U.S. Department of Health and Human Services

Office of Inspector General

Semiannual Report to Congress

April 1, 2022–September 30, 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 September 30, 2022.

As HHS's programs continue to expand, OIG maintains our sharp focus on identifying key vulnerabilities. We use a risk-based approach to provide oversight that supports better health, well-being, program integrity, and opportunities for savings.

We hold accountable bad actors who hurt people and steal from taxpayer-funded programs. In coordination with our law enforcement partners, we strategically bring to bear every criminal, civil, and administrative tool that we have to safeguard the integrity of HHS programs and protect the people they serve. During this reporting period, OIG aggressively pursued entities and individuals committing fraud and abuse. We endeavor to send a strong signal that theft and abuse will not be tolerated in HHS programs, including fraud schemes that exacerbate the opioid epidemic, cheat child care programs, and endanger patients. OIG's investigative work led to $1.29 billion in expected investigative recoveries during this reporting period.

Findings from our audits and evaluations help to construct actionable strategies that will yield meaningful improvements. Examples from this reporting period include how HHS can reduce patient harm in hospitals, better protect children in foster care from sex trafficking, and strengthen its cybersecurity posture. Our work identified suggested ways to better protect Federal funds from misuse, including improvements in awarding and monitoring emergency response contracts and implementing the Provider Relief Fund Program. We reported on issues that, if addressed, would better ensure that HHS programs run efficiently and effectively, including programs related to confirmatory trials for drugs, prior authorization requests for Medicare services, and caring for unaccompanied children served by the Office of Refugee Resettlement.

OIG is steadfast in our commitment to drive positive change in HHS programs and in the lives of people served by these programs. My top priority is propelling meaningful improvement in the quality and safety of care in the more than 15,000 Medicare- and Medicaid-certified nursing homes nationwide. During this reporting period, we identified deficiencies in compliance with life safety and emergency preparedness requirements that put residents at increased risk of injury and death. We are continuing work on 21 audits and evaluations that address a wide range of issues involving nursing homes. Looking forward, we will delve deeply to understand the factors that contribute to poor nursing home performance, what should be done to improve residents' experience in nursing homes, and how frontline oversight of nursing homes can be more effective.

The independent, objective oversight described in this *Semiannual Report to Congress* reflects the excellence and innovation of the OIG workforce as well as the breadth and complexities of work in overseeing the more than 100 programs at HHS. We deploy a multidisciplinary approach and leverage data and cutting-edge technology to detect risks and strategically plan the most high-impact oversight across HHS programs and services. The reach, range, and impact of our work are bound only by our

constrained resources. With an eye on problems on the horizon, a focus on equity, and a firm grounding in our oversight mission, we will continue to pursue wrongdoers, recover misspent funds, and promote the health and well-being of the Nation.

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

Christi A. Grimm
Inspector General

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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 enable OIG components to conduct their work efficiently and effectively.

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 *OIG's Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs* (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, 2022, through September 30, 2022. We also provide data for accomplishments for FY 2022. 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 April 1, 2022, through September 30, 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 both the semiannual reporting period and the entirety of FY 2022. We then highlight significant results from selected audits, evaluations, and enforcement activities completed during the reporting period.

At-a-Glance Highlights

Statistic	FY 2022 (10/1/2021–9/30/2022)
Audit Reports Issued	114
Evaluations Issued	43
Expected Audit Recoveries	$1,199,088,845
Questioned Costs	$2,173,082,045
Potential Savings	$279,087,234
New Audit and Evaluation Recommendations	445
Recommendations Implemented by HHS OpDivs	424
Expected Investigative Recoveries	$2.73 billion
Criminal Actions	710
Civil Actions	736
Exclusions	2,332

Results for the Semiannual Reporting Period

During this semiannual reporting period (April 1, 2022, through September 30, 2022), we issued 68 audit reports and 29 evaluation reports. Our audit work identified $62.9 million in expected recoveries as well as $612.6 million in questioned costs (costs questioned by OIG because of an alleged violation, costs not supported by adequate documentation, or expenditures of funds for which intended purposes were unnecessary or unreasonable). Our audit work also identified $117 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 309 new audit and evaluation recommendations crucial to encouraging positive change in HHS programs. Meanwhile, HHS OpDivs implemented 130 prior recommendations, resulting in positive impacts for HHS programs and enrollees.

OIG also remains at the forefront of the Nation's effort to fight fraud in HHS programs and hold wrongdoers accountable. Along with our partners, including DOJ, Medicaid Fraud Control Units (MFCUs or Units), and various Federal, State, and local law enforcement agencies, we detect, investigate, and prosecute fraud through a coordinated, data-driven approach. OIG's investigative work led to $1.29 billion in expected investigative recoveries and 390 criminal actions during this reporting period. OIG also took civil actions, such as assessing monetary penalties against 416 individuals and entities, and excluded 1,290 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 this reporting period, organized by subject area. A comprehensive list of OIG work during this reporting period follows, and appendices A through G provide data to meet the reporting requirements of the Inspector General Act of 1978.

Responding to the COVID-19 Pandemic and Other Emergencies

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: (1) protect people; (2) protect funds; (3) protect infrastructure; and (4) promote the effectiveness of HHS programs, now and into the future. 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 oversight work completed during this reporting period related to the COVID-19 pandemic includes the following reports:

- *FDA Repeatedly Adapted Emergency Use Authorization Policies To Address the Need for COVID-19 Testing* (OEI-01-20-00380), September 2022;
- *FDA's Work With the Tri-Agency Task Force for Emergency Diagnostics Helped Labs Implement COVID-19 Tests* (OEI-01-20-00381), September 2022;
- *HHS Did Not Fully Comply With Federal Requirements and HHS Policies and Procedures When Awarding and Monitoring Contracts for Ventilators* (A-02-20-02002), September 2022; and
- *HHS's and HRSA's Controls Related to Selected Provider Relief Fund Program Requirements Could Be Improved* (A-09-21-06001), September 2022.

