories for actuarial equivalence and this review helps guard against plans imposing discriminatory cost-sharing on beneficiaries.
- Supplemental Benefits—CMS conducts several reviews in this area, including a review of supplemental benefits that helps make sure that any optional supplemental benefits offered are of reasonable value, as well as a review to make certain the benefits are offered in a non-discriminatory fashion.

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

Encounter Data Processing System

CMS requires MAOs to submit encounter data for each item and service provided to MA plan enrollees. CMS established and maintains the Encounter Data System (EDS), which to date, has collected approximately 7 billion encounter data records (EDRs).

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

Beginning in CY 2015, CMS began to use encounter data as an additional source of diagnoses to risk adjust payments to MAOs. In CY 2016, CMS continued the transition and calculated risk scores using both Risk Adjustment Processing System (RAPS) and encounter data, with RAPS-based risk scores weighted at 90 percent and encounter data-based risk scores weighted at 10 percent. In CY 2019, CMS increased the use of encounter data for calculating risk scores with encounter data-based risk scores receiving a weight of 25 percent and RAPS-based risk scores a weight of 75 percent. In CY 2020, CMS continued the transition to using encounter data for risk adjustment and increased the weighting of encounter data-based risk scores to 50 percent and reduced the weighting of RAPS-based risk scores to 50 percent. For CY 2021, CMS finalized a new blend of 75 percent encounter data-based risk scores and 25 percent RAPS-based risk

scores. In CY 2022, CMS will calculate MAO risk scores using diagnoses entirely from encounter data and FFS data.

Encounter Data Oversight and Integrity Activities

Since complete and accurate encounter data are integral to risk adjustment payments and other uses of encounter data, CMS has developed an encounter data oversight and integrity plan to support efforts to ensure the completeness and accuracy of the MA data collected by CMS. This plan aligns with direction provided by the GAO and lays out an incremental approach to assess and drive encounter data submission and quality over multiple years. Major components of the plan include outreach, analysis, monitoring, and compliance of MAOs' encounter data submissions.

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

Each year, CMS publishes national improper payment rates for Medicare Part C and Part D in accordance with the Payment Integrity Information Act of 2019.

The Part C 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 2021 (CY 2019), the projected Part C improper payment estimate is 10.28 percent, representing $23.19 billion in improper payments. The Part C error rate estimate is not directly comparable to prior years because CMS refined the error rate calculation methodology as well as the denominator to only include Part C payments reviewed and at risk for diagnostic error. Prior to FY 2021, the Part C denominator methodology reflected total MA payments and included some payments that were non-risk adjusted or were based on a different model resulting in a reported error biased downward, or potentially understated.

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

- Contract-Level Risk Adjustment Data Validation (RADV) Audits: RADV audits are CMS's primary corrective action to recoup overpayments. RADV uses medical record review to verify the accuracy of enrollee diagnoses submitted by MA organizations for risk adjusted payment. CMS expects payment recovery will have a sentinel effect on risk adjustment data quality submitted by plans for payment because contract-level RADV audits increase the incentive for MA organizations to submit valid and accurate diagnosis information. Contract-level RADV audits also encourage MA organizations to self-identify, report, and return overpayments. In FY 2021, CMS completed the payment year (PY) 2014 RADV audit medical record review phase and the PY 2015 RADV audit

medical record submission phase. Due to COVID-19, CMS suspended the PY 2015 audit in March 2020 and resumed it in September 2020.

- Part C Plan Sponsor Audits: CMS conducts audits of Part C plan sponsors to reduce improper payments. The audits conducted during FY 2021 consisted of three program integrity audits, with the goal of educating Part C plan sponsors on issues of fraud, waste, and abuse.

- Training: CMS conducted training sessions for Medicare Part C and Part D sponsors on program integrity initiatives, investigations, data analyses, and potential fraud schemes. In FY 2021, CMS held Opioid Education Missions via webinar in December 2020 and May 2021. CMS also conducted an updated COVID-19 fraud, waste, and abuse webinar in February 2021 and an MA Organization and Prescription Drug Plan fraud, waste, and abuse webinar in August 2021.

The Part D gross improper payment estimate reported for FY 2021 (based on the 2019 payment year) was 1.58 percent or $1.37 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.

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

- Part D Plan Sponsor Audits: CMS conducts audits of Part D plan sponsors, with a focus on drugs that are at high risk of improper payments. Each type of audit is different in scope but with the same goal of educating Part D plan sponsors on issues of fraud, waste, and abuse, as well as identifying, reducing and recovering inappropriate payments under Part D. In FY 2021, CMS conducted 13 Part D audits.

- Training: In FY 2021, CMS continued national training sessions on payment and data submission with detailed instructions as part of the improper payment estimation process for Part D sponsors.

- CMS also conducted in-person training sessions for Medicare Part C and Part D sponsors on program integrity initiatives, investigations, data analysis, and potential fraud schemes. In FY 2021, CMS held Opioid Education Missions via webinar in December 2020 and May 2021. CMS also conducted an updated COVID-19 fraud, waste, and abuse webinar in February 2021 and a Medicare Advantage Organization and Prescription Drug Plan fraud, waste, and abuse webinar in August 2021.

- Outreach: CMS continued formal outreach to plan sponsors with respect to invalid or incomplete documentation. CMS distributed Final Findings Reports to all Part D

sponsors participating in the PDE review process. This report provided feedback on their submission and validation results against an aggregate of all participating plan sponsors.

Additional information on Medicare Part C and Part D improper payments can be found in the FY 2021 Agency Financial Report[32] and CMS website.[33]

CMS Exchange Program Integrity

The Federally-facilitated Exchanges (FFEs) and the State-based Exchanges (SBEs) continued to expand their focus on program integrity. In FY 2021, CMS triaged more than 15,000 complaints from consumers who alleged they were enrolled in FFE insurance policies without their consent or that incorrect information was submitted on an application by an insurance agent or broker, or that other misconduct had occurred. CMS worked with health insurance issuers to verify unauthorized enrollments and cancel over 6,000 fraudulent 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 dozens of investigations of outlier and high-risk agents and brokers, and referred egregious cases to HHS-OIG and state Departments of Insurance (DOI). CMS also performed license verifications to identify agents and brokers potentially noncompliant with states' licensure statutes and regulations and reported license non-compliance to the appropriate DOIs. When cases of agent and broker misconduct warranted it, CMS took administrative actions including blocking access to the FFE to prevent consumer harm, and suspending or terminating CMS's agreements with the agents and brokers. CMS also supported ongoing HHS-OIG and DOI investigations by fulfilling requests for records regarding consumer FFE enrollments and financial assistance, complaints, and results of CMS investigations. Thirty-two (32) such requests were received and fulfilled in FY 2021. Last, CMS hosted meetings with SBEs every other month to share best practices for identifying and deterring fraud and notifying SBEs of specific schemes and schemers being investigated by the FFE and/or one or more SBEs.

Following an FY 2016 risk assessment, HHS concluded the 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 FFE and anticipates reporting an improper payment estimate for the FFE in the FY 2022 AFR. HHS continues to develop the improper payment measurement methodology for the SBEs. As with similar HHS programs, developing an effective and efficient improper payment measurement program requires multiple time-intensive steps, including contractor procurement; developing measurement policies, procedures, and tools; and extensive pilot testing to ensure an accurate improper payment estimate.

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

Provide Greater Transparency into Program Integrity Issues within Medicare and Medicaid

CMS is dedicated to providing greater transparency into program integrity issues through education, outreach, partnership, strategic communications, and data releases. CMS is well-positioned to work with its partners and stakeholders to share 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 position itself as a leading body for the health care industry to reduce fraud, waste, and abuse by:

- Providing an unparalleled cross-payer data source, representing the full spectrum of the health care industry, to enable the performance of sophisticated data analytics and information-sharing for the benefit of all partners;
- Achieving meaningful participation by partners and establishing strategic collaborations with diverse stakeholders; and
- Leveraging HFPP resources and relationships to generate real-time, comprehensive approaches that materially impact efforts to reduce health care fraud, waste, and abuse.

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

In FY 2021, the HFPP reached a total membership level of 222 partner organizations, comprised of five federal agencies, 56 law enforcement agencies, 13 associations, 98 private payers, and 50 state and local partners.

The HFPP uses a diverse variety of approaches to identify vulnerabilities in Partner data. These methods include standard searches to detect anomalies that may implicate the existence of fraud, waste, and abuse; scanning of incoming claims information against existing data sets, such as lists of deactivated providers; creation of reference files that list providers that may be suspect based on known risks; and creation of informational content to support stakeholders in addressing vulnerabilities (e.g., white papers). The HFPP has also expanded its study methodology to collect frequently updated data, including, and consistent with all applicable privacy requirements, personally identifiable information (PII) and protected health information (PHI). The HFPP is currently using professional and institutional claims and has begun collecting pharmacy claims to be used in studies beginning in FY 2022.

Over 35 billion professional claim lines were submitted by partners through FY 2021 for the purpose of conducting cross-payer analyses, and the HFPP has commenced 13 studies during FY 2021 providing participating partners with detailed results that can be used for corrective actions

within their organizations. Examples of studies initiated in FY 2021 include the identification of problematic billing in the following areas:

- Self-care/home management training;
- Deactivated rendering providers;
- Sleep studies;
- Allergy services;
- Psychotherapy, physical therapy/occupational therapy improbable days; and
- COVID-19 add-on laboratory testing.

The HFPP also continued its efforts to foster collaboration among partners in FY 2021 by hosting five virtual information-sharing sessions and initiating a new Executive Board, that will meet quarterly. 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.

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 and teaching hospitals (collectively referred to as covered recipients). As of January 1, 2021, covered recipients also include physician assistants and advanced practice nurses. 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 this information, which is self-reported annually by reporting entities, on the public website, where the reported data can be searched, downloaded, and evaluated.

For Program Year 2020 (January 1, 2020-December 31, 2020), CMS published over $9.12 billion in payments and ownership and investment interests that were made from reporting entities to covered recipients. This amount is comprised of approximately 6.38 million total records attributable to 487,152 physicians and 1,213 teaching hospitals. Payments in the three major reporting categories included:

- $2.03 billion in general (i.e., non-research related) payments;
- $5.97 billion in research payments; and
- $1.12 billion of ownership or investment interests held by physicians or their immediate family members.

Over the past seven years, CMS has published a total of 78.55 million records, accounting for $53.01 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 2021, HHS allocated $20.0 million in HCFAC appropriations, plus an additional $35,621 in carryover funding from FY 2020 to the Administration for Community Living (ACL) to support SMP program infrastructure and provide grants to SMPs in 54 states and territories.

Until FY 2016, ACL received funding from a separate Congressional appropriation (the Older Americans Act) to support SMP grants. However, the Consolidated Appropriations Act of 2016 required the SMP program to be fully funded by CMS discretionary HCFAC appropriations beginning in FY 2016. This language was modified in FY 2018 to require that the program be funded at no less than $17.6 million, still from CMS discretionary HCFAC appropriations. In FY 2021, Congress increased the floor for SMP funding to $20.0 million from CMS discretionary HCFAC appropriations. In addition, Congress provided ACL, for the first time, with authority to be funded from CMS discretionary appropriations, wedge funding or both. Based on that authority, in FY 2021 ACL requested and received $2.0 million for a one-time effort supported by wedge funding to expand the virtual capacity of the program both nationally and at the state and local level.

SMP Project Activities and Outcomes

ACL uses the majority of its HCFAC allocation to fund SMP projects in every state, the District of Columbia, Puerto Rico, Guam, and the U.S. Virgin Islands. During FY 2018, ACL held a new SMP grant competition and awarded $15.5 million in funding to 54 SMPs nationwide, including eight new SMP grantees. In FY 2021, ACL provided continuation awards to the 54 grantees totaling $17.6 million. Each SMP grantee received a standard, base amount of funding to support the operation of their project, as well as an additional, variable amount of funding based on the number of Medicare beneficiaries residing in the state and the rural areas of the state. SMP projects use this funding to educate and empower Medicare beneficiaries to prevent, detect, and report Medicare fraud, errors, and abuse.

<u>COVID-19 Fraud Schemes</u>

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

Throughout this crisis, ACL has carefully recorded and analyzed complaint details nationally and prepared sanitized summary reports that are shared regularly with the SMP grantees, HHS-OIG, and CMS.

In addition, ACL, the HHS-OIG, and the SMP National Resource Center worked together on national level media campaigns to get the word out on COVID-19 related fraud schemes. The SMP National Resource Center developed, released, and continually updated COVID-19 Consumer Fraud Alerts focused on coronavirus fraud schemes occurring nationally in order to warn Medicare beneficiaries and their families to take precautions. These materials advise beneficiaries to be suspicious of strangers who offer unsolicited COVID-linked items, services, or testing. They also advise beneficiaries to be wary of scare tactics used to pressure them into taking action, and to be cautious about sharing their personal information, including their Medicare identification number. In addition, these materials warn that personal information could be used to fraudulently bill Medicare and Medicaid. Materials include consumer tip sheets on a variety of general and specific COVID-focused topics, Medicare coverage FAQs, six infographics, and three 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: 2020 Performance Data for the Senior Medicare Patrol Projects (OEI-02-21-00180)), the SMP projects conducted 350 group education events covering COVID-19 fraud issues in 2020, reaching a total of 11,775 people. In addition, they conducted 578 instances of media outreach on this topic, reaching an estimated 14.8 million people.

COVID-19 Toolkit for ACL Grantees

The SMP National Resource Center, in coordination with ACL, the State Health Insurance Assistance Program (SHIP) National Technical Assistance Center, the National Center for Benefits, Outreach, and Enrollment, and grantees from the SMP, SHIP, and Medicare Improvement for Patients and Providers Act (MIPPA) programs, worked together to prepare an all-encompassing toolkit of materials to support professionals across the aging network to work remotely during this pandemic. Over six months of workgroup meetings were held to brainstorm gaps in knowledge, compile subject matter expertise, prepare cohesive materials, and publish this essential set of materials. The goal of the resulting toolkit is to enhance existing solutions for safely serving the public under COVID-19, particularly during the busy Medicare Open Enrollment Period (October 15 - December 7). It contains successful practices, templates, and checklists created by ACL grantees, and includes sample guidelines for using technology to reach beneficiaries, delivering sensitive information safely, managing volunteers or staff working remotely, and more. Over 25 materials are included within this compendium of invaluable resources that supports the network to continue to reach our target audience despite pandemic-related limitations and challenges.

Genetic Testing Fraud Schemes

Genetic testing fraud continued to be a widespread issue nationally in FY 2021 with company representatives approaching seniors and other Medicare beneficiaries to solicit genetic tests at senior and community centers, health/senior fairs, other community events, and senior housing complexes. In mid-FY 2021, scammers started offering Medicare beneficiaries cardiac genetic testing (cardiogenetics) in order to obtain their Medicare information for fraudulent purposes.

The SMP grantees have received reports of company representatives going door-to-door in the community and within housing complexes in addition to extensive advertising on Facebook and other social media platforms. ACL and the SMP grantees continued to conduct targeted public education and outreach efforts on this topic during this period along with the HHS-OIG. The SMP projects conducted 641 group education events covering genetic testing fraud issues since early CY 2020; these events reached 24,443 people. In addition, they conducted 102 instances of media outreach on this topic, reaching 850,374 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 2020 (OEI-02-21-00180). In CY 2020, the SMP projects had a total of 5,720 active team members who conducted 9,870 group outreach and education events, reaching an estimated 425,103 people. In addition, the projects had 249,134 individual interactions with, or on behalf of, a Medicare beneficiary. For CY 2020, the SMP projects reported $16.8 million in expected Medicare recoveries. Cost avoidance totaled $53,768, while savings to beneficiaries and others totaled $33,554. Over half of these recoveries came from one project that uncovered a fraud scheme in which a provider paid beneficiaries to receive home health services that were never rendered. The provider then submitted fraudulent claims to Medicare for millions of dollars while also receiving illegal kickback payments from the home health agencies. The provider was sentenced and ordered to pay a total of $9.5 million in restitution and forfeitures. Another project reported nearly $5 million in expected Medicare recoveries after uncovering multiple statewide fraud schemes that involved enrolling beneficiaries in medically unnecessary hospice services. These services were often provided against the beneficiaries' wishes, and at times, interfered with their proper medical care and medications.

Since the SMP programs inception, the program has received more than 3.5 million inquiries from Medicare beneficiaries about preventing, detecting, and reporting billing errors, potential fraud, or other discrepancies. SMP projects have also educated more than 42.1 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 and 2021 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 $138.9 million in savings attributable to the SMP program since its inception in 1997.

SMP Infrastructure and Program Support

SMP Resource Center

During FY 2020, ACL competed and selected the Northeast Iowa Area Agency on Aging for a new five-year grant to serve as the SMP National Resource Center (the Center). In FY 2021, the Center received a continuation award totaling approximately $1.25 million. The Center has provided technical assistance, support, and training to the SMP projects since 2003. The goal of the Center is to provide professional expertise and technical support, serve as an accessible and responsive central source of information, maximize the effectiveness of the SMP projects in health care fraud outreach and education, and ensure a comprehensive national approach to reaching Medicare beneficiaries. The Center has also been instrumental in supporting ACL efforts to forge national visibility for the SMP program. Highlights of the SMP National Resource Center's planned work during the next five-year period include maintaining a new national SMP-focused mobile application, producing additional in-depth grantee resources and SMP Consumer Alerts as need arises, and acting as a clearinghouse for ACL on complex case data and referral information in emerging fraud trends.

SMP Information and Reporting System

Since FY 2016, ACL has supported a national SMP information and reporting system (SIRS) to support the evolving needs of the SMP projects. SIRS is expected to last at least 10 years and provides SMPs with advanced reporting features and data analytics to help them better manage their programs. In FY 2021, 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 SHIP/SMP National Beneficiary Satisfaction Survey contract. The goal of this contract, which entered Year 2 in FY 2021, is to ascertain the quality and effectiveness of the services provided by the SHIP and SMP program. The scope of the Beneficiary Surveys is to evaluate and measure satisfaction with SHIP and SMP educational presentations and Medicare one-on-one counseling sessions. The surveys assess how beneficiaries value the services and information they receive, identify opportunities for continuous improvement, and comply with regulatory requirements regarding data collection. The evaluation includes two types of surveys: (1) for individual counseling sessions with Medicare Beneficiaries, and (2) for individuals that attended an educational presentation. The results will create a baseline understanding of satisfaction with counseling services and educational presentations and identify opportunities for recognition as well as overall network improvements.

The first 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:

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

One-on-One Interactions:

- 4.25 – "SMP provided me with useful information"
- 4.30 – "Overall, I was satisfied with my interaction with SMP"
- 4.34 – "I would contact SMP again for assistance"
- 4.33 – "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 2021, HHS allocated the Office of the General Counsel (OGC) $7.4 million in HCFAC funding to support OGC's program integrity activities. Such activities focused on litigation aimed at the recovery of program funds and review of CMS programs to strengthen them against potential fraud, waste, and abuse. OGC's HCFAC activities in FY 2021 helped the Government establish over $ 1.08 billion in judgments, settlements, or other types of recoveries, savings, or receivables.

FCA and Qui Tam Actions

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

In FY 2021, 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 Records incentive programs, kickbacks and other unlawful marketing practices in connection with the marketing of EHR products, billing for grossly substandard skilled nursing services, and billing for rehabilitation therapy services that were not reasonable, necessary, or skilled. OGC efforts on these and other FCA matters in FY 2021 helped the Federal Government recover approximately $712.53 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' commitment to policing this area.

OGC obtained several favorable outcomes regarding the imposition of CMPs during FY 2021, a period during the core of the COVID-19 pandemic that has especially spotlighted health care facilities' response to infection control issues. OGC has advised CMS on numerous actions related to facilities' responses to infection outbreak and has also worked with CMS on nursing home enforcement actions involving infection control, including cases associated with COVID-19 and other pathogens. For example, OGC successfully defended CMS's determination of immediate jeopardy and its imposition of CMPs totaling $624,015 for a long-term care facility that failed to properly implement its infection control policy on COVID-19 surveillance and transmission prevention. The surveyors who inspected the facility discovered that staff had been systematically ignoring the facility's infection control protocols. Prior to the survey, an outbreak of COVID-19 in the facility resulted in the infection of 44 residents and the deaths of eight. The administrative law judge (ALJ) found that the evidence in the case overwhelmingly supported CMS's allegations of noncompliance and rejected the facility's due process argument that no specific regulatory requirements supported CMS's allegations. He found that the plain language of 42 C.F.R § 483.80 required facilities to design and implement infection control policies, and that it was broad enough to mandate a policy to protect residents from COVID-19. The ALJ also found that a determination of immediate jeopardy was appropriate because of the clear risk that COVID-19 posed to vulnerable residents and the staff's failure to properly wear masks.

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 2021, OGC successfully defended CMS's revocation of a physician's enrollment and its placement of the physician on the preclusion list. CMS, through its administrative contractor, informed the physician that it was initiating a Targeted Probe and Educate review after finding that he was in the top one percent of providers paid for certain CPT codes. Over the course of the three-round review, the physician repeatedly failed to submit acceptable documentation in response to letters requesting information to support his claims. The ALJ found that the physician engaged in a pattern or practice of submitting claims that did not meet Medicare requirements when he repeatedly failed to submit the required documentation. She also found

that CMS had a legitimate basis to revoke the physician's enrollment and billing privileges and to place him on its preclusion list.

Part C and Part D Compliance

During FY 2021, OGC provided extensive advice to CMS on a variety of Part C and Part D compliance issues, including identifying enforcement options against plan sponsors that were noncompliant or violated program rules. When challenged, OGC defends CMS's imposition of CMPs in administrative hearings and, in conjunction with DOJ, in federal court. OGC also continued its review of compliance-related correspondence that CMS issues to Part C plans and Part D sponsors, which include warning letters, imposition of corrective action plan letters, intermediate sanctions, CMP notices, and non-renewal or termination notices. OGC also defends CMS non-renewal or termination actions of Part C and Part D plan contracts.

Regulatory Review and Programmatic Advice

In FY 2021, OGC advised CMS on a variety of regulatory and program issues aimed at combating fraud and preventing the wrongful disbursement of program funds in the first instance. For example:

- To support CMS's response to the public health emergency related to the COVID-19 pandemic, OGC continues to provide counsel on a wide variety of topics in the context of Medicare, Medicaid, and CHIP. OGC has advised on issues related to section 1135 waivers, adjustments to permissible sites of care, Emergency Medical Treatment and Labor Act requirements, survey and certification processes, including enforcement and oversight policies, the applicability of the President's executive orders regarding vaccines for federal contractors, payment for certain ambulance services and ambulance-related waivers, provider/supplier enrollment, COVID-19 accelerated and advanced payments, debt recovery requirements, improper payment measurement processes, beneficiary incentives to receive a COVID-19 vaccine, and waivers of the Stark Law and other fraud and abuse requirements. OGC has provided expeditious responses to support the clearance of numerous rules that address the COVID-19 public health emergency.

- OGC continues to spend extensive time on various opioid-related issues, primarily related to potential CMS monetary recoveries stemming from other parties' settlements, judgments, and bankruptcy actions.

- OGC continues to counsel the CMS Quality, Safety, and Oversight Group (QSOG), formerly known as the Survey & Certification Group, which provides oversight and enforcement of certified institutional providers with program health and safety requirements intended to assure basic levels of quality and safety. OGC advises QSOG regarding the development of enforcement policies, authorities regarding various enforcement remedies such as CMPs and program termination, rulemaking, reviewing interpretive guidance, and administrative litigation issues.

- OGC reviewed several rules designed to improve Medicare program integrity, including proposed rules related to enrollment and medical review requirements.

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

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

Physician Self-Referral (Stark Law)

In FY 2021, OGC provided extensive counsel to CMS in its ongoing implementation of the Medicare Physician Self-Referral Disclosure Protocol, which was created to enable Medicare providers to self-disclose technical violations of the Stark law's physician self-referral prohibition. OGC continued to assist and advise CMS on its Stark reform efforts following its Final Rule, which went on display on November 20, 2020, modernizing and clarifying the Stark regulations. Further, OGC assisted CMS in its issuance of blanket waivers of sanctions under the Stark law for COVID-19 purposes, which action provides vital flexibility for physicians and providers in the fight against COVID-19. In addition, as discussed above, OGC continued to provide guidance to CMS and DOJ in navigating the complexities of the physician self-referral law in FCA cases. These consultations help build stronger cases and focus investigatory efforts, leading to successful results for the Government.

Medicare Secondary Payer

OGC's efforts to recover Medicare's conditional payments for which other payers bear primary payment responsibility directly support the HCFAC statutory goal of facilitating the enforcement of all applicable legal remedies for program fraud and abuse. As part of this work in FY 2021, OGC assisted DOJ in its efforts to protect federal Medicare and Medicaid interests in federal opioid lawsuits as HHS continues to find ways to abate the opioid epidemic.

Denial of Claims and Payments

CMS and its contractors engaged in various activities and initiatives to detect and prevent abusive and fraudulent billing practices. These measures included provider, supplier, and beneficiary education, use of claim sampling techniques, and rigorous scrutiny of claims with increased medical review. In FY 2021, OGC continued to play a major role in advising CMS regarding the development and implementation of these types of program integrity measures and in defending CMS in litigation brought by providers and suppliers challenging these efforts. For example, in *Hammad v. Azar*, the U.S. District Court for the Northern District of Florida affirmed a Medicare Appeals Council decision upholding the sampling methodology used in a post payment audit of a physician's Medicare claims. The ruling noted the physician had failed to show that another sampling methodology would have materially affected the calculation of the amount of overpayment.

Bankruptcy Litigation

OGC protects Medicare funds from waste in bankruptcy cases by asserting CMS recoupment rights to collect overpayments, arguing to continue suspension or termination actions against debtors, seeking adequate assurances from the bankruptcy court that CMS interests in the debtor's estate will be protected, arguing for the assumption of Medicare provider agreements as executory contracts, and petitioning for administrative costs where appropriate. OGC also handles change of ownership issues related to bankrupt Medicare providers to ensure successor financial liability and to protect patient health and safety. For example, in FY 2021, OGC handled several matters involving novel issues arising under the COVID-19 Advanced and Accelerated Payments (CAAP) program and bankruptcy. In one matter, when an Illinois hospital filed for bankruptcy under Chapter 11, it owed over $28.0 million in CAAP payments to CMS. However, CAAP statutory provisions prohibited recoupment of any part of the CAAP debt during the four-month period between the February 2021 petition date and the one-year anniversary of the CAAP payment in June 2021. OGC advised CMS regarding its ability to withhold Medicare payments for pre-petition services before the CAAP payment was due. Although CMS was prohibited by statute from demanding the payment of the balance due on the CAAP debt until November 2022, the parties voluntarily agreed to have the hospital repay the CAAP debt in full.

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 2021 that have upheld millions of dollars in disallowances.

