

U.S. Department of Health and Human Services
Office of Inspector General

Semiannual Report to Congress

October 1, 2021–March 31, 2022



A Message From Christi A. Grimm, Inspector General

I am pleased to submit this Semiannual Report to Congress summarizing the activities of the Department of Health and Human Services (HHS), Office of Inspector General (OIG), for the 6-month period ending on March 31, 2022.

OIG's multidisciplinary workforce—composed of more than 1,600 auditors, attorneys, evaluators, investigators, and professionals—is dedicated to the mission of promoting the economy, efficiency, effectiveness, and integrity of HHS's programs. We are steadfast in our commitment to conduct independent and objective oversight work to drive positive change in the HHS programs upon which all Americans rely.



More than 2 years have passed since the emergence of COVID-19. The pandemic's toll is apparent as we surpass the tragic milestone of 1 million American lives lost due to the virus. At the same time, we see increases in mental health conditions, including depression, anxiety, substance use disorder, drug overdoses, and suicide. The pandemic created unprecedented strains on our health care system and exposed longstanding problems. Hospitals, nursing facilities, and other health care providers have struggled with staffing, operational, and emergency response challenges. Nursing home residents have been disproportionately affected by COVID-19, and many residents are experiencing the added pain of social isolation. The disparate impacts exacted by this virus also highlight longstanding disparities and the need to promote health equity and better serve vulnerable populations.

OIG offers pragmatic recommendations to drive sustained and meaningful change. In our December 2021 report *Many Medicare Beneficiaries Are Not Receiving Medication To Treat Their Opioid Use Disorder*, we found that only 16 percent of Medicare beneficiaries diagnosed with an opioid use disorder in 2020 received medication treatment, and we recommended that CMS take steps to improve access. In our January 2022 report *CMS Should Take Further Action To Address States With Poor Performance in Conducting Nursing Home Surveys*, we found that slightly more than half of States repeatedly failed to meet one or more performance measures—most commonly, timeliness requirements—for conducting nursing home surveys. We recommended that CMS act to improve State oversight of nursing home care to better protect people residing in nursing homes.

In this reporting period, OIG continued to drive a positive return on investment from enforcement and oversight. Working with our law enforcement and agency partners, for every \$1 dollar invested in the Health Care Fraud and Abuse Control Program, we recovered more than \$4 for taxpayers. We combated fraud through 320 criminal actions and \$1.4 billion in expected investigative recoveries. Throughout the pandemic, working with our Federal and State law enforcement partners, we have aggressively pursued bad actors who are exploiting the public health emergency. OIG's work has resulted in numerous major nationwide law enforcement actions. In April 2022, we participated in a coordinated law enforcement action against 21 defendants for their alleged participation in various COVID-19 health care fraud schemes that generated more than \$149 million in false billings. OIG also participated in a May 2022 enforcement

action targeting fraud schemes involving 5.1 million illegally prescribed controlled substance pills and roughly \$7 billion billed in opioid-related fraud loss. As these law enforcement efforts demonstrate, OIG is uncompromising in finding and prosecuting criminals who steal for personal gain at the expense of all Americans.

In addition to punishing fraudsters and recouping taxpayers' money, we remain focused on preventing fraud. We rigorously analyze data to detect concerning trends and outliers, issue compliance guidance for the health care industry, and make recommendations to HHS to improve program integrity. We strive to ensure that programs are designed with integrity at the forefront—not as an afterthought—to prevent downstream issues with efficiency and effectiveness. OIG's deep expertise in fraud, waste, and abuse enables us to offer HHS and its operating divisions technical assistance to design safeguards that mitigate risk in new and expanded programs.

OIG employs modern technologies and tools to ensure good financial stewardship of American taxpayers' \$2.4 trillion investment in HHS. We perform cutting-edge analyses in evolving and emergent areas, including telehealth and cybersecurity. Our diligent and innovative workforce has experience in overseeing complex and consequential initiatives and produces outsized impact. Our capacity to achieve high-impact results is limited only by our resources, which have not kept pace with the growing size of HHS programs in recent years. OIG will continue to pursue the mission of providing independent, objective, standards-based oversight and enforcement to protect HHS's more than 100 programs and the people they serve.

We appreciate the continued support of Congress and HHS for this important work.

Table of Contents

A Message From Christi A. Grimm, Inspector General	2
OIG’s Approach to Driving Positive Change	4
Highlights of OIG Accomplishments	5
Selected Acronyms and Abbreviations	16
Medicare and Medicaid Reports and Reviews	17
Legal and Investigative Activities Related to Medicare and Medicaid	33
Public Health and Human Service Agency Reports and Reviews	52
Legal and Investigative Activities Related to Public Health and Human Service Agencies	57
Other HHS-Related Reviews and Investigative Activities	59
Appendix A: Questioned Costs and Funds To Be Put to Better Use	65
Appendix B: Peer Review Results	70
Appendix C: Summary of Sanction Authorities	73
Appendix D: Reporting Requirements in the Inspector General Act of 1978	76
Appendix E: Reporting Requirements in the Inspector General Empowerment Act of 2016	78
Appendix F: Anti-Kickback Statute—Safe Harbors	86

OIG’s Approach to Driving Positive Change

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), Office of Inspector General (OIG), provides independent and objective oversight that promotes economy, efficiency, and effectiveness in HHS programs and operations. OIG’s program integrity and oversight activities are shaped by legislative and budgetary requirements and adhere to professional standards established by the Government Accountability Office (GAO), Department of Justice (DOJ), and Inspector General community. Through a nationwide network of audits, investigations, and evaluations, OIG carries out its mission to protect the integrity of HHS programs and the health and welfare of the people served by those programs. OIG’s work is conducted by the Office of Audit Services (OAS), Office of Evaluation and Inspections (OEI), Office of Investigations (OI), Office of Counsel to the Inspector General (OCIG), and Mission Support and Infrastructure (MSI).

OIG Organization

Office of Audit Services

OAS conducts audits of HHS programs and operations either through its own resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or

of HHS's grantees and contractors in carrying out their respective responsibilities and provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote the economy, efficiency, and effectiveness of programs and operations throughout HHS.

Office of Evaluation and Inspections

OEI conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, and abuse and promoting economy, efficiency, and effectiveness in HHS programs. OEI reports also present practical recommendations for improving program operations.

Office of Investigations

OI conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in almost every State, the District of Columbia, and Puerto Rico, OI coordinates with DOJ and other Federal, State, and local law enforcement authorities. OI also coordinates with OAS and OEI when audits and evaluations uncover potential fraud. OI's investigative efforts often lead to criminal convictions, administrative sanctions, or civil monetary penalties (CMPs).

Office of Counsel to the Inspector General

OCIG provides legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including the False Claims Act, program exclusion, self-disclosure, and CMP cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements (CIAs). OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry about the anti-kickback statute and other OIG enforcement authorities.

Mission Support and Infrastructure

MSI is composed of the Immediate Office of the Inspector General and the Office of Management and Policy. MSI is responsible for coordinating OIG activities and providing mission support, including setting vision and direction for OIG's priorities and strategic planning; ensuring effective management of budget, finance, human resource management, and other operations; and serving as a liaison with HHS, Congress, and other stakeholders. MSI plans, conducts, and participates in a variety of cooperative projects within HHS and with other Government agencies. MSI provides critical data analytics, data management, and information technology (IT) infrastructure that enables OIG components to conduct their work efficiently and effectively.

OIG Strategic Publications

HHS-OIG Strategic Publications



HHS-OIG Strategic Plan

OIG’s [Strategic Plan](#) outlines the approach to protecting the integrity of HHS programs. The plan has three key goals: (1) to fight fraud, waste, and abuse; (2) to promote quality, safety, and value in HHS programs and for HHS beneficiaries; and (3) to advance excellence and innovation. These goals drive OIG’s work planning for audits and evaluations as well as OIG’s approach to enforcement. These goals also serve as a starting point for OIG’s assessment of its own effectiveness.

OIG Work Plan

OIG’s [Work Plan](#) sets forth projects that OIG plans to undertake during the fiscal year (FY) and beyond. Projects listed in the Work Plan span HHS’s operating divisions (OpDivs), which include the Centers for Medicare & Medicaid Services (CMS), public health agencies such as the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), and human services agencies such as the Administration for Children and Families (ACF) and the Administration for Community Living (ACL). The Work Plan also includes oversight of State and local governments’ use of Federal funds as well as the administration of HHS. Some of the projects described in the Work Plan are statutorily required.

OIG's Top Recommendations

OIG drives positive change by not only identifying risks, problems, abuses, and deficiencies, but also recommending solutions to address them. OIG maintains a list of recommendations it has made to address vulnerabilities detected in its reviews, and it keeps track of whether these recommendations have been implemented. OIG systematically follows up on its recommendations with the relevant HHS programs. From among the recommendations that have not been implemented, OIG identifies the top recommendations that, if implemented, are likely to garner significant savings and improvements in quality, efficiency, and effectiveness. OIG compiles these recommendations in the [Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs: OIG's Top Recommendations](#) (previously known as the *Compendium of Unimplemented Recommendations*).

Top Management and Performance Challenges Facing HHS

To focus HHS's attention on the most pressing issues, each year OIG identifies the [Top Management and Performance Challenges](#) facing HHS. These top challenges arise across HHS programs and cover critical HHS responsibilities, including delivering quality services and benefits, exercising sound fiscal management, safeguarding public health and safety, and enhancing cybersecurity.

OIG's Semiannual Report to Congress

OIG's [Semiannual Report to Congress](#) (Semiannual Report) describes OIG's work on identifying significant problems, abuses, deficiencies, remedies, and investigative outcomes relating to the administration of HHS programs and operations that were disclosed during the reporting period. In the report below, we present OIG expected recoveries, criminal and civil actions, and other statistics as a result of our work for the semiannual reporting period of April 1, 2021, through September 30, 2021. We also provide data for accomplishments for FY 2021. We also highlight some of our work completed during this semiannual reporting period.

Highlights of OIG Accomplishments

HHS-OIG’S Semiannual Report describes OIG’s work identifying significant risks, problems, abuses, deficiencies, remedies, and investigative outcomes relating to the administration of HHS programs and operations that were disclosed during the semiannual reporting period of October 1, 2021, through March 31, 2022. In this highlights section, we present data on OIG reports issued, expected recoveries, criminal and civil actions, and other statistics resulting from our work for the semiannual reporting period. We then highlight significant results from selected audits, evaluations, and enforcement activities completed during the reporting period.

At-a-Glance Highlights

Statistic	Semiannual Reporting Period (10/1/2021—3/31/2022)
Audit Reports Issued	47
Evaluations Issued	14
Expected Audit Recoveries	\$1.14 billion
Questioned Costs	\$1.6 billion
Potential Savings	\$162.1 million
New Audit and Evaluation Recommendations	130
Recommendations Implemented by HHS OpDivs	265
Expected Investigative Recoveries	\$1.44 billion
Criminal Actions	320
Civil Actions	320
Exclusions	1043

Results for the Semiannual Reporting Period

During this semiannual reporting period (October 1, 2021, through March 31, 2022), we issued 47 audit reports and 14 evaluation reports. Our audit work identified \$1.14 billion in expected recoveries, as well as \$1.6 billion in questioned costs (costs questioned by OIG because of an alleged violation, costs not supported by adequate documentation, or the expenditure of funds where the intended purpose is unnecessary or unreasonable). Our audit work also identified \$162.1 million in potential savings for HHS—funds that could be saved if HHS implemented all of OIG’s audit recommendations. During this reporting period, OIG made 130 new audit and evaluation recommendations, which are crucial to encourage positive change in HHS programs. Meanwhile, HHS OpDivs implemented 265 prior recommendations, leading to positive impact for HHS programs and beneficiaries.

OIG also remains at the forefront of the Nation’s efforts to fight fraud in HHS programs and hold wrongdoers accountable for their actions. Along with our partners DOJ, Medicaid Fraud Control Units (MFCUs or Units), and other Federal, State, and local law enforcement agencies, we detect, investigate, and prosecute fraud through a coordinated and data-driven approach. OIG’s investigative work led to \$1.44 billion in expected investigative recoveries and 320 criminal actions during this reporting period. OIG also took civil actions, such as assessing monetary penalties against 320 individuals and entities, and excluded 1,043 individuals and entities from Federal health care programs.

OIG continues to focus on the most significant and high-risk issues in health care and human services. Our mission is to provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve. Below we highlight results from selected OIG oversight and enforcement activities from the semiannual reporting period of October 1, 2021, through March 31, 2022, organized by subject area. A comprehensive list of OIG work during the reporting period follows, and Appendices A through F provide data to meet the reporting requirements in the Inspector General Act of 1978.

Responding to the COVID-19 Pandemic and Other Emergencies

OIG continues to prioritize work related to COVID-19 response and recovery. With 70 audits and evaluations underway, assessing a wide range of urgent issues—from health disparities to vaccine administration to nursing home oversight and preparedness, among others—and the issuance of fraud alerts, OIG continues to advance the four goals that drive OIG’s strategic planning and mission execution with respect to HHS’s COVID-19 response and recovery. These goals are to: (1) protect people, (2) protect funds, (3) protect infrastructure, and (4) promote effectiveness of HHS programs, now and into the future.

OIG is coordinating our COVID-19 work with key oversight and law enforcement partners, including the Pandemic Response Accountability Committee; Federal, State, local, and Tribal entities; and GAO, among others, to ensure adequate oversight, avoid duplication, and share insights. Additional information about the OIG COVID-19 strategic plan, emerging fraud schemes, and work related to COVID-19 is available on our website, [COVID-19 Portal](#).

Significant OIG work completed during this semiannual reporting period related to the COVID-19 pandemic includes the following:

[OIG found that COVID-19 tests drove an increase in total Medicare Part B spending on laboratory tests in 2020.](#) During the same time period, non-COVID-19 tests decreased significantly. Medicare Part B spent \$1.5 billion on COVID-19 tests in 2020, while non-COVID-19 tests declined by \$1.2 billion. In total, laboratory spending increased by 4 percent, but the decrease in utilization of non-COVID-19 tests raises concerns about potential impacts on beneficiary health. (See report [OEI-09-21-00240](#).)

[OIG’s survey of States found that most had implemented changes due to COVID-19 to ease restrictions on prior authorization and early refill requirements for prescription drugs.](#) Additionally, States made changes to their prescription quantity limits to allow pharmacies to dispense increased quantities of

some prescription drugs and removed the requirement to obtain a signature upon receipt of a prescription. All 24 States in our survey indicated that they are providing updated guidance to all stakeholders to ensure that beneficiaries can obtain their prescriptions. (See report [A-06-20-04007](#).)

OIG found that the Assistant Secretary for Administration (ASA) awarded and managed five sole source contracts for COVID-19 testing in accordance with Federal and contract requirements. ASA complied with sole source justification requirements when awarding the contracts and set reasonable payment rates for COVID-19 tests. In addition, ASA appropriately managed the contracts by establishing and maintaining communications with contractors, verifying that laboratory result numbers matched the number of tests administered, and reviewing invoices to ensure that payment rates were in accordance with the contract terms and conditions. (See report [A-05-21-00014](#).)

OIG found that, from March to the end of 2020, 84 percent of beneficiaries received telehealth services from providers with whom they had an established relationship. On average, these beneficiaries tended to see their providers in person about 4 months prior to their first telehealth service. Beneficiaries enrolled in traditional Medicare were more likely to receive services from providers with whom they had an established relationship, compared to beneficiaries in Medicare Advantage. (See report [OEI-02-20-00521](#).)

Leveraging Oversight To Better Protect Nursing Home Residents

Improving nursing homes so that they work better for residents is a top priority for OIG. We are deploying the PRO strategy: (1) *Performance*—understanding what makes poor performing nursing homes fail; (2) *Residents First*—ensuring that nursing homes prioritize quality of care and quality of life for residents; and (3) *Oversight*—ensuring that the entities responsible for nursing home oversight—CMS and the States—detect problems quickly and insist on rapid remediation. Past OIG work on nursing homes has uncovered widespread and persistent problems in providing quality care and reporting problems when they occur. Nursing home residents have been among the hardest hit by the COVID-19 pandemic, in part because of their age, underlying medical conditions, and close living quarters. According to CMS, as of April 10, 2022, more than 1,016,000 nursing home residents had confirmed COVID-19 and more than 151,000 of those residents died from the virus. Additionally, more than 1,072,000 nursing home staff had confirmed COVID-19 and 2,357 nursing home staff died.

In March 2022, the Biden Administration launched an initiative to improve nursing home quality and safety. The initiative focuses on several areas, including areas that align with OIG work such as: (1) improving nursing home staffing levels and training, (2) holding poorly performing nursing homes accountable for failures in quality of care, and (3) raising transparency about nursing home performance to enable for residents and families to find the best available options.

Going forward, OIG plans to expand its nursing home oversight, continue to monitor identified areas of concern, push for implementation of unimplemented recommendations, and issue new recommendations

as problems and solutions are identified. Information about ongoing nursing home work can be found on OIG's webpage.

Significant OIG work completed during this semiannual reporting period related to protecting beneficiaries in nursing homes includes the following:

OIG found that more than half of States failed to meet performance measures for their oversight of nursing homes in three or four consecutive years during FYs 2015–2018. States most commonly missed performance measures related to survey timeliness. State surveys of nursing homes are the primary safeguard for ensuring quality of care and resident safety. The remedy that CMS consistently imposed on States for missing performance measures was requiring submission of corrective action plans. However, 10 percent of plans were missing from CMS files and many others lacked substantive details. In three States, CMS escalated concerns about performance to senior State officials, but it rarely imposed formal sanctions and never initiated action to terminate any of its agreements with States for conducting surveys. (See report [OEI-06-19-00460](#).)

OIG found that the current extent of facility-initiated discharges remains unknown. Inappropriate facility-initiated discharges can be unsafe and traumatic for nursing home residents. However, neither ACL nor CMS collect data on the number of facility-initiated discharges. Although nursing homes must send facility-initiated discharge notices to State Ombudsmen, many do not count or track the notices they receive. Following CMS's 2018 initiative to review and take appropriate enforcement action in cases of noncompliance with requirements, State agencies cited more nursing homes for noncompliance, but CMS has not yet determined trends and outcomes of its initiative. (See report [OEI-01-18-00250](#).)

Ensuring Health and Safety of Vulnerable Beneficiaries Served by HHS

OIG has devoted substantial oversight efforts to protect vulnerable beneficiaries, including children and developmentally disabled adults, served by HHS programs such as Medicaid, the Unaccompanied Children (UC) Program, and the Child Care and Development Fund (CCDF).

Significant OIG work completed during this semiannual reporting period related to ensuring health and safety of vulnerable beneficiaries includes the following:

OIG found that more than one-third of Medicaid-enrolled children in five States did not receive required blood lead screening tests. Of the 1 million children who were required to receive 12- and 24-month blood lead screening tests, more than one-third received neither test. Additionally, of the approximately 209,000 children continuously enrolled in Medicaid from birth through 3 years of age, 1 in 5 children in the selected States never received screening by age 3. (See report [OEI-07-18-00371](#).)

OIG found that Arkansas did not fully comply with requirements to report and monitor critical incidents in Medicaid beneficiaries with developmental disabilities residing in community-based

[settings](#). Arkansas lacked internal controls to ensure that incidents of abuse, neglect, or death were reviewed and reported to the appropriate authority. As a result, Arkansas did not ensure that community-based providers properly report all incidents of suspected adult or child abuse to the appropriate hotline; provide evidence of review and followup action on all incidents of adult or child abuse; and review all deaths of beneficiaries receiving waiver services. (See report [A-06-17-01003](#).)

OIG found that [1,178 children were separated from a parent or legal guardian and referred to ORR's care between June 27, 2018, and November 15, 2020](#). Seventy percent of separated children referred to ORR care had been separated by immigration officials because of a parent's criminal history. Additionally, separated children spent longer in ORR's care and were less likely than non-separated children to be released to a sponsor. Of the 1,178 separated children referred to ORR during this time period, 182 children (15 percent) were reunified with the parent from whom the child was separated. (See report [OEI-BL-20-00680](#).)

OIG found that [the District of Columbia's monitoring did not ensure compliance with criminal background check requirements for 7 of 30 sampled child care providers](#). Errors occurred in the background check process because: (1) providers did not send the in-State child abuse and neglect check results to the District, (2) District law did not allow Child Protection Register check results to be sent directly to the District unless the individual was found not to be suitable for employment, and (3) processing delays resulted in incomplete Federal Bureau of Investigation (FBI) fingerprint checks and inter-State checks. In response to our report, the District completed background checks for 52 of the 55 individuals, from the 7 sampled providers who did not complete background checks. (See report [A-03-20-00252](#).)

OIG found that [Louisiana's monitoring did not ensure compliance with criminal background check requirements for 8 of 30 sampled child care providers](#). Providers did not initiate a timely background check request for 15 of the 264 individuals requiring background checks at the 8 providers that did not complete background checks. Because the State agency relies on child care providers to initiate the background check process, it was unaware that these individuals lacked required background checks, potentially endangering the safety and well-being of children at these facilities. (See report [A-06-19-02001](#).)

Preventing and Treating Opioid Misuse

OIG continued to prioritize oversight and enforcement activities to protect beneficiaries from prescription drug abuse and improve access to medication-assisted treatment.

Significant OIG work completed during this semiannual reporting period related to preventing and treating opioid misuse includes the following:

[OIG found that of the roughly 1 million Medicare beneficiaries diagnosed with opioid use disorder in 2020, less than 16 percent received medication to treat their opioid use disorder](#). Further raising concerns that beneficiaries face challenges accessing treatment, less than half of beneficiaries who

received medication to treat opioid use disorder also received behavioral therapy. We also found that beneficiaries in Florida, Texas, Nevada, and Kansas were less likely to receive medication to treat their opioid use disorder than beneficiaries nationwide; that Asian/Pacific Islander, Hispanic, and Black beneficiaries were less likely to receive medication than White beneficiaries; and that older beneficiaries and those who did not receive the Part D low-income subsidy were also less likely to receive medication to treat their opioid use disorder. (See report [OEI-02-20-00390](#).)

[OIG found that the Substance Abuse and Mental Health Services Administration’s \(SAMHSA’s\) oversight generally ensured that the commission on accreditation of rehabilitation facilities \(CARFs\) verified that opioid treatment programs \(OTPs\) met Federal opioid treatment standards.](#)

SAMHSA’s oversight activities included: (1) reviewing CARF’s renewal application, (2) inspecting a selected sample of OTPs that CARF accredited and surveyed, and (3) reviewing accreditation reports submitted by CARF. SAMHSA also ensured that CARF’s renewal application included a review of CARF’s policies and procedures for hiring surveyors with required education and experience, training provided to surveyors, selecting surveyors for each survey, and avoiding conflicts of interest. (See report [A-09-20-01002](#).)

[A former doctor was sentenced to 20 years in prison for unlawful drug distribution and maintaining a drug-involved premises.](#) Patrick Titus unlawfully distributed or dispensed a variety of powerful opioids—including fentanyl, morphine, methadone, OxyContin, and oxycodone—outside the usual scope of professional practice and for illegitimate medical purposes.