OIG also conducted enforcement activities during this reporting period. Following are two examples of successful outcomes from these cases:

- An individual was sentenced to 37 months in prison, followed by 3 years of supervised release, after making threats against Dr. Anthony Fauci. The individual further admitted to threatening other individuals within and outside HHS with the intent of intimidating or interfering with performance of their official duties regarding COVID-19 and its testing and prevention.

- A health system agreed to pay $1.75 million in restitution for facilitating COVID-19 vaccinations for individuals who were falsely characterized as "staff" and "volunteers" and ineligible to participate in the CDC's vaccine program specifically designed to vaccinate long-term care facility residents and staff during the vaccine rollout, when vaccines were in short supply.

Leveraging Oversight To Better Protect Nursing Home Residents

Improving nursing home care is a top priority for OIG. Decades of OIG oversight of nursing homes revealed significant challenges and vulnerabilities, and the COVID-19 pandemic brought challenges at nursing homes to the forefront. To better understand contributing factors; identify fraud, inefficiency, and substandard care; and aid policymakers, our oversight work is guided by a a three-part strategy:

- Performance. Understanding what drives nursing home performance, and in particular what contributes to poorly performing nursing homes.
- Residents First. Ensuring that nursing homes prioritize quality of care and quality of life for residents.
- Oversight. Ensuring that entities responsible for nursing home oversight—CMS and States—detect problems quickly and insist on rapid remediation.

Currently, OIG has 21 ongoing audits and evaluations of nursing home issues. We are continuing 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 Nursing Homes web page. Significant OIG work completed during this reporting period related to protecting residents in nursing homes includes the following:

- *An Estimated 91 Percent of Nursing Home Staff Nationwide Received the Required COVID-19 Vaccine Doses, and an Estimated 56 Percent of Staff Nationwide Received a Booster Dose* (A-09-22-02003), June 2022; and

- *Audits of Nursing Home Life Safety and Emergency Preparedness in Eight States Identified Noncompliance With Federal Requirements and Opportunities for the Centers for Medicare & Medicaid Services To Improve Resident, Visitor, and Staff Safety* (A-02-21-01010), July 2022.

OIG uses its authorities to exclude entities and individuals engaging in fraud and abuse. For example, OIG excluded an individual who owned seven nursing homes during this reporting period. OIG had previously excluded the individual's seven nursing homes that had been excluded for housing residents during Hurricane Ida in an unsanitary warehouse without proper food, water, or waste facilities.

Ensuring Health and Safety of Vulnerable People Served by HHS

OIG has devoted substantial oversight effort to protect vulnerable people—including the elderly, children, and adults with developmental disabilities—who are served by HHS programs such as Medicare, Medicaid, the Unaccompanied Children (UC) Program, and the Child Care and Development Fund (CCDF).

Significant OIG work completed during this reporting period related to ensuring the health and safety of vulnerable people served by HHS programs includes the following:

- *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018* (OEI-06-18-00400), May 2022;
- *Office of Refugee Resettlement's Influx Care Facility and Emergency Intake Sites Did Not Adequately Safeguard Unaccompanied Children From COVID-19* (A-06-21-07002), June 2022;
- *HHS Should Improve Internal Coordination Regarding Unaccompanied Children*, (OEI-BL-20-00670), May 2022;
- *Operational Challenges Within ORR and the ORR EIS at Fort Bliss Hindered Case Management for Children* (OEI-07-21-00251), September 2022;
- *National Snapshot of State Agency Approaches To Reporting and Locating Children Missing From Foster Care* (A-07-20-06095), May 2022;
- *In Five States, There Was No Evidence That Many Children in Foster Care Had a Screening for Sex Trafficking When They Returned After Going Missing* (OEI-07-19-00371), July 2022; and
- *ACF Should Improve Oversight of Head Start To Better Protect Children's Safety* (OEI-BL-19-00560), September 2022.

OIG uses its authorities to suspend or debar individuals or entities engaged in grant or contract fraud. For example, OIG debarred individuals and entities due to criminal convictions during this reporting period. Multiple individuals and entities were debarred after being criminally convicted for their role in a scheme to defraud child care programs, partially funded by the CCDF, by submitting claims for children who did not attend day care programs.

Preventing and Treating Opioid Misuse

OIG continued to prioritize oversight and enforcement activities to protect enrollees from prescription drug abuse and improve access to medications for opioid use disorder.

Significant OIG work completed during this reporting period related to preventing and treating opioid use disorder includes the report *Opioid Overdoses and the Limited Treatment of Opioid Use Disorder Continue To Be Concerns for Medicare Beneficiaries* (OEI-02-22-00390), September 2022.

OIG works with and supports DOJ's efforts to identify and criminally prosecute bad actors in Federal health care programs. Following are two examples of successful criminal prosecutions related to improper opioid prescriptions and distributions during this reporting period:

- An individual was sentenced to 20 years in prison, followed by 5 years of supervised release, and was ordered to pay a $40,000 fine and almost $4 million in restitution for running a prescription "pill mill" and providing unwarranted medications.

- An individual was sentenced to 48 months in Federal prison for conspiring to distribute and possess with intent to inappropriately distribute opioid pain medications and other controlled substances.

Ensuring Equitable Access to High-Quality Care in Departmental Programs

OIG works to ensure that people served by HHS programs have equitable access to quality care. OIG is also focused on identifying disparities in access to high-quality care by ensuring that HHS program data capture demographic data accurately and through analysis of that program data identify, assess, or remediate health disparities when relevant.

Significant OIG work completed during this reporting period related to promoting equitable access to high-quality care includes the following:

- *Certain Medicare Beneficiaries, Such as Urban and Hispanic Beneficiaries, Were More Likely Than Others To Use Telehealth During the First Year of the COVID-19 Pandemic* (OEI-02-20-00522), September 2022;

- *CDC Found Ways To Use Data To Understand and Address COVID-19 Health Disparities, Despite Challenges With Existing Data* (OEI-05-20-00540), July 2022; and

- *Inaccuracies in Medicare's Race and Ethnicity Data Hinder the Ability To Assess Health Disparities* (OEI-02-21-00100), June 2022.

Reducing Prescription Drug Spending for HHS Programs and Enrollees

OIG performs work to assess areas in which HHS programs or people enrolled in them may be paying more than necessary for vital drugs.