In summary, OGC's efforts in FY 2021 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 2021, over $6.1 million in HCFAC funding was made available for the FDA Pharmaceutical Fraud Program (PFP). The PFP was instituted to enhance the health care fraud-related activities of FDA's Office of Criminal Investigations (OCI) and the Office of the General Counsel Food and Drug Division (OGC-FDD). OCI, with the support of OGC-FDD, investigates criminal violations of the Federal Food, Drug, and Cosmetic Act (FDCA), the Federal Anti-Tampering Act, and related federal statutes.

The PFP is designed to detect, prosecute, and prevent pharmaceutical, biologic, and medical device fraud. The PFP gathers information from sources inside and outside FDA and focuses on fraudulent marketing schemes, application fraud, clinical trial fraud, and flagrant manufacturing- related violations concerning biologics, drugs, and medical devices. The goal of the program is the early detection and prosecution of such fraudulent conduct. This furthers FDA's public health mission by protecting the public from potentially dangerous medical products, helping to reduce health care costs, in most cases before they are incurred, and deterring future violators. By initiating investigations of medical product fraud schemes earlier in their lifecycle, FDA is able to preclude potential public harm by barring medical products, which have not followed the legal FDA approval processes and do not meet FDA standards, from making it to market, saving valuable health care dollars from being spent.

The PFP has identified multiple alleged medical product fraud schemes through various avenues. Since the inception of the PFP, OCI has opened a total of 314 criminal HCFAC investigations. In FY 2021, OCI, through its PFP, opened 15 criminal investigations, including investigations involving drug compounders, clinical trials, and foreign and domestic medical-product manufacturers. FDA is committed to tackling emerging public health concerns. In FY 2021, the PFP has opened two COVID-19 related criminal investigations.

The investigations opened in FY 2021 consist of allegations involving:

- Application fraud, involving individuals or companies who may have submitted false or fraudulent information to FDA to obtain an approval or clearance; or who did not submit the required information to legally market or test drugs, devices, or biologics.

- Questionable manufacturing practices, involving the distribution of foreign-manufactured active pharmaceutical ingredients (APIs), drug compounding pharmacies, and biologic tissue products.

- Clinical trial fraud, involving possible falsification of study documents and/or fraudulent study subject enrollments. The investigations consist in part of individuals suspected of falsifying and/or manipulating clinical trial data or conducting clinical trials without FDA oversight.

- Fraudulent marketing schemes, involving the promotion of products through false or misleading claims, including for medical indications and stem cell biologic products.

As noted in previous reports, the types of criminal investigations conducted through the PFP are typically complex investigations, such as application fraud and marketing fraud, requiring extensive document review. It is not unusual for these complex fraud investigations to last for five years or more from initiation to conclusion. Yet investigations under the PFP have produced numerous prosecutions.

In October 2020, in the Eastern District of Kentucky, a compounding pharmacy and its owner entered into a plea agreement for unlawful wholesale distribution of prescription drugs. The

company unlawfully distributed unapproved new drugs as well as distributed prescription drugs without proper licensing. Sentencing included 36 months of probation, $20,100 in fines and $5,366,720 in asset forfeiture.

In January 2021, in the District of Utah, a pharmacist pled guilty to receiving misbranded chloroquine from China with the intent to sell the drug in the United States. The defendant imported over 50 kilograms of misbranded and mislabeled chloroquine labeled as "Boswellia Serrata Extract." Chloroquine was initially thought to provide some medical benefits for the treatment patients with COVID-19. In June 2020, the FDA revoked the Emergency Use Authorization of oral hydroxychloroquine sulfate and chloroquine phosphate for the treatment of COVID-19. The defendant was sentenced to three years of probation, a $10,000 fine and to pay for the destruction of the drugs.

In February 2021, in the District of Nevada, a drug manufacturer pled guilty to concealing and destroying records prior to an FDA plant inspection in India. The firm was sentenced to a criminal fine of $30,000,000 and forfeited an additional $20,000,000. The company also agreed to implement a compliance and ethics program to prevent, detect and correct violations of U.S. Law related to drug manufacturing.

In March 2021, in the Southern District of Florida, four individuals were charged for their roles in a scheme to falsify clinical trial data regarding an asthma medication. The clinical trial was designed to investigate the safety and efficacy of an asthma medication in children aged 4 to 11. Three of the defendants have been sentenced to 107 months confinement, 96 months of probation, $300.00 in fines, $455,214 in restitution, and $257,000 in forfeiture. The fourth defendant is awaiting trial.

In July 2021, in the District of Massachusetts, two defendants were re-sentenced after the First Circuit Court of Appeals affirmed the criminal convictions. The initial sentences were vacated. The defendants were sentenced in connection with a nationwide fungal meningitis outbreak that killed more than 100 patients and infected another 793 people. The former co-owner of the pharmacy was re-sentenced to 174 months in prison, ordered to forfeit $1.4 million and pay $82.0 million in restitution. The former supervisory pharmacist was re-sentenced to 126 months in prison, three years supervised release, ordered to pay forfeiture of approximately $473,584 and restitution of $82.0 million.

In August 2021, in the Southern District of Florida, two defendants were sentenced in connection with their participation in falsifying data related to clinical drug trials. The defendants pled guilty to falsifying data in connection with two clinical trials where they fabricated medical records to make it appear subjects were participating in the clinical trials when they were not. They were sentenced to a combined 76 months in prison and ordered to pay $2,134,503 in restitution.

The FDA believes that various investigations already initiated under the PFP may lead to future judicial action that may include criminal prosecution and monetary recoveries. These investigations include drug manufacturers and clinical investigators under investigation for data

integrity and other violations, which possibly pose a risk to the public's health and safety.

Finally, the FDA continues to train its employees and conduct outreach activities to maximize the agency's ability to prevent and detect fraud involving medical products. Due to the COVID-19 pandemic, FDA moved to a virtual training model to adapt to the needs of its workforce.

DEPARTMENT OF JUSTICE

United States Attorneys

The United States Attorneys were allocated $63.5 million in FY 2021 HCFAC funding for civil and criminal health care fraud enforcement efforts. These funds supported attorneys, paralegals, auditors, and investigators, as well as litigation expenses for health care fraud investigations and cases. The USAOs play a major role in health care fraud enforcement by bringing criminal and affirmative civil cases to recover funds wrongfully taken from the Medicare Trust Funds and other taxpayer-funded health care systems through fraud and false claims.

Criminal Prosecutions[34]

In FY 2021, the USAOs opened 831 new criminal health care fraud investigations and filed criminal charges in 462 cases involving 741 defendants. During that same time period, 312 defendants were convicted of health care fraud-related crimes.

Civil Matters and Cases[35]

In FY 2021, the USAOs opened 805 new civil health care fraud investigations and had 1,432 civil health care fraud matters pending at the end of the fiscal year.

The USAOs litigate the full spectrum of health care fraud matters, both independently and in partnership with the Civil and Criminal Divisions. USAOs receive many health care fraud referrals directly from investigative agencies and increasingly are developing cases in-house through data analytics. They also receive referrals through the filing of qui tam (or 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 sprawl across district borders and new schemes marketed to and taken up by providers nationwide.

Qui tam cases and other civil cases either are handled jointly with trial attorneys in the Civil Fraud Section or litigated independently by USAOs. 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 twelve areas across the country. Each Strike Force team consists of dedicated AUSAs and support personnel from the USAO, as well as from the Criminal Division.

[34] FY 2021 numbers are actual data through the end of September 2021. This data includes records classified with the primary 03G–Health Care Fraud program code.
[35] FY 2021 numbers are actual data through the end of September 2021. This data includes those records classified with the primary FRHC–Health Care Fraud civil code.

Since 2018, the USAOs for 10 federal districts in six states[36] have joined the Health Care Fraud Unit in the Criminal Division's Fraud Section (HCF Unit), as well as law enforcement partners at the FBI, HHS-OIG, and DEA, to form the ARPO Strike Force, a joint law enforcement effort to identify and investigate health care fraud schemes in the Appalachian region and surrounding areas, and to effectively and efficiently prosecute medical professionals and others involved in the illegal prescription and distribution of opioids.

In addition, the USAO allocation supports AUSAs in eleven districts under the Opioid Fraud and Abuse Detection Unit (OFAD) program. OFAD focuses specifically on opioid-related health care fraud using data to identify and prosecute individuals that are contributing to the prescription opioid epidemic.

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

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

Examples of successful health care fraud cases are discussed above, but notably USAOs are handling complex, resource-intensive cases involving a number of emerging trends including:

- Multi-district telehealth lab and DME schemes;
- EHR kickback and other schemes;
- Medicare Part C fraud involving the manipulation of diagnosis codes of millions of beneficiaries;
- Sophisticated kickback and other fraud schemes involving complex ownership structures of healthcare entities, including by private equity and real estate investment vehicles;
- Nationwide investigations of alleged Controlled Substances Act violations by pharmacy chains; and
- Pharmaceutical pricing cases brought under the FCA and AKS based on allegations of price-fixing and market allocation in the generic pharmaceutical industry.

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

In addition to funding attorneys, auditors, paralegals and investigators, the Executive Office of the U.S. Attorneys (EOUSA) provides critical litigation support for these complex health care fraud investigations and litigation. EOUSA supports contract forensic investigators and auditors, as well as nurse consultants, who have been indispensable to the USAOs' success 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 the field, including the Special Investigation Resource and Intelligence System (SIRIS) Resource Center, which gives USAO personnel access to the NHCAA's SIRIS database.

In addition to managing national-level support, EOUSA provides districts with case-specific funding for litigation support for extraordinary needs. In FY 2021, HCFAC money funded more than 43 such requests from USAOs. This support pays for consultants in such highly technical areas as software experts in EHR cases, economic experts in pharmaceutical pricing cases, and medical consultants in highly paid specialties, and is indispensable to investigating and developing these complex cases.

To ensure a focused and coordinated approach to health care fraud enforcement, each USAO has designated criminal and civil health care fraud coordinators. These coordinators host working group and/or task force meetings within their districts, attended by federal investigative agencies, state MFCUs, private sector representatives and others. Coordinators also conduct training and outreach to a variety of audiences, including medical and hospital associations, the defense and relators' bar, and Medicare beneficiaries.

EOUSA also organizes extensive training for AUSAs, as well as paralegals, investigators, and auditors on a wide variety of health care fraud enforcement matters. Although in-person training was not possible in FY 2021, EOUSA presented numerous webinars throughout the year focused on emerging health care fraud issues.

Civil Division

The Civil Division received approximately $45.5 million in FY 2021 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 2021, the Fraud Section and the USAOs won or negotiated more than $5.0 billion in health care fraud settlements and judgments.[37]

[37] As stated earlier, the amount reported as won or negotiated only reflects the federal settlements and judgments and therefore does not reflect state Medicaid monies won or negotiated as part of any global federal-state settlements.

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 fraud schemes arising from the opioid epidemic, and significant resolutions during the past year included civil settlements with Indivior Solutions (Indivior), Purdue Pharma (Purdue), and the Sackler family. The Indivior civil matter resolved allegations associated with the marketing of the opioid-addiction-treatment drug Suboxone, including allegations that Indivior companies knowingly promoted the sale and use of Suboxone to physicians who were writing prescriptions that were not for a medically accepted indication and that lacked a legitimate medical purpose, were issued without any counseling or psychosocial support, were for uses that were unsafe, ineffective, and medically unnecessary, and were often diverted. The Purdue civil matter resolved allegations that the opioid manufacturer promoted its drugs to health care providers it knew were prescribing opioids for uses that were unsafe, ineffective, and medically unnecessary, and that often led to abuse and diversion, and further resolved allegations that Purdue engaged in three different kickbacks schemes to induce prescriptions of its opioids by paying kickbacks to doctors, an electronic health records company, and certain specialty pharmacies. As noted, Purdue incorporated the criminal and civil settlements into its plan of reorganization, but the district court subsequently reversed a bankruptcy court order confirming the plan and litigation over the plan continues. The Sackler matter resolved allegations that certain individual members of the Sackler family who were shareholders and board members of Purdue knew that the legitimate market for Purdue's opioids had contracted, but nevertheless requested that Purdue executives recapture lost sales and increase Purdue's share of the opioid market, including by approving a new marketing program through which Purdue sales representatives intensified their marketing of OxyContin to extreme, high-volume prescribers, causing health care providers to prescribe opioids for uses that were unsafe, ineffective, and medically unnecessary, and that often led to abuse and diversion.

The Fraud Section has also pursued 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 EHR technology vendor Athena paid unlawful kickbacks to generate sales of its EHR product. The Fraud Section also resolved allegations that generic pharmaceutical manufacturers Taro, Sandoz, and Apotex paid and received compensation prohibited by the AKS through arrangements on price, supply, and allocation of customers with other pharmaceutical manufacturers for certain generic drugs manufactured by the companies, resulting in higher drug prices for federal health care programs and beneficiaries. Other matters relating to AKS violations involved psychiatric hospitals and a substance use treatment facility (Oglethorpe), home health care agencies (BAYADA), hospitals (AGHS), pharmaceutical

companies (Biogen), diabetic supplies (Arriva), diagnostic testing (Alliance), and medical devices (MMSI).

As in years past, the Fraud Section also resolved a number of matters in which providers billed federal health care programs for medically unnecessary services or services not rendered as billed. Such matters involved allegations that providers, including a cardiologist, a psychiatric service provider, skilled nursing facilities, and hospitals billed for services that the patients did not need (such as the UM, Oglethorpe, SMMC, Sava, and SMRS matters discussed earlier). In addition, the Fraud Section continues to focus on inadequate care and on other fraud in nursing facilities, which provide care to a particularly vulnerable population (such as the Sava and SMRS matters discussed earlier).

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

Because the Fraud Section receives every FCA complaint filed by whistleblowers across the country, it has a unique vantage point over health care fraud trends and developments nationwide and therefore regularly handles some of the most complex matters and coordinates national investigations with its law enforcement partners. Likewise, given the diversity of health care fraud cases pursued by the Fraud Section, it frequently provides training and guidance on the FCA and health care fraud issues to AUSAs and agents. The Section works closely with HHS-OIG, including its Office of Counsel, in all settlements of health care fraud allegations to ensure that the administrative remedies possessed by HHS are appropriately considered and to enable the negotiation of compliance terms that diminish the risk that the offending conduct will be repeated. The Section also collaborates with and counsels HHS-OIG and CMS on interagency initiatives and proposed rules and regulations.

Finally, the Elder Justice Initiative, which is overseen by the Civil Division, coordinates and supports law enforcement efforts to combat elder abuse, neglect, and financial exploitation. The Initiative helps law enforcement efforts by maintaining an information bank of Elder Justice related materials (including briefs, opinions, indictments, plea agreements, and subpoena templates); funding medical reviewers, auditors, and other consultants to assist DOJ attorneys and AUSAs in their nursing home and/or long term care facility cases; hosting quarterly teleconferences with DOJ attorneys and AUSAs across the country to discuss issues or developments in connection with nursing home and failure of care cases; and coordinating

nationwide investigations of skilled nursing facilities. In addition to supporting law enforcement efforts, the Initiative continues to fund research projects awarded by the Office of Justice Programs, National Institute of Justice, to study the abuse, neglect, and exploitation of elderly individuals and residents of residential care facilities.

Elder Justice Initiative members represent the Department on Interagency Working Groups such as the Elder Justice Coordinating Council. The Civil Division also maintains the Elder Justice Website (www.elderjustice.gov), a valuable resource for elder abuse victims and their families, state and local prosecutors, elder abuse researchers, and practitioners.

The Consumer Protection Branch

The Consumer Protection Branch ("CPB" or "the Branch") enforces consumer protection laws to deter and punish dangerous practices that both risk and result in harm to Americans. The Branch aggressively pursues both civil and criminal cases against those who unlawfully manufacture, distribute, or sell pharmaceuticals, medical devices, and dietary supplements, causing harm and loss to consumers and the government. As the Department component charged with enforcing the Federal Food, Drug, and Cosmetic Act (FDCA), the Branch works closely with the FDA, the DEA, and other law enforcement agencies to investigate matters. It also coordinates closely with USAOs and the Commercial Litigation Branch's Fraud Section to prosecute matters, including major health care fraud cases. In recent years, and especially over the last year, the Branch has dedicated particular focus to advancing civil and criminal actions against individuals and entities up and down the prescription opioid supply chain, seeking to hold accountable those responsible for the opioid crisis and to recoup billions of dollars for the United States and victims, and resulting in more than $5.8 billion in fines, forfeitures, and penalties for the federal fisc.

With respect to opioid-related work, the Branch is leading a number of multi-component investigations and active cases against pharmaceutical opioid manufacturers, wholesale distributers, pharmacies, and health care providers. The Branch is advancing this work through state-of-the-art data analysis and evidence-review tools, a large contract staff, and an enormous commitment of prosecutorial resources. Indeed, Branch prosecutors dedicated more than 24,000 hours to the matters in FY 2021. The Branch is projected to exceed that amount in FY 2022. Each of the matters has the potential to return hundreds of millions, or even billions, of dollars to the federal government. The Branch also is continuing coordination responsibilities established through the Department's Prescription Interdiction and Litigation Task Force.

Over the last year, the Branch, partnering with the U.S. Attorneys' Offices for the Districts of New Jersey and Vermont, obtained a guilty plea from Purdue Pharma LP. Purdue pled guilty to conspiracies to defraud the United States and violate the anti-kickback statute. The company represented to the DEA that it maintained an effective anti-diversion program when, in fact, Purdue continued to market its opioid products to more than 100 health care providers whom the company had reason to believe were diverting opioids. Purdue also reported misleading information to the DEA to boost Purdue's manufacturing quotas. The misleading information comprised prescription data that included OxyContin prescriptions written by doctors that Purdue had reason to believe were engaged in diversion. The conspiracy also involved aiding

and abetting violations of the Federal Food, Drug, and Cosmetic Act by facilitating the dispensing of its opioid products, including OxyContin, without a legitimate medical purpose, and thus without lawful prescriptions. Under the terms of the plea agreement, Purdue agreed to the imposition of the largest penalties ever levied against a pharmaceutical manufacturer, including a criminal fine of over $3.5 billion and an additional $2.0 billion in criminal forfeiture (which is subject to a credit of up to approximately $1.8 billion against recoveries by state and local government creditors in the Purdue bankruptcy).

The result involving Purdue builds on the Branch's recent success involving Indivior Inc., a pharmaceutical manufacturer that committed fraud with respect to the safety of its opioid addition treatment drug, Suboxone. As part of the criminal resolution reached with the company by the Branch and the U.S. Attorney's Office for the Western District of Virginia, the company's main subsidiary, Indivior Solutions, pled guilty to a felony charge of false statements involving a health care program, and the company agreed to pay $289.0 million in criminal penalties. Combined with a $300.0 million civil settlement with the company, a $1.4 billion global resolution with its former corporate parent, and guilty pleas entered by two of its former executives, the criminal resolution with Indivior capped off a more than $2.0 billion enforcement effort.

With respect to chain pharmacies, the Branch led a multi-component effort that, in December 2020, filed suit against Walmart, Inc., asserting nationwide violations of the Controlled Substances Act in the dispensing of opioids from, and distribution of opioids to, Walmart's more than 5,500 pharmacies. The complaint details Walmart's substantial contribution to the opioid epidemic and seeks billions of dollars for the government and significant injunctive relief. The case is now in litigation, taking up thousands of federal attorney and contractor time each month and requiring a significant litigation-support apparatus. And the Branch also is litigating to enforce a subpoena against CVS. The Branch expects in the coming year to reach resolutions, or advance investigations and litigation, as to other companies in the opioid supply chain, including other chain pharmacies and certain large distributors.

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

In addition to its opioid enforcement efforts, the Branch continued to lead the Department in prosecuting pharmaceutical, dietary supplement, and medical device manufacturers and their executives for violations of the FDCA in the manufacturing and marketing of their products. These efforts include the Branch's response to consumer fraud related to the COVID-19 pandemic. In FY 2021, CPB invested almost 18,000 hours into FDCA work, and another4,500 hours into COVID fraud work, for a total of nearly 23,000 hours. The Branch is

projected to exceed that amount in FY 2022.

The Branch's work under the FDCA touches a wide variety of fraudulent conduct. For example, in July 2021, Avanos Medical Inc., a U.S.-based multinational medical device corporation, agreed to pay more than $22.0 million to resolve a criminal charge relating to the company's fraudulent misbranding of its MicroCool surgical gowns. Acting in conjunction with the Criminal Division's Fraud Section and the U.S. Attorney's Office for the Northern District of Texas, the Branch established that Avanos fraudulently claimed that its medical gowns met safety standards that they did not, in fact, meet. Avanos's activities exposed health care professionals and patients to serious risk. After being confronted with results of the Branch's investigation, Avanos agreed to set up a victim compensation fund of almost $9.0 million, pay a criminal monetary penalty of $12.6 million, disgorge $689,000 in profits, and implement important compliance terms.

Similarly, Branch attorneys secured a criminal guilty plea and $50.0 million fine and forfeiture judgment against Fresenius Kabi Oncology Limited for concealing and destroying records in advance of an FDA inspection. The Branch's investigation revealed that the destroyed records showed that the company was manufacturing drug ingredients for cancer-treatment drugs in contravention of FDA requirements meant to protect patients from harm.

This year, the Branch advanced a major initiative to address fraud affecting clinical trials for prescription drugs and medical devices. Working with the U.S. Attorney's Office for the Southern District of Florida, Branch attorneys obtained criminal convictions against three individuals and brought charges against another alleged to have engaged in a scheme of falsifying clinical trial data regarding a pediatric asthma medication. The prosecution caused the data in question to be corrected before harm could result to children. In another clinical trial fraud matter, two individuals pled guilty earlier this year, and four others face trial on charges that they knowingly enrolled subjects in trials when those subjects failed to meet eligibility criteria, falsified laboratory results, falsified medical records, and falsely represented that subjects were taking the drugs being studied when in fact they were not. The Branch is advancing other investigations in the clinical trial fraud arena, as well. The results obtained in these actions have sent a powerful message against fraud in clinical trials and drug-approval submissions to FDA.

Branch attorneys also obtained injunctive relief to: stop a California company's fraudulent marketing of the supplement "Poly-MVA," which falsely claimed to a be a cure, mitigation, or prevention for diseases including cancer; stop a Nevada company from falsely marketing adulterated tap water that had caused five cases of non-viral hepatitis in children; stop a New York company from manufacturing dietary supplements that did not meet product specifications and did not properly identify their contents; and stop a Washington company from distributing adulterated fruit juice products that were being widely disseminated in school lunch programs.

Further, the Branch continued its efforts against fraud related to the COVID-19 pandemic. In one example, Branch attorneys conducted an international investigation into the operators of a Vietnamese website that purported to sell popular COVID-related items like facemasks and other

personal protective equipment. Despite assurances of authenticity, consumers who paid for such equipment never received any goods, and the operators simply kept the money they received through online payment systems. The Department obtained injunctions against the operators, now imprisoned in Vietnam, and shut the websites down. In addition, the Branch is continuing to litigate cases that started last year, including civil and criminal enforcement matters against fraudulent purveyors of bleach, colloidal silver, and other dangerous or ineffective products all touted as a COVID-19 cures. The Branch also continues to advise U.S. Attorneys' Offices across the country on COVID-related cases, guiding prosecutors in the use of enforcement tools under the Federal Food, Drug, and Cosmetic Act.

As vaccines rolled out this year, Branch attorneys helped to ensure that the supply was safe and protected. Most notably, the Branch partnered with the U.S. Attorney's Office in the Eastern District of Wisconsin to prosecute a hospital worker who intentionally spoiled doses of the Moderna vaccine, putting dozens of patients at risk. That defendant recently was sentenced to three years in prison.

The Department also brought the first enforcement effort under the newly enacted COVID-19 Consumer Protection Act. The civil complaint, filed in April 2021, seeks preliminary and permanent injunctions, civil penalties, and other equitable relief against a St. Louis-based chiropractor who advertised, without competent scientific evidence, vitamin D and zinc nutritional supplements as more effective than vaccines at preventing COVID-19. The Branch is coordinating with FTC to bring additional actions under the Act to combat ongoing COVID-19 fraud affecting consumers and health care programs.

Criminal Division

The Criminal Division was allocated $34.4 million in FY 2021 HCFAC funding to support criminal health care fraud litigation and interagency coordination, which is carried out primarily by the Fraud Section's Health Care Fraud Unit and, to a lesser extent, the Organized Crime and Gang Section.

The Fraud Section

The Fraud Section's HCF Unit employs criminal prosecutors who focus exclusively on investigating and prosecuting health care fraud matters and prescription opioid distribution and diversion schemes. In sum, the HCF Unit's core mission is to: (1) protect the public fisc from fraud, waste, and abuse; and (2) detect, limit, and deter fraud and illegal prescription, distribution, and diversion offenses resulting in patient harm. The HCF Unit also supports the USAO community by providing legal, investigative and data analytics support, guidance and training on criminal health care fraud and opioid-related matters.

Beginning in March 2007, the Fraud Section, working with the local USAO, the FBI, HHS-OIG, and state and local law enforcement agencies, launched the Health Care Fraud Strike Force in

Miami-Dade County, Florida, to investigate and prosecute individuals and entities that do not provide legitimate health care services but instead defraud Medicare and other government health care programs. In FY 2021, the HCF Unit's Strike Force program provided attorney staffing, litigation support, and leadership and management to the Strike Forces operating in 24 federal judicial districts across the United States. The current strike forces include operations in cities including, but not limited to, Miami and Tampa/Orlando, Florida; Nashville, Tennessee; Ft. Mitchell, Kentucky; Los Angeles, California; Detroit, Michigan; Houston, San Antonio and Dallas, Texas; Brooklyn, New York; Baton Rouge and New Orleans, Louisiana; Chicago, Illinois; Newark, New Jersey/Philadelphia, Pennsylvania, along with the NRRSF located in Washington, D.C.

In 2018, the HCF Unit created the ARPO Strike force, a joint effort between DOJ, HHS-OIG, FBI, DEA, and local law enforcement partners to combat health care fraud and the opioid epidemic in nine federal districts. As of September 30, 2021, ARPO has charged 95 defendants involving more than 105 million prescribed opioid doses. These efforts have resulted in 55 guilty pleas and four trial convictions.

In FY 2021, the HCF Unit achieved the following results:

- Filed 131 indictments, criminal informations and complaints involving charges against 185 defendants who allegedly collectively billed federal health care programs and private insurers approximately $1.7 billion;
- Obtained 160 guilty pleas and litigated 13 jury trials, with guilty verdicts against 10 defendants; and
- Securing imprisonment for 79 defendants sentenced, with an average sentence of over 61 months.

Since its inception, Strike Force prosecutors filed more than 2,400 cases charging more than 5,000 defendants who collectively billed federal health care programs and private insurers approximately $24.7 billion, more than 3,300 defendants pled guilty and over 400 others were convicted in jury trials, and more than 3,000 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. Each year, the HCF Unit coordinates large-scale, law enforcement actions with its partners.