[A former doctor was sentenced to 24 months in Federal prison as a result of conspiring to violate the Federal anti-kickback statute.](#) Jeffrey Kesten conspired to take approximately \$344,000 in bribes and kickbacks from a pharmaceutical company in exchange for prescribing a powerful fentanyl spray to his chronic pain patients.

Reducing Costs to Beneficiaries for Part D Drugs

OIG performs work to assess areas where beneficiaries may be paying more for Part D vital drugs than necessary.

Significant OIG work completed during this semiannual reporting period related to Part D drug pricing includes the following:

[OIG found that biosimilars have the potential to significantly reduce costs for Medicare Part D and beneficiaries.](#) Biosimilars are lower cost, highly similar alternatives to existing biologic drugs approved by the Food and Drug Administration (FDA). In 2019, Part D spending on biologics with available biosimilars could have decreased by \$84 million, or 18 percent, if all biosimilars had been used as frequently as the most-used biosimilars. Additionally, beneficiaries’ out-of-pocket costs for these drugs could have decreased by \$1.8 million, or 12 percent. As currently designed, Part D formularies could limit wider utilization of and access to these biosimilar drugs for beneficiaries. (See report [OEI-05-20-00480](#).)

Promoting Good Financial Stewardship of Traditional Medicare

OIG continues to devote resources to promote good financial stewardship, reduce improper payments, and protect the integrity of the Medicare program. In the 2021 Medicare Trustees report, actuaries projected that assets in the Part A trust fund will be depleted by 2026, adding urgency to ensuring that funds are conserved and used appropriately to ensure that the Medicare program continues to operate.

Significant OIG work completed during this semiannual reporting period related to Medicare oversight includes the following:

OIG found that more than 40 percent of the health care providers did not comply with Medicare requirements when they billed for neurostimulator implantation surgeries. We estimated that during 2016 and 2017, providers received \$636 million in unallowable Medicare payments associated with neurostimulator implantation surgeries, and beneficiaries paid \$54 million in related unnecessary copays and deductibles. These unallowable payments occurred because providers did not include sufficient documentation in the medical records to support that Medicare coverage requirements were met. (See report [A-01-18-00500](#).)

OIG found that Medicare could have saved approximately \$993 million in 2017 and 2018 if CMS had expanded its inpatient rehabilitation facility (IRF) transfer payment policy to apply to early discharges to home health care. We determined that this payment policy would generally result in payments to IRFs that would cover their costs to provide care. When CMS announced its proposed IRF transfer payment policy in 2001, it stated that it would analyze claim data to compare billing patterns prior to and after its implementation and refine IRF payments in the future, if warranted. (See report [A-01-20-00501](#).)

OIG found that Medicare and beneficiaries pay more for preadmission services at affiliated hospitals than at wholly owned settings. Because the diagnosis-related group (DRG) window policy does not cover affiliated hospitals, Medicare and beneficiaries paid \$168 million and \$77 million, respectively, in 2019 for admission-related outpatient services that—if provided at wholly owned hospitals—would not have required separate outpatient payments. These findings indicate that Medicare and beneficiaries may be overpaying for these services. (See report [OEI-05-19-00380](#).)

OIG identified trends that indicate Medicare could be paying twice for items and services provided to beneficiaries in hospice care. Nonhospice payments for Medicare Part A services and Part B items and services totaled \$6.6 billion from 2010 through 2019 for beneficiaries in hospice care. Hospice beneficiaries should receive all of their medical care needs through the Medicare hospice benefit. If providers bill Medicare for nonhospice items and services that potentially should be covered by hospices, Medicare could pay for the same items or services twice. (See report [A-09-20-03015](#).)

Fighting Medicare Fraud

OIG recognizes the importance of not only identifying and mitigating fraud risks in the Medicare program, but also holding accountable those who defraud Medicare, beneficiaries, and taxpayers. OIG's Office of Investigations conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries.

Significant OIG work completed during this semiannual reporting period related to Medicare enforcement includes the following:

[The former owner of a home health firm was extradited from the Republic of Cameroon to the United States after absconding to avoid an 80-year prison sentence.](#) Between 2006 and 2015, Ebong Aloysius Tilong, a top 10 most wanted fugitive; his wife, Marie Neba; and their co-conspirators used their company, Fiango Home Healthcare Inc., to corruptly obtain more than \$13 million by submitting false and fraudulent claims to Medicare for home health care services that Fiango's patients did not need or receive.

[A home health care worker was sentenced to 56 months in prison and ordered to pay \\$6.3 million in restitution for her participation in a conspiracy to commit health care and wire fraud.](#) Angelita Newton falsified patient visit records that were used to support claims billed to Medicare. Between 2011 and 2017, Care Specialists, a home health care company fraudulently billed Medicare at least \$6.3 million. At trial, the Government demonstrated that approximately 90 percent of Care Specialists' patients were not homebound and did not qualify for the types of care that Care Specialists had billed to Medicare. Further, many patients received cash bribes to receive home health "visits," some of which were performed in the visiting nurse's car.

[Co-owners of a durable medical equipment \(DME\) company were sentenced to 151 months in prison and were ordered to pay more than \\$27 million in restitution for a Medicare kickback conspiracy.](#) Leah and Michael Hagen owned and operated two DME companies. From March 2016 to January 2019, the defendants paid kickbacks and bribes to their co-conspirator's call center in the Philippines in exchange for signed doctors' orders for DME that were used to submit false claims in excess of \$59 million to Medicare. As a result of those false claims, Medicare paid the defendants more than \$27 million.

[A medical device company agreed to pay \\$16 million to resolve allegations that it violated the False Claims Act by paying kickbacks that caused the submission of false claims to the Medicare program.](#) The settlement resolves allegations that Arthrex agreed to provide remuneration to an orthopedic surgeon in the form of royalty payments purportedly for the surgeon's contributions to Arthrex's products when the remuneration was in fact intended to induce the surgeon's use and recommendation of Arthrex's products. In connection with the settlement, Arthrex entered into a 5-year CIA with HHS-OIG.

Telemarketing executives were sentenced for their roles in a conspiracy to defraud Federal health benefit programs, including Medicare and the Civilian Health and Medical Program of the Department of Veterans Affairs. Michael Nolan was sentenced to 78 months in Federal prison and Richard Epstein was sentenced to 63 months in Federal prison as a result of their scheme as executives of REMN Management that targeted the elderly to generate thousands of medically unnecessary physicians' orders for DME and cancer genetic testing (CGx). Epstein and Nolan also created and operated a telemedicine company through which they illegally bribed physicians to sign the orders regardless of medical necessity.

A laboratory owner was sentenced to 82 months in Federal prison and ordered to pay more than \$61 million in restitution for his role in a \$73 million conspiracy to defraud Medicare. Leonel Palatnik's scheme exploited growing acceptance and use of telehealth during the COVID-19 pandemic. Palatnik admitted that, as a co-owner of Panda Conservation Group, he conspired with other co-owners and with Michael Stein to pay kickbacks to Stein in exchange for his work arranging for telemedicine providers to authorize genetic testing orders for Panda's laboratories.

Promoting Integrity and Effectiveness in Medicare Advantage

In Medicare, more than 40 percent of beneficiaries are currently enrolled in Medicare Advantage Organizations (MAOs).

Significant OIG work completed during this semiannual reporting period related to managed care includes the following:

OIG found that most of the selected diagnosis codes that UPMC Health Plan, Inc. (UPMC) submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. CMS relies on Medicare Advantage (MA) organizations to collect diagnosis codes from their providers and submit these codes to CMS. Inaccurate diagnosis code submissions that portray an MAO's patient population as higher risk result in overpayments to MAOs. These errors occurred because the policies and procedures that UPMC had to ensure compliance with CMS's program requirements, as mandated by Federal regulations, were not always effective. (See report [A-07-19-01188](#).)

OIG found that SCAN Health Plan (SCAN) did not submit some diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. We estimated that SCAN received at least \$54.3 million in net overpayments for 2015. As demonstrated by the errors found in our sample, SCAN's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. (See report [A-07-17-01169](#).)

Ensuring Medicaid Program Integrity

Medicaid is the largest Federal health care program, with nearly 78 million individuals enrolled, and represents more than one-sixth of the national health economy. Medicaid is administered by States in

accordance with Federal requirements. The program is funded jointly by the Federal Government and States. CMS estimated Federal and State Medicaid expenditures of \$671.2 billion in 2020.

Significant OIG work completed during this semiannual reporting period related to Medicaid program integrity includes the following:

OIG found that Tennessee did not comply with Federal requirements for claiming certified public expenditures (CPEs) for public hospital unreimbursed costs. Of the \$2 billion in expenditures that Tennessee claimed during our audit period, \$909.4 million was allowable and supported. However, the remaining \$1.1 billion (\$767.5 million Federal share) exceeded the amount allowed. This amount included \$482.1 million (\$337.5 million Federal share) of excess CPEs that Tennessee claimed but did not return after calculating actual CPEs. (See report [A-04-19-04070](#).)

Counselor sentenced to Federal prison for wide-ranging Medicaid fraud scheme. In a case investigated by OIG, Courtney Dunlap was sentenced to 57 months of imprisonment, followed by 3 years of supervised release, for operating a wide-ranging scheme that defrauded the Connecticut Medicaid Program of more than \$1.3 million. Dunlap submitted claims for psychotherapy services that were purportedly provided to Medicaid clients. The vast majority of the claims were for occasions and dates of service when no psychotherapy services of any kind had been provided to the Medicaid clients identified in the claims.

Promoting Proper Departmental Management and Operations

OIG reviews programs across the breadth of the department to ensure that programs are being administered correctly, efficiently, and without waste.

Significant OIG work completed during this semiannual reporting period related to proper departmental management includes the following:

OIG found that FDA did not always identify contracts eligible for closeout and did not always follow Federal Acquisition Regulations (FAR) requirements for closing contracts timely but otherwise generally closed contracts in accordance with acquisition policies and procedures. FDA did not always identify and close contracts timely because FDA utilized manual processes for some contract closeout review functions when an automated process may have been more efficient. Because contracts were not always closed timely, FDA may not have identified unused funds that could be deobligated and released to another appropriate need. (See report [A-03-20-03004](#).)

OIG found that the National Cancer Institute's (NCI's) post-award process for providing oversight and monitoring of grants was generally effective in ensuring that grantees met the program objectives and that NCI was able to identify potential problems. However, for 12 of the 20 grants in our sample that were closed in FY 2019, the grantee did not submit final reports within 120 days of the end of the period of performance as required. If grantees submit final reports late, it could

indicate an issue with the grantee’s ability to comply with grant requirements, including accounting for grant funds and tracking the progress and outcomes of the grant. (See report [A-03-20-03001](#).)

OIG found that the Office of Intergovernmental and External Affairs’ (IEA’s) travel card program did not always comply with Federal requirements. These deficiencies occurred because IEA had a high staff turnover rate, and IEA’s internal controls were not adequate to ensure that staff, approving officials, and travel card program coordinators understood and executed their responsibilities. (See report [A-03-19-00501](#).)

Protecting Cybersecurity

OIG continues to recognize cybervulnerabilities as major risks to effectively managing and safeguarding the Department’s programs and is prioritizing oversight of the Department’s cybersecurity. Repeated cyberintrusions focused on accessing critical information found in HHS systems has added urgency to developing departmental cybersafeguards over the course of the COVID-19 pandemic in addition to normal operations.

During this reporting period, OIG continued to conduct work looking at HHS’s cybersecurity controls to strengthen HHS’s cybersecurity posture.

Selected Acronyms and Abbreviations

ACA	Patient Protection and Affordable Care Act
ACF	Administration for Children and Families
ACL	Administration for Community Living
CDC	Centers for Disease Control and Prevention
CIA	corporate integrity agreement
CMP	civil monetary penalty
CMS	Centers for Medicare & Medicaid Services
DOJ	Department of Justice
DME	durable medical equipment
EMTALA	Emergency Medical Treatment and Labor Act
FDA	Food and Drug Administration
GAO	Government Accountability Office
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
MCO	managed care organization
MFCU	Medicaid Fraud Control Unit
NIH	National Institutes of Health
OAS	Office of Audit Services
OASH	Office of Safety and Health
OCIG	Office of Counsel to the Inspector General
OEI	Office of Evaluation and Inspections
OI	Office of Investigations
OIG	Office of Inspector General
OMB	Office of Management and Budget
OS	Office of the Secretary
SAMHSA	Substance Abuse and Mental Health Services Administration

Medicare and Medicaid Reports and Reviews

Medicare Program Reports and Reviews

Financial Management and Improper Payments

Medicare Overpaid \$636 Million for Neurostimulator Implantation Surgeries ([A-01-18-00500](#)), October 2021

More than 40 percent of the health care providers covered by our audit did not comply with Medicare requirements when they billed for neurostimulator implantation surgeries. On the basis of our sample results, we estimated that during calendar years (CYs) 2016 and 2017, providers received \$636 million in unallowable Medicare payments associated with neurostimulator implantation surgeries, and that beneficiaries paid \$54 million in related unnecessary copays and deductibles. These unallowable payments occurred because providers did not include sufficient documentation in the medical records to support that Medicare coverage requirements were met.

CMS concurred with our recommendations that it instruct the Medicare contractors to: (1) recover the portion of the identified Medicare potential overpayments for the 54 incorrectly billed claims that are within the 4-year reopening period; (2) instruct the providers identified with the incorrectly billed claims to refund coinsurance amounts that have been collected from the sampled beneficiaries for claims within the 4-year reopening period; (3) determine which of the remaining claims in our sampling frame were incorrectly billed, recover Medicare overpayments that are within the reopening period, and instruct the providers to refund beneficiary coinsurance amounts; and (4) notify the providers with potential overpayments, so they can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule. We also recommended that CMS: (1) conduct provider outreach and education regarding the Medicare coverage requirements for neurostimulator implantation surgeries and (2) require prior authorization for neurostimulator implantation surgeries for Parkinson's disease and seizure disorders.

Medicare Advantage Diagnosis Codes

To determine the health status of enrollees, CMS relies on MA organizations to collect diagnosis codes from their providers and submit these codes to CMS. Some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS. During this reporting period, OIG conducted four audits that were designed to assess whether selected diagnosis codes that MA organizations submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements. Complete recommendations and providers' responses can be found in the final reports, which are summarized below.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS (A-07-17-01173), October 2021

With respect to the six high-risk groups covered by our audit, most of the selected diagnosis codes that Coventry Health Care of Missouri, Inc. (Coventry), submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. These errors occurred because the policies and procedures that Coventry had to detect and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, were not always effective. As a result, Coventry received \$548,852 of net overpayments for 2014 through 2016.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS (A-07-19-01188), November 2021

With respect to the 10 high-risk groups covered by our audit, most of the selected diagnosis codes that UPMC submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. These errors occurred because the policies and procedures that UPMC had to ensure compliance with CMS's program requirements, as mandated by Federal regulations, were not always effective. On the basis of our sample results, we estimated that UPMC received at least \$6.4 million of net overpayments for these high-risk diagnosis codes for 2015 and 2016.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS (A-02-18-01029), January 2022

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that Healthfirst Health Plan, Inc. (Healthfirst), submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. These errors occurred because the policies and procedures that Healthfirst had to detect and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, were not always effective. On the basis of our sample results, we estimated that Healthfirst received at least \$5.2 million in net overpayments for these high-risk diagnosis codes in 2015 and 2016.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Tufts Health Plan (Contract H2256) Submitted to CMS (A-01-19-00500), February 2022

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that Tufts Health Plan (Tufts) submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. These errors occurred because the policies and procedures that Tufts had to ensure compliance with CMS's program requirements, as mandated by Federal regulations, could be improved. On the basis of our sample results, we estimated that Tufts received at least \$3.7 million of net overpayments for these high-risk diagnosis codes in 2015 and 2016.

Medicare Improperly Paid Suppliers an Estimated \$117 Million Over 4 Years for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Provided to Hospice Beneficiaries (A-09-20-03026), November 2021

For 121 of 200 sampled durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items, Medicare improperly paid suppliers for DMEPOS items they provided to hospice beneficiaries. These items should have been provided directly by the hospices or under arrangements between the hospices and the suppliers.

The improper payments occurred because: (1) the majority of the suppliers were unaware that they had provided DMEPOS items to hospice beneficiaries, (2) the system edit processes that should have prevented the improper payments were not effective or did not exist, and (3) the suppliers inappropriately used the GW modifier—which indicates that the service is unrelated to the patient’s terminal diagnosis. On the basis of our sample results, we estimated that Medicare could have saved \$116.9 million in payments during our audit period, and beneficiaries could have saved \$29.8 million in deductibles and coinsurance that may have been incorrectly collected from them or from someone on their behalf.

CMS concurred with our recommendations that it improve the prepayment edit process by instructing the DME Medicare contractors to deny DMEPOS claims submitted by suppliers without the GW modifier for DMEPOS items provided to hospice beneficiaries; and direct the DME and hospice Medicare contractors, or other contractors as appropriate, to conduct prepayment or postpayment reviews of supplier claims billed with the GW modifier. CMS did not concur with our recommendations that it implement a postpayment edit process and study the feasibility of including palliative items and services not related to a beneficiary’s terminal illness and related conditions within the hospice per diem.

Medicare and Beneficiaries Pay More for Preadmission Services at Affiliated Hospitals Than at Wholly Owned Settings (OEI-05-19-00380), December 2021

Because the DRG window policy does not cover affiliated hospitals, Medicare and beneficiaries paid \$168 million and \$77 million, respectively, in 2019 for admission-related outpatient services that—if provided at wholly owned hospitals—would not have required separate outpatient payments. (The policy states that if a beneficiary is furnished outpatient hospital services and is admitted to the hospital shortly afterward for the same condition, the outpatient services are considered part of the admission and are included in the pre-set inpatient payment amount, rather than resulting in separate payments for the outpatient services). These findings indicate that Medicare and beneficiaries may be overpaying for these services, as affiliated settings are similar to wholly owned settings in key ways. CMS neither concurred nor nonconcurred with our recommendation, which was for it to evaluate the potential impacts of updating the DRG window policy to include affiliated hospitals, and seek the necessary legislative authority to update the policy as appropriate.

COVID-19 Tests Drove an Increase in Total Medicare Part B Spending on Lab Tests in 2020, While Use of Non-COVID-19 Tests Decreased Significantly (OEI-09-21-00240), December 2021

Medicare Part B spent \$1.5 billion on COVID-19 tests in 2020, while at the same time, spending on non COVID-19 tests declined by \$1.2 billion. The result was a net spending increase of 4 percent, but the decrease in utilization of non-COVID-19 tests raises questions about the potential impact on beneficiary health. Our data brief contained no recommendations.

Medicare Could Have Saved Approximately \$993 Million in 2017 and 2018 if It Had Implemented an Inpatient Rehabilitation Facility Transfer Payment Policy for Early Discharges to Home Health Agencies (A-01-20-00501), December 2021

Medicare could have saved approximately \$993 million in CYs 2017 and 2018 if CMS had expanded its IRF transfer payment policy to apply to early discharges to home health care. We determined that this payment policy would generally result in payments to IRFs that would cover their costs to provide care. When CMS announced its proposed IRF transfer payment policy in 2001, it stated that it would analyze claim data to compare billing patterns prior to and after its implementation and refine IRF payments in the future, if warranted. For this audit, CMS officials did not explain why CMS has not expanded the IRF transfer payment policy to cover discharges to home health care. CMS also did not analyze claim data to compare billing patterns prior to and after the implementation of the prospective payment system for IRFs in January 2002, which could have provided information in support of expanding the IRF transfer payment policy to include early discharges to home health care.

CMS stated that it would consider our recommendation that it take the necessary steps to establish an IRF transfer payment policy for early discharges to home health care. If this expanded policy had been in place, Medicare could have saved \$993,134,059 in 2017 and 2018.

Medicare Hospital Provider Compliance Audit: St. Joseph's Hospital Health Center (A-02-20-01004), December 2021

St. Joseph's Hospital Health Center (the Hospital) complied with Medicare billing requirements for 94 of the 100 inpatient and outpatient claims we audited. However, the Hospital did not fully comply with Medicare billing requirements for the remaining six claims, resulting in overpayments of \$68,897 for the audit period. Specifically, five inpatient claims and one outpatient claim had billing errors.

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$389,000 for the audit period. As of the publication of this report, this amount included claims outside of the Medicare 4-year claim-reopening period.

We recommend that the Hospital: (1) refund to the Medicare contractor \$389,000 in estimated overpayments for the audit period for the claims that it incorrectly billed that are within the 4-year

claim reopening period; (2) based on the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation; and (3) strengthen controls to ensure full compliance with Medicare requirements. The Hospital partially disagreed with our first recommendation, stated that it complied with our second recommendation, and contended that it did not need to implement our third recommendation.

Medicare Advantage Compliance Audit of Diagnosis Codes That SCAN Health Plan (Contract H5425) Submitted to CMS (A-07-17-01169), February 2022

SCAN did not submit some diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. First, although most of the diagnosis codes that SCAN submitted were supported in the medical records and therefore validated 1,413 of the 1,577 sampled enrollees' hierarchical condition categories (HCCs), the remaining 164 HCCs were not validated and resulted in overpayments. These 164 unvalidated HCCs included 20 HCCs for which we identified 20 other HCCs for more and less severe manifestations of the diseases. Second, there were an additional 21 HCCs for which the medical records supported diagnosis codes that SCAN should have submitted to CMS but did not.

Thus, the risk scores for the 200 sampled enrollees should not have been based on the 1,577 HCCs. Rather, the risk scores should have been based on 1,454 HCCs (1,413 validated HCCs plus 20 other HCCs plus 21 additional HCCs). As a result, we estimated that SCAN received at least \$54.3 million in net overpayments for 2015. As demonstrated by the errors found in our sample, SCAN's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved.

SCAN disagreed with our recommendations that it refund to the Federal Government the \$54.3 million of net overpayments and continue to improve its policies and procedures to prevent, detect, and correct noncompliance with Federal requirements for diagnosis codes that are used to calculate risk-adjusted payments.

Medicare Payments of \$6.6 Billion to Nonhospice Providers Over 10 Years for Items and Services Provided to Hospice Beneficiaries Suggest the Need for Increased Oversight (A-09-20-03015), February 2022

Our analysis of trends and patterns in payments for items and services provided to Medicare beneficiaries outside the Medicare hospice benefit during a hospice period of care (which we refer to as "nonhospice payments") demonstrate an increase in Medicare nonhospice payments for beneficiaries. Nonhospice payments for Medicare Part A services and Part B items and services totaled \$6.6 billion from 2010 through 2019. If providers bill Medicare for nonhospice items and services that potentially should be covered by hospices, Medicare could pay for the same items or services twice.