Significant OIG work completed during this reporting period related to prescription drug spending includes the following:

- *Tennessee Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations* (A-07-21-06096), September 2022; and

- *Part D Plan Preference for Higher-Cost Hepatitis C Drugs Led to Higher Medicare and Beneficiary Spending* (OEI-BL-21-00200), August 2022.

Promoting Program Integrity and Good Financial Stewardship in Traditional Medicare

The 2022 Medicare Trustees' report projected that assets in the Part A trust fund will be depleted by 2028, adding urgency to efforts to ensure good stewardship and appropriate use of scarce Medicare funds. OIG recognizes the importance of identifying and mitigating fraud risks in the Medicare program and holding accountable those who defraud Medicare, beneficiaries, and taxpayers.

Significant OIG work completed during this reporting period related to Medicare program integrity and financial stewardship includes the following:

- *Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks* (OEI-02-20-00720), September 2022; and

- *Reducing Medicare's Payment Rates for Intermittent Urinary Catheters Can Save the Program and Beneficiaries Millions of Dollars Each Year* (OEI-04-20-00620), September 2022.

OIG uses its authorities to pursue affirmative administrative action against entities and individuals engaging in conduct that violates the Civil Monetary Penalties Law (CMPL). Following are four examples of affirmative administrative litigation in the Medicare program during this reporting period:

- A physician entered into a $1,905,070.74 settlement agreement with OIG to resolve allegations of submitting false claims to Medicare for the application, monitoring, and removal of medical devices as well as improper claims for reimbursement of devices not covered by the Medicare program.

- An ambulance company entered into a $1,578,412 settlement agreement to resolve allegations that claims submitted to Medicare Part B for ambulance transportation to and from skilled nursing

facilities were already covered under Part A.

- A physician entered into a $919,644.34 settlement agreement with OIG to resolve allegations of presenting to Medicare claims for items or services that were not provided as claimed and were false or fraudulent.

- An individual and associated clinics entered into a $409,809.88 settlement agreement with OIG to resolve allegations that procedure claims submitted to Medicare for facet joint injections and denervations exceeded the coverage limitation of sessions in a rolling, 12-month period.

Promoting Integrity and Effectiveness in Medicare Advantage and Medicaid Managed Care

Almost half of people with Medicare are currently enrolled in Medicare Advantage Organizations. Enrollment is expected to continue to grow to cover 53 percent—a majority of Medicare enrollees—by 2031.

Managed care is now the predominant payment model in Medicaid. State and Federal expenditures on Medicaid managed care are growing. These expenditures totaled $421 billion and represented 59 percent of all Medicaid expenditures in 2021.

Significant OIG work completed during this reporting period related to Medicare Advantage and Medicaid managed care includes the following:

- *Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care* (OEI-09-18-00260), April 2022;

- *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc.*, (Contract H4461) Submitted to CMS (A-02-20-01009), July 2022;

- *CMS Has Opportunities To Strengthen States' Oversight of Medicaid Managed Care Medical Loss Ratios* (OEI-03-20-00231), September 2022; and

- *Nearly All States Made Capitation Payments for Beneficiaries Who Were Concurrently Enrolled in a Medicaid Managed Care Program in Two States* (A-05-20-00025), September 2022.

Ensuring Medicaid Program Integrity

Medicaid is the largest Federal health care program, with nearly 89 million enrollees as of May 2022. Medicaid is administered by States per 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 reporting period related to Medicaid program integrity includes the following:

- *New York Claimed $196 Million, Over 72 Percent of the Audited Amount, in Federal Reimbursement for NEMT Payments to New York City Transportation Providers That Did Not Meet or May Not Have Met Medicaid Requirements* (A-02-21-01001), September 2022; and

- *UPICs Hold Promise To Enhance Program Integrity Across Medicare and Medicaid, But Challenges Remain* (OEI-03-20-00330), September 2022.

OIG uses its authorities to exclude entities and individuals engaging in fraud and abuse. For example, during this reporting period, OIG excluded an individual for 30 years who was an owner and operator of a billing agency and who was convicted of conspiracy to commit Medicaid fraud.

Promoting Proper Departmental Management and Operations

OIG reviews programs across the Department to ensure that programs are being administered effectively, efficiently, and without waste.

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

- *FDA: The Food and Drug Administration's Foreign For-Cause Drug Inspection Program Can Be Improved To Protect the Nation's Drug Supply* (A-01-19-01500), June 2022;

- *Delays in Confirmatory Trials for Drugs Granted FDA's Accelerated Approval Raise Concerns* (OEI-01-21-00401), September 2022;

- *Indian Health Service Capacity To Manage Supplemental $3.5 Billion Allocated to Its Sanitation Facilities Construction Program* (OEI-06-22-00320), September 2022; and

- *Opportunities Exist To Strengthen NIH Grantees' Oversight of Investigators' Foreign Significant Financial Interests and Other Support* (OEI-03-20-00210), May 2022.

Cybersecurity Protection

OIG continues to recognize cybersecurity vulnerabilities as major risks to effectively managing and safeguarding the Department's programs. Oversight of the Department's cybersecurity is being prioritized. Repeated cyberattacks focused on accessing critical information in HHS systems added

urgency to the task of developing departmental cybersafeguards—in addition to conducting normal operations—over the course of the COVID-19 pandemic.

During this reporting period, OIG conducted work examining HHS's cybersecurity controls to strengthen HHS's cybersecurity posture including:

- *The Centers for Medicare & Medicaid Services Had Policies and Procedures in Place To Mitigate Vulnerabilities in a Timely Manner, but Improvements Are Needed* (A-18-20-06500), July 2022;

- *IHS Telehealth System Was Deployed Without Some Required Cybersecurity Controls* (A-18-21-03100), September 2022; and

- *National Institutes of Health Grant Program Cybersecurity Requirements Need Improvement* (A-18-20-06300), September 2022.

OIG Participation in Congressional Hearings

6/28/2022	Erin Bliss, Assistant Inspector General, Office of Evaluation and Inspections	"Protecting America's Seniors: Oversight of Private Sector Medicare Advantage Plans," U.S. House Committee on Energy and Commerce.