The nature and scope of health care fraud has evolved rapidly over the past few years with the advent of new technologies that have broadened the reach of health care and, consequently, health care fraud. As a result, the Fraud Section recently developed and launched the NRRSF: a way to respond quickly to multi-jurisdictional health care fraud cases and priorities, without diverting attorneys from district-specific Strike Forces. NRRSF prosecutors, who are based in Washington, D.C. (and, where appropriate, based in certain existing Strike Force locations), are dedicated exclusively to the immediate and decisive response to new and emerging health care fraud trends. Like the other Strike Forces, the NRRSF coordinates with USAOs and federal and state law enforcement partners prosecute these significant multi-jurisdictional and corporate

fraud cases. Examples of the types of matters under this Strike Force's purview include a large-scale rural hospitals billing fraud matter indicted in the Middle District of Florida, charges against former NFL players for their alleged roles in a nationwide fraud scheme that targeted a plan that provided tax-free reimbursement of out-of-pocket medical care expenses that were not covered by insurance, the recent sprawling telemedicine cases involving billions of dollars in alleged fraud loss, and prosecutions of those seeking to criminally exploit the COVID-19 pandemic through health care fraud and related financial fraud schemes.

The HCF Unit chairs an interagency COVID-19 fraud working group with federal law enforcement and public health agencies to identify and combat health care fraud trends emerging during the COVID-19 crisis. This has involved coordinating and training other Criminal Division and USAO prosecutors and offering support to their investigations and cases, including data analytics support. The HCF Unit expects that the COVID-19 working group will continue to generate criminal prosecutions in several areas, including COVID-19 test bundling schemes, securities fraud cases involving health care technology companies, and CARES Act Provider Relief Fund (PRF) fraud cases.

The HCF Unit conducted the May 2021 National COVID-19 Health Care Fraud Enforcement Action, which involved criminal charges against 14 defendants in seven federal districts across the United States for their alleged participation in various health care fraud schemes that exploited the COVID-19 pandemic and resulted in over $143.0 million in false billings. The defendants were alleged to have engaged in various health care fraud schemes designed to exploit the COVID-19 pandemic, including by defrauding the PRF, exploiting regulatory waivers that were designed to encourage access to care, and offering COVID-19 tests and misusing the information and samples to submit claims to Medicare for medically unnecessary, and far more expensive laboratory tests.

As part of the May 2021 Enforcement Action, for example, the president of a publicly traded medical technology company was charged along with two others in connection with the submission of over $70.0 million in false and fraudulent claims for allergy and COVID-19 testing. The conspiracy involved false and fraudulent statements about the existence, regulatory status, and accuracy of the company's COVID-19 test and allegedly sought to commit securities fraud and induce the ordering of the company's COVID-19 test and medically unnecessary allergy test. The charges against the company's president were the first criminal securities fraud prosecution related to the COVID-19 pandemic that was brought by the DOJ, and were the result of a collaboration among the Fraud Section's HCF and Market Integrity Major Fraud Units and the U.S. Attorney's Office for the Northern District of California. Four defendants have pled guilty in connection with the scheme and the company's president is awaiting trial.

The HCF Unit also has led efforts across the country to prosecute misuse of COVID-19 vaccination record cards. In the Northern District of Illinois, the HCF Unit charged a licensed pharmacist with crimes related to his alleged theft and sale of authentic Centers for Disease Control and Prevention (CDC) vaccination cards on eBay. In the Northern District of California, the HCF Unit and the USAO charged a California-licensed naturopathic doctor for her alleged

scheme to sell homeoprophylaxis immunization pellets and to falsify COVID-19 vaccination cards by making it appear that customers had received the FDA-authorized Moderna vaccine. The case in the Northern District of Illinois was the first federal criminal fraud prosecution related to fake vaccination cards.

The HCF Unit has brought criminal charges in the past year against nine defendants across the country who allegedly engaged in the misuse of the PRF monies. The PRF was intended to provide relief to health care providers and maintain the access to medical care during the pandemic, money set aside to help Americans get needed medical care in a global health and economic crisis. The defendants in these cases allegedly intentionally misappropriated government funds that were designed to aid medical providers in the treatment of patients suffering from COVID-19 and used them for their own personal expenses, including for gambling debts at a Las Vegas casino and payments to a luxury car dealership.

Increased USAO outreach by the Strike Force partners is another positive measure that reflects the overall impact of the HCFAC program. This year, the HCF Unit coordinated and hosted its largest ever National Health Care Fraud and Opioid Training Conference, which was attended virtually by more than 800 attendees (representing more than 67 U.S. Attorney's Offices) and law enforcement personnel from FBI, DEA, HHS-OIG, IRS-Criminal Investigation, Department of Defense (DOD), and U.S. Postal Service (USPS). The Conference provided training on investigative techniques and tools, trial skills, case studies, and persistent and emerging schemes in both health care fraud and opioid abuse and drug diversion.

Since 2007, the HCF Unit has deployed data analytics combined with investigative intelligence to great success. In 2018, the HCF Unit formed its own in-house data team, which now consists of eight analysts with deep experience in Medicare and Medicaid data analysis, as well as financial analysis, who identify egregious health care fraud and prescription opioid-related targets to ensure the HCF Unit and its partners efficiently identify the worst offenders. The concept and structure of the Data Analytics Team is regarded as ground-breaking for the Department. The team uses data to identify billing patterns, suspicious prescribing practices, and curious relationships between doctors and patients that signify high-risk targets. The investigations are then prosecuted by HCF Unit prosecutors or referred to USAOs and law enforcement partners in a "targeting package," which includes data summaries and descriptions of why a pattern is suspect, such as submission of claims for dead beneficiaries, beneficiaries who live a great distance from the clinic they purportedly regularly attended in person, etc.[38] In FY 2021, the team has completed approximately 5,643 requests for data analysis assistance. During this same time, it has also created a multitude of specific district-by-district targeting packages to help advance the HCF Unit's mission. During this same time, it has also created hundreds of specific district-by-district targeting packages to help advance the HCF Unit's mission.

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

The Organized Crime and Gang Section (OCGS)

The Criminal Division's Organized Crime and Gang Section (OCGS) supports and conducts investigations of health care fraud and abuse targeting private sector health plans sponsored by employers and/or unions as well as health care fraud and abuse perpetrated by domestic and international organized crime groups. There are more that 2.3 million such private sector health plans which cover some 135 million Americans. OCGS also works to improve strategic coordination in the identification and prosecution of domestic and international organized crime groups engaged in sophisticated frauds posing a threat to the health care industry and provides legal advice and necessary approvals in the use of the RICO statute to combat health care fraud and abuse.

In FY 2021, six OCGS attorneys conducted health care fraud prosecutions and investigations.

In Knoxville, Tennessee, two OCGS attorneys continued working with the USAO for the Eastern District of Tennessee on the prosecution of a pain clinic co-owner and nurses for their roles in running "pill mills." The co-owner and three nurse practitioners were convicted following a three-month trial. In October 2020, the clinic co-owner was sentenced to more than 33 years in prison and forfeiture of $3.6 million for her convictions of RICO conspiracy, two counts of drug conspiracy, money laundering offenses, and maintaining drug-involved premises. Then in December 2020, three nurse practitioners were sentenced to prison terms ranging from 30 to42 months for their convictions of maintaining drug involved premises. The drug conspiracy involved the operation of four clinics which were basically pill mills which distributed over 11 million tablets of oxycodone, oxymorphone, and morphine that generated over $21.0 million in clinic revenue, with a corresponding street value of $360.0 million. Two part-owners charged with RICO conspiracy remain under indictment and are scheduled for trial in FY 2022. This partnership between OCGS and the Eastern District of Tennessee has resulted in the investigation and prosecution of over 140 individuals. This case was part of the Department's Organized Crime Drug Enforcement Task Force (OCDETF) and the FBI High Intensity Drug Trafficking Area (HIDTA) programs. OCDETF is the primary weapon of the United States against the highest-level drug trafficking organizations operating within the United States, importing drugs into the United States, or laundering the proceeds of drug trafficking. This case is summarized above in the Highlights of Significant Criminal and Civil Investigations.

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

Another two OCGS attorneys managed the investigation of health care fraud, embezzlements and other criminal abuses involving third party administrators to private sector health plans.

OCGS attorneys routinely provide litigation support and advice to AUSAs and criminal investigative agencies in the investigation and prosecution of corruption and abuse of private employment-based group health plans covered by the Employee Retirement Income Security Act (ERISA) including fraud schemes by corrupt entities that sell unlicensed group health insurance. Private sector employment-based group health plans are the leading source of health care coverage for individuals not covered by Medicare or Medicaid. OCGS provides litigation support as requested at any stage of the prosecution from indictment through trial and appeal.

OCGS attorneys provide health care fraud and abuse training and legal guidance to AUSAs and to criminal investigators and agents of the Department of Labor's Employee Benefits Security Administration and Office of Inspector General, FBI and IRS. Such training and guidance cover prosecutions involving abuse of private sector employee health plans subject to ERISA and health plans sponsored by labor organizations, as well as fraud and abuse committed in connection with the operation of MEWAs. OCGS is also responsible for drafting and reviewing criminal legislative proposals affecting employee health benefit plans. Finally, OCGS provides legal guidance to prosecutors and required approvals in the use of the RICO statute in prosecutions of racketeering enterprises involved in the distribution of opioids, fentanyl, and other pharmaceuticals; Medicare and Medicaid frauds; and private sector health care frauds.

Civil Rights Division

The Civil Rights Division was allocated $6.9 million in FY 2021 HCFAC funding to support Civil Rights Division litigation activities related to health care fraud and abuse. The Civil Rights Division pursues relief affecting public, residential, and nonresidential health care facilities and service systems, and conducts investigations to eliminate abuse and grossly substandard care in public, Medicare, and Medicaid funded long-term care facilities. Consistent with the ADA's integration mandate set forth in 28 C.F.R. § 35.130(d), and the Supreme Court's ruling in *Olmstead v. L.C.,* 527 U.S. 581 (1999), the Division also works to prevent the unnecessary segregation of individuals who require health care supports and services.

The Division plays a critical role in the HCFAC Program. The Special Litigation Section of the Civil Rights Division is the sole DOJ component responsible for enforcing the Civil Rights of Institutionalized Persons Act, 42 U.S.C. §1997 (CRIPA). CRIPA authorizes the investigation of conditions of confinement at residential institutions owned or operated by or for state or local governments, including facilities for persons with developmental disabilities or mental illness, and nursing facilities, and initiation of a civil action for injunctive relief to remedy a pattern or practice violation of the Constitution or federal statute. In addition, both the Special Litigation Section and the Disability Rights Section have engaged in interagency coordination with the goal of combatting the misuse of Medicaid funding related to the unnecessary segregation of persons with disabilities.

The Disability Rights Section of the Civil Rights Division has primary enforcement authority for the Americans with Disabilities Act (ADA). Title II of the ADA authorizes the investigation of allegations of discrimination by public entities against individuals with

disabilities, including discrimination in the form of unnecessarily segregating persons who require health care supports and services. See *Olmstead*, 527 U.S. 581. Title II also authorizes the initiation of civil actions to remedy discrimination in violation of the ADA. In addition to violating the civil rights of individuals with disabilities, such unnecessary segregation often increases Medicaid costs. Both the Disability Rights Section and the Special Litigation Section enforce the ADA's prohibition on unnecessary segregation.

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

FY 2021 Accomplishments

Key litigation and enforcement accomplishments in FY 2021 of the Civil Rights Division are:

- Number of matters in active enforcement: 17
- Cumulative estimate of individuals with disabilities affected:[39] 69,523
- Number of institutional facilities affected: 2,178

Special Litigation Section

In FY 2021, the Section's enforcement efforts affected more than 1,400 health care facilities in seven states, and included post-trial remedial efforts involving the unnecessary segregation of people with serious mental illness, the opening of two new investigations, the filing of a statement of interest,[40] and monitoring compliance with six agreements impacting over 25,000 individuals with disabilities.

In October 2020, the Section and the United States Attorney's Office for the District of New Jersey opened an investigation under CRIPA into New Jersey Veterans Memorial Home at Menlo Park and New Jersey Veterans Memorial Home at Paramus (Veterans Homes). The investigation is examining whether the Veterans Homes engage in a pattern or practice of violating the constitutional rights of residents by denying them appropriate medical care generally, and during the coronavirus pandemic in particular. The investigation continues.

In December 2020, the Section initiated an investigation of the State of Alaska under the ADA. The investigation will determine whether Alaska provides services to children with mental health disabilities in the most integrated settings appropriate. That same month, the Section opened an

[39] Cumulative estimates of individuals with disabilities affected for FYs 2018-2020 are updated as follows: FY 2018, from 55,685 to 58,422; FY 2019, from 59,090 to 59,422; FY 2020, from 52,990 to 59,422.
[40] The Statement of Interest, filed in *Disability Rights Arkansas v. Solomon Graves* 4:20-cv-01081, (E.D. Ark.) in February 2021, concerned medical records access for federal protection and advocacy organizations that monitor and enforce the rights of people with disabilities.

investigation into whether Nevada provides services to children with mental health disabilities in the most integrated settings appropriate. Both investigations are ongoing. In December 2020, the Section also issued a CRIPA findings report concluding that there is reasonable cause to believe the State of Iowa subjects Glenwood Resource Center (Glenwood) residents to unreasonable harm and risk of harm, in violation of their Fourteenth Amendment rights. Specifically, the Division found reasonable cause to believe that Iowa has subjected people with intellectual disabilities residing at Glenwood to: (1) uncontrolled and unsupervised experimentation; (2) inadequate physical and behavioral healthcare; and (3) inadequate protection from harm, including deficient safety and oversight mechanisms. The Section and the State are discussing necessary remedial measures at Glenwood.[41]

In April 2021, the Section issued a report concluding there is reasonable cause to believe that Alameda County, California is violating the ADA in its provision of mental health services. The Section's investigation found that the County fails to provide services to qualified individuals with mental health disabilities in the most integrated setting appropriate to their needs. Instead, it unnecessarily institutionalizes them at a public institution, John George Psychiatric Hospital, and in other facilities. As a result, hundreds of people are institutionalized for lengthy stays at one of several large, locked psychiatric facilities in the County or are hospitalized at John George Psychiatric Hospital, while others are at serious risk of admission to these psychiatric institutions because of the lack of community-based services.

In September 2021, the district court in *United States v. Mississippi*, 16-cv-622 (S.D. Miss.), issued a final remedial order after five years of contested litigation. The order requires the state to divert adults with serious mental illness from unnecessary admission to the state's four psychiatric hospitals. It also requires the development and implementation of community-based services statewide to support individuals who are diverted from hospitalization or transitioned from a state Hospital. Going forward, the Section will be monitoring compliance with the order in conjunction with a court-appointed monitor.

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

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

In its pending litigation with the State of Texas regarding the right to receive community-based services for people with intellectual and developmental disabilities (IDD) housed in Texas

[41] In December 2021 (FY 2022), the Division issued a CRIPA and ADA findings report concluding that Iowa fails to provide services to people with intellectual/developmental disabilities in the most integrated setting appropriate to their needs.

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 2021, the Disability Rights Section monitored compliance with seven settlement agreements, under which more than 24,900 people collectively will obtain relief, issued a letter of findings in one investigation, continued litigation of another case involving unnecessary segregation of people with disabilities, and submitted a statement of interest in pending private litigation.

In December 2020, the Section reached a settlement agreement with the State of North Dakota resolving complaints that the state unnecessarily institutionalizes adults with physical disabilities in nursing facilities. Under the agreement, North Dakota will expand access to community-based services so that individuals who are in, or at risk of entering, nursing facilities can choose to live in their own homes. The state will provide these services to more than 2,500 individuals with physical disabilities over the term of the eight-year agreement.

On June 4, 2021, the United States entered into a settlement agreement with the Maine Department of Health and Human Services (DHHS) to resolve a complaint alleging that Maine's restrictions on services placed a young man with intellectual disabilities at serious risk of having to move from his own home to a group home or institution. The United States issued a findings letter on February 10, 2020, concluding that Maine is violating the ADA's integration mandate in its provision of services under the State's "Home and Community Services for Adults with Intellectual Disabilities or Autism Spectrum Disorder" Medicaid waiver program. Following an investigation, the Department found that Maine failed to provide the complainant with necessary services in the most integrated setting appropriate to the complainant's needs, and failed to reasonably modify its relevant service program to avoid discrimination, thereby placing the complainant at serious risk of unnecessary segregation. The settlement agreement requires DHHS to implement remedial measures, including establishing and implementing a process for individuals to obtain an exception to the waiver program's cap on in-home services, and modifying the program's service planning process to ensure that members' individual needs and preferences determine the services they receive and the setting(s) in which they receive them. For the complainant, the agreement requires DHHS to provide access to all needed in-home services and pay $100,000 in damages.

The Section continued to monitor the implementation of its settlement agreement with the State of North Carolina, under which the State is providing opportunities to individuals with mental illness in adult care homes to transition to less costly, integrated service settings. As of August 30, 2021, 4,671 individuals had been diverted or moved from large adult care homes to permanent supported housing since the agreement went into effect in 2012. This total includes 2,605 individuals who were diverted from adult care homes upon discharge from a State psychiatric hospital or upon being considered for admission to an adult care home, and 2,066 individuals who moved out of adult care homes into the community. Of the 4,671 individuals who have moved into permanent supported housing, 2,989 (or 64 percent) continue to receive

services in the community. In addition, 5,760 individuals were receiving assertive community treatment services, and 2,640 individuals in the agreement's target population had received supported employment services over the course of the agreement.

The Section also continued to monitor its two settlement agreements with the State of Rhode Island, addressing the unnecessary segregation of individuals with disabilities in sheltered workshop and facility-based day programs. Under the agreements, the State will provide supported employment placements to roughly 2,100 individuals with IDD by 2024, and roughly 3,600 individuals will benefit from changes to the State's employment and day service systems. Thus far, 964 individuals have obtained competitive, integrated employment over the course of these agreements.

The Section, along with the USAO for the Eastern District of New York, continued monitoring a second amended settlement agreement with the State of New York and private plaintiffs regarding New York's mental health service system. The agreement benefits at least 2,500 people and remedies discrimination by the State in the administration of its mental health service system. Under the agreement, individuals with serious mental illness who reside in 22 large institutional settings known as adult homes in New York City are provided the opportunity to receive services in the most integrated setting appropriate to their needs consistent with the ADA and *Olmstead*. These individuals can choose to live and receive services in the community, enabling them to live, work, and participate fully in community life. To date, more than 1,000 former adult home residents have transitioned to and received services in the community, and over 2,000 additional adult home residents have expressed interest in doing so.

The Section is working with class plaintiffs to monitor a settlement agreement with the State of Oregon. Pursuant to the agreement, the State is decreasing its reliance on segregated employment settings and increasing supported employment services to help individuals with IDD obtain competitive integrated employment. The State committed to provide supported employment services and related employment services so that by June 30, 2022, 1,115 working-age individuals receiving sheltered workshop services would newly obtain competitive integrated employment. The State also agreed that by July 1, 2022, it would provide employment services to at least 7,000 target population members, including 4,900 youths aged 14 to 24, and Individual Plans for Employment to at least half of those youths. The State has reported that as of March 2021, it had reduced the census of segregated sheltered workshop settings to 0. The State has also reported that through the end of June 2021, it had provided supported employment services and related employment services so that 1,110 individuals receiving sheltered workshop services have newly obtained competitive integrated employment. The State has also reported that through the end of June 2021, 6,815 target population members had received a new employment service, including, 4,675 transition-aged youths, and 4,025 of those youths had received an Individual Plan for Employment.

The Section received a ruling on the State's petition for rehearing filed with the U.S. Court of Appeals for the Eleventh Circuit in *United States v. Florida*. In 2013, the Section commenced litigation against the State of Florida, alleging among other things, that the state administers its Medicaid service system for children with significant medical needs in violation of Title II of the

ADA by unnecessarily segregating them in nursing facilities, when they could, and want to, be served at home or in other community-based settings. On September 20, 2016, U.S. District Court for the Southern District of Florida issued an order dismissing the United States' claims. The United States filed a notice of appeal with the U.S. Court of Appeals for the Eleventh Circuit, which on September 17, 2019, issued an opinion reversing the District Court's order of dismissal and remanding and on December 22, 2021, the petition for rehearing was denied.

Educational Opportunities Section

The Educational Opportunities Section (EOS) has participated in the HCFAC Program for the past eight years. The Section has carefully analyzed the legal issues related to unnecessary segregation in the context of K-12 schools. In pending litigation against the State of Georgia, the Section alleges that the State is violating Title II of the ADA in its use of segregated educational services for approximately4,5000 Georgia students with emotional and behavioral disabilities. A multi-year stay of that litigation was lifted in May 2020 and discovery is ongoing with the State with an anticipated 2022 trial date. In another matter, the Section is actively investigating the State of Alabama about the State's practice of placing children from the foster care system in psychiatric residential treatment facilities based on a need for care spaces, and then providing educational services only at segregated on-site "schools." The Section recently settled a major case involving districts sending children home on "shortened days" repeatedly segregating them from their peers without disabilities. Finally, we have opened investigations of five school districts across the country that routinely segregate students with disabilities through seclusion and restraint practices in violation of the ADA.

Office of the Inspector General

The Office of the Inspector General (DOJ-OIG) was allocated $1.4 million in FY 2021 HCFAC funding to address health care fraud as it directly impacts the DOJ operations. The DOJ spends over $1.0 billion a year to provide health care to inmates of the Federal Bureau of Prisons (BOP) and the U.S. Marshals Service (USMS); and expends more than $115.0 million a year in annual workers' compensation payments related to disabled and injured DOJ employees and informants.

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

Additionally, the DOJ-OIG Investigations Division collaborates with the DOJ-OIG Audit Division's Office of Data Analytics (ODA) to detect and deter fraud, waste and abuse in these

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

In FY 2020 and FY 2021, these efforts resulted in four cases for the Investigations Division and a Management Advisory Memorandum (MAM) to BOP, recommending that BOP establish and implement a procurement plan for air ambulance services that includes procedures for processing both claims billed through existing and future comprehensive medical services contracts and claims billed by air ambulance providers. Secondly, upon establishing a procurement plan for air ambulance claims, the BOP should issue guidance to its health services administrators and contracting staff about how to appropriately adjust and process air ambulance claims.

During FY 2021, the DOJ-OIG continued participating in two healthcare fraud working groups and continued to collaborate with other federal agencies that investigate healthcare fraud. These efforts have provided opportunities for the DOJ-OIG to collaborate and share ideas with other organizations. Additionally, the DOJ-OIG sought refreshed healthcare claims data directly from BOP comprehensive medical service providers. The additional data will help to build upon the DOJ-OIG's comprehensive BOP healthcare data bank, ensuring the ability to use historical data as the foundation for predictive analytics efforts.

Due to the COVID-19 pandemic, DOJ-OIG did not receive U.S. Department of Labor workers' compensation claims data until the second half of FY 2021. Since the OIG has received FY 2020 and FY 2021 workers' compensation data, efforts have resumed in identifying potentially fraudulent billing patterns by providers as well as anomalous prescription drug claims and continuing to build upon DOJ-OIG's predictive analytics abilities. The analysis of the Department's workers' compensation data resulted in the initiation of multiple ongoing investigations.

In FY 2021, a BOP comprehensive medical services (CMS) contractor agreed to settle to resolve False Claims Act allegations. The prison health care provider agreed to pay $694,593 for submitting claims for payment to the BOP that falsely represented the medical services provided to inmates. The DOJ-OIG also identified approximately $44,126 in overpaid non-hospital laboratory claims to a BOP CMS contractor. Through analysis of claims data, the DOJ-OIG determined the CMS contractor billed the BOP at the outpatient physician rate rather than the in-network laboratory services rate. Since receiving initial funding, the DOJ-OIG has opened a total of 25 investigations related to DOJ healthcare-related activities and programs.
The DOJ-OIG Evaluation and Inspections Division is conducting an ongoing evaluation of USMS drug costs and continues to monitor BOP efforts to implement recommendations made in

an FY 2020 report on BOP drug costs.

FY 2021 Accomplishments

Key oversight accomplishments in FY 2021 for the DOJ-OIG include:

- Recoveries from False Claims Allegation Settlement: $694,593,
- Identified overpayments: $44,126,
- Management Advisory Memo's issued to reduce program waste: 1,
- Audits performed to reduce program waste: 2, and
- Ongoing Evaluations performed to reduce program waste: 1

APPENDIX

Federal Bureau of Investigation

The FBI was allocated $152.4 million in funding from HIPAA to support the facilitation, coordination and accomplishment of the goals of the HCFAC Program. In addition, the FBI received $6.9 million of the DOJ FY 2021 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 2021 was used to support 836 positions (505 Agent, 331 Support). In addition to funding personnel resources, the FBI utilized HCFAC funding to support undercover operations, financial and investigative analysis support, offsite HCF Task Force locations, operational travel, and other investigative and operational costs.

In FY 2021, the FBI opened 593 new health care fraud (HCF) investigations. 2,947 investigations were pending at the end of FY 2021. Investigative efforts throughout the fiscal year produced 470 criminal HCF convictions, 526 indictments, and 281 prosecutors' informations. In addition, investigative efforts resulted in over 559 operational disruptions of criminal fraud organizations and the dismantlement of more than 107 HCF criminal enterprises.

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

The FBI seeks to approach the HCF crime problem in a threat-based and intelligence-driven manner. The approach employs the prioritization of threats and enforcement efforts, at both the national and field office levels, to ensure limited resources are focused on the most significant entities committing health care fraud and abuse. As part of the HCF threat review and prioritization process, the FBI gathers relevant data and information to understand the impact of the HCF crime problem and to identify intelligence gaps, or areas which require additional research and analysis. The process is on-going and requires collaboration not only among FBI components, but also with its partners in the public and private sectors. As a result of the process, the FBI has designated criminal enterprises, corporate-level fraud and abuse, and public safety issues, to include those arising from the ongoing prescription opioid abuse epidemic, as the priority HCF threat areas of focus. 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.

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 Strike Forces, HCF task forces, and HCF working groups with federal, state, and local law enforcement and regulatory partners, including local USAOs, HHS-OIG, DEA, IRS, FDA, and state MFCUs.

The FBI also conducts significant information sharing and coordination efforts with private insurance partners through the National Health Care Anti-Fraud Association (NHCAA), the National Insurance Crime Bureau (NICB), and private insurance special investigative units. The FBI is also actively involved in the HFPP, an effort to exchange information between the public and private sectors in order 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 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 developed and supported five national program initiatives in FY 2021, to include the Health Care Fraud Task Force and Working Group Initiative, Prescription Drug Initiative, Large-Scale Conspiracies Initiative, Major Provider Fraud Initiative, and the Outreach, Education, and Liaison Initiative.