Psychotherapy Services Billed by a New York City Provider Did Not Comply With Medicare Requirements (A-02-21-01006), March 2022

A New York City provider did not comply with Medicare requirements when billing for psychotherapy services for all 100 sampled beneficiary-days. Specifically, beneficiaries' treatment plans associated with these services were not provided or did not contain required elements (e.g., frequency or duration of services). This heightens the risk that treatments were inappropriate or unnecessary and could have a significant effect on the beneficiaries' quality of care received. We also found that services billed to Medicare did not meet incident-to requirements or were conducted by a therapist who was not licensed or registered in New York State. Also, time spent on psychotherapy services was not documented, and treatment notes were not maintained to support the services billed. In addition, for psychotherapy services provided during 96 sampled beneficiary-days, there was no evidence that beneficiaries' treatment plans were signed by the treating physician.

The provider disagreed with our recommendation that it refund to the Medicare program the estimated \$1.1 million overpayment and partly agreed with our recommendation to exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation. The provider agreed with our recommendation that it develop policies and procedures and provide training to its therapists to ensure that psychotherapy services comply with Medicare requirements.

Medicare Improperly Paid Physicians for Spinal Facet-Joint Denervation Sessions (A-09-21-03002), December 2021

Medicare did not pay physicians for selected facet-joint denervation sessions in accordance with Medicare requirements. Specifically, for our audit period, the Medicare Administrative Contractors (MACs) for the 11 jurisdictions with a coverage limitation of 2 facet-joint denervation sessions per beneficiary for each covered spinal region during a 12-month period made improper payments of \$7.2 million. In addition, the MACs for the 9 jurisdictions with a coverage limitation of 4 facet joints per denervation session and the MACs for the remaining 3 jurisdictions with a coverage limitation of 10 facet joints per denervation session made improper payments of \$2.3 million. In total, Medicare improperly paid physicians \$9.5 million. These improper payments occurred because CMS's oversight was not adequate to prevent or detect improper payments for selected facet-joint denervation sessions.

CMS concurred with our recommendations that it: (1) direct the MACs to recover \$9.5 million in improper payments made to physicians for selected facet-joint denervation sessions; (2) instruct the MACs to, based upon the results of this audit, notify appropriate physicians (i.e., those for whom CMS determines this audit constitutes credible information of potential overpayments) so

that the physicians can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation; (3) assess the effectiveness of oversight mechanisms specific to preventing or detecting improper payments to physicians for facet-joint denervation sessions, and modify the oversight mechanisms based on that assessment; and (4) direct the MACs to review claims for denervation sessions after our audit period to recover any improper payments.

Quality of Care, Safety, and Access

Most Medicare Beneficiaries Received Telehealth Services Only From Providers With Whom They Had an Established Relationship ([OEI-02-20-00521](#)), October 2021

From March 2020 to the end of 2020, most beneficiaries received telehealth services from providers with whom they had an established relationship. These beneficiaries tended to see their providers in person about 4 months prior to their first telehealth service, on average. Beneficiaries enrolled in traditional Medicare were more likely to receive services from providers with whom they had an established relationship, compared to beneficiaries in Medicare Advantage. This data snapshot provides information to policymakers and other stakeholders about the relationship between beneficiaries and providers of telehealth services. These data are critical to informing decisions about how to structure telehealth services in Medicare on a more permanent basis.

Many Medicare Beneficiaries Are Not Receiving Medication to Treat Their Opioid Use Disorder ([OEI-02-20-00390](#)), December 2021

About 1 million Medicare beneficiaries were diagnosed with opioid use disorder in 2020, yet less than 16 percent of these beneficiaries received medication to treat their opioid use disorder and even fewer received both medication and behavioral therapy. These findings show a need to increase the number of Medicare beneficiaries receiving treatment for opioid use disorder.

CMS concurred with the following recommendations: (1) conduct additional outreach to beneficiaries to increase awareness about Medicare coverage for the treatment of opioid use disorder, (2) take steps to increase the number of providers and opioid treatment programs for Medicare beneficiaries with opioid use disorder, (3) create an action plan and take steps to address disparities in the treatment of opioid use disorder, and (4) collect data on the use of telehealth in opioid treatment programs.

CMS did not explicitly indicate whether it concurred or nonconcurred with two recommendations: (1) assist SAMHSA by providing data about the number of Medicare beneficiaries receiving buprenorphine in office-based settings and the geographic areas where Medicare beneficiaries remain underserved and (2) take steps to increase the utilization of behavioral therapy among beneficiaries receiving medication to treat opioid use disorder.

Program Integrity

[Trends in Genetic Tests Provided Under Medicare Part B Indicate Areas of Possible Concern \(A-09-20-03027\)](#), December 2021

Our analysis of nationwide trends in genetic testing under Medicare Part B showed that payments for genetic tests, the number of genetic tests performed, the number of laboratories that received more than \$1 million for performing genetic tests, and the number of providers ordering genetic tests for beneficiaries all increased during our audit period (CYs 2016 through 2019). Although there are legitimate reasons that genetic testing has increased, these increases indicate areas of possible concern, such as excessive genetic testing and fraud, which may negatively affect beneficiaries. In addition, Medicare requirements and guidance related to coverage of genetic testing have been limited and have varied among MAC jurisdictions. Oversight by CMS and the MACs is critical to prevent fraud, waste, and abuse related to genetic testing and to protect Medicare beneficiaries. The information in this data brief may help CMS and other stakeholders to identify changes in the Medicare program, such as increased oversight, that could prevent fraud, waste, and abuse and protect Medicare beneficiaries. This report contains no recommendations.

[Hospitals Did Not Always Meet Differing Medicare Contractor Specifications for Bariatric Surgery \(A-09-20-03007\)](#), February 2022

Not all hospitals' inpatient claims for bariatric surgeries met Medicare national requirements or Medicare contractors' eligibility specifications. Differing eligibility specifications for bariatric surgery contributed to differences in the number of claims that did not meet the specifications among Medicare contractor jurisdiction groups. Jurisdiction groups with more restrictive specifications had more claims that did not meet the eligibility specifications and more specifications that were not met. The Medicare contractors may have issued differing eligibility specifications because CMS's national coverage determination (NCD) requirements were not specific. On the basis of our sample results, we estimated that Medicare could have saved \$47.8 million during our audit period if Medicare contractors had disallowed claims that did not meet Medicare national requirements or Medicare contractor specifications for bariatric surgery.

CMS did not concur with our recommendations that it: (1) determine whether any eligibility specifications in the Medicare contractors' local coverage determinations (LCDs) and local coverage articles (LCAs) should be added to the NCD for bariatric surgery and, if so, take the necessary steps to update the NCD; (2) work with the Medicare contractors to review the eligibility specifications in the applicable Medicare contractors' bariatric surgery LCDs and LCAs and determine which, if any, of those additional specifications should be requirements rather than guidance; and (3) educate hospitals on the NCD requirements for bariatric surgeries if the NCD has been updated in response to our first recommendation.

Drug Pricing and Reimbursement

CMS Should Strengthen Its Prescription Drug Event Guidance To Clarify Reporting of Sponsor Margin for Medicare Part D Bids (A-03-17-00001), November 2021

A Part D sponsor (Sponsor) complied with CMS's prescription drug event (PDE) reporting requirements. However, we also found that CMS's PDE reporting guidance does not adequately address a sponsor service delivery model in which a sponsor owns the pharmacy it uses and does not have a negotiated contract with the pharmacy. CMS clarified that it does not consider pharmacy margin to be sponsor margin, and CMS's current guidance allows pharmacy margin but not sponsor margin to be included in the PDE record. Any sponsor margin included in the PDE record cannot be identified and separated from pharmacy costs. In sponsors' Part D bid submissions, sponsor margin is reported separately from ingredient costs. Any sponsor margin included in PDE records may not be evaluated during the bid review.

Because of the lack of clarity about margin in the PDE records for sponsors with an integrated service delivery model, the inclusion of margin in ingredient costs prevents CMS from being able to readily identify and evaluate all margin that accrues to such sponsors in future years' Part D bids. Therefore, CMS cannot readily determine whether the amounts included in those Part D bids are reasonable.

CMS did not concur with our recommendation that it update its PDE guidance to address margin under sponsor delivery models in which a sponsor owns a pharmacy. We did not make any recommendations to the Sponsor because it followed PDE guidance for the period we audited.

Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Second Quarter of 2021 (OEI-03-22-00060), November 2021; and Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Third Quarter of 2021 (OEI-03-22-00190), February 2022

OIG identified seven drug codes in the second quarter of 2021 and eight drug codes in the third quarter of 2021 that met CMS's criteria for price substitution. OIG compares average sales prices (ASPs) to average manufacturer prices (AMPs) every quarter and identifies Part B-covered drug codes eligible for price substitutions. If OIG finds that the ASP for a drug exceeds the AMP by a certain percentage—currently, 5 percent—the ASP-based payment amount is substituted with a lower calculated rate. This difference, between the ASP and AMP prices, serves as a mechanism for monitoring market prices and limiting potentially excessive payment amounts. OIG provides these drug codes to CMS for its review. CMS reviews this information and determines whether to implement price substitutions that would limit excessive payments for Part B drugs.

Medicare Part D and Beneficiaries Would Realize Significant Spending Reductions With Increased Biosimilar Use (OEI-05-20-00480), March 2022

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

Medicaid Program Reports and Reviews

Financial Management and Improper Payments

Tennessee Medicaid Claimed Hundreds of Millions of Federal Funds for Certified Public Expenditures That Were Not in Compliance With Federal Requirements (A-04-19-04070), October 2021

Tennessee did not comply with Federal requirements for claiming certified public expenditures (CPEs) for public hospital unreimbursed costs. Of the \$2 billion in CPEs that Tennessee claimed during our audit period, \$909.4 million was allowable and supported. However, the remaining \$1.1 billion (\$767.5 million Federal share) exceeded the amount allowed. This amount included \$482.1 million (\$337.5 million Federal share) of excess CPEs that Tennessee claimed but did not return after calculating actual CPEs.

In addition, the actual CPEs that Tennessee calculated included another \$609.4 million (\$430 million Federal share) that exceeded the allowable amount. It was composed of \$522.3 million (\$370.1 million Federal share) of unsupported net costs of caring for institutions for mental diseases (IMDs) uninsured patients, \$53.6 million (\$37.9 million Federal share) of unallowable net costs of caring for TennCare IMD patients between ages 21 and 64, and \$33.5 million (\$22 million Federal share) of overstated costs because of incorrect calculations.

Tennessee generally disagreed with our recommendations that it: (1) refund \$397.4 million in overpayments to the Federal Government for CPEs that it claimed in excess of the allowable amount, (2) provide support for or refund to the Federal Government \$370.1 million for the net costs of caring for uninsured IMD patients for which it did not provide detailed supporting documentation, and (3) establish additional policies and procedures to ensure compliance with Federal requirements.

Kentucky Made Almost \$2 Million in Unallowable Capitation Payments for Beneficiaries With Multiple Medicaid ID Numbers (A-04-20-07094), December 2021

Kentucky made unallowable capitation payments on behalf of beneficiaries with multiple Medicaid ID numbers. Of the 100 beneficiary matches in our sample, Kentucky correctly made capitation payments on behalf of 3. However, it incorrectly made capitation payments that totaled \$455,296 (\$323,126 Federal share) on behalf of the remaining 97.

The unallowable capitation payments occurred because the beneficiaries had multiple Medicaid ID numbers. According to Kentucky, the beneficiaries had multiple ID numbers because either the beneficiaries or the caseworkers entered demographic data incorrectly during the application process.

On the basis of our sample results, we estimated that Kentucky made unallowable capitation payments totaling approximately \$2.7 million (\$1.9 million Federal share) on behalf of beneficiaries with multiple Medicaid ID numbers during our audit period.

We recommended that Kentucky: (1) refund to the Federal Government approximately \$1.9 million (Federal share) in unallowable payments, (2) review capitation payments that fell outside of our audit period and refund any unallowable payments, and (3) enhance or establish new controls to ensure that no beneficiary is issued multiple Medicaid ID numbers. Kentucky agreed with our findings but disagreed with refunding the extrapolated amount.

New Jersey's Medicaid School-Based Cost Settlement Process Could Result in Claims That Do Not Meet Federal Requirements (A-02-20-01012), March 2022

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

CMS concurred with our recommendation that it direct New Jersey to revise the Process Guide to ensure that New Jersey's methodology for claiming Medicaid school-based health care services

costs complies with Federal requirements. The detailed recommendations are listed in the body of the report.

New Mexico Did Not Claim \$12.4 Million of \$222.6 Million in Medicaid Payments for Services Provided by Indian Health Service Facilities in Accordance With Federal and State Requirements (A-06-19-09005), March 2022

New Mexico claimed \$209.4 million of \$222.6 million in Indian Health Service (IHS) expenditures in accordance with Federal and State requirements. However, New Mexico claimed \$12.4 million in IHS expenditures that did not meet Federal and State requirements. Specifically, New Mexico claimed: (1) \$6.2 million in unsupported expenditures under its older waivers, which New Mexico did not identify because it did not reconcile initial expenditures with IHS encounter data; (2) \$3.6 million in unsupported expenditures under its current waiver because its reconciliations did not account for encounter data adjustments; and (3) \$2.6 million in expenditures for encounter data that managed care organizations (MCOs) submitted beyond the 2-year limit outlined in the MCO contracts.

Additionally, New Mexico may have claimed \$750,811 for inpatient encounter data with dates-of-service spans that did not support the number of paid inpatient days.

New Mexico concurred with our recommendation that it use the entered date to determine whether the MCO submitted an encounter within the 2-year limit. New Mexico did not address our recommendations that it: (1) refund \$12.4 million to the Federal Government, (2) work with CMS to determine the appropriate amount of the additional \$750,811 that it should have claimed and refund the Federal share difference, and (3) establish policies and procedures to account for adjustments MCOs make to IHS encounter data after reconciliations are completed. We made additional recommendations in the audit report.

Quality of Care, Safety, and Access

More Than One-Third of Medicaid-Enrolled Children in Five States Did Not Receive Required Blood Lead Screening Tests (OEI-07-18-00371), October 2021

In 5 States, we found that more than 380,000 Medicaid-enrolled children did not receive a blood lead screening test at 12 months or 24 months of age, as required by Medicaid's schedule. Prevention is key to avoiding the permanent developmental effects of lead exposure in children. Scheduled blood lead screening tests can help support early detection of elevated lead levels, timely followup, and improved outcomes. CMS concurred with all of our recommendations, which were: (1) monitor national Early and Periodic Screening, Diagnostic, and Treatment program performance data for blood lead screening tests and target efforts toward low-performing States to develop action plans for increasing the provision of blood lead screening tests, according to Medicaid's schedule; (2) ensure consistency across CMS guidance related to actionable blood lead

reference values (i.e., the blood lead level at which public health actions should be initiated) and blood lead screening test definitions; and (3) coordinate with partners to develop and disseminate to State Medicaid agencies educational resources that reaffirm requirements and schedules for blood lead screening tests.

Changes Made to States' Medicaid Programs To Ensure Beneficiary Access to Prescriptions During the COVID-19 Pandemic (A-06-20-04007), October 2021

Most States from which we obtained information responded that, as a result of the pandemic, they had implemented changes to ease restrictions on prior authorizations and early refill requirements, made changes to their prescription quantity limits to allow pharmacies to dispense increased quantities of some prescription drugs, and removed the requirement of obtaining a signature upon receipt of a prescription.

In addition, most States from which we obtained information responded that they have implemented changes that give physicians greater flexibility to prescribe drugs to both new and established patients following telehealth episodes during the COVID-19 pandemic. All 24 States in our survey indicated that they are providing updated guidance to all stakeholders to ensure that beneficiaries can obtain their prescriptions.

We summarized the selected States' actions to share the information with CMS and States for their use. This report contains no recommendations.

Arkansas Did Not Fully Comply With Federal and State Requirements for Reporting and Monitoring Critical Incidents Involving Medicaid Beneficiaries With Developmental Disabilities (A-06-17-01003), December 2021

Arkansas did not fully comply with Federal Medicaid waiver and State requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities residing in community-based settings. These issues occurred because Arkansas did not have controls in place to ensure that incidents of abuse, neglect, or death were investigated and reported to the appropriate authority. Additionally, Arkansas did not ensure that all incidents involving Medicaid beneficiaries, including incidents of death, were reported because it did not have waiver requirements to report incidents that occurred outside of State custody or State facilities. Also, Arkansas did not have adequate internal controls in place to detect unreported incidents.

Arkansas generally concurred with our recommendations that it: (1) ensure that community-based providers report all suspected adult or child abuse and neglect to the appropriate adult or child abuse hotline; (2) follow waiver guidance for incidents that appear to be abuse that require review and followup; (3) follow waiver guidance to conduct reviews of the deaths of beneficiaries receiving waiver services; (4) consider amending critical incident reporting requirements, including those

related to incidents of death, to clearly apply to circumstances in which Arkansas employees or contractors are providing waiver services at a non-State facility, such as a private home, and a critical incident occurs; and (5) perform analytical procedures, such as data matches, on Medicaid claims data to identify potential critical incidents that have not been reported and investigate as needed.

New York Verified That Medicaid Assisted Living Program Providers Met Life Safety and Emergency Planning Requirements But Did Not Always Ensure That Assisted Living Program Services Met Federal and State Requirements (A-02-19-01017), March 2022

New York verified that life safety and emergency planning requirements were met at the five judgmentally selected assisted living program (ALP) providers we visited. However, it claimed reimbursement for some unallowable ALP services during our random sample of 100 beneficiary-months. Despite New York's efforts, some ALP providers did not comply with the requirements for: (1) documenting beneficiary assessments and care plans and (2) claiming reimbursement only for services in accordance with Medicaid billing requirements and beneficiary care plans.

On the basis of our sample results, we estimated that New York improperly claimed at least \$1.9 million in Federal Medicaid reimbursement for ALP services during our audit period. In addition, the health and safety of some Medicaid beneficiaries may have been put at risk because their assessments and care plans were not valid or were missing, and some nurse's aides' qualifications were not documented. As a result, beneficiaries may have: (1) not received ALP services that they were entitled to, (2) received services that were not needed, or (3) received services from some nurse's aides that were not qualified to perform the services furnished.

New York did not indicate concurrence or nonconcurrence with our recommendations that it refund \$1.9 million to the Federal Government and that it strengthen its oversight and monitoring of its ALP to ensure that providers comply with Federal and State requirements.

Program Integrity

Michigan Did Not Report Calendar Year 2019 Medicaid Third-Party Liability Cost Avoidance Data to the Centers for Medicare & Medicaid Services (A-05-20-00058), October 2021

CMS requires States to identify Medicaid beneficiaries' third-party health coverage and determine the third-party liability (TPL) for the services. Michigan did not report Medicaid TPL Medicare cost avoidance for all four quarters in CY 2019, totaling \$3.4 billion. Inaccurate amounts reported on the CMS-64 could impact CMS's monitoring and evaluation of the effectiveness of the State's TPL activity.

Michigan said the TPL Medicare cost avoidance was omitted in error because there was no process in place to ensure that the amounts were reported on the CMS-64. This error was corrected, and

the full amount was reported on the CMS-64 for the third quarter of Federal FY 2020. Michigan said it added steps for entering TPL cost avoidance as part of its quarterly preparation checklist that must be completed and reviewed prior to certifying the CMS-64 quarterly reports. This report contains no recommendations.

Missouri Properly Converted Provisionally Enrolled Medicaid Providers to Permanent Providers (A-07-21-03248), November 2021

Missouri correctly followed up with the provisionally enrolled Medicaid providers to ensure that all documentation was obtained in accordance with applicable provider screening and enrollment requirements, or that the Medicaid provider was terminated, after the regular enrollment practices resumed for all 100 sampled provisionally enrolled Medicaid providers. Missouri's provisional enrollment process involved tracking provisionally enrolled providers on a spreadsheet and terminating them if they did not provide the necessary documents required for a regular enrollment. Because we identified no errors in our sample review, we concluded that Missouri's controls over the provisional enrollment process were effective.

Prior Audits of Medicaid Eligibility Determinations in Four States Identified Millions of Beneficiaries Who Did Not or May Not Have Met Eligibility Requirements (A-02-20-01018), February 2022

Our previous audits of 4 States' Medicaid eligibility determinations found that during 2014 and 2015, Medicaid payments were made on behalf of 109 of 460 sampled newly eligible beneficiaries and 98 of 515 sampled non-newly eligible beneficiaries who did not meet or may not have met Medicaid eligibility requirements. We determined that both human and system errors, as well as a lack of policies and procedures, contributed to these improper or potentially improper payments. Although the States concurred with all 31 recommendations from our prior audits to address these deficiencies, 15 of these recommendations remain unimplemented.

On the basis of our sample results, we estimated that the 4 States made Federal Medicaid payments on behalf of newly eligible beneficiaries totaling almost \$1.4 billion for more than 700,000 ineligible or potentially ineligible beneficiaries. We also estimated that the 4 States made Federal Medicaid payments on behalf of non-newly eligible beneficiaries totaling more than \$5 billion for almost 5 million ineligible or potentially ineligible beneficiaries.

CMS disagreed with our recommendation that it work with States to implement all of the recommendations made in OIG's prior audits. CMS agreed with our recommendations that it: (1) maintain its efforts to provide training, technical advice, and guidance to States to address the causes identified in OIG's prior audits and (2) use all available remedies to prevent and reduce the amount of improper payments made on behalf of ineligible beneficiaries.

Minnesota MMIS and E&E Systems Controls Were Generally Effective, but Some Improvements Are Needed (A-18-20-08002), February 2022

Due to the current public health emergency and increased cyberactivity, we are only posting the title of our cybersecurity audits.

The Centers for Medicare & Medicaid Services' Eligibility Review Contractor Adequately Determined Medicaid Eligibility for Selected States Under the Payment Error Rate Measurement Program (A-02-20-01006), March 2022

We determined that CMS's eligibility review contractor correctly determined Medicaid eligibility for the beneficiaries associated with all 100 sampled claims. Based on our sample results, we concluded that CMS's eligibility review contractor adequately determined Medicaid eligibility for three States (Connecticut, Pennsylvania, and Virginia) under CMS's Payment Error Rate Measurement program in accordance with Federal and State requirements. This report contains no recommendations.

Two HHS Systems Were Launched Without Foundational Cybersecurity Controls (A-18-20-06800), November 2021.

Due to the current public health emergency and increased cyberactivity, we are only posting the title of our cybersecurity audits.

Nursing Home Reports and Reviews

CMS Should Take Further Action To Address States With Poor Performance in Conducting Nursing Home Surveys (OEI-06-19-00460), January 2022

Slightly more than half of State survey agencies (States) repeatedly failed to meet requirements for conducting nursing home surveys during FYs 2015–2018, yet CMS rarely imposed higher-level sanctions in contrast to the more frequently used remedies and alternative sanctions such as training or improvement plans. Without effective oversight of nursing homes by the States, residents may be at increased risk for harm and poor care.

CMS concurred with the following recommendations: (1) actively monitor the use and effectiveness of States' corrective action plans and other remedies, with a focus on making the remedies specific and outcome oriented; (2) establish guidelines for progressive enforcement actions, including the use of sanctions, when persistent or egregious performance problems emerge; (3) engage with senior State officials earlier and more frequently to address State performance problems; and (4) revise the State Operations Manual to reflect current CMS practices in overseeing State survey performance.