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
CMPL	Civil Monetary Penalties Law
CMS	Centers for Medicare & Medicaid Services
DEA	Drug Enforcement Administration
DOJ	Department of Justice
DME	durable medical equipment
EMTALA	Emergency Medical Treatment and Labor Act
FBI	Federal Bureau of Investigation
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
MAC	Medicare administrative contractor
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

Medicare and Medicaid Reports and Reviews

Medicare Program Reports and Reviews

Financial Management and Improper Payments

Medicare Improperly Paid Durable Medical Equipment Suppliers an Estimated $8 Million of the $40 Million Paid for Power Mobility Device Repairs (A-09-20-03016), May 2022

We found that not all suppliers complied with Medicare requirements when billing for power mobility device (PMD) repairs. For the 922 PMD repairs associated with 100 sampled beneficiaries, 261 PMD repairs associated with 76 beneficiaries did not comply with those requirements. Specifically, documentation did not adequately support the charges for PMD repairs, the labor time associated with PMD repairs was not documented, or PMD repair charges were not reasonable and necessary. We also identified questionable charges for 183 PMD repairs associated with 19 sampled beneficiaries. Although the billing of these PMD repairs did not reflect noncompliance with Medicare requirements, suppliers did not meet documentation standards established by guidance or submitted charges that may not have been reasonable and necessary.

On the basis of our sample results, we estimated that $7.9 million of the $40.1 million paid for PMD repairs was improperly paid. We also estimated that Medicare could have saved as much as an additional $3.7 million for questionably paid PMD repairs. In addition, we estimated that Medicare beneficiaries could have saved as much as $3 million in coinsurance for the improperly and questionably paid PMD repairs.

CMS generally concurred with our recommendations that it instruct the durable medical equipment (DME) Medicare contractors to: (1) recover $41,137 in overpayments for PMD repairs; (2) notify suppliers to refund $10,494 in coinsurance; and (3) based on the results of this audit, notify appropriate suppliers so that they can exercise reasonable diligence to identify, report, and return any overpayments. We also made four procedural recommendations.

Vanderbilt University Medical Center: Audit of Outpatient Outlier Payments (A-06-20-04003), May 2022

Vanderbilt University Medical Center (VUMC) did not properly bill the claims related to 81 outlier payments of 117 sampled claims, resulting in improper outlier payments during our audit period. These 81 claims, which had outlier payments totaling $427,644, contained 110 billing errors. The billing errors primarily occurred because VUMC did not have adequately designed controls or billing system capabilities to prevent coding errors, charge errors, and billing for services not covered by Medicare Part B.

VUMC concurred with our recommendations that it: (1) refund to the Medicare contractor the portion of the $686,500 in estimated outpatient outlier net overpayments for incorrectly billed claims that are within the 4-year reopening period and (2) improve procedures, provide education, and implement changes to its billing system to ensure that claims billed to Medicare are accurate.

Accuracy of Risk Adjustment and Capitated Payments in Medicare Advantage

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 seven 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. In some cases, we identified underpayments and netted them against overpayments. We conducted two audits that examined all diagnosis codes. 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 Peoples Health Network (Contract H1961) Submitted to CMS (A-06-18-05002), May 2022

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that Peoples Health Network (Peoples Health) 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 Peoples Health 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 Peoples Health received at least $3.3 million in overpayments for these high-risk diagnosis codes for 2015 and 2016.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS (A-02-20-01009), July 2022

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that Cariten Health Plan, Inc. (Cariten) 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 Cariten 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 Cariten received at least $9.2 million in net overpayments for these high-risk diagnosis codes for 2016 and 2017.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That WellCare of Florida, Inc., (Contract H1032) Submitted to CMS (A-04-19-07084), August 2022

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that WellCare of Florida, Inc. (WellCare) 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 WellCare had to prevent, 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 WellCare received at least $3.5 million of net overpayments for these high-risk diagnosis codes for 2015 and 2016.

Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS (A-03-18-00002), August 2022

Cigna HealthSpring 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 Cigna HealthSpring submitted were supported in the medical records and therefore validated 1,401 of the 1,470 sampled enrollees' Hierarchical Condition Categories (HCCs), the remaining 69 HCCs were not validated and resulted in overpayments. Second, there were an additional 18 HCCs for which the medical records supported diagnosis codes that Cigna HealthSpring should have submitted to CMS but did not.

As a result, Cigna HealthSpring received $39,612 of net overpayments for 2015 for the sampled enrollees. As demonstrated by the errors found in our sample, Cigna HealthSpring's policies to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3817) Submitted to CMS (A-09-20-03009), September 2022

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that Regence BlueCross BlueShield of Oregon (Regence) submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, for 111 of the 179 sampled enrollee-years, the diagnosis codes were not supported in the medical records and resulted in net overpayments of $248,885. As demonstrated by the errors in our sample, the policies and procedures that Regence had to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. On the basis of our sample results, we estimated that Regence received at least $1.8 million of net overpayments for these high-risk diagnosis codes for 2015 and 2016.

Medicare Advantage Compliance Audit of Diagnosis Codes That Inter Valley Health Plan, Inc. (Contract H0545), Submitted to CMS (A-05-18-00020), September 2022

Inter Valley Health Plan, Inc. (Inter Valley) 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 Inter Valley submitted were supported in the medical records and therefore validated 1,411 of the 1,553 sampled enrollees' HCCs, the remaining 142 HCCs were not validated and resulted in overpayments. These 142 unvalidated HCCs included 23 HCCs for which we identified 23 other, replacement HCCs for more and less severe manifestations of the diseases. Second, there were an additional 12 HCCs for which the medical records supported diagnosis codes that Inter Valley should have submitted to CMS but did not.