The Health Care Fraud Task Force and Working Group Initiative

The Health Care Fraud Task Force and Working Group Initiative was established to encourage the formation of joint FBI-led HCF task forces and working groups. Joint task forces and working groups combine federal, state, and local law enforcement and regulatory resources to address the health care fraud threat. Task forces serve as a force multiplier for FBI efforts by bringing the experience, expertise, and resources of our federal, state, local, and tribal partners to bear to mitigate the HCF threat. Task forces and working groups result in improved sharing of threat-related intelligence among participating agencies and expand criminal and civil tools for participants to use to identify and disrupt criminal activity. Task force participants and their employing agencies also benefit from increased access to FBI training and equitable sharing arrangements. In FY 2021, the FBI opened more than 170 joint HCF investigations among 13 established task forces and opened more than 290 joint HCF investigations bureau-wide among its task force and working group partners.

The FBI participates in DOJ Medicare Fraud and ARPO Strike Force throughout the country. Specifically, the FBI supports DOJ HCF Strike Forces located in Florida (Miami, Tampa, Orlando), Los Angeles, Texas (Houston, Dallas, McAllen/Rio Grande), the Gulf Coast (New Orleans, Baton Rouge, and Southern Mississippi), Detroit, Brooklyn (NYC), Chicago, Newark / Philadelphia, ARPO North (Kentucky, Ohio, Virginia, and West Virginia), ARPO South (Tennessee and Northern Alabama), and Washington D.C. NRRSF.

In addition, 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.

In September 2021, the FBI participated in a DOJ national HCF Law Enforcement Action that resulted in criminal charges against 117 subjects, including 39 doctors, nurses, and other licensed medical professionals, for their alleged participation in HCF schemes involving approximately $1.1 billion in false billings. The continued support of DOJ Strike Force operations is a top priority for the FBI. Additionally, the FBI coordinates and shares intelligence with HHS and DOJ components on other prevention and enforcement activities, to include efforts associated with the Large-Scale Conspiracies, Major Provider Fraud, and Prescription Drug Initiatives.

As part of the DOJ ARPO Strike Force initiative to address the illegal diversion of prescription opioids in the Appalachian Region, DOJ provided additional funding to the FBI to support the deployment of Special Agents dedicated to identifying and investigating individuals, including medical professionals, who divert prescription opioids, and thus contribute to the nation's opioid epidemic. The ARPO Strike Force operates in Birmingham, Cincinnati, Knoxville, Louisville, Memphis, Pittsburgh, and Richmond.

In September 2020 a physician, who was one of the highest prescribers of opiates in North Alabama, and who routinely accepted kickbacks in various forms in exchange for referrals for prescriptions, urine drug testing, durable medical equipment, and other studies, along with six other individuals, including his wife, son, and a brother, were arrested and charged in furtherance of the ARPO Initiative. The subjects were charged with distribution and conspiracy to distribute controlled substances, health care fraud, violating the anti-kickback statute, and money laundering. During the course of the investigations, approximately $41 million in fraudulent claims were submitted to Medicare, Tricare, and private insurance programs, out of which approximately $14.0 million was paid to the subjects.

The Prescription Drug Initiative

The Prescription Drug Initiative identifies and targets criminal enterprises and other groups or individuals engaged in prescription drug schemes, and prosecutes improper prescribing and dispensing practices of controlled substances. These schemes are a significant crime problem as they impact public health and safety. In Detroit, a physician was sentenced to 10 years imprisonment and assessed a $20,000 fine after pleading guilty to one count of conspiracy to distribute controlled substances and 19 counts of unlawful distribution of controlled substances. This physician conspired with others to issue a large number of prescription opioids to recruited patients who did not have a legitimate medical need, in exchange for cash payment. During the pendency of the scheme, the physician prescribed more than one million dosage units of Schedule II drugs, predominantly oxycodone and oxymorphone, in addition to benzodiazepines, with a street value in excess of $22.0 million. The FBI coordinated efforts in this case with the Detroit City Medicare Strike Force

The Large-Scale Conspiracies Initiative

The Large-Scale Conspiracies Initiative seeks to identify and target criminal enterprises and

other groups whose schemes result in significant monetary losses, or potential losses, to government health care benefit programs and private health insurance plans. This initiative focuses predominantly on organized groups of individuals who co-opt medical providers to collaborate in fraud schemes. Examples of the complex schemes carried out by these criminal organizations include the sharing and selling of beneficiaries' personal identifying information, multi-tiered kickback schemes involving fraudulent referrals, and billing for medically unnecessary services or medical services that were never provided.

In furtherance of this initiative, an investigation into a compounding pharmacy located in Massachusetts was opened after a nationwide outbreak of fungal meningitis occurred. The outbreak was traced back to contaminated vials of preservative-free methylprednisolone acetate (MPA) manufactured in the compounding pharmacy. The CDC reported that 753 patients in 20 states were diagnosed with a fungal infection after receiving injections from the compounding pharmacy. Of those 753 patients, more than 100 patients died and approximately 800 patients were sickened. The outbreak was the largest public health crisis ever caused by a contaminated pharmaceutical drug. Fourteen individuals were indicted including a co-owner and head pharmacist, and a supervisory pharmacist. In FY 2021, the co-owner/head pharmacist was sentenced to 14.5 years in prison, ordered to forfeit $1.4 million in assets, and to pay $82.0 million in restitution. The supervisory pharmacist was sentenced to 10.5 years in prison, 3 years of supervised release, and ordered to pay $82.0 million in restitution. The case was worked jointly with the FDA Office of Criminal Investigations, Department of Veterans Affairs OIG, Department of Defense OIG, Defense Criminal Investigative Service, and the U.S. Postal Inspection Service.

Major Provider Fraud Initiative

The Major Provider Fraud Initiative seeks to identify and target major medical providers, such as corporations, companies, and other groups engaging in significant medical billing fraud schemes that result in, or are intended to result in, large monetary losses to taxpayer funded, government health care benefit programs and private health care plans. This initiative is intended to focus FBI operations on the most significant schemes impacting public and private health insurance programs and plans, to include focusing on large civil suits and threats to life. Investigations targeting major providers are typically identified and initiated based upon data analytics, the review of civil qui tam filings, coordination with HHS, and coordination with DOJ's civil and criminal components. Due to the complexity of major provider investigations, the FBI's HCFU provides ongoing support to field offices that initiate them, including coordinating investigative activity among multiple field offices and investigative support from the Health Care Fraud Case Support Team and the Health Care Fraud National Rapid Response Team. Many FBI investigations conducted jointly with our partners on DOJ's Medicare Fraud Strike Forces fall under this initiative.

An example of an investigation opened in furtherance of the Major Provider Fraud Initiative is the investigation into Purdue Pharma, LLC. From the mid-1990s through February 2018, Purdue Pharma heavily marketed its opioid products and spent up to $1.5 billion a year on opioid marketing efforts for its branded products, including Butrans (buprenorphine), Dilaudid (hydromorphone), Hysingla ER (hydrocodone bitartrate), MS Contin (morphine sulphate), and

OxyContin ER (oxycodone hydrochloride). Between 2010 and 2018, Purdue Pharma paid doctors and pharmacies illegal kickbacks to encourage medically unnecessary opioid prescriptions, resulting in fraudulent claims to government healthcare programs. In FY 2021, Purdue Pharma plead guilty to one count of dual-object conspiracy to defraud the United States and to violate the Food, Drug, and Cosmetic Act, and two counts of conspiracy to violate the AKS Purdue also agreed to pay a total of $8.3 billion to resolve criminal and civil charges. The FBI Washington Field Office coordinated efforts in this case with the US Attorney's offices for the District of New Jersey and the District of Vermont; and the DOJ, Civil Division, Consumer Protection Branch.

Outreach, Education, and Liaison initiative

In FY 2021, the FBI established the Outreach, Education, and Liaison initiative to ensure that the FBI initiates and maintains ongoing and frequent contact with our law enforcement, regulatory, and private sector partners, as well as the general public 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 efforts to meet with our partners to share information and educate the public about the health care fraud threat. To assist in these efforts, the HCFU is working with the FBI's Office of Public Affairs to launch a campaign to increase public awareness of potential indicators of health care fraud. The campaign will consist of information that will assist the public in identifying health care fraud activity and how they can report it. The campaign will also provide guidance to the public through various media advertisements, including a social media outreach component. Furthermore, the HCFU updated the FBI.gov web site with helpful information such as common health care fraud schemes and tips on how to avoid becoming a victim of health care fraud scams.

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 2021, the HCFU continued its virtual trainings to address the educational needs of the FBI personnel throughout the pandemic in lieu of in-person training. The virtual training platform made training more accessible to FBI personnel. In FY 2021, twelve sessions were hosted with an attendance of 920 participants. Some of the topics covered included current trends in HCF, working with private insurance special investigations units, and HCF data analytics, among others. The FBI HCF program will continue to support employee's attendance to qualified virtual and in-person training offered by federal and local law enforcements agencies along with the private sector.

Return on Investment Calculation

- The return on investment (ROI) for the HCFAC program is calculated by dividing the total monetary results to the federal government (not including relator payments) by the annual appropriation for the HCFAC Account in a given year (not including portions of CMS funding dedicated to the Medicare Integrity Program listed in the table on page 123).

- 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 2021, 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[42]	**Fiscal Year 2021**
Office of Inspector General	$213,886,600
Health and Human Services Wedge[43]	40,908,373
Medicare Integrity Program[44]	941,463,113
MIP/Medicare (non-add)	*869,042,874*
Medi-Medi (non-add)	*72,420,239*
Department of Justice Wedge[41]	66,781,285
Federal Bureau of Investigation[45]	152,394,202
Subtotal, Mandatory HCFAC	**$1,415,433,573**
Discretionary Resources	
Office of Inspector General	$99,000,000
CMS Program Integrity	616,000,000
CMS Program Integrity (non-add)	*596,000,000*
Senior Medicare Patrols (ACL non-add)	*20,000,000*
Department of Justice	92,000,000
Subtotal, Discretionary HCFAC	807,000,000
Grand Total, HCFAC	**$2,222,433,573**

[42] Section 3709 of the CARES Act (P.L. 116-136) suspended Medicare sequestration from May 1, 2020 through December 31, 2020; the Consolidated Appropriations Act, 2021 (P.L. 116-260) extended this suspension to March 31, 2021; and the Medicare sequester moratorium included in P.L. 117-7 extended the suspension again until December 31, 2021. This sequester adjustment was meant to provide an economic boost to Medicare providers treating patients during the COVID-19 PHE and has resulted in additional funding for the HCFAC program. The three bills overlap to cover the entirety of FY 2021. The FY 2022 sequester amount will reflect a pro-rated period from October 1, 2021 to December 31, 2021.

[43] 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.

[44] 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.

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

Glossary of Common Terms

The Account—The Health Care Fraud and Abuse Control Account

ACA—Affordable Care Act

AKS—Anti-Kickback Statute

ACL—Department of Health and Human Services, Administration for Community Living

AUSA—Assistant United States Attorney

CHIP—Children's Health Insurance Program

CIA—Corporate Integrity Agreement

CMP—Civil Monetary Penalty

CMPL—Civil Monetary Penalties Law

CMS—Department of Health and Human Services, Centers for Medicare & Medicaid Services

CPI—Center for Program Integrity

CY—Calendar Year

DEA—Drug Enforcement Administration

DME—Durable Medical Equipment

DOJ—The Department of Justice

FBI—Federal Bureau of Investigation

FCA—False Claims Act

FDA—Food and Drug Administration

FFS—Fee-for-Service

FY—Fiscal Year

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

HEAT—Health Care Fraud Prevention & Enforcement Action Team

HFPP—Health care Fraud Prevention Partnership

HHA—Home Health Agency

HHS—The Department of Health and Human Services

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

HI—Hospital Insurance Trust Fund

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

MA – Medicare Advantage

MAO—Medicare Advantage Organization

MFCU—Medicaid Fraud Control Unit

MEDIC—Medicare Drug Integrity Contractors

OCGS—Organized Crime and Gang Section

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

PECOS—Provider Enrollment, Chain and Ownership System

PERM—Payment Error Rate Measurement

PFP—Pharmaceutical Fraud Pilot Program

The Program—The Health Care Fraud and Abuse Control Program

Secretary—The Secretary of the Department of Health and Human Services

SMP—Senior Medicare Patrol

UPIC—Unified Program Integrity Contractor

USAO—United States Attorney's Office

Use of the False Claims in Heath Care Fraud Investigations and Litigation

Moderator:
Adam J. Katz, Esq.

Panelists:
Erica B. Hitchings, Esq.
Geoffrey R. Kaiser, Esq.

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JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Tuesday, February 1, 2022

Justice Department's False Claims Act Settlements and Judgments Exceed $5.6 Billion in Fiscal Year 2021

Second Largest Amount Recorded, Largest Since 2014

The Justice Department obtained more than $5.6 billion in settlements and judgments from civil cases involving fraud and false claims against the government in the fiscal year ending Sept. 30, 2021, Acting Assistant Attorney General Brian M. Boynton of the Justice Department's Civil Division announced today. This is the second largest annual total in False Claims Act history, and the largest since 2014. Settlement and judgments since 1986, when Congress substantially strengthened the civil False Claims Act, now total more than $70 billion.

"Ensuring that citizens' tax dollars are protected from fraud and abuse is among the department's top priorities," said Acting Assistant Attorney General Boynton. "The False Claims Act is one of the most important tools available to the department both to deter and to hold accountable those who seek to misuse public funds."

Of the more than $5.6 billion in settlements and judgments reported by the Department of Justice this past fiscal year, over $5 billion relates to matters that involved the health care industry, including drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories and physicians. The amounts included in the $5 billion reflect recoveries arising from only federal losses, and, in many of these cases, the department was instrumental in recovering additional amounts for state Medicaid programs.

In addition to being used to combat health care fraud, the False Claims Act serves as the government's primary civil tool to redress false claims involving a multitude of other government operations and functions. The act helps to support our military and first responders by ensuring that government contractors provide equipment that is safe, effective and cost efficient; to safeguard American businesses and workers by promoting compliance with customs laws, trade agreements, visa requirements and small business protections; and to protect other critical government programs ranging from the provision of disaster relief funds to nutrition benefits for needy families.

In 1986, Congress strengthened the act by increasing incentives for whistleblowers to file lawsuits alleging false claims on behalf of the government. These whistleblower, or *qui tam*, actions comprise a significant percentage of the False Claims Act cases that are filed. If the government prevails in a *qui tam* action, the whistleblower, also known as the relator, typically receives a portion of the recovery ranging between 15% and 30%. Whistleblowers filed 598 *qui tam* suits in fiscal year 2021, and this past year the department reported settlements and judgments exceeding $1.6 billion in these and earlier-filed suits.

Health Care Fraud

Health care fraud was once again the leading source of the department's False Claims Act settlements and judgments this past year. The department's health care fraud enforcement efforts restore funds to federal programs such as Medicare, Medicaid and TRICARE, the health care program for service members and their families. But just as important, the department's vigorous pursuit of health care fraud prevents billions more in losses by deterring others who might try to cheat the system for their own gain. In many cases, the department's efforts also protect patients from medically unnecessary or potentially harmful actions. The department investigates and resolves matters involving a wide array of health care providers, goods and services.

Combatting the Opioid Epidemic

Opioid abuse remains a serious problem for our nation, with tens of thousands of Americans dying from opioid overdoses each year. Civil enforcement actions against the parties responsible for triggering and fueling the opioid epidemic are a critical part of the department's ongoing efforts to address this crisis.

Consistent with this focus, the largest False Claims Act settlements in the past year resulted from significant resolutions with prescription opioid manufacturers: Indivior Inc. and Indivior plc (Indivior), and Purdue Pharma (Purdue). As part of a $600 million global resolution of criminal and civil liability, the Indivior companies agreed to pay $209.3 million to the federal government to resolve civil allegations that the companies, among other things, promoted the opioid-addiction-treatment drug Suboxone to physicians who were writing prescriptions that were not for a medically accepted indication and were often diverted; and made false and misleading claims that Suboxone Film was less susceptible to diversion and abuse and to accidental pediatric exposure than other buprenorphine products.

As part of a global resolution of criminal and civil liability, in October 2020, Purdue agreed to an allowed, unsubordinated, general unsecured bankruptcy claim for $2.8 billion to resolve civil allegations that the company promoted its opioid drugs to health care providers it knew were prescribing opioids for uses that were unsafe, ineffective, and medically unnecessary, and that often led to abuse and diversion. The civil settlement also resolved allegations that Purdue paid kickbacks to doctors, certain specialty pharmacies and an electronic health records developer to increase prescriptions of Purdue's opioid products. Purdue incorporated the civil settlement into its plan of reorganization, but the district court subsequently reversed a bankruptcy court order confirming the plan and litigation over the plan continues. Separately, certain individual members of the Sackler family who were shareholders and board members of Purdue agreed to pay $225 million to resolve civil False Claims Act allegations that they approved a new marketing program that intensified marketing of OxyContin to extreme, high-volume prescribers, causing opioid prescriptions for uses that were unsafe, ineffective and medically unnecessary, and that often led to abuse and diversion.

Medicare Advantage Program (Medicare Part C)

Another important priority for the department has been investigating and litigating a growing number of matters related to the Medicare Advantage program, also known as Medicare Part C, which is Medicare's managed care program. Medicare Part C pays a capitated amount to private health insurance carriers for each patient enrolled in their plans, rather than a payment for each distinct patient admission or service. CMS adjusts the payments for various "risk" factors that affect expected healthcare expenditures to ensure that plans are paid more for enrollees who pose a greater risk. In 2021, more than 26 million Medicare beneficiaries were enrolled in Part C plans, and the Congressional Budget Office projected that CMS would pay more than $343 billion to private carriers who offered those plans.

The department has pursued plans and healthcare providers that manipulated the risk adjustment process by submitting unsupported diagnosis codes to make their patients appear sicker than they actually were. This year, Sutter Health, a California-based health care services provider, paid $90 million to resolve allegations that it knowingly submitted unsupported diagnosis codes for certain patient encounters, resulting in inflated payments to be made to the Medicare Advantage Plans and Sutter Health. In addition, Kaiser Foundation Health Plan of Washington, formerly known as Group Health Cooperative (GHC), paid $6.3

million to resolve allegations that it submitted invalid diagnoses and received inflated payments as a result. In addition, the department intervened and filed complaints in separate lawsuits against Independent Health Corporation and members of the Kaiser Permanente consortium alleging that those Medicare Advantage organizations submitted or caused the submission of inaccurate information about the health status of beneficiaries enrolled in their plans to increase reimbursement from Medicare.

Unlawful Kickbacks

Kickbacks in the healthcare industry are pernicious because of their potential to subvert medical decision-making and to increase healthcare costs. In addition to pursuing improper payments by drug manufacturers, the department resolved other schemes involving the willful solicitation or payment of illegal remuneration to induce the purchase of a good or service paid for by a federal health care program.

For example, mail-order diabetic testing supply company Arriva Medical LLC and its parent, Alere Inc., agreed to pay $160 million to settle allegations that Arriva paid kickbacks to Medicare beneficiaries by providing them "free" or "no cost" diabetic testing glucometers and by routinely waiving or not making reasonable efforts to collect their copayments for glucometers and diabetic testing supplies. In another example, the department resolved its claims against pain management clinics and urine drug testing (UDT) laboratories owned and operated by Daniel McCollum for paying unlawful kickbacks to providers to induce their referrals of urine drug tests, obtaining default judgments against the clinics and laboratories totaling more than $140 million and a $9 million civil consent judgment against McCollum.

Electronic health records (EHR) technology vendor Athenahealth Inc. paid $18.25 million to resolve allegations that it invited customers and prospective customers to lavish all-expense-paid sporting, entertainment, and recreational events to generate sales of its EHR product. Generic pharmaceutical manufacturers Taro, Sandoz, and Apotex paid over $400 million to resolve allegations that they paid and received compensation prohibited by the Anti-Kickback Statute through arrangements on price, supply and allocation of customers with other pharmaceutical manufacturers as part of a conspiracy to fix the price of certain generic drugs.

Other matters relating to kickback violations involved psychiatric hospitals and a substance abuse treatment facility (Oglethorpe Inc.), home health care agencies (BAYADA), hospitals (Akron General Health System, Texas Heart Hospital of the Southwest LLP, and Prime Healthcare Services), pharmaceutical companies (Biogen Inc.), diagnostic testing (Alliance Family of Companies LLC) and medical devices (Merit Medical Systems Inc).

Unnecessary Medical Services

As in years past, the department also resolved a number of matters in which providers billed federal health care programs for medically unnecessary services or services not rendered as billed. For example, SavaSeniorCare LLC and related entities agreed to pay $11.2 million for alleged false claims for rehabilitation therapy services provided as a result of aggressive corporate targets without regard for its patients' actual clinical needs, resulting in the provision of medically unreasonable, unnecessary or unskilled services to Medicare patients. The settlement also resolved allegations that Sava provided grossly and materially substandard and/or worthless skilled nursing services.

Alere Inc. and Alere San Diego Inc. (collectively, Alere) paid $38.75 million to resolve allegations that they billed, and caused others to bill, for defective rapid point-of-care testing devices used by Medicare beneficiaries to monitor blood coagulation when taking anticoagulant drugs. In another matter, Apria Healthcare LLC paid $40.5 million to resolve allegations that it submitted false claims for the rental of costly non-invasive ventilators to program beneficiaries who did not need the devices or were not using them. St. Jude Medical Inc. paid $27 million to settle allegations that it knowingly sold defective, implantable heart devices and failed to disclose serious adverse health events in connection with premature battery depletion in those devices. Regency Inc. and its owner agreed to a civil settlement up to $20.3 million to resolve allegations that they falsified documentation to enable the billing of federal healthcare programs for medically

unnecessary durable medical equipment. In addition, the department continues to focus on inadequate care and other fraud in nursing facilities, which provide care to a particularly vulnerable population (as reflected by the resolutions this year with SavaSeniorCare LLC, discussed above, and Select Medical Rehabilitation Services Inc).

Procurement Fraud

In the past year, the department also pursued a variety of fraud matters involving the government's purchase of goods and services. In some cases, the department pursued allegations that government contractors falsified pricing data. For example, Navistar Defense LLC paid $50 million to resolve allegations that it fraudulently induced the U.S. Marine Corps to enter into a contract modification at inflated prices for a suspension system for armored vehicles known as Mine-Resistant Ambush Protected vehicles. In another case, Insitu Inc. paid $25 million to settle allegations that it knowingly submitted materially false cost and pricing data for contracts with the U.S. Special Operations Command and the Department of the Navy to supply and operate Unmanned Aerial Vehicles. The department also recovered $7.1 million from furniture maker Workrite Ergonomics LLC to resolve allegations that the company did not provide the General Services Administration with accurate information about its commercial sales practices during contract negotiations for office furniture, and subsequently violated the terms of its contract by failing to extend lower prices to government customers.

In other cases, the department pursued allegations that government contractors provided goods or services that did not comply with contract requirements. For example, United Airlines Inc. paid $32.1 million to resolve allegations relating to its execution of contracts to deliver mail internationally on behalf of the U.S. Postal Service. In another case, Cognosante LLC paid $18.9 million to resolve allegations that it used unqualified labor and overcharged the government for health care and IT services provided to federal agencies under two General Services Administration contracts. The department also recovered $11 million from AAR Corp. and its subsidiary, AAR Airlift Group Inc., to resolve allegations that AAR Airlift knowingly failed to maintain nine helicopters in accordance with Department of Defense contract requirements and that the helicopters, which were billed under two U.S. Transportation Command contracts to transport cargo and personnel in support of missions in Afghanistan and Africa, were not airworthy and should not have been certified as fully mission capable.

The department also resolved matters involving allegations of kickbacks in government contracts. For example, Level 3 Communications LLC paid $12.7 million to resolve allegations that the owner of two subcontractors paid kickbacks to Level 3 senior managers in return for favorable treatment for those subcontractors on government contracts. The United States also alleged that Level 3 managers misstated compliance with woman-owned small business subcontracting requirements and knowingly obtained protected competitor bid information on the government contract to gain an advantage in bidding on task orders. In another example, Schneider Electric Buildings Americas Inc. paid more than $9 million to resolve allegations that one of its senior project managers solicited kickbacks from subcontractors and that the company fraudulently charged the government for design costs by disguising those costs and spreading them across unrelated pricing components.

COVID-Related Fraud

In response to the COVID-19 crisis, Congress authorized historic levels of emergency funding for federal agencies to provide direct financial assistance to individuals, businesses and state, local, and Tribal governments. Since the start of the COVID-19 pandemic, the department has worked closely with various Inspector Generals and other agency stakeholders to identify, monitor and investigate the misuse of critical pandemic relief monies.

The department's efforts in this area have included the pursuit of cases involving improper payments under the Paycheck Protection Program (PPP), which was enacted to provide loans guaranteed by the U.S. Small Business Administration (SBA) to eligible small businesses for payroll, rent, utility payments and other business-related costs. For example, the department has pursued small businesses that improperly received multiple PPP loans. Sandeep S. Walia and his medical practice paid a combined $70,000 to resolve allegations under the False Claims Act and the Financial Institutions Reform, Recovery and Enforcement Act (FIRREA) that Dr. Walia, on behalf of his practice, falsely certified in an application for a second PPP loan that the medical practice had not previously

received a PPP loan. The medical practice also agreed to repay the second PPP loan to the lender, relieving the SBA of liability for the federal guaranty of over $430,000 on the improper loan.

Sextant Marine Consulting LLC, a Florida-based duct cleaning company, paid $30,000 to settle allegations that it improperly obtained more than one PPP loan. Sextant also repaid the duplicative PPP funds in full to its lender, relieving the SBA of liability for the federal guaranty of approximately $170,000 on the improper loan. The department has also pursued cases against eligible borrowers who used PPP funds to pay for impermissible expenses. For example, Seth A. Bernstein, the owner of jet charter company All in Jets LLC dba JetReady, paid $287,055 to settle allegations that he diverted PPP funds to pay for personal, non-company related expenses.

Other Fraud Recoveries

The judgments and settlements announced during fiscal year 2021 reflect the diversity of fraud recoveries arising under the False Claims Act. For example, the United States leases federal lands for the production of natural gas in exchange for the payment of royalties on the value of the gas produced. The department recovered $6.15 million from oil and natural gas exploration and production company Devon Energy Corp. to resolve allegations that it underpaid and underreported royalties for natural gas from federal lands in Wyoming and New Mexico.

Stargate Apparel Inc., Rivstar Apparel Inc., and the chief executive officer of both companies paid $6 million to resolve allegations that they engaged in two schemes to fraudulently underpay customs duties owed to the United States in connection with the garments that they brought into the country.

Concept Schools NFP, agreed to pay $4.5 million for allegedly engaging in non-competitive bidding practices in connection with the Federal Communications Commission's (FCC) E-Rate Program, which subsidizes eligible equipment and services to make internet access and internal networking more affordable for needy public schools and libraries. Concept Schools, a charter school management company, rigged the bidding for E-Rate contracts in favor of chosen technology vendors so that its network of charter schools could select those vendors without a meaningful, fair and open bidding process. Additionally, the government alleged that Concept Schools' chosen vendors provided equipment at higher prices than other vendors approved by the FCC for equipment with the same functionality, and that Concept Schools failed to maintain sufficient control over equipment reimbursed by the FCC.