CMS did not concur or nonconcur with the remaining recommendation to disseminate results of State performance reviews more widely to ensure stakeholders become aware of problems.

Facility-Initiated Discharges in Nursing Homes Require Further Attention ([OEI-01-18-00250](#)), November 2021

Our findings raise concerns about weaknesses in the safeguards to protect nursing home residents from harm that may result from inappropriate facility-initiated discharges. Our findings can help ACL assist Ombudsmen with responding to potentially inappropriate facility-initiated discharges. Our findings can also help CMS improve its oversight of inappropriate facility-initiated discharge in nursing homes.

CMS concurred with our recommendations to: (1) provide training for nursing homes on Federal requirements for facility-initiated discharge notices, (2) assess the effectiveness of its enforcement of inappropriate facility-initiated discharges, and (3) implement its deferred initiatives to address inappropriate facility-initiated discharges.

ACL concurred with our recommendations to: (1) assist State Ombudsman programs in establishing a data-collection system for facility-initiated discharge notices and (2) establish guidance for analysis and reporting of data collected by State Ombudsman programs from facility-initiated discharge notices.

ACL and CMS did not explicitly state whether they concurred with our joint recommendation to coordinate to strengthen safeguards to protect nursing home residents from inappropriate facility-initiated discharges.

ACL and CMS concurred with our joint recommendation to ensure all State Ombudsmen, State agencies, and CMS Regional Offices have an ongoing venue to share information about facility-initiated discharges and potentially other systemic problems in nursing homes.

Legal and Investigative Activities Related to Medicare and Medicaid

OIG investigates allegations of fraud, waste, and abuse in all HHS programs. Our largest body of work involves investigating matters related to the Medicare and Medicaid programs, such as patient harm; billing for services not rendered, medically unnecessary services, or upcoded services (i.e., services billed for at a level higher than warranted); illegal billing, sale, and diversion of prescription drugs; the marketing of off-label uses for prescription drugs; and solicitation and receipt of kickbacks, including illegal payments

to patients for involvement in fraud schemes and illegal referral arrangements between physicians and medical companies.

OIG also conducts investigations regarding organized criminal activity, including medical identity theft and fraudulent medical schemes established for the sole purpose of stealing Medicare dollars. Investigators are opening an increasing number of cases against health care providers who engage in these health care fraud schemes. Those who participate in the schemes may face heavy fines, jail time, and exclusion from participation in Federal health care programs.

One of the most common types of fraud perpetrated against Medicare, Medicaid, and other Federal health care programs involves filing false claims for reimbursement. False claims may be pursued under Federal and State criminal statutes and, when appropriate, under the False Claims Act. Depending on the types of fraud or other violations involved, OIG investigations may culminate in criminal or civil court judgments and decisions, administrative sanctions and decisions, and/or negotiated settlement agreements. Investigative outcomes take many forms, including incarceration, restitution, fines, penalties, forfeitures, assessments, and exclusion of individuals or entities from participation in all Federal health care programs. Frequently used exclusion and penalty authorities are described on our website at <http://oig.hhs.gov/fraud/enforcement/cmp/>.

During this semiannual reporting period, we reported 307 criminal and 313 civil actions against individuals or entities that engaged in offenses related to health care. We also reported more than \$1.18 billion in investigative receivables due to HHS and more than \$262.0 million in non-HHS investigative receivables, including civil and administrative settlements or civil judgments related to Medicare, Medicaid, and other Federal, State, and private health care programs.

Criminal and Civil Enforcement Activities Related to Medicare and Medicaid

The following recently completed actions and settlements are organized by the type of provider or entity involved. Additional cases appear in the Medicare Fraud Strike Force Activities section below.

Psychotherapy

The following case example involves psychotherapy:

Connecticut—On March 11, 2022, Courtney Dunlap was sentenced to 57 months of imprisonment, followed by 3 years of supervised release, for operating a wide-ranging scheme that defrauded the Connecticut Medicaid Program of more than \$1.3 million. According to court documents and statements in court, from 2014 to 2020, Dunlap was a Licensed Professional Counselor with offices located on Brainard Road in Hartford. Dunlap also owned two entities, Inspirational Care, and KEYS Program Inc., through which he managed group homes in Hartford, Bristol, Cromwell, and Waterbury, including residences for women and children who were victims of domestic abuse.

From August 2018 through October 2020, Dunlap engaged in a scheme to defraud the Connecticut Medicaid Program by submitting claims for psychotherapy services that were purportedly provided to Medicaid clients. The vast majority of the claims were for occasions and dates of service when no psychotherapy services of any kind had been provided to the Medicaid clients identified in the claims. On a limited number of occasions, some of the services were rendered by unlicensed individuals who were not qualified or licensed to provide psychotherapy.

Genetic Testing

The following case example involves genetic testing fraud and kickback schemes related to a telemedicine company:

Florida—On November 9, 2021, Leonel Palatnik was sentenced to 82 months in Federal prison and ordered to pay more than \$61 million in restitution for his role in a \$73 million conspiracy to defraud Medicare by paying kickbacks to a telemedicine company to arrange for doctors to authorize medically unnecessary genetic testing. The scheme exploited temporary amendments to telehealth restrictions enacted during the COVID-19 pandemic that were intended to ensure access to care for Medicare beneficiaries. According to court documents, Leonel Palatnik admitted that, as a co-owner of Panda Conservation Group LLC, he conspired with other co-owners and with Michael Stein, the owner of 1523 Holdings LLC, to pay kickbacks to Stein in exchange for his work arranging for telemedicine providers to authorize genetic testing orders for Panda’s laboratories. Panda’s owners and Stein entered into a sham contract for purported IT and consultation services to disguise the true purpose of these payments. Then 1523 Holdings exploited temporary amendments to telehealth restrictions enacted during the pandemic by offering telehealth providers access to Medicare beneficiaries, for whom they could bill Medicare for consultations. In exchange, these providers agreed to refer beneficiaries to Panda’s laboratories for expensive and medically unnecessary CGx.

Pharmaceutical Companies

The following case example involves a pharmaceutical company:

Massachusetts—On November 9, 2021, kaléo Inc., a Virginia-based pharmaceutical manufacturer, agreed to pay the United States \$12.7 million to resolve allegations that it caused the submission of false claims to the Medicare program and other Federal health care programs for the drug Evzio, an injectable form of naloxone hydrochloride indicated for use to reverse opioid overdose. Evzio was the highest-priced naloxone hydrochloride product on the market, and insurers frequently required the submission of prior authorization requests before they would approve coverage for Evzio. Between March 14, 2017, and April 30, 2020, kaléo directed prescribing doctors to send Evzio prescriptions to

certain preferred pharmacies that in turn submitted false prior authorization requests to insurers. The prior authorization requests misrepresented that the prescribing physicians submitted the request when the pharmacies did so and/or contained false or misleading assertions about the patients' medical histories, such as false statements that patients had previously tried and failed less costly alternatives to Evzio. The pharmacies also dispensed Evzio without collecting or attempting to collect required copayments from Government beneficiaries. The United States contends that kaléo knew of or deliberately ignored this pharmacy misconduct, but nevertheless kept directing business to these pharmacies. The United States also alleged that kaléo provided illegal remuneration to prescribing physicians and their office staff in violation of the anti-kickback statute to induce and reward their prescribing of Evzio.

DME Companies

The following case examples involve DME companies:

Alabama—On December 2, 2021, Phillip Minga was sentenced to 78 months in prison for health care fraud and conspiracy to commit health care fraud. The court also ordered Minga to forfeit \$7.1 million and to repay more than \$16.1 million in restitution. According to documents filed by the Government, on October 17, 2016, Minga signed a written agreement in which he agreed to be excluded from the Medicare Program for 10 years. The exclusion agreement provided that Medicare would not pay claims submitted by anyone who employed Minga in a management or administrative role. Nevertheless, from 2016 until 2021, Minga committed health care fraud by continuing to manage and control pharmacies that submitted claims for payment to Medicare. To avoid detection, Minga ensured that those submitting Medicare enrollment or revalidation paperwork for these pharmacies would not disclose Minga's ownership interest or managerial role in these pharmacies. From October 17, 2016, to August 16, 2021, Medicare paid more than \$16 million to the pharmacies in which Minga had an ownership interest or managerial role.

Florida—On November 5, 2021, Michael Nolan and Richard Epstein were sentenced for their roles in a conspiracy to defraud Federal health benefit programs, including Medicare and the Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA). Nolan was sentenced to 78 months in Federal prison and Epstein was sentenced to 63 months in Federal prison. As part of their sentences, the court also entered a monetary judgment against the defendants in the amount of \$2.1 million and \$3 million, respectively, which were proceeds of the conspiracy. Nolan and Epstein were also ordered to pay restitution, jointly and severally with each other and other conspirators, in the amount of \$29,020,304. According to court documents, from around October 2016 through around April 2019, Epstein and Nolan ran a telemarketing company in Tampa called REMN Management LLC that targeted the elderly to generate thousands of medically unnecessary physicians' orders for DME and CGx. Epstein and Nolan also created

and operated Comprehensive Telcare, LLC, a telemedicine company through which they illegally bribed physicians to sign the orders regardless of medical necessity. Epstein and Nolan then illegally sold the signed physicians' orders to client-conspirators for use as support for false and fraudulent claims submitted to Medicare and CHAMPVA. The conspiracy resulted in the submission of at least \$134 million in fraudulent claims to the Federal health benefit programs, resulting in approximately \$29 million in payments.

Pharmacies

The following case example involves a pharmacy:

Oregon—On December 10, 2021, Matthew Hogan Peters, who owned and operated two compounding pharmacies, was sentenced to 3 years in Federal prison and ordered to pay more than \$3 million in restitution to the Internal Revenue Service (IRS) for evading the payment of approximately \$5.5 million in personal income taxes and submitting false reimbursement claims to CVS Caremark, a national pharmacy benefit manager. According to court documents, HHS-OIG, the Oregon Department of Justice's Medicaid Fraud Unit, and other agencies pursued a multiyear investigation into alleged illegal kickback arrangements at compounding pharmacies owned by Peters and members of his family in several states. Two such pharmacies, Professional Center Pharmacy and Professional Center 205 Pharmacy, were located in Southeast Portland. The investigation ultimately revealed that Peters had devised various indirect means of incentivizing health care providers to write prescriptions for compounded drugs—custom-mixed medications that generate outsized reimbursement from Medicare, Medicaid, and other health care-benefit programs—and to direct those prescriptions to his pharmacies for dispensing. These arrangements proved enormously profitable for Peters' pharmacies. Peters' health care fraud conviction stemmed from his requests for approximately \$3.4 million in reimbursement from CVS Caremark for medication his pharmacies had purportedly dispensed. In mid-2015, CVS Caremark audited Peters' reimbursement claims and identified nearly a quarter-million dollars in potentially unwarranted reimbursement. Many of the reviewed claims lacked records proving customers' receipt of medications.

In October 2015, seeking to resolve these discrepancies and avoid possible suspension from CVS Caremark's network, Peters submitted to CVS Caremark a total of 41 forged patient attestations, purportedly confirming individual patients' receipt of prescriptions. CVS Caremark auditors noticed that the patient attestations all bore the same unique digital code and, after further investigation, suspended Peters' pharmacies from their network. A subsequent Federal investigation confirmed that Peters had used DocuSign, an electronic signature application, from his personal computer to sign the attestations.

Prescription Drugs

The following case examples involve prescription drugs:

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

South Dakota—On November 2, 2021, Frenchone One Horn (also known as Frenchone Kills In Water) was sentenced to 60 months in Federal prison to be served consecutively on each count of assault resulting in serious bodily injury. One Horn was sentenced to 24 months in Federal prison on the charge of health care fraud, to be served consecutively to the assault charges. As to the charge of obtaining controlled substances by fraud, One Horn was sentenced to 12 months in Federal prison. In total, One Horn was sentenced to 12 years in Federal prison, followed by 3 years of supervised release, and ordered to pay \$400 in special assessments to the Federal Crime Victims Fund. One Horn assaulted others, including her minor children, to obtain prescriptions from medical providers for the injuries she intentionally inflicted. As a result of One Horn’s actions, three victims lost four fingers to amputation. One Horn fabricated stories as to how the individuals received their injuries, and also provided false statements to health care providers to obtain controlled substances and health care benefits. Once the individuals received controlled substances, One Horn took the controlled substances, despite the individuals having significant bodily injuries.

Kickbacks

The following case examples involve kickbacks:

Colorado—On March 1, 2022, Jeffrey Kesten was sentenced to 24 months in Federal prison, to be followed by 3 years of supervised release for conspiring to violate the anti-kickback statute in connection with a scheme to take bribes and kickbacks from a pharmaceutical company in exchange for prescribing a powerful fentanyl spray to his chronic pain patients.

According to the plea agreement, beginning in late 2012 and continuing through November 2015, the defendant conspired with pharmaceutical company employees to take approximately \$344,000 in bribes and kickbacks from Insys Therapeutics, Inc., the manufacturer of Subsys, a powerful sublingual fentanyl spray approved by the FDA in 2012 to treat breakthrough pain in cancer patients. The bribes were disguised as payments or honoraria for purportedly delivering educational speaker programs to the defendant's medical peers. In fact, the defendant often delivered no programs at all—at one point taking payments of more than \$40,000 from Insys for 17 "programs" he allegedly delivered to his own staff at his medical clinic. As part of the plea agreement, the defendant admitted that he entered into a quid pro quo relationship with Insys, and that the payments affected his prescribing decisions. He abused his position of trust vis-à-vis his patients and the Federal health care programs in which he was enrolled, becoming one of Insys's top revenue-generating prescribers. Prescriptions for Subsys typically cost thousands of dollars each month, and Medicare and Medicaid paid millions of dollars to cover Subsys prescriptions written by Dr. Kesten. Fentanyl is at least 50 times more powerful than morphine, and to ensure patient safety, the FDA requires Subsys prescribers, patients, and pharmacies to enroll in and comply with the Transmucosal Immediate Release Fentanyl Risk Evaluation and Mitigation Strategy (TIRF REMS) program. The defendant disregarded the rules imposed by this program, failing to notify his patients of the risks posed by the Schedule II controlled substance.

Missouri—On January 18, 2022, Brandy McKay, was sentenced to 36 months in Federal prison, to be followed by 3 years of supervised release and ordered to pay more than \$7.5 million in restitution. On October 6, 2021, Brandy McKay pleaded guilty to one count health care fraud, one count of making false statements concerning health care matters and one count of illegal kickbacks for health care program referrals. According to the plea agreement, between 2017 and 2019, McKay owned or managed multiple DME companies, including three located in Cape Girardeau, Missouri. The DME companies paid kickbacks for orders and prescriptions signed by telemedicine doctors and nurse practitioners, who in almost all cases did not examine the patients, had no contact with the patients, and did not otherwise determine that the patients needed DME. The DME companies then submitted reimbursement claims to Medicare and Medicaid. Based on the fraudulent claims submitted by McKay and her co-conspirators, Medicare and Medicaid reimbursed the DME companies for the medically unnecessary equipment. In many cases, patients received DME equipment from several DME companies, which they had neither requested nor needed.

Patient Harm

The following case example involves patient harm:

South Dakota—On December 21, 2021, Pedro Ibarra-Perocier, a physician at the Wagner Indian Health Service Clinic, was sentenced to 120 months in Federal prison, followed by 5 years of supervised release, a \$35,000 fine, after he pled guilty to five counts of abusive sexual contact. The conviction stemmed from several incidents that occurred between approximately February 2007 and August 2018, when Ibarra-Perocier was a licensed physician practicing at the Wagner Indian Health Service Clinic and sexually abused five Native American women who came to see him at the clinic for medical appointments. Ibarra-Perocier frequently locked the door to the examination room before he sexually abused those women. Ibarra-Perocier threatened or placed some of them in fear that they would not receive the medications or medical care they needed unless they complied with his sexual demands in the clinic examination rooms..

Home Health

The following case example involves home health:

Illinois—On November 30, 2021, Angelita Newton was sentenced to 56 months in prison and ordered to pay \$6.3 million in restitution for her participation in a conspiracy to commit health care and wire fraud. According to court documents and the evidence presented at trial, Angelita Newton worked at Care Specialists, a home health care company owned by Ferdinand Echavia and later his wife, Ma Luisa Echavia. Ferdinand Echavia and Ma Luisa Echavia were previously sentenced to 84 months and 60 months in prison, respectively, for their role in the conspiracy. Between 2011 and 2017, Care Specialists fraudulently billed Medicare at least \$6.3 million. At trial, the Government demonstrated that around 90 percent of Care Specialists' patients were not homebound and did not qualify for the types of care that Care Specialists had billed to Medicare. Furthermore, many patients received cash bribes to receive home health "visits," some of which were performed in the visiting nurse's car. Newton facilitated the conspiracy by falsifying patient visit records that were used to support claims billed to Medicare, and she was convicted by a federal jury on February 14, 2020. Another participant in the conspiracy, Reginald Onate, who pleaded guilty and cooperated with the Government throughout the investigation, was sentenced to 3 years' probation.

Medical Device Company

The following case example involves a medical device company:

Massachusetts—On November 8, 2021, Arthrex Inc., a Florida-based medical device company, agreed to resolve allegations that it violated the False Claims Act by paying kickbacks that caused the submission of false claims to the Medicare program. According to the settlement, Arthrex Inc., which specializes in orthopedic products, has agreed to pay \$16 million for allegedly paying kickbacks to a Colorado-based orthopedic surgeon. The

settlement resolves allegations that Arthrex agreed to provide remuneration to the surgeon in the form of royalty payments purportedly for the surgeon's contributions to Arthrex Inc.'s SutureBridge and SpeedBridge products when the remuneration was in fact intended to induce the surgeon's use and recommendation of Arthrex Inc.'s products. The United States contended that Arthrex Inc.'s participation in this arrangement violated the Federal anti-kickback statute and, in turn, the False Claims Act, by causing the submission of false or fraudulent Medicare claims. In connection with the settlement, Arthrex, Inc. entered into a 5-year CIA with HHS-OIG.

Medicare Fraud Strike Force Activities

In 2007, Medicare Fraud Strike Force teams began an effort to combine resources of Federal, State, and local law enforcement entities to prevent and combat health care fraud, waste, and abuse. These partnerships among OIG and HHS, DOJ, U.S. Attorneys' Offices, FBI, and State and local law enforcement have a common goal: to analyze health care fraud data and investigative intelligence to quickly identify fraud and bring prosecutions. Strike Force teams operate in 11 areas: Miami and Tampa/Orlando, 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 located in Washington, DC. During this semiannual reporting period, Strike Force efforts resulted in the filing of charges against 72 individuals or entities, 91 criminal actions, and more than \$227.6 million in investigative receivables.

In October 2018, DOJ announced the creation of a new initiative to combat the Nation's opioid epidemic. The Appalachian Regional Prescription Opioid Strike Force covers 10 Federal judicial districts in Alabama, Kentucky, Ohio, Tennessee, Virginia, and West Virginia. OIG's Office of Investigations is working closely with its law enforcement partners at the Drug Enforcement Administration (DEA), FBI, and the MFCUs to provide investigative support. Cases involve physicians and pharmacies that are responsible for medically unnecessary opioid prescriptions and dangerous drug combinations that are being paid for by Medicare and Medicaid. In many instances, there are other allegations of wrongdoing relating to kickbacks, health care fraud, and quality of care, including patient overdoses and deaths.

The following case example involves a Strike Force case:

Texas—On December 16, 2021, Leah Hagen and Michael Hagen were sentenced to 151 months in prison and were ordered to pay more than \$27 million in restitution for a Medicare kickback conspiracy. According to the evidence presented at trial, Leah and Michael Hagen owned and operated two DME companies, Metro DME Supply LLC and Ortho Pain Solutions LLC. From March 2016 to January 2019, the defendants paid kickbacks and bribes to their co-conspirator's call center in the Philippines in exchange for signed doctors' orders for DME that were used to submit false claims in excess of \$59 million to Medicare. As a result of those claims, Medicare paid the

defendants more than \$27 million. The defendants transferred millions of dollars overseas to purchase a home in Spain, among other things. To conceal the payments of kickbacks and bribes from the authorities, the defendants, through their DME companies, signed sham contracts that disguised payments as marketing and business process outsourcing. The DME claims submitted by the defendants to Medicare were for services that were medically unnecessary and not provided as represented. In some cases, beneficiaries were convinced to accept braces they did not need or want and were offered gift cards in exchange for accepting those braces.

Most Wanted Fugitives List

OIG's Most Wanted Fugitives website continues to garner national and international attention and has greatly assisted in helping to capture fugitives charged with defrauding Federal health care programs and stealing millions of taxpayer dollars. The Most Wanted Fugitives website is continually updated and features a profile for each fugitive as well as an online tip form and a hotline number for individuals to report fugitive-related information to OIG, in English or Spanish, 24 hours a day, 365 days a year. The Most Wanted Fugitives list is available at <https://oig.hhs.gov/fraud/fugitives/>. During this semiannual reporting period, four fugitives were captured.

The following case example involves a captured fugitive:

Texas—On December 10, 2021, Ebong Aloysius Tilong (Tilong) was extradited from the Republic of Cameroon to the United States to serve an 80-year prison sentence he received in absentia 4 years ago after he pleaded guilty in two separate cases to conspiracy, health care fraud, money laundering, and tax offenses. The trial evidence and court documents showed that between 2006 and 2015, Tilong, Neba, and their co-conspirators used Tilong and Neba's company, Fiango Home Healthcare Inc. (Fiango), to corruptly obtain more than \$13 million by submitting false and fraudulent claims to Medicare for home health care services that Fiango's patients did not need or receive. Additional evidence demonstrated that Tilong attempted to destroy evidence and to blackmail and induce witnesses to commit perjury. After the first week of trial, Tilong pleaded guilty to one count of conspiracy to commit health care fraud, three counts of health care fraud, one count of conspiracy to pay and receive health care kickbacks, three counts of payment and receipt of health care kickbacks, and one count of conspiracy to launder monetary instruments. In August 2017, Neba was sentenced to 75 years in prison for the Medicare fraud scheme at Fiango. The U.S. District Court scheduled Tilong's sentencing for October 13, 2017, but court records show that on the morning of his sentencing hearing, Tilong removed an ankle bracelet monitoring his location and failed to respond to phone calls from, or appear in, the U.S. District Court for his sentencing. On December 8, 2017, the U.S. District Court sentenced Tilong in absentia to 80 years in prison for his role in the Medicare and tax fraud schemes. After Tilong absconded, the FBI Houston Field Office located Tilong in Cameroon, and worked collaboratively with the FBI Legal Attaché in Abuja, Nigeria, HHS-OIG, IRS Criminal Investigation (IRS-CI) Fraud Section, and the Office of the President of the Republic of Cameroon to ensure Tilong's capture. The National Police Force of Cameroon arrested Tilong in January 2019. Prior to

his extradition from Cameroon, Tilong was wanted by the FBI and was listed among HHS-OIG’s Top 10 Most Wanted Fugitives.