Thus, the risk scores for the 200 sampled enrollees should not have been based on the 1,553 HCCs. Rather, the risk scores should have been based on 1,446 HCCs (1,411 validated HCCs + 23 other HCCs + 12 additional HCCs). As a result, we estimated that Inter Valley received at least $5.3 million in net overpayments for 2015. These errors occurred because Inter Valley's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BlueCross BlueShield of Tennessee, Inc. (Contract H7917) Submitted to CMS (A-07-19-01195), September 2022

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that BlueCross BlueShield of Tennessee, Inc. (BCBST), submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 210 of the 270 sampled enrollee-years, the medical records that BCBST provided did not support the diagnosis codes and resulted in $491,269 in overpayments.

As demonstrated by the errors found in our sample, BCBST's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. On the basis of our sample results, we estimated that BCBST received approximately $7.8 million in overpayments for 2016 and 2017.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (Contact H3916) Submitted to CMS (A-03-19-00001), September 2022

With respect to the six high-risk groups covered by our audit, most of the selected diagnosis codes that Highmark Senior Health Company (Highmark) submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 160 of the 226 sampled enrollee-years, the diagnosis codes were not supported in the medical records.

The errors occurred because the policies and procedures that Highmark had to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. As a result, the HCCs (diagnosis code groupings based on similarity of clinical characteristics, severity, and cost implications) for these high-risk diagnosis codes were not validated. On the basis of our sample results, we estimated that Highmark received at least $6.2 million of net overpayments for 2015 and 2016.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract R5826) Submitted to CMS (A-05-19-00039), September 2022

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that HumanaChoice submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 207 of the 270 sampled enrollee-years, the diagnosis codes that HumanaChoice submitted to CMS were not supported in the medical records and resulted in $574,430 of overpayments for the 270 enrollee-years.

These errors occurred because the policies and procedures that HumanaChoice had to prevent, detect, and correct noncompliance with CMS's program requirements as mandated by Federal regulations could be improved. On the basis of our sample results, we estimated that HumanaChoice received at least $34.4 million of overpayments for these high-risk diagnosis codes in 2016 and 2017.

Medicare and Beneficiaries Paid Substantially More to Provider-Based Facilities in Eight Selected States in Calendar Years 2010 Through 2017 Than They Paid to Freestanding Facilities in the Same States for the Same Type of Services (A-07-18-02815), June 2022

Both the Medicare program and its beneficiaries could have realized significant savings for evaluation and management (E&M) services if those services had been paid as if provided at freestanding facilities. If the physicians in the selected States had been paid at the freestanding Physician Fee Schedule (PFS) nonfacility rate and hospitals paid nothing under the Outpatient Prospective Payment System for our audit period, the Medicare program and its beneficiaries could have realized cost savings of more than $1.6 billion. In addition, beneficiaries would have been required to make only one coinsurance payment rather than two (as they are currently required to do), and the cost-sharing would generally be lower because it would be based only on the freestanding facility rate.

CMS has taken some steps intended to equalize payments. If these changes had been in effect during the period covered by our audit, the potential cost savings of these changes for E&M services in the selected States for our audit period could have been a combined $1.4 billion for the Medicare program and its beneficiaries. However, the combined $1.4 billion in potential cost savings would still have been less than the $1.6 billion in potential cost savings if E&M services had been paid at the freestanding PFS nonfacility rate.

CMS did not directly agree or disagree with our recommendation that it pursue legislative or regulatory changes to lower costs for both the Medicare program and beneficiaries, by equalizing payments as appropriate between provider-based facilities and freestanding facilities for E&M services.

The Reduced Outlier Threshold Applied to Transfer Claims Did Not Significantly Increase Medicare Payments to Hospitals (A-05-19-00019), July 2022

Medicare's reduced outlier threshold for transfer claims did not have a significant impact on the total Medicare payments to the 30 hospitals we audited. Of the 5,303 transfer claims, the total Medicare payments for 3,668 transfer claims were less than what Medicare would have paid the hospitals if they had discharged the beneficiaries. However, the total Medicare payments for the remaining 1,635 transfer claims were $2.9 million more than what Medicare would have paid the hospitals if they had discharged the beneficiaries. Specifically, under the transfer policy, Medicare decreased DRG rate payments by $10.8 million, but because of the reduced outlier threshold, Medicare increased outlier payments by $13.7 million, resulting in a net increase of $2.9 million in total Medicare payments compared to what hospitals would have been paid if they had discharged the beneficiaries.

The $2.9 million net increase in total Medicare payments for these 1,635 transfer claims occurred because the outlier payment increase using the reduced outlier threshold was greater than the DRG payment decrease under the transfer policy.

Medicare's reduced outlier threshold for transfer claims does not have a significant enough impact for us to recommend a policy change. Therefore, we do not have any recommendations.

CMS Reported Collecting Just Over Half of the $498 Million in Medicare Overpayments Identified by OIG Audits (A-04-18-03085), July 2022

We verified that CMS collected $120 million of the $498 million in sustained Medicare overpayments identified in HHS-OIG audit reports issued during our audit period. Of this sustained amount, CMS reported that it had collected $272 million (55 percent) and that it had not collected $226 million (45 percent). CMS provided documentation to support that it had collected $120 million of the $272 million. However, CMS did not provide adequate documentation to support that it had collected the remaining $152 million. In addition, CMS did not take corrective action in response to all of the recommendations made in our prior audit report, *Obstacles to Collection of Millions in Medicare Overpayments*. In that audit report, issued on May 18, 2012, we made six recommendations, and CMS agreed to implement four of them. Of those four recommendations, CMS implemented two, partially implemented one, and did not implement one.

We recommended that CMS: (1) continue its efforts to recover any collectible portion of the $226 million in uncollected overpayments, (2) determine what portion of the $152 million was collected and recorded in its accounting system, (3) revise 42 CFR section 405.980 and corresponding manual instructions related to the reopening period for claims to be consistent with statutory provisions contained in section 1870 of the Social Security Act, and (4) develop a plan for resolving cost reports applicable to the nine audit reports discussed in this report. We also made other procedural recommendations. CMS generally did not concur with our findings or recommendations.