Educational services provider Innovative Educational Programs LLC paid $1.1 million to resolve allegations that it fraudulently obtained federal funds for tutoring services for underprivileged New York City students that it never provided. The New York City Department of Education had paid Innovative to tutor students using funds made available to New York State by the United States under the Elementary and Secondary Education Act of 1965, as amended by the No Child Left Behind Act of 2001.

Guild Mortgage Company paid $24.9 million to resolve allegations that it failed to maintain quality control programs to prevent and correct underwriting deficiencies and to self-report materially deficient loans insured by the Federal Housing Administration.

Cybersecurity Initiative

Malicious cyber activity threatens the health and safety of the American people, and the national and economic security of our country. On May 12, 2021, President Biden signed an Executive Order announcing that preventing, detecting, assessing and remediating cybersecurity incidents affecting federal government networks is a top priority, and set forth an expectation that all federal systems will meet the necessary thresholds for cybersecurity protections. On Oct. 6, 2021, the Deputy Attorney General announced the department's Civil Cyber-Fraud Initiative to use the False Claims Act to combat new and emerging cyber threats.

Civil enforcement plays an essential role in the department's cyber defense efforts. The department will pursue misrepresentations by companies in connection with the government's acquisition of information technology, software, cloud-based storage and related services designed to protect highly-sensitive government information from cybersecurity threats and compromises.

Information on how to report cyber fraud can be found here: https://www.justice.gov/civil/report-fraud.

Holding Individuals Accountable

The department continued its commitment to use the False Claims Act to deter and redress fraud by individuals as well as corporations. In addition to the settlements noted above with certain members of the Sackler family and with corporate entities that included payments by senior executives or owners, the following are additional examples of recoveries involving individuals.

Dr. Ashish Pal, a cardiologist based in Orlando, Florida, paid $6.75 million to resolve allegations that he performed medically unnecessary ablations and vein stent procedures. The government alleged that Dr. Pal performed the ablations and stent procedures on veins that did not qualify for treatment under accepted standards of medical practice and falsified patient medical records to justify the procedures. In addition, many of the ablations were allegedly performed either exclusively or primarily by one or more ultrasound technicians outside their scope of practice.

Two Texas physicians, Robert Wills and Brannon Frank, paid a total of $3.9 million to resolve allegations that they billed federal health care programs for medically unnecessary urine drug testing. The settlements resolved allegations that the physicians, formerly co-owners of now-defunct Austin Pain Associates, knowingly ordered excessive and unnecessary urine drug testing for patients without any individualized assessment of clinical need.

Substance abuse treatment provider A.R.E.B.A.-Casriel Inc. dba Addiction Care Interventions Chemical Dependency Treatment Centers (ACI) and its primary owner and former CEO, Steven Yohay, agreed to pay a total of $6 million to resolve allegations that they provided kickbacks and engaged in fraudulent conduct in connection with the enrollment of Medicaid beneficiaries into ACI's inpatient treatment program. The United States alleged that ACI offered food and cash to homeless individuals to induce them to enroll in ACI's inpatient treatment program, offered sham employment to an individual to induce her to refer patients to ACI programs, and used medical admissions forms containing photocopied physician signatures to make it appear that new patients had been evaluated by a qualified health care professional. ACI agreed to pay $3 million, and Yohay agreed to pay an additional $3 million and divest himself of ownership and control of ACI.

Recoveries in Whistleblower Suits

Of the $5.6 billion in settlements and judgments reported by the government in fiscal year 2021, over $1.6 billion arose from lawsuits filed under the *qui tam* provisions of the False Claims Act. During the same period, the government paid out $237 million to the individuals who exposed fraud and false claims by filing these actions.

The number of lawsuits filed under the *qui tam* provisions of the Act has grown significantly since 1986, with 598 *qui tam* suits filed this past year – an average of over 11 new cases every week.

"Industry insiders are uniquely positioned to expose fraud and false claims and often risk their careers to bring these schemes to light," said Acting Assistant Attorney General Boynton. "Our efforts to protect taxpayer funds benefit from the courageous actions of these whistleblowers, and they are justly rewarded under the False Claims Act."

In 1986, Senator Charles Grassley and Representative Howard Berman led the successful efforts in Congress to amend the False Claims Act to, among other things, encourage whistleblowers to come forward with allegations of fraud. In 2009 and 2010, further improvements were made to the False Claims Act and its whistleblower provisions.

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Acting Assistant Attorney General Boynton expressed appreciation for all the work over the past year by the many public servants who supported the department's efforts to protect the public: "We owe a debt of gratitude to the employees in the Civil Division, the U.S. Attorneys' Offices, the agency Offices of Inspector General and Offices of General Counsel and the many other federal and state agencies who have worked tirelessly to protect the public fisc from fraud."

Except where indicated, the government's claims in the matters described above are allegations only and there has been no determination of liability. The numbers contained in this press release may differ slightly from the original press releases due to accrued interest.

Attachment(s):
Download FCA FY2021 Statistics.pdf

Topic(s):
False Claims Act

Component(s):
Civil Division

Press Release Number:
22-83

Updated February 1, 2022

KeyCite Yellow Flag - Negative Treatment
Unconstitutional or Preempted Limited on Constitutional Grounds by U.S. v. Hawley, N.D.Iowa, Aug. 01, 2011

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 31. Money and Finance (Refs & Annos)
Subtitle III. Financial Management
Chapter 37. Claims (Refs & Annos)
Subchapter III. Claims Against the United States Government (Refs & Annos)

31 U.S.C.A. § 3729

§ 3729. False claims

Currentness

(a) Liability for certain acts.--

(1) In general.--Subject to paragraph (2), any person who--

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

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is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410 [1]), plus 3 times the amount of damages which the Government sustains because of the act of that person.

(2) Reduced damages.--If the court finds that--

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

(B) such person fully cooperated with any Government investigation of such violation; and

(C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation,

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of that person.

(3) Costs of civil actions.--A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

(b) Definitions.--For purposes of this section--

(1) the terms “knowing” and “knowingly” --

(A) mean that a person, with respect to information--

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud;

(2) the term “claim”--

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(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that--

(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government--

(I) provides or has provided any portion of the money or property requested or demanded; or

(II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property;

(3) the term "obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and

(4) the term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

(c) Exemption from disclosure.--Any information furnished pursuant to subsection (a)(2) shall be exempt from disclosure under section 552 of title 5.

(d) Exclusion.--This section does not apply to claims, records, or statements made under the Internal Revenue Code of 1986.

CREDIT(S)

(Pub.L. 97-258, Sept. 13, 1982, 96 Stat. 978; Pub.L. 99-562, § 2, Oct. 27, 1986, 100 Stat. 3153; Pub.L. 103-272, § 4(f)(1)(O), July 5, 1994, 108 Stat. 1362; Pub.L. 111-21, § 4(a), May 20, 2009, 123 Stat. 1621.)

Notes of Decisions (2054)

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Footnotes

1 So in original. Probably should read "Public Law 101-410".

31 U.S.C.A. § 3729, 31 USCA § 3729
Current through P.L. 117-167. Some statute sections may be more current, see credits for details.

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KeyCite Yellow Flag - Negative Treatment
Unconstitutional or Preempted Limitation Recognized by United States ex rel. Maharaj v. Estate of Zimmerman, D.Md., Dec. 12, 2019

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

31 U.S.C.A. § 3730

§ 3730. Civil actions for false claims

Effective: July 22, 2010
Currentness

(a) Responsibilities of the Attorney General.--The Attorney General diligently shall investigate a violation under section 3729. If the Attorney General finds that a person has violated or is violating section 3729, the Attorney General may bring a civil action under this section against the person.

(b) Actions by private persons.--(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. [1] The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall--

(A) proceed with the action, in which case the action shall be conducted by the Government; or

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(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(5) When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

(c) Rights of the parties to qui tam actions.--(1) If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).

(2)(A) The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

(B) The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.

(C) Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment, the court may, in its discretion, impose limitations on the person's participation, such as--

(i) limiting the number of witnesses the person may call;

(ii) limiting the length of the testimony of such witnesses;

(iii) limiting the person's cross-examination of witnesses; or

(iv) otherwise limiting the participation by the person in the litigation.

(D) Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

(3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

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(4) Whether or not the Government proceeds with the action, upon a showing by the Government that certain actions of discovery by the person initiating the action would interfere with the Government's investigation or prosecution of a criminal or civil matter arising out of the same facts, the court may stay such discovery for a period of not more than 60 days. Such a showing shall be conducted in camera. The court may extend the 60-day period upon a further showing in camera that the Government has pursued the criminal or civil investigation or proceedings with reasonable diligence and any proposed discovery in the civil action will interfere with the ongoing criminal or civil investigation or proceedings.

(5) Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

(d) Award to qui tam plaintiff.--(1) If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. Where the action is one which the court finds to be based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting [2] Office report, hearing, audit, or investigation, or from the news media, the court may award such sums as it considers appropriate, but in no case more than 10 percent of the proceeds, taking into account the significance of the information and the role of the person bringing the action in advancing the case to litigation. Any payment to a person under the first or second sentence of this paragraph shall be made from the proceeds. Any such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(3) Whether or not the Government proceeds with the action, if the court finds that the action was brought by a person who planned and initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive under paragraph (1) or (2) of this subsection, taking into account the role of that person in advancing the case to litigation and any relevant circumstances pertaining to the violation. If the person bringing the action is convicted of criminal conduct arising from his or her role in the violation of section 3729, that person shall be dismissed from the civil action and shall not receive any share of the proceeds of the action. Such dismissal shall not prejudice the right of the United States to continue the action, represented by the Department of Justice.

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(4) If the Government does not proceed with the action and the person bringing the action conducts the action, the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.

(e) Certain Actions Barred.--(1) No court shall have jurisdiction over an action brought by a former or present member of the armed forces under subsection (b) of this section against a member of the armed forces arising out of such person's service in the armed forces.

(2)(A) No court shall have jurisdiction over an action brought under subsection (b) against a Member of Congress, a member of the judiciary, or a senior executive branch official if the action is based on evidence or information known to the Government when the action was brought.

(B) For purposes of this paragraph, "senior executive branch official" means any officer or employee listed in paragraphs (1) through (8) of section 101(f) of the Ethics in Government Act of 1978 (5 U.S.C. App.).

(3) In no event may a person bring an action under subsection (b) which is based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party.

(4)(A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed--

(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;

(ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or

(iii) from the news media,

unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

(B) For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

(f) Government not liable for certain expenses.--The Government is not liable for expenses which a person incurs in bringing an action under this section.

(g) Fees and expenses to prevailing defendant.--In civil actions brought under this section by the United States, the provisions of section 2412(d) of title 28 shall apply.

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(h) Relief from retaliatory actions.--

(1) In general.--Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violations of this subchapter.

(2) Relief.--Relief under paragraph (1) shall include reinstatement with the same seniority status that employee, contractor, or agent would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees. An action under this subsection may be brought in the appropriate district court of the United States for the relief provided in this subsection.

(3) Limitation on bringing civil action.--A civil action under this subsection may not be brought more than 3 years after the date when the retaliation occurred.

CREDIT(S)

(Pub.L. 97-258, Sept. 13, 1982, 96 Stat. 978; Pub.L. 99-562, §§ 3, 4, Oct. 27, 1986, 100 Stat. 3154, 3157; Pub.L. 100-700, § 9, Nov. 19, 1988, 102 Stat. 4638; Pub.L. 101-280, § 10(a), May 4, 1990, 104 Stat. 162; Pub.L. 103-272, § 4(f)(1)(P), July 5, 1994, 108 Stat. 1362; Pub.L. 111-21, § 4(d), May 20, 2009, 123 Stat. 1624; Pub.L. 111-148, Title X, § 10104(j)(2), Mar. 23, 2010, 124 Stat. 901; Pub.L. 111-203, Title X, § 1079A(c), July 21, 2010, 124 Stat. 2079.)

Notes of Decisions (2619)

Footnotes

1 See, now, Rule 4(i) of the Federal Rules of Civil Procedure.

2 So in original. Probably should be “Accountability”.

31 U.S.C.A. § 3730, 31 USCA § 3730
Current through P.L. 117-167. Some statute sections may be more current, see credits for details.

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KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

31 U.S.C.A. § 3731

§ 3731. False claims procedure

Currentness

(a) A subpena requiring the attendance of a witness at a trial or hearing conducted under section 3730 of this title may be served at any place in the United States.

(b) A civil action under section 3730 may not be brought--

(1) more than 6 years after the date on which the violation of section 3729 is committed, or

(2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,

whichever occurs last.

(c) If the Government elects to intervene and proceed with an action brought under 3730(b), [1] the Government may file its own complaint or amend the complaint of a person who has brought an action under section 3730(b) to clarify or add detail to the claims in which the Government is intervening and to add any additional claims with respect to which the Government contends it is entitled to relief. For statute of limitations purposes, any such Government pleading shall relate back to the filing date of the complaint of the person who originally brought the action, to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint of that person.

(d) In any action brought under section 3730, the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.

(e) Notwithstanding any other provision of law, the Federal Rules of Criminal Procedure, or the Federal Rules of Evidence, a final judgment rendered in favor of the United States in any criminal proceeding charging fraud or false statements, whether upon a verdict after trial or upon a plea of guilty or nolo contendere, shall estop the defendant from denying the essential elements of the offense in any action which involves the same transaction as in the criminal proceeding and which is brought under subsection (a) or (b) of section 3730.

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CREDIT(S)

(Pub.L. 97-258, Sept. 13, 1982, 96 Stat. 979; Pub.L. 99-562, § 5, Oct. 27, 1986, 100 Stat. 3158; Pub.L. 111-21, § 4(b), May 20, 2009, 123 Stat. 1623.)

Notes of Decisions (186)

Footnotes

1 So in original. Probably should be preceded by ‘‘section’’.

31 U.S.C.A. § 3731, 31 USCA § 3731
Current through P.L. 117-167. Some statute sections may be more current, see credits for details.

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31 U.S.C.A. § 3732

§ 3732. False claims jurisdiction

Currentness

(a) Actions under section 3730.--Any action under section 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred. A summons as required by the Federal Rules of Civil Procedure shall be issued by the appropriate district court and served at any place within or outside the United States.

(b) Claims under State Law.--The district courts shall have jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises from the same transaction or occurrence as an action brought under section 3730.

(c) Service on State or local authorities.--With respect to any State or local government that is named as a co-plaintiff with the United States in an action brought under subsection (b), a seal on the action ordered by the court under section 3730(b) shall not preclude the Government or the person bringing the action from serving the complaint, any other pleadings, or the written disclosure of substantially all material evidence and information possessed by the person bringing the action on the law enforcement authorities that are authorized under the law of that State or local government to investigate and prosecute such actions on behalf of such governments, except that such seal applies to the law enforcement authorities so served to the same extent as the seal applies to other parties in the action.

CREDIT(S)

(Added Pub.L. 99-562, § 6(a), Oct. 27, 1986, 100 Stat. 3158; amended Pub.L. 111-21, § 4(e), May 20, 2009, 123 Stat. 1625.)

Notes of Decisions (25)

31 U.S.C.A. § 3732, 31 USCA § 3732
Current through P.L. 117-167. Some statute sections may be more current, see credits for details.

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31 U.S.C.A. § 3733

§ 3733. Civil investigative demands

Currentness

(a) In general.--

(1) Issuance and service.--Whenever the Attorney General, or a designee (for purposes of this section), has reason to believe that any person may be in possession, custody, or control of any documentary material or information relevant to a false claims law investigation, the Attorney General, or a designee, may, before commencing a civil proceeding under section 3730(a) or other false claims law, or making an election under section 3730(b), issue in writing and cause to be served upon such person, a civil investigative demand requiring such person--

(A) to produce such documentary material for inspection and copying,

(B) to answer in writing written interrogatories with respect to such documentary material or information,

(C) to give oral testimony concerning such documentary material or information, or

(D) to furnish any combination of such material, answers, or testimony.

The Attorney General may delegate the authority to issue civil investigative demands under this subsection. Whenever a civil investigative demand is an express demand for any product of discovery, the Attorney General, the Deputy Attorney General, or an Assistant Attorney General shall cause to be served, in any manner authorized by this section, a copy of such demand upon the person from whom the discovery was obtained and shall notify the person to whom such demand is issued of the date on which such copy was served. Any information obtained by the Attorney General or a designee of the Attorney General under this section may be shared with any qui tam relator if the Attorney General or designee determine it is necessary as part of any false claims act [1] investigation.

(2) Contents and deadlines.--

(A) Each civil investigative demand issued under paragraph (1) shall state the nature of the conduct constituting the alleged violation of a false claims law which is under investigation, and the applicable provision of law alleged to be violated.

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(B) If such demand is for the production of documentary material, the demand shall--

(i) describe each class of documentary material to be produced with such definiteness and certainty as to permit such material to be fairly identified;

(ii) prescribe a return date for each such class which will provide a reasonable period of time within which the material so demanded may be assembled and made available for inspection and copying; and

(iii) identify the false claims law investigator to whom such material shall be made available.

(C) If such demand is for answers to written interrogatories, the demand shall--

(i) set forth with specificity the written interrogatories to be answered;

(ii) prescribe dates at which time answers to written interrogatories shall be submitted; and

(iii) identify the false claims law investigator to whom such answers shall be submitted.

(D) If such demand is for the giving of oral testimony, the demand shall--

(i) prescribe a date, time, and place at which oral testimony shall be commenced;

(ii) identify a false claims law investigator who shall conduct the examination and the custodian to whom the transcript of such examination shall be submitted;

(iii) specify that such attendance and testimony are necessary to the conduct of the investigation;

(iv) notify the person receiving the demand of the right to be accompanied by an attorney and any other representative; and

(v) describe the general purpose for which the demand is being issued and the general nature of the testimony, including the primary areas of inquiry, which will be taken pursuant to the demand.

(E) Any civil investigative demand issued under this section which is an express demand for any product of discovery shall not be returned or returnable until 20 days after a copy of such demand has been served upon the person from whom the discovery was obtained.

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(F) The date prescribed for the commencement of oral testimony pursuant to a civil investigative demand issued under this section shall be a date which is not less than seven days after the date on which demand is received, unless the Attorney General or an Assistant Attorney General designated by the Attorney General determines that exceptional circumstances are present which warrant the commencement of such testimony within a lesser period of time.

(G) The Attorney General shall not authorize the issuance under this section of more than one civil investigative demand for oral testimony by the same person unless the person requests otherwise or unless the Attorney General, after investigation, notifies that person in writing that an additional demand for oral testimony is necessary.

(b) Protected material or information.--

(1) In general.--A civil investigative demand issued under subsection (a) may not require the production of any documentary material, the submission of any answers to written interrogatories, or the giving of any oral testimony if such material, answers, or testimony would be protected from disclosure under--

(A) the standards applicable to subpoenas or subpoenas duces tecum issued by a court of the United States to aid in a grand jury investigation; or

(B) the standards applicable to discovery requests under the Federal Rules of Civil Procedure, to the extent that the application of such standards to any such demand is appropriate and consistent with the provisions and purposes of this section.

(2) Effect on other orders, rules, and laws.--Any such demand which is an express demand for any product of discovery supersedes any inconsistent order, rule, or provision of law (other than this section) preventing or restraining disclosure of such product of discovery to any person. Disclosure of any product of discovery pursuant to any such express demand does not constitute a waiver of any right or privilege which the person making such disclosure may be entitled to invoke to resist discovery of trial preparation materials.

(c) Service; jurisdiction.--

(1) By whom served.--Any civil investigative demand issued under subsection (a) may be served by a false claims law investigator, or by a United States marshal or a deputy marshal, at any place within the territorial jurisdiction of any court of the United States.

(2) Service in foreign countries.--Any such demand or any petition filed under subsection (j) may be served upon any person who is not found within the territorial jurisdiction of any court of the United States in such manner as the Federal Rules of Civil Procedure prescribe for service in a foreign country. To the extent that the courts of the United States can assert jurisdiction over any such person consistent with due process, the United States District Court for the District of Columbia shall have the same jurisdiction to take any action respecting compliance with this section by any such person that such court would have if such person were personally within the jurisdiction of such court.

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(d) Service upon legal entities and natural persons.--

(1) Legal entities.--Service of any civil investigative demand issued under subsection (a) or of any petition filed under subsection (j) may be made upon a partnership, corporation, association, or other legal entity by--

(A) delivering an executed copy of such demand or petition to any partner, executive officer, managing agent, or general agent of the partnership, corporation, association, or entity, or to any agent authorized by appointment or by law to receive service of process on behalf of such partnership, corporation, association, or entity;

(B) delivering an executed copy of such demand or petition to the principal office or place of business of the partnership, corporation, association, or entity; or

(C) depositing an executed copy of such demand or petition in the United States mails by registered or certified mail, with a return receipt requested, addressed to such partnership, corporation, association, or entity at its principal office or place of business.

(2) Natural persons.--Service of any such demand or petition may be made upon any natural person by--

(A) delivering an executed copy of such demand or petition to the person; or

(B) depositing an executed copy of such demand or petition in the United States mails by registered or certified mail, with a return receipt requested, addressed to the person at the person's residence or principal office or place of business.

(e) Proof of service.--A verified return by the individual serving any civil investigative demand issued under subsection (a) or any petition filed under subsection (j) setting forth the manner of such service shall be proof of such service. In the case of service by registered or certified mail, such return shall be accompanied by the return post office receipt of delivery of such demand.

(f) Documentary Material.--

(1) Sworn certificates.--The production of documentary material in response to a civil investigative demand served under this section shall be made under a sworn certificate, in such form as the demand designates, by--

(A) in the case of a natural person, the person to whom the demand is directed, or

(B) in the case of a person other than a natural person, a person having knowledge of the facts and circumstances relating to such production and authorized to act on behalf of such person.

The certificate shall state that all of the documentary material required by the demand and in the possession, custody, or control of the person to whom the demand is directed has been produced and made available to the false claims law investigator identified in the demand.

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(2) Production of materials.--Any person upon whom any civil investigative demand for the production of documentary material has been served under this section shall make such material available for inspection and copying to the false claims law investigator identified in such demand at the principal place of business of such person, or at such other place as the false claims law investigator and the person thereafter may agree and prescribe in writing, or as the court may direct under subsection (j)(1). Such material shall be made so available on the return date specified in such demand, or on such later date as the false claims law investigator may prescribe in writing. Such person may, upon written agreement between the person and the false claims law investigator, substitute copies for originals of all or any part of such material.

(g) Interrogatories.--Each interrogatory in a civil investigative demand served under this section shall be answered separately and fully in writing under oath and shall be submitted under a sworn certificate, in such form as the demand designates, by--

(1) in the case of a natural person, the person to whom the demand is directed, or

(2) in the case of a person other than a natural person, the person or persons responsible for answering each interrogatory.

If any interrogatory is objected to, the reasons for the objection shall be stated in the certificate instead of an answer. The certificate shall state that all information required by the demand and in the possession, custody, control, or knowledge of the person to whom the demand is directed has been submitted. To the extent that any information is not furnished, the information shall be identified and reasons set forth with particularity regarding the reasons why the information was not furnished.

(h) Oral Examinations.--

(1) Procedures.--The examination of any person pursuant to a civil investigative demand for oral testimony served under this section shall be taken before an officer authorized to administer oaths and affirmations by the laws of the United States or of the place where the examination is held. The officer before whom the testimony is to be taken shall put the witness on oath or affirmation and shall, personally or by someone acting under the direction of the officer and in the officer's presence, record the testimony of the witness. The testimony shall be taken stenographically and shall be transcribed. When the testimony is fully transcribed, the officer before whom the testimony is taken shall promptly transmit a copy of the transcript of the testimony to the custodian. This subsection shall not preclude the taking of testimony by any means authorized by, and in a manner consistent with, the Federal Rules of Civil Procedure.

(2) Persons present.--The false claims law investigator conducting the examination shall exclude from the place where the examination is held all persons except the person giving the testimony, the attorney for and any other representative of the person giving the testimony, the attorney for the Government, any person who may be agreed upon by the attorney for the Government and the person giving the testimony, the officer before whom the testimony is to be taken, and any stenographer taking such testimony.

(3) Where testimony taken.--The oral testimony of any person taken pursuant to a civil investigative demand served under this section shall be taken in the judicial district of the United States within which such person resides, is found, or transacts business, or in such other place as may be agreed upon by the false claims law investigator conducting the examination and such person.

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(4) Transcript of testimony.--When the testimony is fully transcribed, the false claims law investigator or the officer before whom the testimony is taken shall afford the witness, who may be accompanied by counsel, a reasonable opportunity to examine and read the transcript, unless such examination and reading are waived by the witness. Any changes in form or substance which the witness desires to make shall be entered and identified upon the transcript by the officer or the false claims law investigator, with a statement of the reasons given by the witness for making such changes. The transcript shall then be signed by the witness, unless the witness in writing waives the signing, is ill, cannot be found, or refuses to sign. If the transcript is not signed by the witness within 30 days after being afforded a reasonable opportunity to examine it, the officer or the false claims law investigator shall sign it and state on the record the fact of the waiver, illness, absence of the witness, or the refusal to sign, together with the reasons, if any, given therefor.

(5) Certification and delivery to custodian.--The officer before whom the testimony is taken shall certify on the transcript that the witness was sworn by the officer and that the transcript is a true record of the testimony given by the witness, and the officer or false claims law investigator shall promptly deliver the transcript, or send the transcript by registered or certified mail, to the custodian.

(6) Furnishing or inspection of transcript by witness.--Upon payment of reasonable charges therefor, the false claims law investigator shall furnish a copy of the transcript to the witness only, except that the Attorney General, the Deputy Attorney General, or an Assistant Attorney General may, for good cause, limit such witness to inspection of the official transcript of the witness' testimony.

(7) Conduct of oral testimony.--(A) Any person compelled to appear for oral testimony under a civil investigative demand issued under subsection (a) may be accompanied, represented, and advised by counsel. Counsel may advise such person, in confidence, with respect to any question asked of such person. Such person or counsel may object on the record to any question, in whole or in part, and shall briefly state for the record the reason for the objection. An objection may be made, received, and entered upon the record when it is claimed that such person is entitled to refuse to answer the question on the grounds of any constitutional or other legal right or privilege, including the privilege against self-incrimination. Such person may not otherwise object to or refuse to answer any question, and may not directly or through counsel otherwise interrupt the oral examination. If such person refuses to answer any question, a petition may be filed in the district court of the United States under subsection (j)(1) for an order compelling such person to answer such question.

(B) If such person refuses to answer any question on the grounds of the privilege against self-incrimination, the testimony of such person may be compelled in accordance with the provisions of part V of title 18.

(8) Witness fees and allowances.--Any person appearing for oral testimony under a civil investigative demand issued under subsection (a) shall be entitled to the same fees and allowances which are paid to witnesses in the district courts of the United States.