HHS-OIG Hotline

As part of OIG’s Office of Investigations, the hotline is the public-facing division for OIG’s intake and evaluation of fraud tips. The mission of the HHS-OIG Hotline is to support OIG’s oversight responsibilities in safeguarding the integrity of all programs and personnel under HHS’s purview and protecting them from fraud, waste, and abuse. The hotline achieves its mission through its staff’s dedication to timely intake and analysis of information received from various sources, such as the “Submit a Complaint” link on the HHS-OIG website. During this semiannual reporting period, the OIG Hotline reported expected recoveries of \$97,002,239 as a direct result of cases originating from hotline complaints.

OIG Hotline Activity (4/1/2021–9/30/2021)

Contacts to 1-800-HHS-TIPS phone line, including callers seeking information	53,782
Total tips evaluated	20,391
Tips referred for action	12,110
Closed; no basis provided for further action	1,514
Closed; no HHS violation ¹	933
Closed; other administrative reason	5,834

Sources of tips referred for action

Phone	3,607
OIG website	6,848
Letters or faxes	603
Other	1,052

Medicaid Fraud Control Units

OIG Oversight of Medicaid Fraud Control Units

MFCUs are key partners with OIG in the fight against fraud, waste, and abuse in State Medicaid programs. OIG has oversight responsibility for MFCUs and administers grants that provide Federal funding for their operations. Currently, all 50 States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands operate MFCUs. The Federal Government reimburses 90 percent of a MFCU’s total expenditures during the first 3 years of operation and 75 percent thereafter. MFCUs

investigate and prosecute Medicaid provider fraud as well as abuse or neglect of residents in health care facilities and board and care facilities and of Medicaid beneficiaries in noninstitutional or other settings.

Medicaid Fraud Control Units Fiscal Year 2021 Annual Report (OEI-09-22-00020), March 2022

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

OIG Joint Casework With MFCUs

The following case example involves OIG's joint efforts with MFCUs:

Pennsylvania—On December 7, 2021, Thomas Whitten was sentenced to 57 months in prison and ordered to pay \$8 million in restitution for conspiracy to violate the Federal anti-kickback statute, health care fraud, and conspiracy to distribute Schedule IV controlled substances. Whitten pled guilty on July 22, 2021. During the change of plea hearing, Whitten admitted that, from May 2013 to November 2015, he conspired to receive kickbacks from pharmaceutical company Insys Therapeutics in exchange for prescribing Subsys, a powerful painkiller that is approximately 50 to 100 times more potent than morphine. The FDA approved Subsys only for the management of breakthrough pain in cancer patients. Whitten prescribed Subsys to patients for whom the drug was not medically indicated and received more than \$100,000 as well as other benefits from Insys in exchange for writing those prescriptions. Prescriptions for Subsys typically cost thousands of dollars each month, and Medicare and Medicaid, as well as commercial insurers, including Highmark, paid millions of dollars to cover illegitimate Subsys prescriptions written by Whitten. In addition, from November 2017 through December 12, 2019, Whitten conspired to unlawfully distribute Schedule IV controlled substances, phentermine hydrochloride and diethylpropion, to patients at five weight loss clinics. Based on an agreement between Whitten and the owner of those clinics, Schedule IV controlled substances were dispensed to patients under Whitten's DEA registration numbers, including to new patients and patients who had not been seen at the clinics for years, without any physical examination by Whitten or another appropriately trained licensed medical professional.

The investigation leading to the filing of charges in this case was conducted by the Western Pennsylvania Opioid Fraud and Abuse Detection Unit, a collaborative effort including HHS-OIG; FBI; DEA; IRS-Criminal Investigations; Pennsylvania Office of Attorney General–MFCU; Pennsylvania Office of Attorney General–Bureau of Narcotic Investigations; United States Postal Inspection Service; U.S. Attorney’s Office–Criminal Division, Civil Division and Asset Forfeiture Unit; VA-OIG; OPM-OIG; and the Pennsylvania Bureau of Licensing.

Advisory Opinions and Other Industry Guidance

Advisory opinions, which are developed in consultation with DOJ, are issued to requesting parties regarding the interpretation and applicability of certain statutes relating to Federal health care programs. The Health Insurance Portability and Accountability Act of 1996 (HIPAA), § 205, allows OIG to provide case-specific formal guidance on the application of the anti-kickback statute and safe harbor provisions and other OIG health care fraud and abuse sanctions. During this semiannual reporting period, OIG received 24 requests for advisory opinions and issued 11 advisory opinions.

Sanction Authorities and Other Administrative Actions

Various Federal laws provide authorities the ability to impose administrative sanctions for fraud and abuse as well as other activities that pose a risk to Federal health care programs and their beneficiaries. Sanctions include the exclusion of individuals and entities from Federal health care programs and the imposition of CMPs for submitting false and fraudulent claims to a Federal health care program or for violating the anti-kickback statute, the physician self-referral law (commonly referred to as the “Stark Law”), or the Emergency Medical Treatment and Labor Act (EMTALA), also known as the “patient dumping statute.” Sanctions also include referrals for suspension and debarment in cases of grant and contract fraud.

During this semiannual reporting period, OIG imposed 1,122 administrative sanctions in the form of program exclusions or administrative actions for alleged fraud or abuse or other activities that posed a risk to Federal health care programs and their beneficiaries.

Exclusion and penalty authorities are described in Appendix C and on our website at <http://oig.hhs.gov/fraud/enforcement/cmp/index.asp>.

Program Exclusions

During this semiannual reporting period, OIG excluded 1043 individuals and entities from Medicare, Medicaid, and other Federal health care programs. Most of the exclusions resulted from convictions for crimes relating to Medicare or Medicaid, patient abuse or neglect, financial misconduct, controlled substances, or as a result of license revocation. OIG completed the

deployment of a new service for MFCUs to report convictions through a central web-based portal for exclusions. OIG is also responsible for reinstating providers who apply and have met the requirements of their exclusions. For a list of excluded individuals and entities, see <https://exclusions.oig.hhs.gov/>.

The following are case examples of program exclusions:

New York—On November 18, 2021, a medical doctor was excluded for a minimum period of 30 years based on convictions for Health Care Fraud and Conspiracy to Unlawfully Distribute Controlled Substances. From about 2007 to about September 2014, this physician issued prescriptions for controlled substances without conducting exams, issued prescriptions knowing patients had overdosed and were hospitalized, and continued to prescribe controlled substances that resulted in drug-seeking behavior and patient death. The individual was sentenced to 70 months of incarceration and ordered to pay approximately \$344,500 in restitution. In addition, the New York Department of Health, State Board of Professional Medical Conduct revoked the individual’s license to practice as a medical doctor.

Texas—On November, 18, 2021, a co-owner of a pharmaceutical marketing company was excluded for a minimum period of 50 years based on the individual’s convictions of conspiracy to commit health care fraud and receipt of illegal kickbacks. From about May 2014 to about February 2016, the individual conspired with others to defraud TRICARE with a scheme that involved a sham medical study, a bogus charity, and kickbacks to incentivize patients to obtain expensive pain and scar cream prescriptions. The individual was sentenced to 120 months of incarceration and ordered to pay approximately \$70,417,800 in restitution.

Washington State—On January 19, 2022, a massage therapist was excluded for a minimum period of 55 years based on convictions for one count of rape and three counts of indecent liberties. From about January 2011 to about June 2020, this individual engaged in sexual intercourse with a client/patient during treatment sessions. The individual was sentenced to 132 months of incarceration. In addition, the Washington Department of Health, Massage, Therapist Program accepted the surrender of the individual’s license to practice as a massage therapist.

West Virginia—On February 20, 2022, a nursing assistant was excluded for a minimum period of 97 years based on a conviction of seven counts of second degree murder and one count of assault with intent to commit murder. Specifically, this individual deliberately and without authorization administered lethal doses of insulin to patients under the individual’s care at the Veterans Affairs Medical Center. The nursing assistant was sentenced to pay restitution and serve seven life terms plus 240 months in prison.

Mississippi—On March 20, 2022, a pharmacist was excluded for a minimum period of 80 years based on a conviction of conspiracy to commit health care fraud and money laundering. From about January 2012 to about December 2015, this individual defrauded TRICARE and other health care benefit programs by producing compound medications to maximize reimbursement, submitting false and fraudulent claims for reimbursement, and diverting the proceeds for personal use and benefit. The pharmacist was sentenced to 12 months and 1 day of incarceration and ordered to pay approximately \$182,503,900 in restitution.

Suspensions and Debarments

Suspensions and debarments are administrative tools used by HHS and other Federal agencies to protect the Government from individuals and entities that have engaged in contract fraud, have misused grant funds, or are otherwise not presently responsible. Because these are Governmentwide sanctions, an individual or entity that has been suspended or debarred by HHS or any other agency is ineligible to participate in any future funding opportunities across the Federal Government for a specified period of time.

OIG refers individuals and entities that have potentially engaged in grant or contract fraud or misconduct to the HHS suspension and debarment official, who is responsible for determining whether to impose a suspension or debarment. OIG continues to develop a robust suspension and debarment program and uses this tool to protect Government programs against fraud, waste, poor performance, and noncompliance with contract provisions or applicable law.

The following case example involves debarment:

Nebraska—On January 8, 2022, the HHS Suspension and Debarment Official (SDO) debarred the director of a grant recipient that OIG had referred to the Office of Recipient Integrity Coordination. The grant recipient received reimbursement payments in the form of grants through the Child Care Bureau in the Office of Family Assistance of the Administration for Children and Families. These grants provided childcare subsidies to low-income families where the parents were employed or engaged in job training. After a review of timesheets demonstrated that families were being billed that did not attend daycare during the recorded days and times, the director was convicted of stealing money and property of the United States and sentenced to serve 5 years of probation and pay \$143,099.84 in restitution. In addition to the SDO's 3-year debarment, OIG excluded the director from participating in the Federal health care programs for 6 years.

Civil Monetary Penalties Law

The Civil Monetary Penalties Law (CMPL) authorizes OIG to impose administrative penalties, assessments, and exclusions against a person who, among other things, submits, or causes to be

submitted, claims to a Federal health care program that the person knows, or should know, are false or fraudulent. The exclusions statute also authorizes OIG to exclude a person who violates the CMPL. During this semiannual reporting period, OIG concluded cases involving more than \$32 million in CMPs and assessments.

Affirmative Litigation

The CMPL authorizes OIG to use its administrative remedies to affirmatively pursue cases. OIG may also exclude under the exclusions statute for engaging in conduct that violates the CMPL. When OIG excludes under the exclusions statute for engaging in conduct that violates the CMPL, it is known as an affirmative exclusion.

The following case examples involve affirmative litigation under the CMPL:

Texas—Dr. Steven Lane Casey and Metroplex Pain Consultants, LLC (collectively, Casey) entered into a \$110,748.12 settlement agreement with OIG. The settlement agreement resolves allegations that Casey submitted claims to Medicare while Dr. Casey neither performed the services himself, nor supervised them. This settlement also resolved allegations that Casey billed Medicare for medically unreasonable or unnecessary spinal facet joint injections.

Florida—Meir Daller, M.D., entered a settlement agreement with OIG in which he agreed to pay \$455,400 and be excluded from participation in all Federal health care programs for 3 years under 42 U.S.C. 1320a-7a and 42 U.S.C. 1320a-7(b)(7). The settlement agreement resolves allegations that Dr. Daller submitted or caused to be submitted the following: (1) claims for cystourethroscopy with dilation of urethral stricture where no stricture was present that necessitated urethral dilation; (2) claims for urodynamics testing that was ordered on a routine periodic basis, not out of medical necessity; and (3) claims for evaluation and management (E&M) services related to in-office testosterone injections that were: (i) submitted in conjunction with claims for the testosterone injections, using modifier 25, where no significant and separately identifiable service other than the testosterone injection took place; and (ii) submitted alone where the patient received an in-office testosterone injection but no evaluation or management of the patient took place that justified the billing of an E&M code.

California—Ocean Mind and Body (Ocean) and Laura Rausa (Rausa) entered a \$62,528.73 settlement agreement with OIG, resolving allegations that Ocean and Rausa knowingly made, used, or caused to be made a false statement in a document that is required to be submitted to directly or indirectly receive or retain funds provided in whole or in part by the Secretary of HHS. Specifically, OIG contends that in April 2020, Ocean, a medical supply company, received a Provider Relief Fund payment pursuant to the CARES Act. On April 28, 2020, Rausa, the Chief Executive Officer and owner of Ocean, attested in the HHS

Provider Relief Fund Portal that Ocean was eligible to receive this payment because, among other things, it provides or provided after January 31, 2020, diagnoses, testing, or care for individuals with possible or actual cases of COVID-19. However, Ocean and Rausa did not provide diagnoses, testing, or care for any individuals after January 31, 2020.

Texas—OIG excluded the Woodlands Pain Institute, PLLC, and its owner, Emad Bishai, M.D. for 7 years each under 42 U.S.C. 1320a-7(b)(7) as part of a \$523,331 False Claims Act settlement. The exclusions and settlement resolve allegations that Dr. Bishai, an anesthesiologist, and Woodlands Pain Institute knowingly submitted, or caused to be submitted, claims to Medicare under Healthcare Common Procedure Coding System code L8679, which is designed for “implantable neurostimulator, pulse generator” devices that a surgeon implants into a patient typically in an operating room. Dr. Bishai did not perform surgery and did not implant anything into patients’ bodies. Instead, the underlying services for which the L8679 claims were submitted involved the application of a device used for electroacupuncture. To apply the electroacupuncture device, needles were inserted into patients’ ears and the neurostimulator was taped behind their ears with an adhesive. Medicare does not reimburse for electroacupuncture devices as neurostimulators.

Patient Dumping

Some of the CMPL cases that OIG resolved during this semiannual reporting period were pursued under the Emergency Medical Treatment and Labor Act (EMTALA), a statute designed to prevent hospitals from denying emergency care to patients and to ensure patient access to appropriate emergency medical services.

The following case examples involve EMTALA:

Tennessee—OIG entered a settlement agreement for \$725,000 with Tristar Centennial Medical Center (Centennial), a 741-bed acute care hospital located in Nashville, Tennessee. OIG identified 29 incidents in which Centennial violated EMTALA, 42 U.S.C. § 1395dd(g). In each of these incidents, a patient presented to Centennial’s Emergency Department (ED) with an unstable psychiatric emergency medical condition. In each incident, Centennial failed to provide, with the staff and facilities available at Centennial, further medical examination and treatment required to stabilize the patient’s emergency medical condition. In two of these incidents, rather than admitting the patient to Parthenon Pavilion, Centennial’s inpatient psychiatric unit, which had the capability and capacity to treat the patient, Centennial discharged the patient home with an unstable emergency medical condition. For other presentments, rather than admitting the patient to Parthenon Pavilion, Centennial held the patient inappropriately in its ED for more than 24 hours before transferring the patient to other surrounding facilities. The decision to transfer the patient, and where to transfer the patient, was made by Centennial and the Tristar Behavioral Health Transfer Center and was based, in part, on the patient’s insurance status.

Tennessee—OIG entered a settlement agreement for \$725,000 with Tristar Skyline Medical Center (Skyline), a 353-bed acute care hospital located in Nashville, Tennessee. OIG identified 25 incidents in which Skyline violated EMTALA. In each of these incidents, a patient presented to Skyline’s ED with an unstable psychiatric emergency medical condition. In each incident, Skyline failed to provide, with the staff and facilities available at Skyline, further medical examination and treatment required to stabilize the patient’s emergency medical condition. Rather than admitting the patient to Skyline’s inpatient psychiatric unit that had the capability and capacity to treat the patient, Skyline held the patient inappropriately in its ED for more than 24 hours before transferring the patient to Middle Tennessee Mental Health Institute, a State psychiatric hospital. The decision to transfer the patient, and where to transfer the patient, was made by Skyline and the Tristar Behavioral Health Transfer Center and was based, in part, on the patient’s insurance status. Skyline asserts that its decision to transfer the patients was based on a recommendation from the State of Tennessee’s Mobile Crisis Services team.

Self-Disclosure Programs

Health care providers, suppliers, or other individuals or entities subject to CMPs can apply for acceptance into the Provider Self-Disclosure Protocol, a program created in 1998 for voluntary disclosure of self-discovered evidence of potential fraud. The Self-Disclosure Protocol may give providers the opportunity to avoid costs or disruptions associated with Government-directed investigations and civil or administrative litigation.

Application processes for two additional self-disclosure programs were recently added to the OIG website for HHS contractors and grantees. The OIG contractor self-disclosure program provides contractors the opportunity to self-disclose when they have potentially violated the False Claims Act or other Federal criminal laws prohibiting fraud, conflict of interest, bribery, or gratuity. This self-disclosure process is only available to those with a FAR-based contract with HHS. The OIG Grant Self-Disclosure Program is available for application by HHS grantees or HHS grant subrecipients and provides the opportunity for voluntary disclosure to OIG of potential fraud. OIG evaluates the reported results of each internal investigation under the provider self-disclosure protocol to determine the appropriate course of action. The self-disclosure guidelines are available on the OIG website at <https://oig.hhs.gov/compliance/self-disclosure-info/index.asp>. During this semiannual reporting period, provider self-disclosure cases resulted in more than \$26.6 million in HHS receivables.

The following case examples pertain to provider self-disclosure settlements:

Florida—Lee Memorial Health System dba Lee Health, and Cape Memorial Hospital, Inc. dba Cape Coral Hospital (collectively, “Lee Health”) entered a \$12,721,885.58 settlement agreement with OIG. In its submission to the OIG Self-Disclosure Protocol, Lee Health

disclosed that during the period of January 1, 2011, through May 10, 2018, Lee Health submitted claims to the Medicare, Medicaid, and TRICARE programs for professional and technical fees for certain pain management procedures and evaluation and management services performed by two independent contractor physicians (E.D.M, M.D., and G.A, M.D.) at Lee Health’s facilities that did not meet Federal health care program coverage criteria. The specific procedures that were improperly billed by Lee Health include epidurals, paravertebral facet joint blocks, implantable infusion pumps for treatment of intractable pain, sacroiliac joint injections, injection of trigger points, destruction of paravertebral facet joint nerves, and radiology services.

Texas—After it self-disclosed conduct to OIG, Texas Centers for Infectious Disease Associates (TCIDA) entered a settlement agreement for \$609,579.93. The agreement resolves TCIDA’s liability under the CMPL for its submission of claims to Medicare Part D for the entire vial of certain drugs to particular patients when in fact, the patients had been dispensed only part of the vial of the drug, and for overbilling Medicare Part D for dispensed doses.

Vermont—After it self-disclosed conduct to OIG, Visiting Nurse Association and Hospice of Vermont and New Hampshire, Inc. (VNH), agreed to pay \$2,389,706.26 for allegedly violating the CMPL. OIG alleged that VNH submitted claims for home health services based on orders signed by a qualified clinician but not cosigned by a physician or allowed practitioner.

Indiana—After it self-disclosed conduct to OIG, Advanced OrthoPro Inc. (AOP) agreed to pay \$7,191,730.77 for allegedly violating the CMPL. OIG alleged that AOP submitted false claims for DME dispensed at AOP locations not enrolled as DME providers with CMS, where the claims were submitted under the enrollment number of an AOP location on North Illinois Street in Indianapolis, Indiana.

Corporate Integrity Agreements

Many health care providers elect to settle their cases before litigation. As part of the settlements, providers often agree to enter into CIAs with 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 Medicare and Medicaid rules. The compliance programs are designed, in part, to prevent future fraud. OIG monitors providers’ compliance with these agreements and may impose penalties on parties that fail to comply with the requirements of their CIAs.

The following case example involves CIA enforcement:

Puerto Rico—On December 8, OIG entered a \$518,923 CMPL settlement with Walgreen Co. Walgreens is under a CIA with OIG that became effective on January 11, 2019. On June 29, 2021, Walgreens reported to OIG that it paid improper remuneration to induce referrals in violation of the anti-kickback statute and physician self-referral law. Specifically, Walgreens paid remuneration in the form of discounts on retail product purchases at Walgreens locations in Puerto Rico to 1,719 health care professionals who wrote prescriptions for items filled at Walgreens locations in Puerto Rico that were paid for by a Federal health care program.

Public Health and Human Service Agency Reports and Reviews

Public Health Agency Reports and Reviews

Office of the Secretary

Two Critical HHS Systems Were Deployed Without Authorizations To Operate, November 2021

Due to the current public health emergency and increased cyberactivity, we are posting only the title of our cybersecurity audits.

Office of the Assistant Secretary for Preparedness and Response

HHS's Suspension and Debarment Program Helped Safeguard Federal Funding, But Opportunities for Improvement Exist (OEI-04-19-00570), January 2022

Most HHS suspension and debarment referrals received between FYs 2015 and 2019 resulted in actions to protect Federal funds, but opportunities to improve program timeliness, efficiency, and effectiveness exist. (Suspensions are preliminary, immediate actions that exclude persons from receiving new funds. Debarments are final determinations that exclude persons from receiving new funds for a specified time.) Our findings and recommendations can help the Assistant Secretary for Financial Resources (ASFR) strengthen HHS's suspension and debarment program and better safeguard Federal funds.

ASFR concurred with all four of our recommendations, which were for it to: (1) take steps to ensure that HHS's suspension and debarment program has more consistent senior leadership and sufficient staffing, (2) improve the case management and tracking of referrals, (3) develop and disseminate guidance regarding how to prepare and submit complete referrals, and (4) conduct outreach and provide additional training about the suspension and debarment program to HHS awarding agencies that make few or no referrals.

Food and Drug Administration

The Food and Drug Administration Needs To Improve Its Contract Closeout Processes To Identify Contracts Eligible for Closeout and Close Contracts Timely (A-03-20-03004), December 2021

FDA did not always identify contracts eligible for closeout and did not always follow FAR requirements for closing contracts timely but otherwise generally closed contracts in accordance with the FAR, the HHS Acquisition Regulation, and other HHS acquisition policies and procedures. FDA did not always identify and close contracts timely because FDA utilized manual processes for some contract closeout review functions when an automated process may have been more efficient. In addition, FDA personnel did not always communicate to each other information that would have helped identify contracts eligible for closeout, contracting officers and contracting officer's representatives (CORs) were not required to notify contract closeout specialists that a contract was complete, and the CORs' change requests were not always submitted before the CORs left their positions. Finally, FDA contract closeout specialists did not have the ability to run ad hoc query reports from the Purchase Request Information System, the system that HHS uses to formulate, administer, and distribute contract documents.

Because contracts were not always closed timely, FDA may not have identified unused funds that could be deobligated and released to another appropriate need. Specifically, we found that two of the contracts that should have been closed had remaining funds of \$88,152 that should have been deobligated and released to another appropriate need.

FDA agreed with our recommendation that it deobligate \$88,152 in contract funding and close the six contracts that remain open but eligible for closeout. We also made several procedural recommendations for improving the contract closeout process.

National Institutes of Health

The National Institutes of Health Administered Superfund Appropriations During Fiscal Year 2020 in Accordance With Federal Requirements (A-04-21-04081), October 2021

During FY 2020, NIH administered Superfund appropriations in accordance with applicable Federal requirements. Specifically, NIH obligated and disbursed Superfund appropriations in accordance with Federal requirements and in similar proportions to prior years. In addition, the Institute's monitoring of Superfund grants generally ensured that grantees met requirements for financial, performance, and audit reporting. This report contains no recommendations.