Medicare Critical Care Services Provider Compliance Audit: Lahey Clinic, Inc. (A-03-20-00002), July 2022

Lahey Clinic, Inc. (Lahey) complied with Medicare billing requirements for 36 of the 92 critical care services that we reviewed. However, Lahey did not comply with Medicare billing requirements for the remaining 56 critical care services. All 10 of the inpatient admissions reviewed included at least 1 critical care service that did not comply with Medicare billing requirements. Specifically, Lahey billed for 54 critical care services for patients whose conditions did not indicate that the critical care services were medically necessary or for which the physician did not directly provide services that were at the level of care required for critical care services. In addition, Lahey billed for two critical care services that were billed using an incorrect Current Procedural Terminology (CPT) code for the critical care service provided.

These billing errors resulted in Lahey receiving $6,015 in unallowable Medicare payments. These errors occurred because Lahey did not have adequate policies and procedures to ensure that: (1) physicians correctly documented in the patient's medical record and identified critical care services that met Medicare requirements and (2) coders made correct determinations for critical care services that met Medicare requirements.

We recommended that Lahey refund to the MAC $6,015 in overpayments for critical care services, and we also made procedural recommendations for Lahey to strengthen its policies and procedures. Lahey partially agreed with our recommendations.

Medicare Hospice Provider Compliance

The Medicare hospice benefit allows providers to claim Medicare reimbursement for hospice services provided to individuals with a life expectancy of 6 months or less and who have elected hospice care. Previous OIG reviews found that Medicare inappropriately paid for hospice services that did not meet certain Medicare requirements. Complete recommendations and providers' responses can be found in the final reports, which are summarized below.

Medicare Hospice Provider Compliance Audit: Vitas Healthcare Corporation of Florida (A-02-19-01018), July 2022

Vitas Healthcare Corporation of Florida (Vitas) did not comply with Medicare requirements for 89 of the 100 claims in our sample. These improper payments occurred because Vitas' policies and procedures were not effective to ensure that it maintained documentation to support the level of care and hospice services claimed for Medicare reimbursement. On the basis of our sample results, we estimated that Vitas received at least $140 million in improper Medicare reimbursement for hospice services that did not comply with Medicare requirements.

Medicare Hospice Provider Compliance Audit: Hospice of Palm Beach County, Inc. (A-02-20-01001), September 2022

Hospice of Palm Beach County, Inc. (HPBC) received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Improper payment of these claims occurred because HPBC's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis, that the appropriate level of care was provided, and that services were supported. On the basis of our sample results, we estimated that HPBC received at least $42.3 million in improper Medicare reimbursement for hospice services.

We made a series of recommendations to Vitas, including that it refund to the Federal Government the portion of the estimated $140 million in Medicare overpayments that are within the 4-year claims reopening period; identify, report, and return any overpayments in accordance with the 60-day rule; and strengthen its policies and procedures to ensure that hospice services comply with Medicare requirements. Vitas disagreed with some of our recommendations and partially agreed with our findings.

Reducing Medicare's Payment Rates for Intermittent Urinary Catheters Can Save the Program and Beneficiaries Millions of Dollars Each Year (OEI-04-20-00620), September 2022

In Medicare Part B, suppliers of intermittent urinary catheters received $407 million in FY 2020, more than three times the suppliers' estimated acquisition costs of $121 million. Our findings demonstrate that Medicare and its beneficiaries have the opportunity to achieve substantial savings while allowing suppliers adequate payments for the items and services they provide. CMS did not explicitly indicate whether it concurred with our recommendation; instead, CMS stated that it will take our recommendation under consideration as it determines appropriate next steps. Our recommendation was for CMS to lower Medicare's payment rates for intermittent urinary catheters.

CMS's System Edits Significantly Reduced Improper Payments to Acute-Care Hospitals After May 2019 for Outpatient Services Provided to Beneficiaries Who Were Inpatients of Other Facilities (A-09-22-03007), September 2022

During our audit period, Medicare inappropriately paid acute-care hospitals $39.3 million for outpatient services they provided to beneficiaries who were inpatients of other facilities (i.e., long-term care hospitals, inpatient rehabilitation facilities, inpatient psychiatric facilities, and critical access hospitals). None of the $39.3 million should have been paid because the inpatient facilities were responsible for payment. Each type of inpatient facility covered by our audit must: (1) provide directly all services furnished during an inpatient stay or (2) arrange for services to be provided on an outpatient basis by an acute-care hospital and include those outpatient services on its inpatient claims submitted to Medicare.

CMS generally concurred with our recommendations that it: (1) direct the Medicare contractors to recover the portion of the $39.3 million in improper payments for our audit period that are within the 4-year reopening period, (2) instruct acute-care hospitals to refund beneficiaries up to $9.8 million in deductible and coinsurance amounts that may have been incorrectly collected from them or from someone on their behalf, (3) direct the Medicare contractors to recover any improper payments after our audit period, and (4) continue to review the system edits to determine whether any refinements are necessary to prevent overpayments to acute-care hospitals for outpatient services provided to beneficiaries who are inpatients of other facilities. The report includes one other recommendation.

Medicare Part B Overpaid and Beneficiaries Incurred Cost-Share Overcharges of Over $1 Million for the Same Professional Services (A-06-21-05003), September 2022

Not all Medicare Part B payments made to Critical Access Hospitals (CAHs) for professional services and payments made to health care practitioners complied with Federal requirements. For the 40,026 claims we audited, CAHs and health care practitioners each submitted an equal number of claims. However, for each date of service, only one of the claims complied with Federal requirements. As a result, Medicare administrative contractors (MACs) paid providers $907,438 more than they should have been paid, and beneficiaries were held responsible for $281,321 more than they should have been.

These overpayments occurred because CMS did not have claim system edits to prevent and detect duplicate professional services claims for the same date of service, beneficiary, and procedure.

CMS generally concurred with our recommendations that it: (1) direct the MACs to recover the $331,448 from the CAHs for 12,156 claims for which the health care practitioners had not reassigned their billing rights to the CAHs and $83,412 in cost-sharing overcharges to Medicare beneficiaries that are within the 4-year reopening period and (2) direct the MACs to recover the $575,990 from health care practitioners for 7,857 claims for which the health care practitioners had reassigned their billing rights to the CAHs and $197,909 in cost-sharing overcharges to beneficiaries that are within the 4-year reopening period.