(i) Custodians of documents, answers, and transcripts.--

(1) Designation.--The Attorney General shall designate a false claims law investigator to serve as custodian of documentary material, answers to interrogatories, and transcripts of oral testimony received under this section, and shall designate such additional false claims law investigators as the Attorney General determines from time to time to be necessary to serve as deputies to the custodian.

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(2) Responsibility for materials; disclosure.--(A) A false claims law investigator who receives any documentary material, answers to interrogatories, or transcripts of oral testimony under this section shall transmit them to the custodian. The custodian shall take physical possession of such material, answers, or transcripts and shall be responsible for the use made of them and for the return of documentary material under paragraph (4).

(B) The custodian may cause the preparation of such copies of such documentary material, answers to interrogatories, or transcripts of oral testimony as may be required for official use by any false claims law investigator, or other officer or employee of the Department of Justice. Such material, answers, and transcripts may be used by any such authorized false claims law investigator or other officer or employee in connection with the taking of oral testimony under this section.

(C) Except as otherwise provided in this subsection, no documentary material, answers to interrogatories, or transcripts of oral testimony, or copies thereof, while in the possession of the custodian, shall be available for examination by any individual other than a false claims law investigator or other officer or employee of the Department of Justice authorized under subparagraph (B). The prohibition in the preceding sentence on the availability of material, answers, or transcripts shall not apply if consent is given by the person who produced such material, answers, or transcripts, or, in the case of any product of discovery produced pursuant to an express demand for such material, consent is given by the person from whom the discovery was obtained. Nothing in this subparagraph is intended to prevent disclosure to the Congress, including any committee or subcommittee of the Congress, or to any other agency of the United States for use by such agency in furtherance of its statutory responsibilities.

(D) While in the possession of the custodian and under such reasonable terms and conditions as the Attorney General shall prescribe--

(i) documentary material and answers to interrogatories shall be available for examination by the person who produced such material or answers, or by a representative of that person authorized by that person to examine such material and answers; and

(ii) transcripts of oral testimony shall be available for examination by the person who produced such testimony, or by a representative of that person authorized by that person to examine such transcripts.

(3) Use of material, answers, or transcripts in other proceedings.--Whenever any attorney of the Department of Justice has been designated to appear before any court, grand jury, or Federal agency in any case or proceeding, the custodian of any documentary material, answers to interrogatories, or transcripts of oral testimony received under this section may deliver to such attorney such material, answers, or transcripts for official use in connection with any such case or proceeding as such attorney determines to be required. Upon the completion of any such case or proceeding, such attorney shall return to the custodian any such material, answers, or transcripts so delivered which have not passed into the control of such court, grand jury, or agency through introduction into the record of such case or proceeding.

(4) Conditions for return of material.--If any documentary material has been produced by any person in the course of any false claims law investigation pursuant to a civil investigative demand under this section, and--

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(A) any case or proceeding before the court or grand jury arising out of such investigation, or any proceeding before any Federal agency involving such material, has been completed, or

(B) no case or proceeding in which such material may be used has been commenced within a reasonable time after completion of the examination and analysis of all documentary material and other information assembled in the course of such investigation,

the custodian shall, upon written request of the person who produced such material, return to such person any such material (other than copies furnished to the false claims law investigator under subsection (f)(2) or made for the Department of Justice under paragraph (2)(B)) which has not passed into the control of any court, grand jury, or agency through introduction into the record of such case or proceeding.

(5) Appointment of successor custodians.--In the event of the death, disability, or separation from service in the Department of Justice of the custodian of any documentary material, answers to interrogatories, or transcripts of oral testimony produced pursuant to a civil investigative demand under this section, or in the event of the official relief of such custodian from responsibility for the custody and control of such material, answers, or transcripts, the Attorney General shall promptly--

(A) designate another false claims law investigator to serve as custodian of such material, answers, or transcripts, and

(B) transmit in writing to the person who produced such material, answers, or testimony notice of the identity and address of the successor so designated.

Any person who is designated to be a successor under this paragraph shall have, with regard to such material, answers, or transcripts, the same duties and responsibilities as were imposed by this section upon that person's predecessor in office, except that the successor shall not be held responsible for any default or dereliction which occurred before that designation.

(j) Judicial Proceedings.--

(1) Petition for enforcement.--Whenever any person fails to comply with any civil investigative demand issued under subsection (a), or whenever satisfactory copying or reproduction of any material requested in such demand cannot be done and such person refuses to surrender such material, the Attorney General may file, in the district court of the United States for any judicial district in which such person resides, is found, or transacts business, and serve upon such person a petition for an order of such court for the enforcement of the civil investigative demand.

(2) Petition to modify or set aside demand.--(A) Any person who has received a civil investigative demand issued under subsection (a) may file, in the district court of the United States for the judicial district within which such person resides, is found, or transacts business, and serve upon the false claims law investigator identified in such demand a petition for an order of the court to modify or set aside such demand. In the case of a petition addressed to an express demand for any product of discovery, a petition to modify or set aside such demand may be brought only in the district court of the United States for the judicial district in which the proceeding in which such discovery was obtained is or was last pending. Any petition under this subparagraph must be filed--

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(i) within 20 days after the date of service of the civil investigative demand, or at any time before the return date specified in the demand, whichever date is earlier, or

(ii) within such longer period as may be prescribed in writing by any false claims law investigator identified in the demand.

(B) The petition shall specify each ground upon which the petitioner relies in seeking relief under subparagraph (A), and may be based upon any failure of the demand to comply with the provisions of this section or upon any constitutional or other legal right or privilege of such person. During the pendency of the petition in the court, the court may stay, as it deems proper, the running of the time allowed for compliance with the demand, in whole or in part, except that the person filing the petition shall comply with any portions of the demand not sought to be modified or set aside.

(3) Petition to modify or set aside demand for product of discovery.--(A) In the case of any civil investigative demand issued under subsection (a) which is an express demand for any product of discovery, the person from whom such discovery was obtained may file, in the district court of the United States for the judicial district in which the proceeding in which such discovery was obtained is or was last pending, and serve upon any false claims law investigator identified in the demand and upon the recipient of the demand, a petition for an order of such court to modify or set aside those portions of the demand requiring production of any such product of discovery. Any petition under this subparagraph must be filed--

(i) within 20 days after the date of service of the civil investigative demand, or at any time before the return date specified in the demand, whichever date is earlier, or

(ii) within such longer period as may be prescribed in writing by any false claims law investigator identified in the demand.

(B) The petition shall specify each ground upon which the petitioner relies in seeking relief under subparagraph (A), and may be based upon any failure of the portions of the demand from which relief is sought to comply with the provisions of this section, or upon any constitutional or other legal right or privilege of the petitioner. During the pendency of the petition, the court may stay, as it deems proper, compliance with the demand and the running of the time allowed for compliance with the demand.

(4) Petition to require performance by custodian of duties.--At any time during which any custodian is in custody or control of any documentary material or answers to interrogatories produced, or transcripts of oral testimony given, by any person in compliance with any civil investigative demand issued under subsection (a), such person, and in the case of an express demand for any product of discovery, the person from whom such discovery was obtained, may file, in the district court of the United States for the judicial district within which the office of such custodian is situated, and serve upon such custodian, a petition for an order of such court to require the performance by the custodian of any duty imposed upon the custodian by this section.

(5) Jurisdiction.--Whenever any petition is filed in any district court of the United States under this subsection, such court shall have jurisdiction to hear and determine the matter so presented, and to enter such order or orders as may be required to carry out the provisions of this section. Any final order so entered shall be subject to appeal under section 1291 of title 28. Any disobedience of any final order entered under this section by any court shall be punished as a contempt of the court.

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(6) Applicability of federal rules of civil procedure.--The Federal Rules of Civil Procedure shall apply to any petition under this subsection, to the extent that such rules are not inconsistent with the provisions of this section.

(k) Disclosure exemption.--Any documentary material, answers to written interrogatories, or oral testimony provided under any civil investigative demand issued under subsection (a) shall be exempt from disclosure under section 552 of title 5.

(l) Definitions.--For purposes of this section--

(1) the term "false claims law" means--

(A) this section and sections 3729 through 3732; and

(B) any Act of Congress enacted after the date of the enactment of this section which prohibits, or makes available to the United States in any court of the United States any civil remedy with respect to, any false claim against, bribery of, or corruption of any officer or employee of the United States;

(2) the term "false claims law investigation" means any inquiry conducted by any false claims law investigator for the purpose of ascertaining whether any person is or has been engaged in any violation of a false claims law;

(3) the term "false claims law investigator" means any attorney or investigator employed by the Department of Justice who is charged with the duty of enforcing or carrying into effect any false claims law, or any officer or employee of the United States acting under the direction and supervision of such attorney or investigator in connection with a false claims law investigation;

(4) the term "person" means any natural person, partnership, corporation, association, or other legal entity, including any State or political subdivision of a State;

(5) the term "documentary material" includes the original or any copy of any book, record, report, memorandum, paper, communication, tabulation, chart, or other document, or data compilations stored in or accessible through computer or other information retrieval systems, together with instructions and all other materials necessary to use or interpret such data compilations, and any product of discovery;

(6) the term "custodian" means the custodian, or any deputy custodian, designated by the Attorney General under subsection (i)(1);

(7) the term "product of discovery" includes--

(A) the original or duplicate of any deposition, interrogatory, document, thing, result of the inspection of land or other property, examination, or admission, which is obtained by any method of discovery in any judicial or administrative proceeding of an adversarial nature;

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(B) any digest, analysis, selection, compilation, or derivation of any item listed in subparagraph (A); and

(C) any index or other manner of access to any item listed in subparagraph (A); and

(8) the term "official use" means any use that is consistent with the law, and the regulations and policies of the Department of Justice, including use in connection with internal Department of Justice memoranda and reports; communications between the Department of Justice and a Federal, State, or local government agency, or a contractor of a Federal, State, or local government agency, undertaken in furtherance of a Department of Justice investigation or prosecution of a case; interviews of any qui tam relator or other witness; oral examinations; depositions; preparation for and response to civil discovery requests; introduction into the record of a case or proceeding; applications, motions, memoranda and briefs submitted to a court or other tribunal; and communications with Government investigators, auditors, consultants and experts, the counsel of other parties, arbitrators and mediators, concerning an investigation, case or proceeding.

CREDIT(S)

(Added Pub.L. 99-562, § 6(a), Oct. 27, 1986, 100 Stat. 3159; amended Pub.L. 111-21, § 4(c), May 20, 2009, 123 Stat. 1623.)

Notes of Decisions (20)

Footnotes

1 So in original. Probably should be ''law''.

31 U.S.C.A. § 3733, 31 USCA § 3733
Current through P.L. 117-167. Some statute sections may be more current, see credits for details.

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KeyCite Yellow Flag - Negative Treatment
Not Followed as Dicta United States ex rel. International Brotherhood of Electrical Workers Local Union No. 98 v. Farfield Company, 3rd Cir.(Pa.), July 13, 2021

136 S.Ct. 1989
Supreme Court of the United States

UNIVERSAL HEALTH SERVICES, INC., Petitioner
v.
UNITED STATES and Massachusetts,
ex rel. Julio Escobar and Carmen Correa.

No. 15–7.
|
Argued April 19, 2016.
|
Decided June 16, 2016.

Synopsis
Background: Parents, as relators, brought qui tam suit against healthcare provider under the False Claims Act (FCA) after their daughter died of a seizure when she was being treated at a mental health clinic by various unlicensed and unsupervised staff in violation of state Medicaid regulations. The United States District Court for the District of Massachusetts, Douglas P. Woodlock, J., 2014 WL 1271757, dismissed, and parents appealed. The United States Court of Appeals for the First Circuit, Stahl, Circuit Judge, 780 F.3d 504, affirmed in part, reversed in part, and remanded. Certiorari was granted.

Holdings: The Supreme Court, Justice Thomas, held that:

[1] the implied false certification theory can be a basis for liability under the FCA in some circumstances, abrogating *U.S. v. Sanford–Brown, Ltd.*, 788 F.3d 696, and

[2] the FCA does not limit liability only to instances where the defendant fails to disclose the violation of a contractual, statutory, or regulatory provision that the government expressly designated a condition of payment, abrogating *Mikes v. Straus,* 274 F.3d 687.

Vacated and remanded.

Procedural Posture(s): On Appeal; Motion to Dismiss.

West Headnotes (26)

[1] **United States** False certification

The "implied false certification theory," providing that when a defendant submits a claim it impliedly certifies compliance with all conditions of payment, can be a basis for liability under the False Claims Act (FCA), at least where two conditions are satisfied: (1) the claim does not merely request payment, but also makes specific representations about the goods or services provided; and (2) the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths; abrogating *U.S. v. Sanford–Brown, Ltd.*, 788 F.3d 696. 31 U.S.C.A. § 3729(a)(1)(A).

249 Cases that cite this headnote

[2] **United States** False claim

By punishing defendants who submit "false or fraudulent claims," the False Claims Act (FCA) encompasses claims that make fraudulent misrepresentations, which include certain misleading omissions. 31 U.S.C.A. § 3729(a)(1)(A).

110 Cases that cite this headnote

[3] **United States** False certification

When a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can, pursuant to the implied false certification theory, be a basis for liability under the False Claims Act (FCA) if they render the defendant's representations misleading with respect to the goods or services provided. 31 U.S.C.A. § 3729(a)(1)(A).

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176 Cases that cite this headnote

[4] **Statutes** Statutory terms with common law meanings

Absent other indication, Congress intends to incorporate the well-settled meaning of the common-law terms it uses.

13 Cases that cite this headnote

[5] **United States** Statutory provisions

Although the False Claims Act (FCA) abrogated the common law in certain respects, including that the Act's scienter requirement required no proof of specific intent to defraud, the court would presume, when interpreting common-law terms used in the Act, that Congress retained all other elements of common-law fraud that were consistent with the statutory text, because there were no textual indicia to the contrary. 31 U.S.C.A. § 3729 et seq.

14 Cases that cite this headnote

[6] **United States** False claim

Because common-law fraud has long encompassed certain misrepresentations by omission, "false or fraudulent claims" within the meaning of the False Claims Act (FCA) include more than just claims containing express falsehoods. 31 U.S.C.A. § 3729(a)(1)(A).

32 Cases that cite this headnote

[7] **United States** False claim

"Half-truths," that is, representations that state the truth only so far as it goes, while omitting critical qualifying information, can be actionable misrepresentations under the False Claims Act (FCA). 31 U.S.C.A. § 3729(a)(1)(A).

38 Cases that cite this headnote

[8] **Fraud** Duty to disclose facts

In tort law, if the defendant does speak, he must disclose enough to prevent his words from being misleading.

1 Cases that cite this headnote

[9] **Fraud** Fraudulent Concealment

A statement that contains only favorable matters and omits all reference to unfavorable matters is as much a false representation as if all the facts stated were untrue. Restatement (Second) of Torts § 529.

4 Cases that cite this headnote

[10] **United States** False certification
United States Materiality

The False Claims Act (FCA) does not limit liability only to instances where the defendant fails to disclose the violation of a contractual, statutory, or regulatory provision that the government expressly designated a condition of payment; abrogating *Mikes v. Straus,* 274 F.3d 687. 31 U.S.C.A. § 3729(a)(1)(A).

12 Cases that cite this headnote

[11] **United States** False certification
United States Materiality

Not every undisclosed violation of an express condition of payment automatically triggers liability under the False Claims Act (FCA). 31 U.S.C.A. § 3729(a)(1)(A).

10 Cases that cite this headnote

[12] **United States** Materiality

Whether a provision allegedly violated by the defendant is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry into whether defendant has made an actionable false or fraudulent claim under the False Claims Act (FCA). 31 U.S.C.A. § 3729(a)(1)(A), (b)(4).

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87 Cases that cite this headnote

[13] **Fraud** Fraudulent Concealment

A statement that misleadingly omits critical facts is a fraudulent misrepresentation irrespective of whether the other party has expressly signaled the importance of the qualifying information.

7 Cases that cite this headnote

[14] **Statutes** Policy considerations; public policy

Policy arguments cannot supersede the clear statutory text.

8 Cases that cite this headnote

[15] **United States** Materiality

A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the government's payment decision in order to be actionable under the False Claims Act (FCA). 31 U.S.C.A. § 3729(a)(1)(A), (b)(4).

266 Cases that cite this headnote

[16] **United States** Materiality

Materiality, for purposes of determining whether a misrepresentation is actionable under the False Claims Act (FCA), looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation. 31 U.S.C.A. § 3729(a)(1)(A), (b)(4).

74 Cases that cite this headnote

[17] **Fraud** Materiality of matter represented or concealed

In tort law, a matter is "material" in only two circumstances: (1) if a reasonable man would attach importance to it in determining his choice of action in the transaction; or (2) if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter in determining his choice of action, even though a reasonable person would not. Restatement (Second) of Torts § 538.

20 Cases that cite this headnote

[18] **United States** Materiality

The False Claims Act's (FCA) materiality standard for an actionable false or fraudulent claim is demanding. 31 U.S.C.A. § 3729(a)(1)(A), (b)(4).

80 Cases that cite this headnote

[19] **United States** False Claims

The False Claims Act (FCA) is not an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations. 31 U.S.C.A. § 3729 et seq.

64 Cases that cite this headnote

[20] **United States** Materiality

A misrepresentation cannot be deemed "material," as required to give rise to liability under the False Claims Act (FCA), merely because the government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment; nor is it sufficient for a finding of materiality that the government would have the option to decline to pay if it knew of the defendant's noncompliance. 31 U.S.C.A. § 3729(a)(1)(A), (b)(4).

156 Cases that cite this headnote

[21] **United States** Materiality

The materiality required for a misrepresentation to be actionable under the False Claims Act (FCA) cannot be found where noncompliance with a particular statutory, regulatory, or contractual requirement is minor or insubstantial. 31 U.S.C.A. §§ 3729(a)(1)(A), (b)(4).

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46 Cases that cite this headnote

[22] **United States** Materiality

Proof of the materiality of a misrepresentation about compliance with a statutory, regulatory, or contractual requirement, as required for the misrepresentation to be actionable under the False Claims Act (FCA), can include, but is not necessarily limited to, evidence that the defendant knows that the government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. 31 U.S.C.A. § 3729(a)(1)(A), (b)(4).

210 Cases that cite this headnote

[23] **United States** Materiality

It is strong evidence that particular statutory, regulatory, or contractual requirements are not material, and thus violations of the requirements do not give rise to liability under the False Claims Act (FCA), if the government pays a particular claim in full despite its actual knowledge that certain requirements were violated, or if the government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position. 31 U.S.C.A. § 3729(a)(1)(A), (b)(4).

214 Cases that cite this headnote

[24] **Federal Civil Procedure** Fraud, mistake and condition of mind

United States Materiality

False Claims Act (FCA) plaintiffs must plead their claims with plausibility and particularity by, for instance, pleading facts to support allegations of materiality. 31 U.S.C.A. § 3729 et seq.; Fed.Rules Civ.Proc.Rules 8, 9(b), 28 U.S.C.A.

19 Cases that cite this headnote

[25] **United States** Materiality

A statutory, regulatory, or contractual violation is not "material," and thus cannot give rise to liability under the False Claims Act (FCA), merely because the defendant knows that the government would be entitled to refuse payment were it aware of the violation. 31 U.S.C.A. § 3729(a)(1)(A), (b)(4).

43 Cases that cite this headnote

[26] **United States** Materiality

United States Double or treble damages

The False Claims Act (FCA) is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations. 31 U.S.C.A. § 3729 et seq.

10 Cases that cite this headnote

****1993** *Syllabus* *

***176** Yarushka Rivera, a teenage beneficiary of Massachusetts' Medicaid program, received counseling services for several years at Arbour Counseling Services, a satellite mental health facility owned and operated by a subsidiary of petitioner Universal Health Services, Inc. She had an adverse reaction to a medication that a purported doctor at Arbour prescribed after diagnosing her with bipolar disorder. Her condition worsened, and she eventually died of a seizure. Respondents, her mother and stepfather, later discovered that few Arbour employees were actually licensed to provide mental health counseling or authorized to prescribe medications or offer counseling services without supervision.

Respondents filed a *qui tam* suit, alleging that Universal Health had violated the False Claims Act (FCA). That Act imposes significant penalties on anyone who "knowingly presents ... a false or fraudulent claim for payment or approval" to the Federal Government, 31 U.S.C. § 3729(a)(1)(A). Respondents sought to hold Universal Health liable

under what is commonly referred to as an "implied false certification theory of liability," which treats a payment request as a claimant's implied certification of compliance with relevant statutes, regulations, or contract requirements that are material conditions of payment and treats a failure to disclose a violation as a misrepresentation that renders the claim "false or fraudulent." Specifically, respondents alleged, Universal Health (acting through Arbour) defrauded the Medicaid program by submitting reimbursement claims that made representations about the specific services provided by specific types of professionals, but that failed to disclose serious violations of Massachusetts Medicaid regulations pertaining to staff qualifications and licensing requirements for these services. Universal Health thus allegedly defrauded the program because Universal Health knowingly misrepresented its compliance with mental health facility requirements that are so central to the provision of mental health counseling that the Medicaid program would have refused to pay these claims had it known of these violations.

The District Court granted Universal Health's motion to dismiss. It held that respondents had failed to state a claim under the "implied ***177** false certification" theory of liability because none of the regulations violated by Arbour was a condition of payment. The First Circuit reversed in relevant part, holding that every submission of a claim implicitly represents compliance with relevant regulations, and that any undisclosed violation of a precondition of payment (whether or not expressly identified as such) renders a claim " false or fraudulent." The First Circuit further held that the regulations themselves provided conclusive evidence that compliance was a material condition of payment because the regulations expressly required facilities to adequately supervise staff as a condition of payment.

Held :

1. The implied false certification theory can be a basis for FCA liability when a defendant submitting a claim makes specific representations about the goods or services provided, but fails to disclose noncompliance with material statutory, regulatory, or contractual requirements that ****1994** make those representations misleading with respect to those goods or services. Pp. 1999 – 2001.

(a) The FCA does not define a "false" or "fraudulent" claim, so the Court turns to the principle that "absent other indication, 'Congress intends to incorporate the well-settled meaning of the common-law terms it uses,' " *Sekhar v. United States,* 570 U.S. ——, ——, 133 S.Ct. 2720, 2724, 186 L.Ed.2d 794. Under the common-law definition of "fraud," the parties agree, certain misrepresentations by omission can give rise to FCA liability. Respondents and the Government contend that every claim for payment implicitly represents that the claimant is legally entitled to payment, and that failing to disclose violations of material legal requirements renders the claim misleading. Universal Health, on the other hand, argues that submitting a claim involves no representations and that the nondisclosure of legal violations is not actionable absent a special duty of reasonable care to disclose such matters. Today's decision holds that the claims at issue may be actionable because they do more than merely demand payment; they fall squarely within the rule that representations that state the truth only so far as it goes, while omitting critical qualifying information, can be actionable misrepresentations. Pp. 1999 – 2000.

(b) By submitting claims for payment using payment codes corresponding to specific counseling services, Universal Health represented that it had provided specific types of treatment. And Arbour staff allegedly made further representations by using National Provider Identification numbers corresponding to specific job titles. By conveying this information without disclosing Arbour's many violations of basic staff and licensing requirements for mental health facilities, Universal Health's claims constituted misrepresentations. Pp. 2000 – 2001.

***178** 2. Contrary to Universal Health's contentions, FCA liability for failing to disclose violations of legal requirements does not turn upon whether those requirements were expressly designated as conditions of payment. Pp. 2000 – 2004.

(a) Section 3729(a)(1)(A), which imposes liability on those presenting "false or fraudulent claim[s]," does not limit claims to misrepresentations about express conditions of payment. Nothing in the text supports such a restriction. And under the Act's materiality requirement, statutory, regulatory, and contractual requirements are not automatically material, even if they are labeled conditions of payment. Nor is the restriction supported by the Act's scienter requirement. A defendant can have "actual knowledge" that a condition is material even if the Government does not expressly call it a condition of payment. What matters is not the label that the Government attaches to a requirement, but whether

the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision. Universal Health's policy arguments are unavailing, and are amply addressed through strict enforcement of the FCA's stringent materiality and scienter provisions. Pp. 2001 – 2003.

(b) A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the FCA. The FCA's materiality requirement is demanding. An undisclosed fact is material if, for instance, "[n]o one can say with reason that the plaintiff would have signed this contract if informed of the likelihood" of the undisclosed fact. *Junius Constr. Co. v. Cohen,* 257 N.Y. 393, 400, 178 N.E. 672, 674. When evaluating the FCA's materiality ****1995** requirement, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular requirement as a condition of payment. Nor is the Government's option to decline to pay if it knew of the defendant's noncompliance sufficient for a finding of materiality. Materiality also cannot be found where noncompliance is minor or insubstantial. Moreover, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. The FCA thus does not support the Government's and First Circuit's expansive view that any statutory, regulatory, or contractual violation is material so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation. Pp. 2002 – 2004.

780 F.3d 504, vacated and remanded.

***179** THOMAS, J., delivered the opinion for a unanimous Court.

Attorneys and Law Firms

Roy T. Englert, Jr., Washington, DC, for Petitioner.

David C. Frederick, Washington, DC, for Respondents.

Malcolm L. Stewart for the United States as amicus curiae, by special leave of the Court, supporting the respondents.

Mark W. Pearlstein, Laura McLane, Evan D. Panich, McDermott Will & Emery LLP, Boston, MA, M. Miller Baker, McDermott Will & Emery LLP, Roy T. Englert, Jr., Gary A. Orseck, Mark T. Stancil, Michael L. Waldman, Donald Burke, Robbins, Russell, Englert, Orseck, Untereiner & Sauber LLP, Washington, DC, for Petitioner.

Thomas M. Greene, Michael Tabb, Elizabeth Cho, Greene LLP, Boston, MA, David C. Frederick, Derek T. Ho, Katherine C. Cooper, Kellogg, Huber, Hansen, Todd, Evans & Figel, P.L.L.C., Washington, DC, for Respondents.

Opinion

***180** Justice THOMAS delivered the opinion of the Court.

The False Claims Act, 31 U.S.C. § 3729 *et seq.,* imposes significant penalties on those who defraud the Government. This case concerns a theory of False Claims Act liability commonly referred to as "implied false certification." According to this theory, when a defendant submits a claim, it impliedly certifies compliance with all conditions of payment. But if that claim fails to disclose the defendant's violation of a material statutory, regulatory, or contractual requirement, so the theory goes, the defendant has made a misrepresentation that renders the claim "false or fraudulent" under § 3729(a)(1)(A). This case requires us to consider this theory of liability and to clarify some of the circumstances in which the False Claims Act imposes liability.

***181** We first hold that, at least in certain circumstances, the implied false certification theory can be a basis for liability. Specifically, liability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement. In these circumstances, liability may attach if the omission renders those representations misleading.

****1996** We further hold that False Claims Act liability for failing to disclose violations of legal requirements does not turn upon whether those requirements were expressly designated as conditions of payment. Defendants can be liable for violating requirements even if they were not expressly designated as conditions of payment. Conversely, even when a requirement is expressly designated a condition of payment, not every violation of such a requirement gives rise to liability. What matters is not the label the Government attaches to a

requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision.