The National Institutes of Health Could Improve Its Post-Award Process for the Oversight and Monitoring of Grant Awards (A-03-20-03001), February 2022

The National Cancer Institute's (NCI's) postaward process for providing oversight and monitoring of grants was generally effective in ensuring that grantees met the program objectives and that NCI was able to identify potential problems. However, for 12 of the 20 grants in our sample that were closed in FY 2019, the grantee did not submit final reports within 120 days of the end of the period of performance as required.

NIH's Division of Grants System Integration (DGSI/Closeout Center) provides outreach on NCI's behalf to grantees with respect to the due dates of the final reports within 10 days of the end of the period of performance but does not provide another reminder until after the final reports are late. This delays the closeout process. A recipient may draw funds up to the date that its Final Federal Financial Report is due to NIH or up to 120 days past the period of performance end date.

If grantees submit final reports late, it could indicate an issue with the grantee's ability to comply with grant requirements, including accounting for grant funds and tracking the progress and outcomes of the grant.

NIH agreed with our recommendation that NCI coordinate with NIH's DGSI/Closeout Center to update policies and procedures for monitoring grantees' submission of closeout documents to include more periodic outreach to grantees before the final reports become delinquent.

Human Services Agency Reports and Reviews

Administration for Children and Families

Characteristics of Separated Children in ORR's Care: June 27, 2018–November 15, 2020 ([OEI-BL-20-00680](#)), November 2021

OIG found that 1,178 children were separated from a parent or legal guardian and referred to ORR's care between June 27, 2018 (the day after a Federal district court halted most family separations) and November 15, 2020 (the date of the most recent complete data available at the time of our review). Separated children were 9 years old on average, with more than a quarter under 5 years old; in comparison, non-separated children were 15 years old on average. Seventy percent of separated children referred to ORR had been separated by immigration officials because of a parent's criminal history, the nature of which varied widely. Separated children spent longer in ORR's care and were less likely than non-separated children to be released to a sponsor. Of the 1,178 separated children referred to ORR during the period we reviewed, ORR ultimately reunified 182 children (15 percent) with the parent from whom the child was separated. This data brief contains no recommendations.

Child Care Background Checks

States that receive funding from the Child Care and Development Fund (CCDF) are required to conduct comprehensive criminal background checks on staff members and prospective staff members of child care providers every 5 years. During this reporting period, OIG conducted two audits that were designed to assess whether the States' monitoring process ensured provider compliance with requirements related to criminal background checks established under the Child Care and Development Block Grant Act. Complete recommendations and providers' responses can be found in the final reports, which are summarized below.

The District of Columbia's Monitoring Did Not Ensure Child Care Provider Compliance With Criminal Background Check Requirements at 7 of 30 Providers Reviewed ([A-03-20-00252](#)), November 2021

The District's monitoring process did not ensure provider compliance related to criminal background checks for 7 of the 30 child care providers (55 of the 541 individuals requiring background checks) we reviewed. In response to our audit, the District took action and completed background checks for 52 of the 55 individuals. The errors we found occurred because: (1) providers did not send the in-State child abuse and neglect (Child Protection Register) check results to the District, (2) District law did not allow Child Protection Register check results to be sent directly to the District unless the individual was found not to be suitable for employment, and (3) processing delays resulted in incomplete FBI fingerprint checks and inter-State checks. To ensure the safety of children at these child care providers, the District needs to strengthen its process for conducting criminal background checks for all individuals who supervise or have routine unsupervised contact with children.

Louisiana's Monitoring Did Not Ensure Child Care Provider Compliance With Criminal Background Check Requirements at 8 of 30 Providers Reviewed ([A-06-19-02001](#)), December 2021

Louisiana's monitoring process did not ensure provider compliance with State requirements for criminal background checks at 8 of the 30 child care provider locations we reviewed. We found that 15 of the 264 individuals requiring a background check did not have 1 or more of the required criminal background checks by the required deadlines.

The providers did not initiate a timely background check request for these 15 individuals. Because the State agency relies on child care providers to initiate the background check process, it was unaware that these individuals were lacking required background checks. As a result, the safety and well-being of children were potentially at risk.

Office of Refugee Resettlement Generally Ensured That Selected Care Provider Facilities for Its Unaccompanied Children Program Complied With Federal Emergency Preparedness Requirements (A-04-20-02025), February 2022

The Office of Refugee Resettlement (ORR) ensured that the 10 selected facilities generally complied with Federal requirements in preparing for and responding to emergency events. Each of the 10 facilities complied with most Federal emergency preparedness requirements, such as having written safety plans that addressed evacuations during emergency events. However, none of the selected facilities complied with the Federal requirement to maintain a complete list of emergency contacts to notify when a child's location changes due to an emergency evacuation. Without a complete emergency contact list, and because ORR's monitoring did not identify this noncompliance with a Federal requirement, facilities were at risk of failing to fully protect children's interests in the event of a future emergency.

ACF neither agreed nor disagreed with our recommendation that ORR issue guidance to ORR facilities regarding the requirement to include all relevant ORR and Department of Homeland Security contacts in their emergency contact lists.

Substance Abuse and Mental Health Services Administration

SAMHSA's Oversight Generally Ensured That the Commission on Accreditation of Rehabilitation Facilities Verified That Opioid Treatment Programs Met Federal Opioid Treatment Standards (A-09-20-01002), October 2021

SAMHSA's oversight generally ensured that the Commission on Accreditation of Rehabilitation Facilities (CARF) verified that opioid treatment programs (OTPs) met Federal opioid treatment standards. As part of its oversight activities, SAMHSA: (1) reviewed CARF's renewal application, which included CARF's policies and procedures and accreditation elements; (2) inspected a selected sample of OTPs that CARF accredited and surveyed; and (3) reviewed accreditation reports submitted by CARF. In addition, SAMHSA's oversight ensured that CARF's survey teams met Federal requirements. Specifically, SAMHSA's review of CARF's renewal application included a review of CARF's policies and procedures for: (1) hiring surveyors with required education and experience, (2) training provided to surveyors, (3) selecting surveyors for each survey, and (4) avoiding conflicts of interest.

SAMHSA could improve its oversight to ensure that CARF's records contain sufficient detail to support each accreditation decision made by CARF. SAMHSA's policies and procedures did not require verification that accreditation bodies' (including CARF's) records contained sufficient detail supporting each accreditation decision. Not reviewing an accreditation body's records to determine whether they contain sufficient detail could make it difficult for SAMHSA to determine whether accreditation decisions are supported and to effectively evaluate the accreditation body's performance.

SAMHSA concurred with our recommendation that it update its policies and procedures to require verification that accreditation bodies maintain records that contain sufficient detail to support each accreditation decision.

Texas Did Not Ensure Documentation Supported That Individuals Met Eligibility Requirements and That Its Annual Report Was Accurate Under Its Projects for Assistance in Transition From Homelessness Program (A-02-21-02001), February 2022

Texas complied with Projects for Assistance in Transition From Homelessness (PATH) program requirements related to certain program costs and non-Federal contributions. However, it did not always comply with PATH program requirements when determining consumers' eligibility and reporting the number of consumers enrolled in its PATH program. In addition, Texas overstated the number of consumers enrolled in its PATH program in its Annual PATH Reports.

These deficiencies occurred because Texas lacked adequate oversight to ensure that PATH providers maintained sufficient documentation to support that consumers met eligibility requirements to enroll in the PATH program. In addition, Texas did not ensure that PATH providers reported accurate enrollment data for the State agency's annual PATH reports to SAMHSA. On the basis of our sample results, we estimated that 1,001 consumers (10 percent) enrolled in Texas' PATH program were ineligible to enroll in the Texas PATH program.

Texas did not indicate concurrence or nonconcurrence with our recommendations that it: (1) expand the scope of its site visits of PATH providers to include reviews of consumers' case files maintained by PATH providers to strengthen its current risk assessment process and ensure that providers only enroll eligible individuals into the PATH program and (2) work with relevant parties to provide guidance and training to PATH providers to ensure that its Annual PATH Report accurately represents the number of consumers served by its PATH program.

Legal and Investigative Activities Related to Public Health and Human Service Agencies

Health Education Assistance Loan Program Exclusions

OIG excludes from Federal health care programs individuals who have defaulted on Health Education Assistance Loan (HEAL) loans. Under the HEAL program, which stopped making loans in 1998, HRSA guaranteed commercial loans to students seeking education in health-related fields. The students can defer repayment of the loans until after they graduate and begin to earn income. Although HHS's Program Support Center (PSC) takes steps to ensure repayment, some loan recipients do not resolve their debt. After PSC has exhausted efforts to secure repayment of a debt, it declares an individual in default.

The Social Security Act permits that thereafter, such individuals may not receive reimbursement under Medicare, Medicaid, and all other Federal health care programs for nonpayment of the loans.

Currently, there is a moratorium on collection activities. Accordingly, PSC is not referring any individuals in default at this time. Therefore, OIG has no figures to report for this semiannual reporting period.

Child Support Enforcement Activities

OIG Investigations

OIG investigates noncustodial parents who violate 18 U.S.C. § 228 by failing to pay court-ordered child support. OIG works with ACF's Office of Child Support Enforcement; DOJ; U.S. Attorneys' Offices; the U.S. Marshals Service; and Federal, State, and local partners to address egregious child support enforcement cases with appropriate law enforcement and prosecutorial action. During this semiannual reporting period, OIG investigations of child support enforcement cases nationwide resulted in 1 criminal action and court-ordered restitution and settlements of \$79,079.

The following case example involves child support enforcement:

South Dakota—On December 3, 2021, Jacob A. Tate was sentenced to 5 years of probation, ordered to pay \$78,979.14 in restitution to the South Dakota Department of Social Services, Office of Child Support Enforcement, and a special assessment to the Federal Crime Victims Fund in the amount of \$100. The conviction stemmed from Tate's failure to pay child support from on or about October 1, 2012, through June 6, 2018. Tate has five children who live in South Dakota. Tate knew that a support order had been issued against him to pay child support, but he willfully did not make payments toward the child support.

Engaging the Public in Capturing Deadbeat Parents

Because of the success of OIG's Most Wanted Fugitives website, OIG launched its Most Wanted Deadbeat Parents website. The site identifies parents who fail to pay court-ordered child support for their children and thereby put an unnecessary strain on the custodial parents and the children as well as on agencies that enforce these matters. The site, which is updated frequently, includes information on OIG's role in pursuing parents who fail to pay court-ordered child support. OIG's Most Wanted Deadbeat Parents website can be found at <https://oig.hhs.gov/fraud/child-support-enforcement/index.asp>.

Other HHS-Related Reviews and Investigative Activities

General Departmental

U.S. Department of Health and Human Services Met the Requirements of the Digital Accountability and Transparency Act of 2014, With Areas That Require Improvement (A-17-21-54000), October 2021

Our performance audit determined that HHS implemented and used Governmentwide financial data standards and complied with the reporting requirements of the Digital Accountability and Transparency Act of 2014 (DATA Act) as stipulated by the Office of Management and Budget (OMB) and Treasury. HHS's overall data quality earned a rating of Excellent based on the areas we tested, indicating that HHS's data were generally reliable. Although HHS met the reporting requirements, our performance audit determined that:

- Although progress was noted from the FY 2020 DATA Act audit and compensating controls were identified, we continue to recommend that management address certain control deficiencies identified within HHS information technology systems that house the source data utilized as part of the reporting of the DATA Act.
- Ernst & Young identified the following: (1) 21 accuracy exceptions for data element 26, the period of performance start date; (2) 10 accuracy exceptions for data element 27, the period of performance end date; and (3) 5 accuracy exceptions for data element 28, the period of performance potential end date. In the 36 period of performance exceptions, the information in Files D1/D2 did not agree with the supporting documentation provided.

We recommend that HHS focus on refreshing the OpDivs' understanding of Departmental guidance and identifying those areas for which OpDiv training would be developed to prevent and detect future accuracy issues related to the performance dates.

The Office of Intergovernmental and External Affairs Needs To Improve Internal Controls Over Its Travel Card Program (A-03-19-00501), November 2021

During our audit period, IEA's travel card program did not always comply with Federal requirements. Specifically, 58 of the 114 travel transactions selected for review did not comply. IEA also did not have signed HHS Traveler Agreements for 17 of the 40 employees who had travel card activity during FY 2018. Of these 17 cardholders, 2 did not complete the required travel card training course.

These deficiencies occurred because IEA had a high staff turnover rate and IEA's internal controls were not adequate to ensure that staff, approving officials, and travel card Program Coordinators understood and executed their responsibilities.

For the FY 2017 transactions that we reviewed, IEA incurred \$7,657 in invitational travel expenditures that may have constituted misuse. (Invitational travel allows individuals not employed by the Federal Government or appointed as consultants or experts to confer on Government business.) In addition, on the basis of our sample results, we estimate that in FY 2018, IEA and its employees may have incurred \$50,046 in travel expenditures that constituted misuse or that were otherwise unallowable.

We made several procedural recommendations, including that IEA develop and distribute to staff a quick reference document that includes key staff responsibilities and requirements to ensure that travel card transactions comply with the Federal Travel Regulation and the HHS Travel Policy Manual. We also recommend that IEA establish an oversight program for travel transactions. The detailed recommendations are in the report. IEA did not indicate concurrence or nonconcurrence with our recommendations.

[Financial Statement Audit of the Department of Health and Human Services for Fiscal Year 2021 \(A-17-21-00001\), November 2021](#)

Based on its audit, Ernst & Young found that the FY 2021 HHS consolidated balance sheets and the related consolidated statements of net cost and changes in net position and combined statements of budgetary resources were presented fairly, in all material respects, in conformity with U.S. generally accepted accounting principles. Ernst & Young was unable to obtain sufficient audit evidence for the amounts presented in the statements of social insurance as of January 1, 2021, 2020, 2019, 2018, and 2017, and the related statements of changes in social insurance amounts for the periods ended January 1, 2021, and 2020. As a result, Ernst & Young was not able to, and did not, express an opinion on the financial condition of the HHS social insurance program and related changes in the social insurance program for the specified periods.

Ernst & Young also noted two matters involving internal controls with respect to financial reporting. Under the standards established by the American Institute of Certified Public Accountants and *Government Auditing Standards*, issued by the Comptroller General of the United States, Ernst & Young did not identify any deficiencies in internal control that it considered a material weakness. Ernst & Young noted improvements over internal controls but continued to identify two significant deficiencies related to HHS's Financial Information Systems and HHS's Financial Reporting Systems, Analyses, and Oversight. Ernst & Young also reported that HHS did not comply with the Payment Integrity Information Act (P.L. No. 116-117), identified potential violations of the Anti-Deficiency Act (P.L. No. 101-508), and determined that HHS did not adjudicate Medicare appeals within the time frames requirements by the Social Security Act (P.L. No. 74-271).

The Assistant Secretary for Administration Awarded and Managed Five Sole Source Contracts for COVID-19 Testing in Accordance With Federal and Contract Requirements (A-05-21-00014), January 2022

The Assistant Secretary for Administration (ASA) awarded and managed five sole source COVID-19 testing contracts, totaling \$1.8 billion, in accordance with Federal regulations and contract requirements. Specifically, ASA complied with sole source justification requirements when awarding the contracts and set reasonable payment rates for COVID-19 tests in accordance with Federal regulations. ASA appropriately managed the contracts by establishing and maintaining ongoing communications with contractors, by verifying that laboratory result numbers matched the number of tests administered, and by reviewing invoices to ensure payment rates were in accordance with the contract terms and conditions. This report contains no recommendations.

Drug Control Attestation Reports

Federal law and the ONDCP Circular *National Drug Control Program Agency Compliance Reviews*, dated September 9, 2021 (ONDCP Compliance Reviews Circular), require OIG to conduct reviews of OpDivs' drug control activities. During this reporting period, OIG conducted two such audits, which are summarized below.

Independent Attestation Review: Centers for Medicare & Medicaid Services Fiscal Year 2021 Detailed Accounting Submission and Budget Formulation Compliance Report for National Drug Control Activities, and Accompanying Required Assertions (A-03-22-00351), January 2022

This report provides the results of our review of the CMS Office of National Drug Control Policy (ONDCP) Detailed Accounting Report, which includes the table of Drug Control Obligations, related disclosures, and management's assertions for the fiscal year ended September 30, 2021. We also reviewed the Budget Formulation Compliance Report, which includes budget formulation information for the fiscal year ending September 30, 2023, and the Chief Financial Officer's or accountable senior executive's assertions relating to the budget formulation information.

Based on our review, we are not aware of any other material modifications that should be made to CMS's Detailed Accounting Report for FY 2021 and CMS's Budget Formulation Compliance Report for FY 2023 for them to be in accordance with the ONDCP Compliance Reviews Circular.

Independent Attestation Report: Food and Drug Administration Budget Formulation Compliance Report and Detailed Accounting Submission for Fiscal Year 2021 National Drug Control Activities, and Accompanying Required Assertions (A-03-22-00352), January 2022

This report provides the results of our review of the FDA ONDCP Budget Formulation Compliance Report, which includes budget formulation information for the fiscal year ending September 30, 2023, and the Chief Financial Officer's or accountable senior executive's assertions relating to the budget formulation information.

We also received FDA’s ONDCP Detailed Accounting Report and management’s assertions for the fiscal year ended September 30, 2021. FDA did not provide this report in sufficient time for OIG to review and authenticate the report. Accordingly, we do not express a conclusion about the reliability of management’s assertions.

Based on our review, FDA did not conform in all material respects to the ONDCP Compliance Reviews Circular. Specifically, FDA did not provide a timely ONDCP Detailed Accounting Report for the fiscal year ended September 30, 2021. Except for this deficiency, we are not aware of any material modifications that FDA should make to be in accordance with the ONDCP Compliance Reviews Circular.

Grants and Contracts

HHS is the largest grant-making organization and one of the largest contracting agencies in the Federal Government. In FY 2019, HHS awarded more than \$531 billion in grants and more than \$39 billion in contracts across all program areas. OIG’s direct annual discretionary appropriation funding is used to conduct program integrity and enforcement activities with regard to the more than 100 public health and human services programs carried out by more than 80,00 employees worldwide. The size and scope of departmental awards make their operating effectiveness crucial to the success of programs designed to improve the health and well-being of the public.

Grant Fraud Investigations

The following case example relates to misuse of grant funds:

Wisconsin—On October 29, 2021, Fredericka DeCoteau was sentenced to 2 years in prison and Edith Schmuck was sentenced to 1 year and 1 day in prison for theft of Federal program funds. DeCoteau and Schmuck were also ordered to jointly pay restitution of \$777,283. DeCoteau and Schmuck worked at Ain Dah Ing (ADI) which has operated as a nonprofit halfway house in Spooner, Wisconsin, since 1971. DeCoteau worked as the Executive Director at ADI from 2002 to 2017. Schmuck worked as the bookkeeper from 1990 to 2017. Both DeCoteau and Schmuck pleaded guilty to embezzling a total of \$777,283 from ADI by paying themselves unauthorized bonuses via payroll checks that were signed using a rubber signature stamp of the ADI Treasurer. The embezzlement lasted from 2007 to 2017.

Recovery Act Retaliation Complaint Investigations

The Recovery Act, § 1553, prohibits non-Federal employers that have received Recovery Act funding from retaliating against employees who disclose evidence of mismanagement of Recovery Act funds or any violation of law related to Recovery Act funds. OIGs are required to include in

their Semiannual Report the retaliation complaint investigations that they decided not to conduct or continue during the reporting period. During this semiannual reporting period, OIG did not close, decline, or give extensions on Recovery Act Retaliation Complaint investigations of whistleblower retaliation.

Contract Audits

Pursuant to the National Defense Authorization Act for FY 2008, § 845, OIGs appointed under the Inspector General Act of 1978 are required to submit information on final completed contract audit reports issued during the period to the contracting activity as part of their semiannual report, pursuant to section 5 of the Inspector General Act. This information must contain significant audit findings. OIG issued no final reports meeting § 845 criteria during this semiannual reporting period.

OIG Reviews of Non-Federal Audits

OIG reviews audits conducted by non-Federal auditors of entities receiving Federal awards. During this semiannual reporting period, OIG's National External Audit Review Center reviewed 157 reports covering \$579.1 billion in audited costs. Federal dollars covered by these audits totaled \$203.8 billion, of which about \$90.3 billion were HHS funds.

Uniform guidance at 2 CFR 200 Subpart F establishes audit requirements for State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards. Under the uniform guidance, covered entities must conduct annual organizationwide "single audits" of all Federal money they receive. These audits are conducted by non-Federal auditors, such as public accounting firms and State auditors. OIG reviews the quality of these audits and assesses the adequacy of the entities' management of Federal funds.

OIG's oversight of non-Federal audit activity informs Federal managers about the soundness of management of Federal programs and identifies any significant areas of internal control weakness, noncompliance, and questioned costs for resolution or followup. We identify entities for high-risk monitoring, alert program officials to any trends that could indicate problems in HHS programs, and profile non-Federal audit findings of a particular program or activity over time to identify systemic problems. We also provide training and technical assistance to grantees and members of the auditing profession. OIG maintains a process to assess the quality of the non-Federal reports received and the audit work that supports the selected reports.

OIG's reports on non-Federal audits reviewed during this reporting period are categorized in the following table.

Non-Federal Audits, October 1, 2021, Through March 31, 2022

Not requiring changes or having minor changes	117
Requiring major changes	6
Having significant technical inadequacies	34
Total Number of Non-Federal Audits	157

Other Reporting Requirements and Reviews

Legislative and Regulatory Reviews

Pursuant to the Inspector General Act, § 4(a)(2), OIG is required to review existing and proposed legislation and regulations relating to HHS’s programs and operations and make recommendations concerning their impact on economy and efficiency or the prevention and detection of fraud and abuse. Most audits and other reviews that we conduct are designed to test compliance with and/or assess the administration and oversight of existing laws and regulations. Our reports of such reviews describe findings, which include questioned costs, inefficiencies, vulnerabilities to fraud, inconsistencies, errors in application, or weaknesses in oversight or supporting systems. Our corresponding recommendations tell HHS and its OpDivs or staff divisions (StaffDivs) what administrative, regulatory, or legislative actions we believe are needed to effectively respond to the findings. Our regularly published core publications reflect the relationship between our work and laws and regulations.

- This report, like our previous Semiannual Reports to Congress, describes findings and recommendations from recently completed reviews, many of which focus on existing laws and regulations.
- Our *Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs: OIG’s Top Recommendations* describes priority findings and recommendations from past periods that remain to be implemented.
- Our *Work Plan* provides citations to laws and regulations that are the subject of ongoing or future reviews.

We also review proposed legislation and regulations related to HHS programs and operations. In addition, we provide independent, objective technical assistance on a bipartisan, bicameral basis to congressional committees and members who request it.