CMS's System Edits Significantly Reduced Improper Payments to Acute-Care Hospitals After May 2019 for Outpatient Services Provided to Beneficiaries Who Were Inpatients of Other Facilities (A-09-22-03007), September 2022

During our audit period, Medicare inappropriately paid acute-care hospitals $39.3 million for outpatient services they provided to beneficiaries who were inpatients of other facilities. None of the $39.3 million should have been paid because the inpatient facilities were responsible for payment. Each type of inpatient facility covered by our audit must: (1) provide directly all services furnished during an inpatient stay or (2) arrange for services to be provided on an outpatient basis by an acute-care hospital and include those outpatient services on its inpatient claims submitted to Medicare.

Before May 2019, the system edits were not working properly. However, after CMS modified the edits in May 2019, only $3.4 million (less than 9 percent of the $39.3 million in improper payments for the entire audit period) was inappropriately paid to acute-care hospitals from June 2019 through December 2021.

CMS generally concurred with our recommendations that it: (1) direct the Medicare contractors to recover the portion of the $39.3 million in improper payments for our audit period that are within the reopening period, (2) instruct acute-care hospitals to refund beneficiaries up to $9.8 million in deductible and coinsurance amounts that may have been incorrectly collected from them or from someone on their behalf, (3) direct the Medicare contractors to recover any improper payments after our audit period, and (4) continue to review the system edits to determine whether any refinements are necessary to prevent overpayments to acute-care hospitals for outpatient services provided to beneficiaries who are inpatients of other facilities.

Medicare Dialysis Services Provider Compliance Audit—Dialysis Clinic, Inc. (A-05-20-00010), September 2022

Dialysis Clinic, Inc. (DCI) claimed reimbursement for dialysis services that did not comply with Medicare requirements for 70 of the 100 sampled claims. Specifically, DCI submitted claims for which: (1) comprehensive assessments or plans of care did not meet Medicare requirements, (2) dialysis treatments were not completed, (3) dialysis services were not documented, (4) beneficiaries' height or weight measurements did not comply with Medicare requirements, and (5) the medical record did not have a monthly progress note by a physician or other qualified professional.

Although DCI had established corporatewide internal controls to monitor and maintain complete, accurate, and accessible medical records at all its facilities, these controls were not always effective in ensuring that DCI's claims for dialysis services complied with Medicare requirements.

We estimated that DCI received unallowable Medicare payments of at least $14,193,677 for dialysis services that did not comply with Medicare requirements. Many of the errors we identified did not

affect DCI's Medicare reimbursement for the services because they were reimbursed on a bundled, per-treatment basis or related to Medicare conditions for coverage. However, the deficiencies could have a significant impact on the quality of care provided to Medicare beneficiaries and could result in the provision of inappropriate or unnecessary dialysis services.

DCI did not concur with our recommendations that it refund an estimated $14,193,677 to the Medicare program. We also made a series of recommendations to strengthen DCI's internal controls to ensure that dialysis services comply with Medicare requirements.

Quality of Care, Safety, and Access

Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care (OEI-09-18-00260), April 2022

Medicare Advantage Organizations (MAOs) sometimes denied prior authorization and payment requests that met Medicare coverage rules; we found that 13 percent of prior authorization requests that MAOs denied, and 18 percent of payment requests that MAOs denied, met Medicare coverage rules and/or MAO billing rules. When MAOs deny requests for Medicare-covered services, they may prevent or delay beneficiaries from accessing needed care and create administrative burden for both beneficiaries and providers.

CMS concurred with our recommendations that: (1) CMS should issue new guidance on the appropriate use of MAO clinical criteria in medical necessity reviews; (2) CMS should update its audit protocols to address the issues identified in this report, such as MAO use of clinical criteria and/or examining particular service types; and (3) CMS should direct MAOs to take additional steps to identify and address vulnerabilities that can lead to manual review errors and system errors.

Posthospital Skilled Nursing Facility Care Provided to Dually Eligible Beneficiaries in Indiana Generally Met Medicare Level-of-Care Requirements (A-05-20-00005), April 2022

Posthospital skilled nursing facility (SNF) care provided to 98 of the 100 dually eligible beneficiaries in Indiana was not associated with potentially avoidable hospitalizations. For the remaining two beneficiaries, our independent medical review contractor found that because the nursing facilities did not have effective prevention strategies, the beneficiaries were hospitalized and later discharged to SNF care at the same facility.

Posthospital SNF care provided to 98 of the 100 beneficiaries met the Medicare SNF level-of-care requirements. The remaining two beneficiaries did not meet the Medicare SNF level-of-care requirements because the SNF physicians incorrectly determined that the beneficiaries required either skilled nursing or skilled rehabilitation services, or both, on a daily basis.

For all 100 beneficiaries, physicians ordered SNF services. We noted that records from the hospitals where 33 beneficiaries had a qualifying inpatient stay did not contain a clear and definitive hospital physician discharge order for SNF care. Hospital physicians mainly discharged beneficiaries "back to nursing facility" without specifying the level of care. In these cases, SNF physicians certified the SNF level of care. The physician order not only affects level-of-care determination but also has a financial impact on the nursing facilities.

Our independent medical review contractor found that SNF care provided to dually eligible beneficiaries in Indiana during our audit period generally: (1) was not associated with potentially avoidable hospitalizations and (2) met the Medicare level-of-care requirements. As a result, we do not have any recommendations. However, the quality of care in nursing facilities remains a concern for OIG.

Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018 (OEI-06-18-00400), May 2022

One in four Medicare patients experienced patient harm events during their hospital stays in October 2018. Patient harm events indicate that a patient's care resulted in an undesirable clinical outcome not caused by underlying disease. Forty-three percent of these harm events could have been prevented. Our findings will help CMS and the Agency for Healthcare Research and Quality (AHRQ) track and reduce patient harm in hospitals and improve patient safety.