A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act. We clarify below how that rigorous materiality requirement should be enforced.

Because the courts below interpreted § 3729(a)(1)(A) differently, we vacate the judgment and remand so that those courts may apply the approach set out in this opinion.

I

A

Enacted in 1863, the False Claims Act "was originally aimed principally at stopping the massive frauds perpetrated by large contractors during the Civil War." *United States v. Bornstein,* 423 U.S. 303, 309, 96 S.Ct. 523, 46 L.Ed.2d 514 (1976). "[A] series of sensational ***182** congressional investigations" prompted hearings where witnesses "painted a sordid picture of how the United States had been billed for nonexistent or worthless goods, charged exorbitant prices for goods delivered, and generally robbed in purchasing the necessities of war." *United States v. McNinch,* 356 U.S. 595, 599, 78 S.Ct. 950, 2 L.Ed.2d 1001 (1958). Congress responded by imposing civil and criminal liability for 10 types of fraud on the Government, subjecting violators to double damages, forfeiture, and up to five years' imprisonment. Act of Mar. 2, 1863, ch. 67, 12 Stat. 696.

Since then, Congress has repeatedly amended the Act, but its focus remains on those who present or directly induce the submission of false or fraudulent claims. See 31 U.S.C. § 3729(a) (imposing civil liability on "any person who ... knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"). A "claim" now includes direct requests to the Government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs. See § 3729(b)(2)(A). The Act's scienter requirement defines "knowing" and "knowingly" to mean that a person has "actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." § 3729(b)(1)(A). And the Act defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." § 3729(b)(4).

Congress also has increased the Act's civil penalties so that liability is "essentially punitive in nature." *Vermont Agency of Natural Resources v. United States ex rel. Stevens,* 529 U.S. 765, 784, 120 S.Ct. 1858, 146 L.Ed.2d 836 (2000). Defendants are subjected to treble damages plus civil penalties of up to $10,000 per false claim. § 3729(a); 28 CFR § 85.3(a)(9) (2015) (adjusting penalties for inflation).

***183** B

The alleged False Claims Act violations here arose within the Medicaid program, a ****1997** joint state-federal program in which healthcare providers serve poor or disabled patients and submit claims for government reimbursement. See generally 42 U.S.C. § 1396 *et seq.* The facts recited in the complaint, which we take as true at this stage, are as follows. For five years, Yarushka Rivera, a teenage beneficiary of Massachusetts' Medicaid program, received counseling services at Arbour Counseling Services, a satellite mental health facility in Lawrence, Massachusetts, owned and operated by a subsidiary of petitioner Universal Health Services. Beginning in 2004, when Yarushka started having behavioral problems, five medical professionals at Arbour intermittently treated her. In May 2009, Yarushka had an adverse reaction to a medication that a purported doctor at Arbour prescribed after diagnosing her with bipolar disorder. Her condition worsened; she suffered a seizure that required hospitalization. In October 2009, she suffered another seizure and died. She was 17 years old.

Thereafter, an Arbour counselor revealed to respondents Carmen Correa and Julio Escobar—Yarushka's mother and stepfather—that few Arbour employees were actually licensed to provide mental health counseling and that supervision of them was minimal. Respondents discovered that, of the five professionals who had treated Yarushka, only one was properly licensed. The practitioner who diagnosed Yarushka as bipolar identified herself as a psychologist with

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a Ph. D., but failed to mention that her degree came from an unaccredited Internet college and that Massachusetts had rejected her application to be licensed as a psychologist. Likewise, the practitioner who prescribed medicine to Yarushka, and who was held out as a psychiatrist, was in fact a nurse who lacked authority to prescribe medications absent supervision. Rather than ensuring supervision of unlicensed ***184** staff, the clinic's director helped to misrepresent the staff's qualifications. And the problem went beyond those who treated Yarushka. Some 23 Arbour employees lacked licenses to provide mental health services, yet—despite regulatory requirements to the contrary—they counseled patients and prescribed drugs without supervision.

When submitting reimbursement claims, Arbour used payment codes corresponding to different services that its staff provided to Yarushka, such as "Individual Therapy" and "family therapy." 1 App. 19, 20. Staff members also misrepresented their qualifications and licensing status to the Federal Government to obtain individual National Provider Identification numbers, which are submitted in connection with Medicaid reimbursement claims and correspond to specific job titles. For instance, one Arbour staff member who treated Yarushka registered for a number associated with " 'Social Worker, Clinical,' " despite lacking the credentials and licensing required for social workers engaged in mental health counseling. 1 *id.,* at 32.

After researching Arbour's operations, respondents filed complaints with various Massachusetts agencies. Massachusetts investigated and ultimately issued a report detailing Arbour's violation of over a dozen Massachusetts Medicaid regulations governing the qualifications and supervision required for staff at mental health facilities. Arbour agreed to a remedial plan, and two Arbour employees also entered into consent agreements with Massachusetts.

In 2011, respondents filed a *qui tam* suit in federal court, see 31 U.S.C. § 3730, alleging that Universal Health had violated the False Claims Act under an implied false certification theory of liability. The operative complaint asserts that Universal Health (acting through Arbour) submitted ****1998** reimbursement claims that made representations about the specific services provided by specific types of professionals, but that failed to disclose serious violations of regulations pertaining to staff qualifications and licensing requirements for ***185** these services. [1] Specifically, the Massachusetts Medicaid program requires satellite facilities to have specific types of clinicians on staff, delineates licensing requirements for particular positions (like psychiatrists, social workers, and nurses), and details supervision requirements for other staff. See 130 Code Mass. Regs. §§ 429.422–424, 429.439 (2014). Universal Health allegedly flouted these regulations because Arbour employed unqualified, unlicensed, and unsupervised staff. The Massachusetts Medicaid program, unaware of these deficiencies, paid the claims. Universal Health thus allegedly defrauded the program, which would not have reimbursed the claims had it known that it was billed for mental health services that were performed by unlicensed and unsupervised staff. The United States declined to intervene.

The District Court granted Universal Health's motion to dismiss the complaint. Circuit precedent had previously embraced the implied false certification theory of liability. See, *e.g.,* *United States ex rel. Hutcheson v. Blackstone Medical, Inc.,* 647 F.3d 377, 385–387 (C.A.1 2011). But the District Court held that respondents had failed to state a claim under that theory because, with one exception not relevant here, none of the regulations that Arbour violated was a condition of payment. See 2014 WL 1271757, *1, *6–*12 (D.Mass., Mar. 26, 2014).

The United States Court of Appeals for the First Circuit reversed in relevant part and remanded. 780 F.3d 504, 517 (2015). The court observed that each time a billing party submits a claim, it "implicitly communicate[s] that it conformed to the relevant program requirements, such that it was entitled to payment." *Id.,* at 514, n. 14. To determine ***186** whether a claim is " false or fraudulent" based on such implicit communications, the court explained, it "asks simply whether the defendant, in submitting a claim for reimbursement, knowingly misrepresented compliance with a material precondition of payment." *Id.,* at 512. In the court's view, a statutory, regulatory, or contractual requirement can be a condition of payment either by expressly identifying itself as such or by implication. *Id.,* at 512–513. The court then held that Universal Health had violated Massachusetts Medicaid regulations that "clearly impose conditions of payment." *Id.,* at 513. The court further held that the regulations themselves "constitute[d] dispositive evidence of materiality," because they identified adequate supervision as an "express and absolute" condition of payment and "repeated[ly] reference[d]" supervision. *Id.,* at 514 (internal quotation marks omitted).

We granted certiorari to resolve the disagreement among the Courts of Appeals over the validity and scope of the implied false certification theory of liability. 577 U.S. ——, 136 S.Ct. 582, 193 L.Ed.2d 465 (2015). The Seventh Circuit has rejected this theory, reasoning that only express (or affirmative) falsehoods can render a claim "false or fraudulent" under 31 U.S.C. § 3729(a)(1)(A). ****1999** *United States v. Sanford–Brown, Ltd.,* 788 F.3d 696, 711–712 (2015). Other courts have accepted the theory, but limit its application to cases where defendants fail to disclose violations of expressly designated conditions of payment. *E.g.,* *Mikes v. Straus,* 274 F.3d 687, 700 (C.A.2 2001). Yet others hold that conditions of payment need not be expressly designated as such to be a basis for False Claims Act liability. *E.g.,* *United States v. Science Applications Int'l Corp.,* 626 F.3d 1257, 1269 (C.A.D.C.2010) (*SAIC*).

II

[1] **[2]** **[3]** We first hold that the implied false certification theory can, at least in some circumstances, provide a basis for liability. By punishing defendants who submit "false or fraudulent ***187** claims," the False Claims Act encompasses claims that make fraudulent misrepresentations, which include certain misleading omissions. When, as here, a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided.

[4] **[5]** To reach this conclusion, "[w]e start, as always, with the language of the statute." *Allison Engine Co. v. United States ex rel. Sanders,* 553 U.S. 662, 668, 128 S.Ct. 2123, 170 L.Ed.2d 1030 (2008) (brackets in original; internal quotation marks omitted). The False Claims Act imposes civil liability on "any person who ... knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." § 3729(a)(1)(A). Congress did not define what makes a claim "false" or "fraudulent." But "[i]t is a settled principle of interpretation that, absent other indication, Congress intends to incorporate the well-settled meaning of the common-law terms it uses." *Sekhar v. United States,* 570 U.S. ——, ——, 133 S.Ct. 2720, 2724, 186 L.Ed.2d 794 (2013) (internal quotation marks omitted). And the term "fraudulent" is a paradigmatic example of a statutory term that incorporates the common-law meaning of fraud. See *Neder v. United States,* 527 U.S. 1, 22, 119 S.Ct. 1827, 144 L.Ed.2d 35 (1999) (the term "actionable 'fraud' " is one with "a well-settled meaning at common law"). [2]

[6] Because common-law fraud has long encompassed certain misrepresentations by omission, "false or fraudulent claims" include more than just claims containing express falsehoods. The parties and the Government agree that misrepresentations by omission can give rise to liability. Brief for Petitioner ***188** 30–31; Brief for Respondents 22–31; Brief for United States as *Amicus Curiae* 16–20.

The parties instead dispute whether submitting a claim without disclosing violations of statutory, regulatory, or contractual requirements constitutes such an actionable misrepresentation. Respondents and the Government invoke the common-law rule that, while nondisclosure alone ordinarily is not actionable, "[a] representation stating the truth so far as it goes but which the maker knows or believes to be materially misleading because of his failure to state additional or qualifying matter" is actionable. Restatement (Second) of Torts § 529, p. 62 (1976). They contend that every submission of a claim for payment ****2000** implicitly represents that the claimant is legally entitled to payment, and that failing to disclose violations of material legal requirements renders the claim misleading. Universal Health, on the other hand, argues that submitting a claim involves no representations, and that a different common-law rule thus governs: nondisclosure of legal violations is not actionable absent a special " 'duty ... to exercise reasonable care to disclose the matter in question,' " which it says is lacking in Government contracting. Brief for Petitioner 31 (quoting Restatement (Second) of Torts § 551(1), at 119).

[7] **[8]** We need not resolve whether all claims for payment implicitly represent that the billing party is legally entitled to payment. The claims in this case do more than merely demand payment. They fall squarely within the rule that half-truths—representations that state the truth only so far as it goes, while omitting critical qualifying information—can be actionable misrepresentations. [3] A classic example of an actionable ***189** half-truth in contract law is the seller who reveals that there may be two new roads near a property he is selling, but fails to disclose that a third potential road might bisect the property. See *Junius Constr. Co. v. Cohen,* 257 N.Y. 393, 400, 178 N.E. 672, 674 (1931) (Cardozo,

J.). "The enumeration of two streets, described as unopened but projected, was a tacit representation that the land to be conveyed was subject to no others, and certainly subject to no others materially affecting the value of the purchase." *Ibid.* Likewise, an applicant for an adjunct position at a local college makes an actionable misrepresentation when his resume lists prior jobs and then retirement, but fails to disclose that his "retirement" was a prison stint for perpetrating a $12 million bank fraud. See 3 D. Dobbs, P. Hayden, & H. Bublick, Law of Torts § 682, pp. 702–703, and n. 14 (2d ed. 2011) (citing *Sarvis v. Vermont State Colleges,* 172 Vt. 76, 78, 80–82, 772 A.2d 494, 496, 497–499 (2001)).

So too here, by submitting claims for payment using payment codes that corresponded to specific counseling services, Universal Health represented that it had provided individual therapy, family therapy, preventive medication counseling, and other types of treatment. Moreover, Arbour staff members allegedly made further representations in submitting Medicaid reimbursement claims by using National Provider Identification numbers corresponding to specific job titles. And these representations were clearly misleading in context. Anyone informed that a social worker at a Massachusetts mental health clinic provided a teenage patient with individual counseling services would probably—but wrongly—conclude that the clinic had complied with core Massachusetts Medicaid requirements (1) that a counselor "treating children [is] required to have specialized training and experience in children's services," 130 Code Mass. Regs. § 429.422, and also (2) that, at a minimum, the social worker ***190** possesses the prescribed qualifications for the job, § 429.424(C). By using payment and other codes that conveyed this information without disclosing Arbour's many violations of basic staff and licensing requirements for mental ****2001** health facilities, Universal Health's claims constituted misrepresentations.

[9] Accordingly, we hold that the implied certification theory can be a basis for liability, at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths. [4]

III

[10] **[11]** **[12]** The second question presented is whether, as Universal Health urges, a defendant should face False Claims Act liability only if it fails to disclose the violation of a contractual, statutory, or regulatory provision that the Government expressly designated a condition of payment. We conclude that the Act does not impose this limit on liability. But we also conclude that not every undisclosed violation of an express condition of payment automatically triggers liability. Whether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry.

A

[13] Nothing in the text of the False Claims Act supports Universal Health's proposed restriction. Section 3729(a)(1)(A) ***191** imposes liability on those who present "false or fraudulent claims" but does not limit such claims to misrepresentations about express conditions of payment. See *SAIC,* 626 F.3d, at 1268 (rejecting any textual basis for an express-designation rule). Nor does the common-law meaning of fraud tether liability to violating an express condition of payment. A statement that misleadingly omits critical facts is a misrepresentation irrespective of whether the other party has expressly signaled the importance of the qualifying information. *Supra,* at 1999 – 2001.

The False Claims Act's materiality requirement also does not support Universal Health. Under the Act, the misrepresentation must be material to the other party's course of action. But, as discussed below, see *infra,* at 2003 – 2004, statutory, regulatory, and contractual requirements are not automatically material, even if they are labeled conditions of payment. Cf. *Matrixx Initiatives, Inc. v. Siracusano,* 563 U.S. 27, 39, 131 S.Ct. 1309, 179 L.Ed.2d 398 (2011) (materiality cannot rest on "a single fact or occurrence as always determinative" (internal quotation marks omitted)).

Nor does the Act's scienter requirement, § 3729(b)(1)(A), support Universal Health's position. A defendant can have "actual knowledge" that a condition is material without the Government expressly calling it a condition of payment. If the Government failed to specify that guns it

orders must actually shoot, but the defendant knows that the Government routinely rescinds contracts if the guns do not shoot, the defendant has "actual knowledge." Likewise, because a reasonable person would realize the imperative of a functioning firearm, a defendant's failure to appreciate the materiality of that condition **2002 would amount to "deliberate ignorance" or "reckless disregard" of the "truth or falsity of the information" even if the Government did not spell this out.

[14] Universal Health nonetheless contends that False Claims Act liability should be limited to undisclosed violations of expressly designated conditions of payment to provide defendants *192 with fair notice and to cabin liability. But policy arguments cannot supersede the clear statutory text. *Kloeckner v. Solis,* 568 U.S. ——, —— – ——, n. 4, 133 S.Ct. 596, 607, n. 4, 184 L.Ed.2d 433 (2012). In any event, Universal Health's approach risks undercutting these policy goals. The Government might respond by designating every legal requirement an express condition of payment. But billing parties are often subject to thousands of complex statutory and regulatory provisions. Facing False Claims Act liability for violating any of them would hardly help would-be defendants anticipate and prioritize compliance obligations. And forcing the Government to expressly designate a provision as a condition of *payment* would create further arbitrariness. Under Universal Health's view, misrepresenting compliance with a requirement that the Government expressly identified as a condition of payment could expose a defendant to liability. Yet, under this theory, misrepresenting compliance with a condition of eligibility to even participate in a federal program when submitting a claim would not.

Moreover, other parts of the False Claims Act allay Universal Health's concerns. "[I]nstead of adopting a circumscribed view of what it means for a claim to be false or fraudulent," concerns about fair notice and open-ended liability "can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements." *SAIC, supra,* at 1270. Those requirements are rigorous.

B

[15] As noted, a misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act. We now clarify how that materiality requirement should be enforced.

Section 3729(b)(4) defines materiality using language that we have employed to define materiality in other federal fraud statutes: "[T]he term 'material' means having a natural *193 tendency to influence, or be capable of influencing, the payment or receipt of money or property." See *Neder,* 527 U.S., at 16, 119 S.Ct. 1827 (using this definition to interpret the mail, bank, and wire fraud statutes); *Kungys v. United States,* 485 U.S. 759, 770, 108 S.Ct. 1537, 99 L.Ed.2d 839 (1988) (same for fraudulent statements to immigration officials). This materiality requirement descends from "common-law antecedents." *Id.,* at 769, 108 S.Ct. 1537. Indeed, "the common law could not have conceived of 'fraud' without proof of materiality." *Neder,* supra, at 22, 119 S.Ct. 1827; see also brief for United States as *Amicus Curiae* 30 (describing common-law principles and arguing that materiality under the False Claims Act should involve a "similar approach").

[16] [17] We need not decide whether § 3729(a)(1)(A)'s materiality requirement is governed by § 3729(b)(4) or derived directly from the common law. Under any understanding of the concept, materiality "look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003) (Williston). In tort law, for instance, a "matter is material" in only two circumstances: (1) "[if] a reasonable man would **2003 attach importance to [it] in determining his choice of action in the transaction"; or (2) if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter "in determining his choice of action," even though a reasonable person would not. Restatement (Second) of Torts § 538, at 80. Materiality in contract law is substantially similar. See Restatement (Second) of Contracts § 162(2), and Comment *c,* pp. 439, 441 (1979) ("[A] misrepresentation is material" only if it would "likely ... induce a reasonable person to manifest his assent," or the defendant "knows that for some special reason [the representation] is likely to induce the particular recipient to manifest his assent" to the transaction). [5]

[18] [19] [20] [21] *194 The materiality standard is demanding. The False Claims Act is not "an all-purpose

antifraud statute," *Allison Engine,* 553 U.S., at 672, 128 S.Ct. 2123 or a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial. See *United States ex rel. Marcus v. Hess,* 317 U.S. 537, 543, 63 S.Ct. 379, 87 L.Ed. 443 (1943) (contractors' misrepresentation that they satisfied a non-collusive bidding requirement for federal program contracts violated the False Claims Act because "[t]he government's money would never have been placed in the joint fund for payment to respondents had its agents known the bids were collusive"); see also *Junius Constr.,* 257 N.Y., at 400, 178 N.E., at 674 (an undisclosed fact was material because "[n]o one can say with reason that the plaintiff would have signed this contract if informed of the likelihood" of the undisclosed fact).

[22] **[23]** **[24]** In sum, when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality ***195** can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual ****2004** knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material. [6]

[25] These rules lead us to disagree with the Government's and First Circuit's view of materiality: that any statutory, regulatory, or contractual violation is material so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation. See Brief for United States as *Amicus Curiae* 30; Tr. of Oral Arg. 43 (Government's "test" for materiality "is whether the person knew that the government could lawfully withhold payment"); 780 F.3d, at 514; see also Tr. of Oral Arg. 26, 29 (statements by respondents' counsel endorsing this view). At oral argument, the United States explained the implications of its position: If the Government contracts for health services and adds a requirement that contractors buy American-made staplers, anyone who submits a claim for those services but fails to disclose its use of foreign staplers violates the False Claims Act. To the Government, liability would attach if the defendant's use of foreign staplers would entitle the Government ***196** not to pay the claim in whole or part—irrespective of whether the Government routinely pays claims despite knowing that foreign staplers were used. *Id*., at 39–45. Likewise, if the Government required contractors to aver their compliance with the entire U.S. Code and Code of Federal Regulations, then under this view, failing to mention noncompliance with any of those requirements would always be material. The False Claims Act does not adopt such an extraordinarily expansive view of liability.

* * *

[26] Because both opinions below assessed respondents' complaint based on interpretations of § 3729(a)(1)(A) that differ from ours, we vacate the First Circuit's judgment and remand the case for reconsideration of whether respondents have sufficiently pleaded a False Claims Act violation. See *Omnicare, Inc. v. Laborers Dist. Council Constr. Industry Pension Fund,* 575 U.S. ——, ——, 135 S.Ct. 1318, 1332–1333, 191 L.Ed.2d 253 (2015). We emphasize, however, that the False Claims Act is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations. This case centers on allegations of fraud, not medical malpractice. Respondents have alleged that Universal Health misrepresented its compliance with mental health facility requirements that are so central to the provision of mental health counseling that the Medicaid program would not have paid these claims had it known of these violations. Respondents may well have adequately pleaded a violation of § 3729(a)(1)(A). But we leave it to the courts below to resolve this in the first instance.

The judgment of the Court of Appeals is vacated, and the case is remanded for further proceedings consistent with this opinion.

It is so ordered.

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All Citations

579 U.S. 176, 136 S.Ct. 1989, 195 L.Ed.2d 348, 84 USLW 4410, 41 IER Cases 709, 14 Cal. Daily Op. Serv. 6223, 2016 Daily Journal D.A.R. 5828, 26 Fla. L. Weekly Fed. S 258

Footnotes

* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.,* 200 U.S. 321, 337, 26 S.Ct. 282, 50 L.Ed. 499.

1 Although Universal Health submitted some of the claims at issue before 2009, we assume—as the parties have done—that the 2009 amendments to the False Claims Act apply here. Universal Health does not argue, and we thus do not consider, whether pre–2009 conduct should be treated differently.

2 The False Claims Act abrogates the common law in certain respects. For instance, the Act's scienter requirement "require[s] no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(B). But we presume that Congress retained all other elements of common-law fraud that are consistent with the statutory text because there are no textual indicia to the contrary. See *Neder,* 527 U.S., at 24–25, 119 S.Ct. 1827.

3 This rule recurs throughout the common law. In tort law, for example, "if the defendant does speak, he must disclose enough to prevent his words from being misleading." W. Keeton, D. Dobbs, R. Keeton, & D. Owen, Prosser and Keeton on Law of Torts § 106, p. 738 (5th ed. 1984). Contract law also embraces this principle. See, *e.g.,* Restatement (Second) of Contracts § 161, Comment *a,* p. 432 (1979). And we have used this definition in other statutory contexts. See, *e.g.,* *Matrixx Initiatives, Inc. v. Siracusano,* 563 U.S. 27, 44, 131 S.Ct. 1309, 179 L.Ed.2d 398 (2011) (securities law).

4 As an alternative argument, Universal Health asserts that misleading partial disclosures constitute fraudulent misrepresentations only when the initial statement partially disclosed unfavorable information. Not so. "[A] statement that contains only favorable matters and omits all reference to unfavorable matters is as much a false representation as if all the facts stated were untrue." Restatement (Second) of Torts, § 529, Comment *a,* pp. 62–63 (1976).

5 Accord, Williston § 69:12, pp. 549–550 ("most popular" understanding is "that a misrepresentation is material if it concerns a matter to which a reasonable person would attach importance in determining his or her choice of action with respect to the transaction involved: which will induce action by a complaining party[,] knowledge of which would have induced the recipient to act differently" (footnote omitted)); *id.,* at 550 (noting rule that "a misrepresentation is material if, had it not been made, the party complaining of fraud would not have taken the action alleged to have been induced by the misrepresentation"); *Junius Constr. Co. v. Cohen,* 257 N.Y. 393, 400, 178 N.E. 672, 674 (1931) (a misrepresentation is material if it "went to the very essence of the bargain"); cf. *Neder v. United States,* 527 U.S. 1, 16, 22, n. 5, 119 S.Ct. 1827, 144 L.Ed.2d 35 (1999) (relying on " 'natural tendency to influence' " standard and citing Restatement (Second) of Torts § 538 definition of materiality).

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6 We reject Universal Health's assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment. The standard for materiality that we have outlined is a familiar and rigorous one. And False Claims Act plaintiffs must also plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality.

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Prescription Drug Diversion

Moderator:
Christopher R. Moran, Esq.

Panelists:
Linda J. Clark, Esq.
Cristina Russo

21 C.F.R. § 1306.04

§ 1306.04 Purpose of issue of prescription.

Effective: October 30, 2020
Currentness

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in § 1301.28 of this chapter.

(d) A prescription may be issued by a qualifying practitioner, as defined in section 303(g)(2)G)(iii) of the Act (21 U.S.C. 823(g)(2)(G)(iii), in accordance with § 1306.05 for a Schedule III, IV, or V controlled substance for the purpose of maintenance or detoxification treatment for the purposes of administration in accordance with section 309A of the Act (21 U.S.C. 829a) and § 1306.07(f). Such prescription issued by a qualifying practitioner shall not be used to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients.

Credits
[36 FR 7799, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37986, Oct. 25, 1974; 70 FR 36343, June 23, 2005; 85 FR 69167, Nov. 2, 2020]

SOURCE: 36 FR 7799, April 24, 1971; 36 FR 13386, July 21, 1971; Redesignated at 38 FR 26609, Sept. 24, 1973; 51 FR 5316, Feb. 13, 1986; 74 FR 15624, April 6, 2009; 85 FR 61601, Sept. 30, 2020; 85 FR 69167, Nov. 2, 2020, unless otherwise noted.

AUTHORITY: 21 U.S.C. 821, 823, 829, 829a, 831, 871(b) unless otherwise noted.

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Notes of Decisions (83)

Current through Sept. 15, 2022, 87 FR 56592, except for 40 CFR § 52.220, which is current through Sept. 1, 2022. Some sections may be more current. See credits for details.

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KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

McKinney's Consolidated Laws of New York Annotated
Public Health Law (Refs & Annos)
Chapter 45. Of the Consolidated Laws (Refs & Annos)
Article 33. Controlled Substances (Refs & Annos)
Title IV. Dispensing to Ultimate Users

McKinney's Public Health Law § 3331

§ 3331. Scheduled substances administering and dispensing by practitioners

Effective: April 1, 2018
Currentness

1. Except as provided in titles III or V of this article, no substance in schedules II, III, IV, or V may be prescribed for or dispensed or administered to an addict or habitual user.

2. A practitioner, in good faith, and in the course of his or her professional practice only, may prescribe, administer and dispense substances listed in schedules II, III, IV, and V, or he or she may cause the same to be administered by a designated agent under his or her direction and supervision.