Appendix A: Questioned Costs and Funds To Be Put to Better Use

The following tables summarize OIG’s monetary recommendations and HHS responses to them. This information is provided in accordance with the Inspector General Act, §§ 5(a)(8) and (a)(9) (5 U.S.C. App. §§ 5(a)(8) and (a)(9)), and the Supplemental Appropriations and Rescissions Act of 1980.

Audit Reports With Questioned Costs

As defined by the Inspector General Act, the term “questioned cost” means a cost that is questioned by OIG because of: (1) an alleged violation of a provision of law, regulation, contract, grant, cooperative agreement, or other agreement or document governing the expenditure of funds; (2) a cost that is not supported by adequate documentation at the time of the audit; or (3) the expenditure of funds for the intended purpose is unnecessary or unreasonable. Questioned costs that HHS program officials have, in a management decision, sustained or agreed, should not be charged to the Government are disallowed costs. Superscripts indicate end notes that follow the tables below.

Table 1: Audit Reports With Questioned Costs

Description	Number of Reports	Dollar Value Questioned	Dollar Value Unsupported
Section 1			
Reports for which no management decisions had been made by the beginning of the reporting period ¹	70	\$2,578,509,000	\$848,834,000
Issued during the reporting period	15	\$1,560,533,000	\$1,060,659,000
Total Section 1	85	\$4,139,042,000	\$1,909,493,000
Section 2			
Reports for which management decisions were made during the reporting period ^{2, 3}			
Disallowed costs	37	*\$1,136,191,000	\$34,849,000
Costs not disallowed	12	\$1,320,759,000	\$813,862,000
Total Section 2	49	\$2,456,950,000	\$848,711,000
* Audit receivables (expected recoveries)			
Section 3			
Reports for which no management decisions had been made by the end of the reporting period (Section 1 minus Section 2)	36	\$1,682,092,000	\$1,060,782,000
Section 4			
Reports for which no management decisions were made within 6 months of issuance ⁴	22	\$519,290,000	\$123,000

Table 1 End Notes

¹ The opening balance was adjusted upward by \$493.4 million because of a reevaluation of previously issued recommendations.

² Revisions to previously reported management decisions:

- A-09-02-00054, *Audit of State of California DSH Program for FY 1998*. CMS subsequent review of the State plan determined that disallowed cost should be reduced by \$33,319,000.
- A-05-09-00021, *Review of Indiana's Reporting Fund Recoveries for Federal and State Programs on the CMS-64*. CMS subsequent review of supporting documentation determined that overpayments totaled \$11,758,489, reducing disallowed cost by \$27,100,000.
- A-02-10-01042, *New Jersey Claimed Excessive Medicaid Disproportionate Share Hospital Payments to Four Hospitals*. CMS subsequent review of the State plan determined that disallowed cost should be reduced by \$22,005,000.
- A-09-01-00098, *Audit of Kern Medical Center Disproportionate Share Hospital Payments for FY 1998*. CMS's subsequent review of State Plan language determined that disallowed cost should be reduced by \$14,166,000.
- Not detailed are reductions to previously disallowed management decisions totaling \$14.2 million.

³ Included are management decisions to disallow \$41,000 in questioned costs that were identified by non-Federal auditors in audits of State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards conducted in accordance with OMB Circular A-133. OIG is currently ensuring that work performed by these non-Federal auditors complies with Federal audit standards; accordingly, OIG tracks, resolves, and reports on recommendations in these audits.

⁴ Because of administrative delays, some of which were beyond management control, resolution of the following 22 audits were not completed within 6 months of issuance of the reports; however, agency management has informed us that the agency is working to resolve the outstanding recommendations before the end of the next semiannual reporting period.

Audits Not Completed Within 6 Months of Issuance

Audit CIN	Audit Title
A-07-16-01165	<i>Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc. (Contract H1036), Submitted to CMS, APR 2021, \$197,720,651</i>
A-02-14-02017	<i>New York Misallocated Costs to Establishment Grants for a Health Insurance Marketplace, NOV 2016, \$149,654,512</i>
A-01-14-02503	<i>Maryland Misallocated Millions to Establishment Grants for a Health Insurance Marketplace, MAR 2015, \$28,400,000</i>

A-04-14-07050	<i>Kentucky Misallocated Millions to Establishment Grants for a Health Insurance Marketplace, FEB 2017, \$25,530,429</i>
A-07-18-04111	<i>Mississippi Needs To Improve Oversight of Its Child Care Payment Program, APR 2020, \$22,284,900</i>
A-02-15-02008	<i>New York Did Not Comply With Federal Grant Requirements for Allocating and Claiming Marketplace Contract Costs, DEC 2017, \$20,415,344</i>
A-07-15-04226	<i>Not All of Missouri's Child Care Subsidy Program Payments Complied With Federal and State Requirements, NOV 2017, \$19,076,167</i>
A-02-18-01028	<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS, FEB 2021, \$14,534,375</i>
A-06-17-07004	<i>Southwest Key Programs Failed To Protect Federal Funds Intended for the Care and Placement of Unaccompanied Alien Children, SEP 2020, \$13,130,848</i>
A-01-15-02500	<i>Vermont Did Not Properly Allocate Millions to Establishment Grants for a Health Insurance Marketplace, SEP 2016, \$11,243,006</i>
A-07-19-05117	<i>Medicare Made Millions of Dollars in Overpayments for End-Stage Renal Disease Monthly Capitation Payments, MAY 2021, \$3,963,618</i>
A-07-19-01187	<i>Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS, MAY 2021, \$3,468,954</i>
A-02-16-02013	<i>The Children's Village Inc., an Administration for Children and Families Grantee, Did Not Always Comply With Applicable Federal and State Policies and Requirements, APR 2019, \$2,623,785</i>
A-07-17-02808	<i>The Colorado Health Insurance Marketplace's Financial Management System Did Not Always Comply With Federal Requirements, JUL 2018, \$2,567,604</i>
A-07-11-06013	<i>The University of Colorado Denver Did Not Always Claim Selected Costs Charged Directly to Department of Health and Human Services Awards in Accordance With Federal Regulations, JUN 2013, \$1,419,524</i>
A-05-14-00045	<i>The Minnesota Marketplace Misallocated Federal Funds and Claimed Unallowable Costs, NOV 2016, \$1,279,677</i>
A-02-18-02011	<i>Gateway Community Action Partnership Claimed Unallowable Costs, Did Not Comply With Federal Regulations on Construction and Major Renovations, and Did Not Accurately Account for Grant Funds, MAY 2021, \$932,907</i>
A-09-14-01007	<i>Nevada Misallocated Costs for Establishing a Health Insurance Marketplace to Its Establishment Grants, FEB 2016, \$893,464</i>
A-03-19-00002	<i>Audit of Medicare Part D Pharmacy Fees: Group Health Cooperative, Inc., JUL 2021, \$122,583</i>
A-03-16-00250	<i>Youth for Tomorrow—New Life Center, Inc., an Administration for Children and Families Grantee, Did Not Comply With All Applicable Federal Policies and Requirements, SEP 2020, \$16,851</i>
A-04-18-02010	<i>Florida's Refugee Medical Assistance Payments Were Generally Allowable, JAN 2020, \$8,772</i>
A-05-18-00015	<i>The University of Minnesota Complied With Federal Requirements To Perform Risk Assessments and Monitor Subrecipients, NOV 2019, \$1,924</i>

TOTAL CINS: 22
TOTAL AMOUNT: \$519,290,000

Audit Reports With Funds Recommended To Be Put to Better Use

The phrase “recommendations that funds be put to better use” means that funds could be used more efficiently if management took action to implement an OIG recommendation through reductions in outlays, de-obligation of funds, and/or avoidance of unnecessary expenditures. Table 2 reports HHS program officials’ decisions to take action on these audit recommendations.

Table 2: Audit Reports With Funds Put to Better Use

Description	Number of Reports	Dollar Value
Section 1		
Reports for which no management decisions had been made by the beginning of the reporting period	8	\$16,271,900,000
Reports issued during the reporting period	4	\$1,157,914,000
Total Section 1	12	\$17,429,814,000
Section 2		
Reports for which management decisions were made during the reporting period		
Value of recommendations agreed to by management		
Based on proposed management action	2	\$162,095,000
Based on proposed legislative action	0	\$0
Value of recommendations not agreed to by management	1	\$20,351,000
Total Section 2	3	\$182,446,000
Section 3		
Reports for which no management decisions had been made by the end of the reporting period ¹ (Sec. 1–Sec. 2)	9	\$17,247,368,000

Table 2 End Notes

¹ Because of administrative delays, some of which were beyond management control, five of the nine audits open at end of the period were not resolved within 6 months of issuance of reports. OIG is working with management to reach resolution on these recommendations before the end of the next semiannual reporting period.

Audits Open at End of the Period

Audit CIN	Audit Title
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A-05-12-00020	<i>Medicare and Beneficiaries Could Save Billions If CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates, APR 2014, \$15,000,000,000</i>
A-03-17-00010	<i>Hospitals Overbilled Medicare \$1 Billion By Incorrectly Assigning Severe Malnutrition Diagnosis Codes To Inpatient Hospital Claims, JUL 2020, \$1,024,623,449</i>
A-03-13-03002	<i>HHS Did Not Identify and Report Antideficiency Act Violations, MAY 2017, \$49,445,025</i>
A-07-17-01176	<i>Incorrect Acute Stroke Diagnosis Codes Submitted by Traditional Medicare Providers Resulted in Millions of Dollars in Increased Payments to Medicare Advantage Organizations, SEP 2020, \$14,417,533</i>
A-09-18-03030	<i>Medicare Incorrectly Paid Providers for Emergency Ambulance Transports From Hospitals to Skilled Nursing Facilities, SEP 2019, \$968,718</i>
TOTAL CINS: 5	
TOTAL AMOUNT: \$16,089,455,000	

Appendix B: Peer Review Results

The Inspector General Act of 1978, as amended, requires OIGs to report the results of peer reviews of their operations conducted by other OIGs, the date of the last peer review, outstanding recommendations from peer reviews, and peer reviews conducted by an OIG of other OIGs in the semiannual reporting period. Peer reviews are conducted by member organizations of the Council of the Inspectors General on Integrity and Efficiency (CIGIE).

Office of Audit Services

During this semiannual reporting period, no peer reviews involving OAS were completed. Information concerning OAS's peer review activity during prior reporting periods are listed below.

OAS	Date	Reviewing Office	Office Reviewed
	September 2021	HHS-OIG, OAS	U.S. Department of the Treasury (Treasury) OIG

The system of quality control for the audit organization of Treasury OIG in effect for the year ending March 31, 2021, has been suitably designed and complied with to provide Treasury OIG with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Federal audit organizations can receive a rating of Pass, Pass With Deficiencies, or Fail. Treasury OIG received a peer review rating of Pass.

OAS	Date	Reviewing Office	Office Reviewed
	March 2021	General Services Administration OIG	HHS-OIG, OAS

The system of quality control for the audit organization of HHS-OIG in effect for the year ending September 30, 2020, has been suitably designed and complied with to provide HHS-OIG with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Federal audit organizations can receive a rating of Pass, Pass With Deficiencies, or Fail. HHS-OIG received a peer review rating of Pass.

Office of Investigations

During this semiannual reporting period, no peer reviews involving OI were completed. Listed below is information concerning OI's peer review activities during prior reporting periods.

OI	Date	Reviewing Office	Office Reviewed
	October 2018	SSA OIG	HHS-OIG, OI

The system of internal safeguards and management procedures for the investigative function of HHS-OIG in effect for the year ending September 30, 2018, was in full compliance with the quality standards established by CIGIE and the Attorney General’s guidelines.

OI	Date	Reviewing Office	Office Reviewed
	August 2017	HHS-OIG, OI	U.S. Postal Service OIG

The system of internal safeguards and management procedures for the investigative function of the U.S. Postal Service OIG in effect for the year ending September 30, 2015, was in full compliance with the quality standards established by CIGIE and the Attorney General’s guidelines.

Office of Evaluation and Inspections

During this semiannual reporting period, no peer reviews involving OEI were completed. Information concerning OEI’s peer review activity during a prior reporting period is also listed below.

OEI	Date	Reviewing Office	Office Reviewed
	November 2020	Department of State, OIG	HHS-OIG, OEI

A CIGIE external peer Review Team assessed the extent to which HHS-OIG, OEI met seven *Quality Standards for Inspection and Evaluation* (Blue Book) standards. The seven covered standards are: Quality Control, Planning, Data Collections and Analysis, Evidence, Records Maintenance, Reporting, and Followup. The assessment included a review of OEI’s internal policies and procedures documented in the OEI procedures manual. It also included a review of four reports issued between June 1, 2019, and June 1, 2020, to determine whether the reports complied with the seven standards and internal policies and procedures. The Review Team determined that OEI’s policies and procedures generally met the seven standards. The four reports reviewed generally met the standards and complied with OEI’s internal policies and procedures.

OEI	Date	Reviewing Office	Office Reviewed
	June 2020	HHS-OIG, OEI	Department of Veterans Affairs (VA) OIG

The Veterans Affairs, Office of Inspector General, Office of Audits and Evaluations and Office of Healthcare Inspections (collectively VA-OIG) policies and procedures addressed the Quality Standards for Inspection and Evaluation of CIGIE. The seven covered standards are: Quality Control, Planning, Data Collections and Analysis, Evidence, Records Maintenance, Reporting, and

Followup. In addition, each of the four reviewed VA-OIG reports complied with those standards and the VA-OIG’s internal policies and procedures. As a result of our findings, there are no recommendations associated with this external peer review. The report also noted a VA-OIG beneficial practice of using specialized staff to conduct independent referencing reviews of its reports to achieve greater consistency in its quality assurance processes.

OEI	Reviewing Office	Office Reviewed
September 2019	HHS-OIG, OEI	U.S. Department of Interior (DOI) OIG

The DOI OIG Inspection and Evaluation component’s policies and procedures mostly met CIGIE’s Blue Book standards. We reviewed four reports: two fully met the applicable Blue Book standards and two did not. DOI OIG concurred with recommendations related to Evidence, Planning, and Data Collection and Analysis but did not concur with recommendations related to Reporting.

OEI	Date	Reviewing Office	Office Reviewed
	September 2018	HHS-OIG, OEI	U.S. Department of Defense (DoD) OIG

The DoD OIG Inspection and Evaluation components’ policies and procedures generally met CIGIE’s Blue Book standards. In addition, the 10 reports reviewed generally met the applicable Blue Book standards. Onsite visits for these reviews were conducted from October 2, 2017, through November 17, 2017.

Appendix C: Summary of Sanction Authorities

The Inspector General Act of 1978, as amended, specifies requirements for semiannual reports to be made to the HHS Secretary for transmittal to Congress. A selection of other authorities appears below.

Program Exclusions

The Social Security Act, § 1128 (42 U.S.C. § 1320a-7), provides several grounds for excluding individuals and entities from participation in Medicare, Medicaid, and other Federal health care programs. Exclusions are required (mandatory exclusion) for individuals and entities convicted of the following types of criminal offenses: (1) Medicare or Medicaid fraud; (2) patient abuse or neglect; (3) felonies for other health care fraud; and (4) felonies for illegal manufacture, distribution, prescription, or dispensing of controlled substances.

OIG is authorized (permissive exclusion) to exclude individuals and entities on several other grounds, including misdemeanors for other health care fraud (other than Medicare or Medicaid); suspension or revocation of a license to provide health care for reasons bearing on professional competence, professional performance or financial integrity; provision of unnecessary or substandard services; submission of false or fraudulent claims to a Federal health care program; or engaging in unlawful kickback arrangements.

The ACA added another basis for imposing a permissive exclusion, that is, knowingly making, or causing to be made, any false statements or omissions in any application, bid, or contract to participate as a provider in a Federal health care program, including managed care programs under Medicare and Medicaid, as well as Medicare's prescription drug program.

Providers subject to exclusion are granted due process rights. These include a hearing before an administrative law judge and appeals to the HHS Departmental Appeals Board and Federal district and appellate courts regarding the basis for and the length of the exclusion.

Civil Monetary Penalties Law

The CMPL, found at Section 1128A of the Social Security Act (42 U.S.C. § 1320a-7a), authorizes penalties, assessments, and exclusion from participation in Federal health care programs for engaging in certain activities. For example, a person who submits, or causes to be submitted, to a Federal health care program a claim for items and services that the person knows, or should know, is false or fraudulent is subject to a penalty of up to \$20,000 for each item or service falsely or fraudulently claimed, an assessment of up to three times the amount falsely or fraudulently claimed, and exclusion.

For the purposes of the CMPL, "should know" is defined to mean that the person acted in reckless disregard or deliberate ignorance of the truth or falsity of the claim. The law and its implementing

regulations also authorize actions for a variety of other violations, including submission of claims for items or services furnished by an excluded person; requests for payment in violation of an assignment agreement; and payment or receipt of remuneration in violation of the anti-kickback statute (42 U.S.C. § 1320a-7b(b)).

The ACA added more grounds for imposing CMPs. These include, among other types of conduct, knowingly making, or causing to be made, any false statements or omissions in any application, bid, or contract to participate as a provider in a Federal health care program (including Medicare and Medicaid managed care programs and Medicare Part D); the ACA authorizes a penalty of up to \$100,000 for each false statement (42 U.S.C. 1320a-7a(9)).

The 21st Century Cures Act (enacted on December 13, 2016) added more grounds for imposing CMPs, assessments, and exclusion from Federal health care programs for fraudulent conduct in an HHS grant, contract, or other agreement. OIG may assess CMPs of up to \$10,000 per claim and assessments of up to three times the amount claimed for knowingly presenting a false or fraudulent claim. In addition, OIG may impose a penalty of up to \$50,000 and assessments of up to three times the amount of funds at issue: (1) for each instance of knowingly making a false statement in a document required to be submitted to receive funds under an HHS contract, grant, or other agreement; (2) for knowingly making or using a false record or statement that is material to a false or fraudulent claim; and (3) for knowingly making or using a false record or statement material to an obligation to pay or transmit funds or property owed to HHS. OIG may impose a penalty of up to \$10,000 per day and assessments of up to three times the amount at issue for knowingly concealing, or knowingly and improperly avoiding or decreasing, an obligation owed to HHS with respect to an HHS grant, contract, or other agreement. Finally, HHS-OIG may impose a penalty of up to \$15,000 per day for failing to grant timely access to OIG upon reasonable request for audits or to carry out other statutory functions in matters involving an HHS grant, contract, or other agreement.

Patient Dumping

The Social Security Act, §1867 (42 U.S.C. § 1395dd), provides that when an individual goes to the ER of a Medicare-participating hospital, the hospital must provide an appropriate medical screening examination to determine whether that individual has an emergency medical condition. If an individual has such a condition, the hospital must provide either treatment to stabilize the condition or an appropriate transfer to another medical facility.

If a transfer is ordered, the transferring hospital must provide stabilizing treatment to minimize the risks of transfer and must ensure that the receiving hospital agrees to the transfer and has available space and qualified personnel to treat the individual. In addition, the transferring hospital must effect the transfer through qualified personnel and transportation equipment. Further, a participating hospital with specialized capabilities or facilities may not refuse to accept an appropriate transfer of an individual who needs services if the hospital has the capacity to treat the individual.

OIG is authorized to collect CMPs of up to \$53,484 against small hospitals (fewer than 100 beds) and up to \$106,965 against larger hospitals (100 beds or more) for each instance in which the hospital negligently violated any of the section 1867 requirements. In addition, OIG may collect a penalty of up to \$106,965 from a responsible physician for each negligent violation of any of the section 1867 requirements and, in some circumstances, may exclude a responsible physician.

Anti-Kickback Statute and Civil False Claims Act Enforcement Authorities

The Anti-Kickback Statute

The Federal anti-kickback statute authorizes penalties against anyone who knowingly and willfully solicits, receives, offers, or pays remuneration, in cash or in kind, to induce or in return for: (1) referring an individual to a person or an entity for the furnishing, or arranging for the furnishing, of any item or service payable under the Federal health care programs; or (2) purchasing, leasing, or ordering, or arranging for or recommending the purchasing, leasing, or ordering, of any good, facility, service, or item payable under the Federal health care programs (Social Security Act, § 1128B(b) (42 U.S.C. § 1320a-7b(b)).

Individuals and entities who engage in unlawful referral or kickback schemes may be subject to criminal penalties under the general criminal anti-kickback statute; a CMP under OIG's authority pursuant to the Social Security Act, § 1127(a)(7) (42 U.S.C. § 1320a-7a); and/or program exclusion under OIG's permissive exclusion authority under the Social Security Act, § 1128(b)(7) (42 U.S.C. § 1320a-7(b)(7)).

The False Claims Act

Under the False Claims Act, as amended by the False Claims Amendments Act of 1986 (31 U.S.C. §§ 3729–3733), a person or an entity is liable for up to treble damages and a penalty between \$11,181 and \$22,363 for each false claim it knowingly submits, or causes to be submitted, to a Federal program. Similarly, a person or an entity is liable under the False Claims Act if it knowingly makes or uses, or causes to be made or used, a false record or statement to have a false claim paid. The False Claims Act defines "knowing" to include the traditional definition and also instances in which the person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information. Under the False Claims Act, no specific intent to defraud is required. Further, the False Claims Act contains a qui tam, or whistleblower, provision that allows a private individual to file a lawsuit on behalf of the United States and entitles that whistleblower to a percentage of any fraud recoveries. The False Claims Act was amended again in 2009 in response to recent Federal court decisions that narrowed the law's applicability. Among other things, these amendments clarify the reach of the False Claims Act to false claims submitted to contractors or grantees of the Federal Government.

Appendix D: Reporting Requirements in the Inspector General Act of 1978

The reporting requirements of the Inspector General Act of 1978, as amended, are listed in the following table along with the location of the required information.