3. A veterinarian, in good faith, and in the course of the practice of veterinary medicine only, may prescribe, administer and dispense substances listed in schedules II, III, IV, and V or he may cause them to be administered by a designated agent under his direction and supervision.

4. No such substance may be dispensed unless it is enclosed within a suitable and durable container, and:

(a) Affixed to such container is a label upon which is indelibly typed, printed or otherwise legibly written the following:

(i) the name and address of the ultimate user for whom the substance is intended, or, if intended for use upon an animal, the species of such animal and the name and address of the owner or person in custody of such animal;

(ii) the name, address, and telephone number of the dispensing practitioner;

(iii) specific directions for use, including but not limited to the dosage and frequency of dosage, and the maximum daily dosage;

(iv) the legend, prominently marked or printed in either boldface or upper case lettering: “CONTROLLED SUBSTANCE, DANGEROUS UNLESS USED AS DIRECTED”;

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(v) the date of dispensing;

(vi) either the name of the substance or such code number assigned by the department for the particular substance pursuant to section thirty-three hundred eighteen of this article;

(b) Such container shall be identified as a controlled substance by either:

(i) an orange label;

(ii) a label of another color over which is superimposed an orange transparent adhesive tape; or

(iii) an auxiliary orange label affixed to the front of such container and bearing the legend, prominently marked or printed "Controlled Substance, Dangerous Unless Used As Directed";

(c) Any label, transparency, or auxiliary label shall be applied in a manner which would inhibit its removal.

5. (a) No more than a thirty day supply or, pursuant to regulations of the commissioner enumerating conditions warranting specified greater supplies, no more than a three month supply of a schedule II, III or IV substance, as determined by the directed dosage and frequency of dosage, may be dispensed by an authorized practitioner at one time.

(b) Notwithstanding the provisions of paragraph (a) of this subdivision, a practitioner, within the scope of his or her professional opinion or discretion, may not prescribe more than a seven-day supply of any schedule II, III, or IV opioid to an ultimate user upon the initial consultation or treatment of such user for acute pain. Upon any subsequent consultations for the same pain, the practitioner may issue, in accordance with paragraph (a) of this subdivision, any appropriate renewal, refill, or new prescription for the opioid or any other drug.

(c) For the purposes of this subdivision, "acute pain" shall mean pain, whether resulting from disease, accidental or intentional trauma, or other cause, that the practitioner reasonably expects to last only a short period of time. Such term shall not include chronic pain, pain being treated as part of cancer care, hospice or other end-of-life care, or pain being treated as part of palliative care practices.

6. A practitioner dispensing a controlled substance shall file information pursuant to such dispensing with the department by electronic means in such manner and detail as the commissioner shall, by regulation, require. This requirement shall not apply to the dispensing by a practitioner pursuant to subdivision five of section thirty-three hundred fifty-one of this article.

7. A practitioner may not administer, prescribe or dispense any substance referred to in subdivision (h) of Schedule II, and subdivision (g) of Schedule III, of section three thousand three hundred six of this article for other than therapeutic purposes. A practitioner may not administer, prescribe or dispense any such substance to any individual without first obtaining the informed consent of such individual, or where the individual lacks capacity to give such consent, a person legally authorized to consent on his or her behalf.

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8. No opioids shall be prescribed to a patient initiating or being maintained on opioid treatment for pain which has lasted more than three months or past the time of normal tissue healing, unless the medical record contains a written treatment plan that follows generally accepted national professional or governmental guidelines. The requirements of this paragraph shall not apply in the case of patients who are being treated for cancer that is not in remission, who are in hospice or other end-of-life care, or whose pain is being treated as part of palliative care practices.

Credits

(Added L.1972, c. 878, § 2, eff. April 1, 1973. Amended L.1973, c. 728, § 1; L.1974, c. 965, § 10; L.1981, c. 415, § 1; L.1986, c. 433, § 1; L.1989, c. 418, § 12; L.1990, c. 640, § 4; L.1998, c. 537, § 4, eff. Nov. 1, 1998; L.2004, c. 58, pt. A, § 6, eff. Oct. 19, 2004; L.2010, c. 178, § 6, eff. July 15, 2010; L.2012, c. 447, pt. C, § 17, eff. Aug. 27, 2012; L.2016, c. 71, pt. C, § 1, eff. July 22, 2016; L.2018, c. 57, pt. D, § 7-a, eff. April 12, 2018, deemed eff. April 1, 2018.)

Notes of Decisions (5)

McKinney's Public Health Law § 3331, NY PUB HEALTH § 3331
Current through L.2022, chapters 1 to 561. Some statute sections may be more current, see credits for details.

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KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

21 U.S.C.A. § 842

§ 842. Prohibited acts B

Effective: October 24, 2018
Currentness

(a) Unlawful acts

It shall be unlawful for any person--

(1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title;

(2) who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration;

(3) who is a registrant to distribute a controlled substance in violation of section 825 of this title;

(4) to remove, alter, or obliterate a symbol or label required by section 825 of this title;

(5) to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II;

(6) to refuse any entry into any premises or inspection authorized by this subchapter or subchapter II;

(7) to remove, break, injure, or deface a seal placed upon controlled substances pursuant to section 824(f) or 881 of this title or to remove or dispose of substances so placed under seal;

(8) to use, to his own advantage, or to reveal, other than to duly authorized officers or employees of the United States, or to the courts when relevant in any judicial proceeding under this subchapter or subchapter II, any information acquired in the course of an inspection authorized by this subchapter concerning any method or process which as a trade secret is entitled

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to protection, or to use to his own advantage or reveal (other than as authorized by section 830 of this title) any information that is confidential under such section;

(9) who is a regulated person to engage in a regulated transaction without obtaining the identification required by 830(a)(3) of this title. [1]

(10) negligently to fail to keep a record or make a report under section 830 of this title or negligently to fail to self-certify as required under section 830 of this title;

(11) to distribute a laboratory supply to a person who uses, or attempts to use, that laboratory supply to manufacture a controlled substance or a listed chemical, in violation of this subchapter or subchapter II, with reckless disregard for the illegal uses to which such a laboratory supply will be put;

(12) who is a regulated seller, or a distributor required to submit reports under subsection (b)(3) of section 830 of this title--

(A) to sell at retail a scheduled listed chemical product in violation of paragraph (1) of subsection (d) of such section, knowing at the time of the transaction involved (independent of consulting the logbook under subsection (e)(1)(A)(iii) of such section) that the transaction is a violation; or

(B) to knowingly or recklessly sell at retail such a product in violation of paragraph (2) of such subsection (d);

(13) who is a regulated seller to knowingly or recklessly sell at retail a scheduled listed chemical product in violation of subsection (e) of such section;

(14) who is a regulated seller or an employee or agent of such seller to disclose, in violation of regulations under subparagraph (C) of section 830(e)(1) of this title, information in logbooks under subparagraph (A)(iii) of such section, or to refuse to provide such a logbook to Federal, State, or local law enforcement authorities;

(15) to distribute a scheduled listed chemical product to a regulated seller, or to a regulated person referred to in section 830(b)(3)(B) of this title, unless such regulated seller or regulated person is, at the time of such distribution, currently registered with the Drug Enforcement Administration, or on the list of persons referred to under section 830(e)(1)(B)(v) of this title;

(16) to violate subsection (e) of section 825 of this title [2] ; or

(17) in the case of a registered manufacturer or distributor of opioids, to fail to review the most recent information, directly related to the customers of the manufacturer or distributor, made available by the Attorney General in accordance with section 827(f) of this title.

As used in paragraph (11), the term "laboratory supply" means a listed chemical or any chemical, substance, or item on a special surveillance list published by the Attorney General, which contains chemicals, products, materials, or equipment used in the manufacture of controlled substances and listed chemicals. For purposes of paragraph (11), there is a rebuttable presumption

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of reckless disregard at trial if the Attorney General notifies a firm in writing that a laboratory supply sold by the firm, or any other person or firm, has been used by a customer of the notified firm, or distributed further by that customer, for the unlawful production of controlled substances or listed chemicals a firm distributes and 2 weeks or more after the notification the notified firm distributes a laboratory supply to the customer. For purposes of paragraph (15), if the distributor is temporarily unable to access the list of persons referred to under section 830(e)(1)(B)(v) of this title, the distributor may rely on a written, faxed, or electronic copy of a certificate of self-certification submitted by the regulated seller or regulated person, provided the distributor confirms within 7 business days of the distribution that such regulated seller or regulated person is on the list referred to under section 830(e)(1)(B)(v) of this title.

(b) Manufacture

It shall be unlawful for any person who is a registrant to manufacture a controlled substance in schedule I or II, or ephedrine, pseudoephedrine, or phenylpropanolamine or any of the salts, optical isomers, or salts of optical isomers of such chemical, which is--

(1) not expressly authorized by his registration and by a quota assigned to him pursuant to section 826 of this title; or

(2) in excess of a quota assigned to him pursuant to section 826 of this title.

(c) Penalties

(1)(A) Except as provided in subparagraph (B), (C), or (D) of this paragraph and paragraph (2), any person who violates this section shall, with respect to any such violation, be subject to a civil penalty of not more than $25,000. The district courts of the United States (or, where there is no such court in the case of any territory or possession of the United States, then the court in such territory or possession having the jurisdiction of a district court of the United States in cases arising under the Constitution and laws of the United States) shall have jurisdiction in accordance with section 1355 of Title 28 to enforce this paragraph.

(B)(i) Except as provided in clause (ii), in the case of a violation of paragraph (5), (10), or (17) of subsection (a), the civil penalty shall not exceed $10,000.

(ii) In the case of a violation described in clause (i) committed by a registered manufacturer or distributor of opioids and related to the reporting of suspicious orders for opioids, failing to maintain effective controls against diversion of opioids, or failing to review the most recent information made available by the Attorney General in accordance with section 827(f) of this title, the penalty shall not exceed $100,000.

(C) In the case of a violation of paragraph (16) of subsection (a) of this section by an importer, exporter, manufacturer, or distributor (other than as provided in subparagraph (D)), up to $500,000 per violation. For purposes of this subparagraph, a violation is defined as each instance of importation, exportation, manufacturing, distribution, or possession with intent to manufacture or distribute, in violation of paragraph (16) of subsection (a).

(D) In the case of a distribution, dispensing, or possession with intent to distribute or dispense in violation of paragraph (16) of subsection (a) of this section at the retail level, up to $1000 per violation. For purposes of this paragraph, the term “at the retail level” refers to products sold, or held for sale, directly to the consumer for personal use. Each package, container or other

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separate unit containing an anabolic steroid that is distributed, dispensed, or possessed with intent to distribute or dispense at the retail level in violation of such paragraph (16) of subsection (a) shall be considered a separate violation.

(2)(A) If a violation of this section is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed, such person shall, except as otherwise provided in subparagraph (B) or (D) of this paragraph, be sentenced to imprisonment of not more than one year or a fine under Title 18, or both.

(B) If a violation referred to in subparagraph (A) was committed after one or more prior convictions of the offender for an offense punishable under this paragraph (2), or for a crime under any other provision of this subchapter or subchapter II or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 2 years, a fine under Title 18, or both.

(C) In addition to the penalties set forth elsewhere in this subchapter or subchapter II, any business that violates paragraph (11) of subsection (a) shall, with respect to the first such violation, be subject to a civil penalty of not more than $250,000, but shall not be subject to criminal penalties under this section, and shall, for any succeeding violation, be subject to a civil fine of not more than $250,000 or double the last previously imposed penalty, whichever is greater.

(D) In the case of a violation described in subparagraph (A) that was a violation of paragraph (5), (10), or (17) of subsection (a) committed by a registered manufacturer or distributor of opioids that relates to the reporting of suspicious orders for opioids, failing to maintain effective controls against diversion of opioids, or failing to review the most recent information made available by the Attorney General in accordance with section 827(f) of this title, the criminal fine under Title 18 shall not exceed $500,000.

(3) Except under the conditions specified in paragraph (2) of this subsection, a violation of this section does not constitute a crime, and a judgment for the United States and imposition of a civil penalty pursuant to paragraph (1) shall not give rise to any disability or legal disadvantage based on conviction for a criminal offense.

(4)(A) If a regulated seller, or a distributor required to submit reports under section 830(b)(3) of this title, violates paragraph (12) of subsection (a) of this section, or if a regulated seller violates paragraph (13) of such subsection, the Attorney General may by order prohibit such seller or distributor (as the case may be) from selling any scheduled listed chemical product. Any sale of such a product in violation of such an order is subject to the same penalties as apply under paragraph (2).

(B) An order under subparagraph (A) may be imposed only through the same procedures as apply under section 824(c) of this title for an order to show cause.

CREDIT(S)

(Pub.L. 91-513, Title II, § 402, Oct. 27, 1970, 84 Stat. 1262; Pub.L. 95-633, Title II, § 202(b)(1), (2), Nov. 10, 1978, 92 Stat. 3776; Pub.L. 100-690, Title VI, § 6056, Nov. 18, 1988, 102 Stat. 4318; Pub.L. 104-237, Title II, § 205, Oct. 3, 1996, 110 Stat. 3103; Pub.L. 105-277, Div. A, § 101(b) [Title I, § 117], Oct. 21, 1998, 112 Stat. 2681-50, 2681-68; Pub.L. 107-273, Div. B, Title IV, § 4002(b)(16), (d)(2)(B), Nov. 2, 2002, 116 Stat. 1808, 1809; Pub.L. 109-177, Title VII, §§ 711(f)(1)(A), (2), 714, Mar. 9, 2006, 120 Stat. 262 to 264; Pub.L. 111-268, §§ 4, 5, Oct. 12, 2010, 124 Stat. 2847, 2848; Pub.L. 113-260, § 3(c), Dec. 18, 2014, 128 Stat. 2931; Pub.L. 115-271, Title III, § 3273(c), Oct. 24, 2018, 132 Stat. 3953.)

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Notes of Decisions (29)

Footnotes

1 So in original. Probably should be "section 830(a)(3) of this title;".

2 Probably should have referred to section 305 of Pub.L. 91-513, which is classified to 21 U.S.C.A. § 825. See References in Text note set out under this section.

21 U.S.C.A. § 842, 21 USCA § 842
Current through P.L. 117-167. Some statute sections may be more current, see credits for details.

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2022 WL 4091669
Only the Westlaw citation is currently available.
United States District Court, E.D. Pennsylvania.

UNITED STATES of America
v.
Mitchell SPIVACK, Spivack, Inc., Todd Goodman, Eric Pestrack, Lee Kamp, Two Million Nine Hundred Thousand Three Hundred Forty-Two Dollars and Sixty Cents in United States Currency ($2,900,342.60)

CIVIL ACTION NO. 22-343
|
Filed September 6, 2022

Attorneys and Law Firms

Anthony D. Scicchitano, U.S. Attorney's Office, Philadelphia, PA, for United States of America.

Rocco C. Cipparone, Jr., Law Offices of Rocco C. Cipparone, Haddon Heights, NJ, for Todd Goodman.

Thomas B. Malone, The Malone Firm LLC, Philadelphia, PA, Jason Bologna, Buchanan, Ingersoll & Rooney PC, Philadelphia, PA, for Eric Pestrack.

Fred Rabner, Rabner Law Offices, Pittsburgh, PA, Jason Bologna, Buchanan, Ingersoll & Rooney PC, Philadelphia, PA, for Lee Kamp.

ORDER

KEARNEY, District Judge

***1 AND NOW**, this 6th day of September 2022, upon considering Defendants Eric Pestrack's and Lee Kamp's joint Motion to dismiss the second amended Complaint (ECF Doc. No. 32), the response from the United States (ECF Doc. No. 34), Defendant Todd Goodman's Motion to dismiss the second Amended Complaint (ECF Doc. No. 33), and the response from the United States (ECF Doc. No. 35), it is **ORDERED**:

1. Defendants Pestrack's and Kamp's joint Motion (ECF Doc. No. 32) and Defendant Goodman's Motion (ECF Doc. No. 33) are **DENIED** requiring Defendants Pestrack, Kamp, and Goodman file an Answer to the second amended Complaint no later than **September 20, 2022**; [1] and,

***2** 2. The United States shall file a Memorandum not exceeding three pages on or before **September 12, 2022** describing each party's position as to why we should not amend the caption to remove the reference to judgment debtors Mitchell Spivack, Spivack, Inc., and the sum of money under our August 11, 2022 Order (ECF Doc. No. 31).

All Citations

Slip Copy, 2022 WL 4091669

Footnotes

1 The United States seeks money damages in this civil case against a part-time pharmacist Todd Goodman and pharmacy technicians or assistants Eric Pestrack and Lee Kamp alleging, while working at the Verree Pharmacy, they violated the Controlled Substances Act, 21 U.S.C. §§ 842(a), 829; violated the False Claims Act by knowingly presenting or causing presentation of false claims in violation of 31 U.S.C. § 3729(a)(1)(A) and conspiring to knowingly present or causing presentation of false claims in violation of 31 U.S.C. § 3729(a)(1)(C); and are further liable for payment by mistake and unjust enrichment under state law.

Messrs. Pestrack, Kamp, and Goodman move to dismiss the Controlled Substances Act and False Claims Act claims but not the payment by mistake and unjust enrichment state law claims. The United States must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662 (2008). We accept as true all factual allegations and

view the facts in the light most favorable to the United States as the non-moving party. *Klotz v. Celentano Stadtmauer and Walentowicz LLP*, 991 F.3d 458, 462 (3d Cir. 2021) (citation omitted).

We deny Messrs. Pestrack's and Kamp's Motion to dismiss.

Messrs. Pestrack and Kamp move to dismiss the Controlled Substances Act and False Claims Act claims arguing: (a) they are pharmacy technicians and cannot be held to the same standard as a licensed pharmacist; (b) the expert used by the United States to evaluate the Defendants' controlled substances dispensing practices at Verree Pharmacy is a "deeply flawed opinion" ignoring the distinctions between pharmacist and pharmacy technician; (c) the United States does not plead the their required mental state under *Ruan v. United States*, 142 S.Ct. 2370 (2022) defining the state of mind the United States must prove to convict a defendant of a criminal violation of the Controlled Substances Act; (d) the United States' accusations "distort the factual reality of [Messrs. Pestrack's and Kamp's] knowledge and behavior"; and, (e) the United States fails to plead fraud with particularity under Rule 9(b) required to state claims under the False Claims Act.

The United States pleads a Controlled Substances Act claim. The United States alleges Messrs. Pestrack and Kamp violated section 842(a)(1) of the Controlled Substances Act. Congress in section 842(a)(1) makes it "unlawful for ***any person*** ... who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title ..." 21 U.S.C. § 842(a)(1) (emphasis added). Part C in turn applies to "***every person*** who dispenses, or who proposes to dispense, any controlled substance...." 21 U.S.C. § 822(a)(2) (emphasis added). Congress in section 829 prohibits the dispensing of a controlled substances without a written prescription by a practitioner issued for a legitimate medical purpose. 21 U.S.C. § 829. Section 842(a)(1) "applies broadly to all persons involved in the manufacture, distribution, and dispensing of controlled substances, including lay-persons ..." *United States v. City Pharmacy, LLC*, No. 16-24, 2016 WL 9045859, at * 2-3 (N.D. W. Va. Dec. 19, 2016). The United States sufficiently alleges Messrs. Pestrack's and Kamp's personal involvement in dispensing controlled substances at the Verree Pharmacy in violation of the Act including specific examples of dispensing large amounts of Schedule II controlled substances despite "red flags" of diversion such as dispensing drugs from altered and forged prescriptions, dispensing a "cocktail" of drugs, and excessive cash payments for drugs.

The Supreme Court's decision in *Ruan* does not apply. In *Ruan*, the Supreme Court addressed the state of mind the United States must prove in convicting two physicians on criminal charges under a different section of the Controlled Substances Act than we address today. The United States criminally charged physicians in different Districts under section 841 of the Act making it unlawful "[e]xcept as authorized[,] ... for any person knowingly or intentionally ... to manufacture, distribute, or dispense ... a controlled substance." 21 U.S.C. § 841(a). The Court held the "knowingly or intentionally" *mens rea* language of section 841 applies to the "except as authorized" clause meaning "once a defendant meets the burden of producing evidence that his or her conduct was 'authorized,' the Government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner." *Ruan*, 142 S.Ct. at 2376. Messrs. Pestrack and Kamp, relying on *Ruan*, argue the United States fails to allege they knew they were acting in an unauthorized manner or intended to do so "as they worked to help pharmacists fill prescriptions at Verree Pharmacy." ECF Doc. No. 32–1 at 9–10.

The Court's analysis of the burdens of proof in a criminal prosecution like *Ruan* is distinguishable. First, the "knowingly or intentionally" language in section 841 at issue in *Ruan* is ***not*** contained in section 842 at issue here. Second, the *mens rea* language of section 841 requires the United States to ***prove*** beyond a reasonable doubt–not plead–in its criminal prosecution the defendant knowingly or intentionally acted in an

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unauthorized manner. This proof standard has nothing to do with pleading requirements of the civil provision in section 842(a). Third, the United States need not at the pleading stage "negative any exemption or exception set forth in this subchapter in any complaint, information, indictment, or other pleading or in any trial, hearing or other proceeding under this subchapter, and the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit." 21 U.S.C. § 855(a)(1). The Court in *Ruan* explained section 855 "can ... be understood as providing a presumptive device, akin to others we have recognized in the criminal context, which 'merely shift[s] the burden of production to the defendant, following the satisfaction of which the ultimate burden of persuasion returns to the prosecution.' " *Ruan*, 142 S.Ct. at 2380 (quoting *Cnty. Court of Ulster Cnty. v. Allen*, 442 U.S. 140, 157–58, n. 16 (1979)). If at all relevant in the civil context, *Ruan* does not require the United States to plead Messrs. Pestrack and Kamp acted knowingly or intentionally to the "except as authorized" language of section 841 where the claim here is a violation of section 842. We reject Messrs. Pestrack's and Kamp's argument the *mens rea* element the Court found in *Ruan* "should be the same" in the civil context. They do not offer, and we are not aware, of authority extending the criminal mental state burdens of proof to a civil case under section 842 of the Controlled Substances Act.

We also reject Messrs. Pestrack's and Kamp's argument the United States' expert referenced in the second amended Complaint is "deeply flawed" because it ignores the distinction between pharmacists and pharmacy technicians and the allegations "distort the factual reality of their knowledge and behavior." These arguments are not a basis for a Rule 12(b)(6) motion which tests only the sufficiency of the allegations to determine whether the United States pleads a claim plausible on its face. Messrs. Pestrack and Kamp may test the factual bases of the United States' allegations and the opinion of its expert in discovery and later motion practice.

The United States pleads a False Claims Act claim. The United States alleges Messrs. Pestrack and Kamp violated section 3729(a)(1)(A) and (a)(1)(C) of the False Claims Act imposing liability causes to be presented, a false or fraudulent claim on "any person who ... knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval ... to the United States Government ..." and "any person who ... conspires to" knowingly present or cause to be presented a false or fraudulent claim for payment to the United States. 31 U.S.C. §§ 3729(a)(1)(A), (C).

To state a claim a claim under section 3729(a)(1)(A), the United States must plead: (1) Defendants "presented or caused to be presented to an agent of the United States a claim for payment;" (2) "the claim was false or fraudulent;", and (3) the Defendants "knew the claim was false or fraudulent." *United States ex rel. Bookwalter v. UPMC*, 946 F.3d 162, 175 (3d Cir. 2019) (citation omitted). Rule 9(b)'s particularity standard applies to pleading claims under the False Claims Act. *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 157–58 (3d Cir. 2014). To allege a conspiracy to violate the False Claims Act under section 3729(a)(1)(C), the United States "is required to allege the underlying fraud with particularity, but the allegations of the conspiracy need only satisfy the notice pleading standards of Rule 8." *United States ex rel. Travis v. Gilead Sciences, Inc.,* —— F. Supp. 3d ——, No. 17-1183, 2022 WL 991382, at * (E.D. Pa. Apr. 1, 2022) (quoting *United States ex rel. Boise v. Cephalon, Inc.*, No. 08-287, 2015 WL 1724572, at * 13 (E.D. Pa. Apr. 15, 2015)). The United States must identify co-conspirators and allege a specific agreement to violate the False Claims Act. *Id.* (citing *U.S. ex rel. Bates v. Dentsply Int'l, Inc.*, No. 12-7199, 2014 WL 4384503, at *9 (E.D. Pa. Sept. 4, 2014)).

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To meet the standards of Rule 9(b), the United States must provide "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted" rather than a "mere opportunity for fraud." *Foglia*, 754 F.3d at 157–58; *Bookwalter*, 946 F.3d at 176. Rule 9(b) requires the United States to allege "all of the essential factual background that would accompany the first paragraph of any newspaper story–that is, the who, what, when, where, and how of the events at issue." *Bookwalter*, 946 F.3d at 175 (quoting *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016)) (internal quotation marks omitted).

The United States alleges Messrs. Pestrack and Kamp from January 27, 2016 to the present, failed to dispense drugs while falsely claiming to dispense them and billing Medicare, Medicaid, the Federal Employee Health Benefit Plan, and Tricare, and knowingly did so, through the "Bill But Don't Fill" scheme. The United States details how the pharmacists and Messrs. Pestrack and Kamp, operated the Bill But Don't Fill scheme. The United States is not required to "plead anything more, such as the date, time, place, or content of every single allegedly false Medicare claim" and details "a set of circumstances that, if true, makes a whole set of claims at least *prima facie* false." *Bookwalter*, 946 F.3d at 176. The United States alleges Messrs. Spivak, Pestrack, Kamp, and Goodman jointly used the "Bill But Don't Fill" code as part of their conspiracy to falsely claim to federal health programs they had dispensed a drug to a patient or beneficiary when they had not and the alleged facts, including one co-conspirator's admission, allow us to find a plausible fact basis as to how the four worked together and agreed to violate the False Claims Act. The United States also alleges the co-conspirators together conspired to submit false billings and claims for controlled substances dispensed and distributed in violation of the Controlled Substances Act and Medicare Part D and Medicare requirements showing an agreement to collectively engage in the scheme to submit false claims to federal health care programs knowing of the fraud and falsity. We deny Messrs. Pestrack's and Kamp's motion to dismiss the False Claims Act claims.

We deny Mr. Goodman's Motion to dismiss.

Mr. Goodman is a pharmacist. He moves to dismiss the Controlled Substances Act and False Claims Act claims against him. Like Messrs. Pestrack and Kamp, Mr. Goodman argues the United States: (a) did not and cannot meet the *mens rea* requirement under the Supreme Court's *Ruan* decision; (b) expert's opinion is "deeply flawed" and impermissible under *Ruan*; (c) makes accusations devoid of factual or legal support distorting the actual and subjective facts of the "reality" of his knowledge and behavior; and (d) fails to meet Rule 9(b)'s particularity standard to plausibly allege claims under the False Claims Act.

We deny Mr. Goodman's motion for all the reasons discussed in dismissing Messrs. Pestrack's and Kamp's motion.

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