Section	Requirement	Location
Section 4		
(a)(2)	Review of legislation and regulations	“Other HHS-Related Reviews and Investigations” section
Section 5		
(a)(1)	Significant problems, abuses, and deficiencies	Throughout this report
(a)(2)	Recommendations with respect to significant problems, abuses, and deficiencies	Throughout this report
(a)(3)	Prior significant recommendations on which corrective action has not been completed	Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs: Top Unimplemented Recommendations
(a)(4)	Matters referred to prosecutive authorities	“Legal and Investigative Activities Related to the Medicare and Medicaid Programs” section
(a)(5)	Summary of instances in which information requested by OIG was refused	None for this reporting period
(a)(6)	List of audit reports	Throughout this report
(a)(7)	Summary of significant reports	Throughout this report
(a)(8)	Statistical Table 1—Reports With Questioned Costs	Appendix A
(a)(9)	Statistical Table 2—Funds Recommended To Be Put to Better Use	Appendix A
(a)(10)	Summary of previous audit reports without management decisions, in which no establishment comment was returned within 60 days, and in which there are any outstanding unimplemented recommendations	Appendix A
(a)(11)	Description and explanation of revised management decisions	Appendix A

Section	Requirement	Location
(a)(12)	Management decisions with which the Inspector General disagrees	None for this reporting period
(a)(13)	Information required by the Federal Information Security Management Act	“Other HHS-Related Reviews and Investigative Activities” section
(a)(14)-(16)	Results of peer reviews of HHS-OIG conducted by other OIGs or the date of the last peer review, outstanding recommendations from peer reviews, and peer reviews conducted by HHS-OIG of other OIGs	Appendix B
(a)(17)	Investigative statistical tables	Appendix E
(a)(18)	Metrics description for statistical tables	Appendix E
(a)(19)	Investigations on senior Government employees	Appendix E
(a)(20)	Description of whistleblower retaliation instances	Appendix E
(a)(21)	Description of attempts to interfere with OIG independence	Appendix E
(a)(22)	Description of closed and nondisclosed reports and investigations regarding senior Government employees	Appendix E

Other Reporting Requirements

Section	Requirement	Location
845	Significant contract audits required to be reported pursuant to the National Defense Authorization Act for FY 2008 (P.L. No. 110-181), § 845.	“Other HHS-Related Reviews and Investigations” section
205	Pursuant to HIPAA (P.L. No. 104-191), § 205, the Inspector General is required to solicit proposals annually via a <i>Federal Register</i> notice for developing new and modifying existing safe harbors to the anti-kickback statute of the Social Security Act, § 1128(b) and for developing special fraud alerts. The Inspector General is also required to report annually to Congress on the status of the proposals received related to new or modified safe harbors.	Appendix F
1553	Pursuant to the American Recovery and Reinvestment Act of 2009, P.L. No. 111-5, § 1553, OIG reports to Congress the retaliation complaint investigations it decided not to conduct or continue during the period.	“Other HHS-Related Reviews and Investigations” section

Appendix E: Reporting Requirements in the Inspector General Empowerment Act of 2016

The Inspector General Empowerment Act of 2016 establishes new reporting requirements for the Semiannual Reports. These requirements amend portions of § 5 of the Inspector General Act. The requirements are below in italics, followed by OIG’s responses.

Each Inspector General shall, not later than April 30 and October 31 of each year, prepare semiannual reports summarizing the activities of the Office during the immediately preceding 6 month periods ending March 31 and September 30. Such reports shall include, but need not be limited to-

(10) A summary of audit, inspection, and evaluation reports issued before the commencement of the reporting period-

(A) for which no management decision has been made by the end of the reporting period (including the date and title of each such report), an explanation of the reasons such management decision has not been made, and a statement concerning the desired timetable for achieving a management decision on each such report;

For audit and evaluation reports issued from FY 2011 through FY 2021 OIG had a total of 87 reports with overdue final management decisions (FMD) as of the end of this reporting period. The breakdown of those 87 reports by HHS OpDiv is as follows:

OpDiv	Overdue FMDs
ACF	22
ASPR	1
CDC	1
CMS	39
IHS	13
NIH	4
OASH	1
OS	6

OIG is unable to provide reasons and timetables for each of these overdue management decisions, because of the volume and that OIG did not historically track this information.

(B) for which no establishment comment was returned within 60 days of providing the report to the establishment; and

For draft reports that include recommendations, OIG typically requests establishment comments within 30 days. In some instances, OIG grants extensions when requested and appropriate. When OIG does not receive establishment comments or a request for extension within the 30-day timeframe, OIG typically issues the report and notes the lack of establishment comments.

For this semiannual reporting period, OIG had no reports for which no establishment comment was returned within 60 days of providing the report to the establishment.

(C) for which there are any outstanding unimplemented recommendations, including the aggregate potential cost savings of those recommendations.

OIG is actively tracking 1,219 unimplemented open recommendations made in reports issued since FY 2011. Given the volume of recommendations OIG makes each year, the table below reflects summary data by FY:

FY (2011–2022)	Number of Reports with Unimplemented Recommendations	Number of Unimplemented Recommendations	Dollar Value of Aggregate Potential Cost Savings
2011	12	17	\$408,135,515
2012	19	22	\$369,932,148
2013	25	38	\$234,261,321
2014	22	40	\$15,072,080,989
2015	21	34	\$301,645,457
2016	18	36	\$184,156,192
2017	29	72	\$1,089,280,765
2018	41	121	\$566,596,322
2019	62	178	\$731,236,787
2020	82	278	\$2,443,603,271
2021	104	259	\$920,907,432
2022	39	124	\$2,705,635,037
Totals	474	1,219	\$25,027,471,236

OIG annually produces a *Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs: OIG's Top Recommendations*, which constitutes OIG's response to a specific requirement of the Inspector General Act, as amended (§ 5(a)(3)). It identifies significant recommendations with respect to problems, abuses, or deficiencies for which corrective actions have not been completed. It also includes an appendix listing OIG's significant unimplemented recommendations, which represent opportunities to achieve expected impact through cost savings, improvements in program

effectiveness and efficiency, or increasing quality of care and safety of beneficiaries. In OIG’s view, these recommendations would most positively impact HHS programs in terms of cost savings and/or quality improvements and should therefore be prioritized for implementation.

(17) Statistical tables showing-

(A) the total number of investigative reports issued during the reporting period;

(B) the total number of persons referred to the DOJ for criminal prosecution during the reporting period;

(C) the total number of persons referred to State and local prosecuting authorities for criminal prosecution during the reporting period; and

(D) the total number of indictments and criminal information during the reporting period that resulted from any prior referral to prosecuting authorities;

Total number of investigative reports issued during the reporting period, including Management Implication Reports and Investigative Advisories	None
Total number of persons referred ³ to Federal prosecuting authorities for criminal prosecution during the reporting period ⁴	1,214
Total number of persons referred to State and local prosecuting authorities for criminal prosecutions during the reporting period	127
Total number of Federal indictments and criminal information during the reporting period that resulted from any prior referral to prosecuting authorities	323
Total number of State and local indictments and criminal information during the reporting period that resulted from any prior referral to prosecuting authorities	48

(18) A description of the metrics used for developing the data for the statistical tables under paragraph (17);

Regarding (17)(A), OIG considers Investigative Reports as Management Implication Reports and Investigative Advisories. A Management Implication Report identifies systemic weaknesses or vulnerabilities within HHS programs, which are generally identified during the course of an OIG investigation and could lead to fraud, waste, or abuse. It provides recommendations to correct or minimize the problem. Corrective actions may require administrative, procedural, policy, regulatory, or legislative change. When a Management Implication Report is issued to an HHS OpDiv or StaffDiv, it is generally signed by the Inspector General. Investigative Advisories are

similar documents that bring renewed attention to an identified HHS issue and are generally signed by the Deputy Inspector General for Investigations.

Regarding (17)(B) and (C), OIG defines this measure as the term “presentations” to both Federal and State/local prosecuting jurisdictions as the representation of the work we do. For example, when OIG opens an investigation, it evaluates the complaint and decides whether to “present” the matter for prosecution. Generally, if the case has prosecutorial merit, and is accepted for Federal prosecution, OIG works with DOJ as the primary investigative agency, as opposed to referring the matter to DOJ without further involvement on OIG’s part. OIG works with State and local prosecutorial authorities in addition to working with DOJ.

Regarding (17)(D), the table above provides the number of indictments/criminal information during the semiannual reporting period, including sealed indictments/criminal information. However, the information cannot be limited to only those that occurred as a result of a presentation in a previous period. In certain situations, the presentation and charging dates are in the same reporting period.

(19) A report on each investigation conducted by the Office involving a senior Government employee where allegations of misconduct were substantiated, including a detailed description of-

(A) the facts and circumstances of the investigation; and

(B) the status and disposition of the matter, including-

(i) if the matter was referred to the Department of Justice, the date of the referral; and

(ii) if the Department of Justice declined the referral, the date of the declination;

To respond fully to this subparagraph, OIG would need to make a finding of misconduct. However, OIG does not make findings regarding its investigations relating to substantiated allegations of departmental employee misconduct. Our reports relay the facts obtained during the investigations (e.g., parties involved, dates of events) related to any substantiated allegations. At the conclusion of an OIG investigation related to substantiated allegations concerning possible employee misconduct, OIG provides a report to management in the employing agency. The agency management makes determinations of employee misconduct. The disposition of the matter and any resulting administrative actions are taken by the agency.

However, we request from the agency a copy of an SF-50 documenting a personnel action, if one is taken. To the extent that we have information regarding subsequent administrative action, OIG can provide that information. However, because there are sometimes settlement agreements that may impact the final action, OIG may not have a complete record of the disposition of the investigation. Accordingly, such information might be more efficiently and effectively provided directly by the employing agency.

For this section, OIG describes investigations during this reporting period, both criminal and administrative, involving senior Government employees for whom allegations of misconduct were substantiated. The descriptions below include a level of detail appropriate for each investigation,

depending on whether the case details were available in public documents. During this reporting period, OIG investigated 1 senior Government employee for misconduct.

(20) A detailed description of any instance of whistleblower retaliation, including information about the official found to have engaged in retaliation and what, if any, consequences the establishment imposed to hold that official accountable;

A For departmental agencies, OIG conducts investigations and gathers facts related to whistleblower complaints. OIG makes a determination as to whether retaliatory action has been taken and includes these findings in its reports, along with recommendations as to what, if any, corrective action(s) should be taken. Under this system, OIG submitted one report that included findings of retaliation to the HHS Office of the Secretary on February 2, 2022. When determining the level of detail to provide for a description of any instance of whistleblower retaliation, OIG is always mindful of the risk that a detailed description of the allegation could inadvertently reveal the whistleblower's identity, thus having a chilling effect on future whistleblowers.

The whistleblower in this matter was an employee of a university which receives funds from CDC through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). The whistleblower made protected disclosures to the immediate supervisor and CDC staff, raising concerns of gross mismanagement of a PEPFAR grant and violations of Federal and local law. The whistleblower also raised allegations that reprisal was suffered in the form of termination. OIG found that it was more likely than not that the whistleblower was subjected to reprisal for whistle blowing activities in this matter for the following reasons.

First, the whistleblower made multiple protected disclosures. Second, management was aware of those communications (because many of the communications were sent to management). Third, an unfavorable personnel action (termination) was taken against the whistleblower during the relevant time period. Fourth, a causal connection existed between the protected disclosure and the unfavorable personnel action because the personnel action occurred weeks after the whistleblower made protected disclosures and the whistleblower's supervisor was unable to succinctly state why the whistleblower was terminated.

The report issued to the Office of the Secretary on February 2, 2022, included the following recommendations for corrective action: (1) that whistleblower protection training be required for the grantee and its employees, as well as CDC employees who work in the PEPFAR program; and (2) that the whistleblower be made whole in the form of reinstatement to his role at the university and backpay since his termination. In accordance with IG Act Section 5(a)(20)(B), OIG will revise this entry in a future report to incorporate any decisions imposed by HHS towards the subject grantee.

For departmental agencies, OIG conducts investigations and gathers facts related to whistleblower complaints. OIG makes a determination as to whether retaliatory action has been taken and includes these findings in its reports, along with recommendations as to what, if any, corrective action(s) should be

taken. Under this system, OIG submitted one report that included findings of retaliation to the HHS Office of the Secretary on February 2, 2022. When determining the level of detail to provide for a description of any instance of whistleblower retaliation, OIG is always mindful of the risk that a detailed description of the allegation could inadvertently reveal the whistleblower's identity, thus having a chilling effect on future whistleblowers.

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First, the whistleblower made multiple protected disclosures. Second, management was aware of those communications (because many of the communications were sent to management). Third, an unfavorable personnel action (termination) was taken against the whistleblower during the relevant time period. Fourth, a causal connection existed between the protected disclosure and the unfavorable personnel action because the personnel action occurred weeks after the whistleblower made protected disclosures and the whistleblower's supervisor was unable to succinctly state why the whistleblower was terminated.

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(21) A detailed description of any attempt by the establishment to interfere with the independence of the Office, including:

(A) with budget constraints designed to limit the capabilities of the Office; and

(B) incidents where the establishment has resisted or objected to oversight activities of the Office or restricted or significantly delayed access to information, including the justification of the establishment for such action; and

Although there have been instances in which HHS agencies have questioned OIG oversight activities or have not provided all information in the precise content, format, and timeline as requested, OIG has not identified any instances in which HHS interfered with the independence of OIG during this reporting period. OIG would immediately take appropriate action in accordance with the Inspector General Act if it were unable to resolve these issues within HHS.

(22) Detailed descriptions of the particular circumstances of each:

(A) inspection, evaluation, and audit conducted by the Office that is closed and was not disclosed to the public; and

The table below lists evaluation and audit reports for this semiannual reporting period that did not result in public reports. However, in some circumstances, a public summary of these nonpublic reports was published.

Nonpublic Reports by Category, October 1, 2021, Through March 31, 2022

Category/Description	Number of Reports
IT security reviews (involve IT systems, e.g., penetration test audits)	2
Other	0
HHS technical assistance reports	0
Finance-related attestation reviews	0
Total	2

(B) Investigation conducted by the Office involving a senior Government employee that is closed and was not disclosed to the public.

In section 5(a)(19), we detail investigations of senior Government employees in which allegations were substantiated. Those investigations are all closed and none have been disclosed to the public. OIG interprets section 5(a)(22)(B) as requiring reporting on investigations with either substantiated or unsubstantiated allegations. As such, we refer to our section 5(a)(19) response to address investigations of senior Government employees in which allegations were substantiated that were closed and not disclosed to the public. Our section 5(a)(22)(B) response describes investigations during this reporting period, both criminal and administrative, involving a senior Government employee in which OIG did not substantiate allegations of misconduct.

When determining the level of detail to provide for the investigations described above, OIG is mindful of the risk that a detailed description of the investigation could inadvertently reveal the subject's identity. During this reporting period, OIG investigated five senior Government employees for misconduct, but OIG determined the allegations to be unsubstantiated. Descriptions of the investigations are below.

Description of Investigation	Status	Disposition	DOJ Referral	DOJ Referral Date	DOJ Declination	DOJ Declination Date
A senior Government employee was allegedly providing insider information to family and friends and receiving kickbacks from them.	Closed	Insufficient evidence	No	N/A	N/A	N/A
A senior Government employee who represented a company on behalf of an OpDiv was said to have a conflict of interest.	Closed	Insufficient evidence	No	N/A	N/A	N/A
Two senior Government employees were accused of retaliation against an employee after the employee reported violations.	Closed	Unsubstantiated	No	N/A	N/A	N/A
A senior Government employee was alleged to own multiple prohibited stocks in pharmaceutical companies, a violation of the U.S. Code.	Closed	Insufficient evidence.	No	N/A	N/A	N/A

Appendix F: Anti-Kickback Statute—Safe Harbors

Pursuant to HIPAA, § 205, the Inspector General is required to solicit proposals annually via a *Federal Register* notice for developing new and modifying existing safe harbors to the Federal anti-kickback statute, section 1128B(b) of the Social Security Act, and for developing special fraud alerts. The Inspector General is also required to report annually to Congress on the status of the proposals received related to new or modified safe harbors.

In crafting safe harbors for a criminal statute, it is incumbent upon OIG to engage in a complete and careful review of the range of factual circumstances that may fall within the proposed safe harbor subject area to uncover all potential opportunities for fraud and abuse by unscrupulous industry stakeholders. Having done so, OIG must then determine, in consultation with DOJ, whether it can develop effective regulatory limitations and controls—not only to foster beneficial or innocuous arrangements—but also to protect the Federal health care programs and their beneficiaries from abusive practices.

Public proposals for new and modified safe harbors

Annual Solicitation

In December 2020, OIG published its annual solicitation in the *Federal Register* (Annual Solicitation).¹ In response to the Annual Solicitation, OIG received the following proposals related to safe harbors:

Proposal	OIG Response
A new safe harbor to protect the use of cash and cash-equivalent payments offered as part of contingency management in the treatment of substance use disorders.	In December 2020, as part of HHS’s broader Regulatory Sprint to Coordinated Care initiative, OIG issued a final rule (the “Regulatory Sprint Final Rule”), ² creating a new safe harbor for patient engagement tools and supports, which could protect certain in-kind incentives in connection with contingency management, if all safe harbor conditions were met. ³ Due to heightened fraud and abuse concerns with respect to incentives in the form of cash or cash equivalents, we elected not to expand the safe harbor to include cash and cash-equivalent

¹ OIG, Solicitation of New Safe Harbors and Special Fraud Alerts, 85 Fed. Reg. 81,439 (Dec. 16, 2020), available at <https://www.govinfo.gov/content/pkg/FR-2020-12-16/pdf/2020-26043.pdf>.

² Medicare and State Health Care Programs: Fraud and Abuse; 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), available at <https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26072.pdf>.

³ 42 CFR 1001.952(hh).

Proposal	OIG Response
	<p>payments offered as part of contingency management interventions or other programs to motivate beneficial behavioral changes. However, and as we explained in the Regulatory Sprint Final Rule, this does not mean that all such cash or cash-equivalent payments offered as part of a contingency management intervention are unlawful, but they would be subject to case-by-case analysis under the Federal anti-kickback statute and the civil monetary penalty provision prohibiting inducements to beneficiaries.</p> <p>For the same reason as set forth in the Regulatory Sprint Final Rule, we decline to adopt this suggestion. We may consider this topic in future rulemaking or through other guidance.</p>
<p>A new safe harbor for Indian Health Care Providers (IHCPs) similar to the safe harbor for federally qualified health centers at 42 CFR § 1001.952(w).</p>	<p>Although not specific to IHCPs, OIG believes existing regulations, including new and modified safe harbors that were finalized in the Regulatory Sprint Final Rule, may offer sufficient regulatory flexibility and can facilitate innovative value-based and care coordination arrangements for American Indians and Alaska Natives. Accordingly, OIG is not adopting this suggestion. We may consider this topic in future rulemaking.</p>
<p>A new safe harbor or modifications to existing value-based safe harbors at 42 CFR § 1001.952(ee), (ff), (gg), and (hh) that would protect remuneration exchanged in value-based arrangements involving pharmaceutical manufacturers and, in circumstances not limited to digital health technology, device manufacturers and durable medical equipment, prosthetics, orthotics, or supplies (“DMEPOS”) companies.</p>	<p>As explained in the Regulatory Sprint Final Rule, remuneration exchanged by pharmaceutical manufacturers and, in certain circumstances, medical device manufacturers and DMEPOS entities, are not eligible for protection under the new value-based safe harbors due to (among other reasons) concerns that such entities could use the safe harbor to protect arrangements that are intended to market their products or inappropriately tether clinicians to the use of a particular product.⁴ Consequently, OIG declines to adopt this suggestion.</p>
<p>New or modified safe harbors to protect remuneration furnished or exchanged by health care suppliers, providers, or manufacturers in</p>	<p>OIG is not adopting this suggestion. We believe that existing regulations, including new and modified safe harbors that were finalized in the Regulatory Sprint Final Rule, offer sufficient regulatory flexibility and protection for beneficiary incentives</p>

⁴ See, e.g., 85 Fed. Reg. at 77,709, 77,782.

Proposal	OIG Response
support of medically underserved communities.	and financial arrangements that may support the care needs of medically underserved communities. We may consider this topic in future rulemaking.
One or more new safe harbors that would protect patient cost-sharing waivers in the following circumstances: (i) clinical trials, (ii) care management, (iii) remote physiological monitoring, and (iv) for the duration of the COVID-19 public health emergency.	<p>OIG has repeatedly expressed concerns regarding routine waivers of Medicare cost-sharing amounts that do not meet an exception to the civil monetary penalty provision prohibiting inducements to beneficiaries at section 1128A(i)(6)(A) of the Social Security Act. Accordingly, we decline to adopt these suggestions.</p> <p>With respect to the COVID-19 public health emergency, we highlight OIG’s March 2020, Policy Statement,⁵ in which we notified providers that, subject to specified conditions, they will not be subject to administrative sanctions for reducing or waiving cost-sharing obligations that Federal health care program beneficiaries may owe for telehealth services furnished during the COVID-19 public health emergency.</p> <p>In addition, on May 5, 2021, OIG published an FAQ addressing ambulance providers or suppliers waiving or discounting beneficiary cost-sharing obligations resulting from ground ambulance services paid for by the Medicare program under a waiver established pursuant to section 1135(b)(9) of the Social Security Act. There, we concluded that such cost-sharing waivers represent a sufficiently low risk of fraud and abuse if certain conditions are met.</p>
A new safe harbor that would protect value-based contracting and outcomes-based contracting for the purchase of pharmaceutical or medical device items and related services.	OIG is not adopting this suggestion. These kinds of manufacturer arrangements raise unique program integrity issues that OIG continues to consider. We may consider this topic in future rulemaking.

⁵ HHS-OIG, OIG Policy Statement Regarding Physicians and Other Practitioners That Reduce or Waive Amounts Owed by Federal Health Care Program Beneficiaries for Telehealth Services During the 2019 Novel Coronavirus (COVID-19) Outbreak (Mar. 17, 2020) available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf>.

Proposal	OIG Response
<p>Modification of the space rental safe harbor to remove the fair market value requirement.</p>	<p>OIG is not adopting this suggestion. With respect to payments made by a lessee to a lessor for the use of premises, we believe that the fair market value requirement helps to ensure that such lease payments are for legitimate purposes and are not a payment to induce referrals or otherwise reward Federal health care program business generated between the parties.</p>
<p>Repeal or modification of the group purchasing organization (“GPO”) safe harbor to facilitate greater public transparency and address potential conflict of interests between GPOs, its members, and contracting vendors.</p>	<p>OIG is not adopting commenters’ suggestion to repeal or modify the GPO safe harbor, but we may consider this topic in future rulemaking. OIG also highlights that there is a statutory exception addressing GPOs at section 1128B(b)(3)(C) of the Social Security Act.</p>
<p>Repeal or modification of the pharmacy benefit manager service fees safe harbor and the point-of-sale reductions in price for prescription pharmaceutical products safe harbor, as finalized in a 2020 rulemaking.⁶</p>	<p>On March 22, 2021, OIG issued a notification of the court-ordered delay of the effective date of this final rule. That notification stated that the effective date of the amendments to 42 C.F.R. § 1001.952(h)(6) through (9), (cc), and (dd) is delayed until January 1, 2023. The notification also stated that the effective date of the corrections published at 86 Fed. Reg. 7815 (Feb. 2, 2021), is delayed from March 22, 2021, to January 1, 2023. See 86 Fed. Reg. 15,132 (Mar. 22, 2021).</p> <p>On November 15, 2021, Public Law 117-58 became law. Section 90006 of Public Law 117-58 states that:</p> <p style="padding-left: 40px;">Notwithstanding any other provision of law, the Secretary of Health and Human Services shall not, prior to January 1, 2026, implement, administer, or enforce the provisions of the final rule published by the Office of the Inspector General of the Department of Health and Human Services on November 30, 2020, and titled “Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription</p>

⁶ OIG, Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 85 Fed. Reg. 76,666 (Nov. 30, 2020), available at <https://www.govinfo.gov/content/pkg/FR-2020-11-30/pdf/2020-25841.pdf>.

Proposal	OIG Response
	<p data-bbox="751 237 1458 310">Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees" (85 Fed. Reg. 76666).</p> <p data-bbox="656 354 1458 462">Consequently, there is a three-year moratorium on implementation of the amendments to 42 C.F.R. § 1001.952(h)(5) and 42 C.F.R. § 1001.952(h)(6) through (9), (cc), and (dd).</p>