CMS and AHRQ concurred with all seven of our recommendations. We recommended to CMS that: (1) CMS should update and broaden its lists of hospital-acquired conditions to capture common, preventable, and high-cost harm events; (2) CMS should explore expanding the use of patient safety metrics in pilots and demonstrations for health care payment and service delivery, as appropriate; and (3) CMS, as OIG previously recommended, should develop and release interpretive guidance to surveyors for assessing hospital compliance with requirements to track and monitor patient harm. We recommended to AHRQ that: (4) AHRQ should with support from HHS leadership coordinate agency efforts to update agency-specific Quality Strategic Plans; (5) AHRQ should optimize use of the Quality and Safety Review System (QSRS), including assessing the feasibility of automating data capture for national measurement and to facilitate local use; (6) AHRQ should develop an effective model to disseminate information on national clinical practice guidelines or best practices to improve patient safety; and (7) AHRQ should continue efforts to identify and develop new strategies to prevent common patient harm events in hospitals.

Certain Medicare Beneficiaries, Such as Urban and Hispanic Beneficiaries, Were More Likely Than Others To Use Telehealth During the First Year of the COVID-19 Pandemic (OEI-02-20-00522), September 2022

Beneficiaries in urban areas were more likely than those in rural areas to use telehealth during the first year of the pandemic. Beneficiaries in Massachusetts, Delaware, and California were more

likely than beneficiaries in some other States to use telehealth. Dually eligible beneficiaries (i.e., those eligible for both Medicare and Medicaid), Hispanic beneficiaries, younger beneficiaries, and female beneficiaries were also more likely than others to use telehealth. In addition, beneficiaries almost always used telehealth from home or other non-health-care settings. Furthermore, almost one-fifth of beneficiaries used certain audio-only telehealth services, with the vast majority of these beneficiaries using these audio-only services exclusively. Older beneficiaries were more likely to use these audio-only services, as were dually eligible and Hispanic beneficiaries. As CMS, HHS, Congress, and other stakeholders consider permanent changes to Medicare telehealth services, it is important that they balance concerns about issues such as access, quality of care, health equity, and program integrity.

CMS did not explicitly indicate whether it concurred with our four recommendations. Our recommendations were that: (1) CMS should take appropriate steps to enable a successful transition from current pandemic-related flexibilities to well-considered long-term policies for the use of telehealth for beneficiaries in urban areas and from the beneficiary's home, (2) CMS should temporarily extend the use of audio-only telehealth services and evaluate their impact, (3) CMS should require a modifier to identify all audio-only telehealth services provided in Medicare, and (4) CMS should use telehealth to advance health care equity.

Opioid Overdoses and the Limited Treatment of Opioid Use Disorder Continue To Be Concerns for Medicare Beneficiaries (OEI-02-22-00390), September 2022

In 2021, almost a quarter of Part D beneficiaries received opioids, about 50,400 Medicare Part D beneficiaries experienced an opioid overdose, and more than 1 million Medicare beneficiaries had a diagnosis of opioid use disorder during 2021. However, fewer than one in five Medicare beneficiaries with opioid use disorder received medication to treat their opioid use disorder. At the same time, the number of beneficiaries receiving prescriptions for naloxone—a drug that reverses opioid overdoses—through Part D grew. Monitoring opioid use and access to medications for the treatment of opioid use disorder as well as to naloxone are critical to addressing the opioid crisis. We did not make any recommendations in this report, however, a December 2021 OIG report recommended that CMS take steps to improve access to medications for the treatment of opioid use disorder and other support services. We continue to call attention to the importance of implementing these recommendations and to ensuring access to treatment for opioid use disorder.

Certain Life Care Nursing Homes May Not Have Complied With Federal Requirements for Infection Prevention and Control and Emergency Preparedness (A-01-20-00004), September 2022

Selected Life Care nursing homes may not have complied with Federal requirements for infection prevention and control and emergency preparedness. Life Care officials attributed the possible noncompliance to: (1) leadership turnover, (2) staff turnover, (3) documentation issues (i.e.,

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

CMS concurred with our recommendation that it instruct State survey agencies SSAs to follow up with the 23 nursing homes that we have identified with possible infection prevention and control and emergency preparedness deficiencies to verify that they have taken corrective actions.

End-Stage Renal Disease Network Organizations' Reported Actions Taken in Response to the COVID-19 Pandemic (A-05-20-00051), September 2022

The 18 end-stage renal disease (ESRD) Network Organizations that we surveyed provided information about the actions they took to aid dialysis clinics and patients and keep CMS informed about quality-of-care issues that arose during the COVID-19 pandemic. Network Organizations also reported to us challenges they encountered in taking those actions during the pandemic.

Despite the unprecedented challenges faced by the Network Organizations during the pandemic, they took actions to ensure continuity of services in a safe manner for high-risk ESRD beneficiaries. Network Organizations served a key role in addressing the additional demands on dialysis clinics during the pandemic through actions such as: (1) disseminating changing guidance, (2) aiding dialysis clinics to address the increased concerns and grievances related to the pandemic, and (3) promoting safe alternative treatment options. Network Organizations also kept CMS informed of quality-of-care issues by communicating through established communication processes and processes modified for better use during the pandemic. This report does not contain any recommendations.

Program Integrity

2021 Performance Data for the Senior Medicare Patrol Projects (OEI-02-22-00310), June 2022

The Senior Medicare Patrol (SMP) projects receive grants from the Administration for Community Living to recruit and train retired professionals and other older adults and community members to prevent, detect, and report health care fraud, errors, and abuse. In 2021, the 54 SMP projects had a total of 5,346 active team members who conducted a total of 12,660 group outreach and education events, reaching an estimated 556,980 people. In addition, the projects had 239,625 individual interactions with, or on behalf of, a Medicare beneficiary. The projects reported

$2.5 million in expected Medicare recoveries. Cost avoidance totaled $41,498, while savings to beneficiaries totaled $40,798.

Inaccuracies in Medicare's Race and Ethnicity Data Hinder the Ability To Assess Health Disparities (OEI-02-21-00100), June 2022

We found that Medicare's enrollment race and ethnicity data are less accurate for some groups, particularly for beneficiaries identified as American Indian/Alaska Native, Asian/Pacific Islander, and Hispanic. Data that are not accurate limit the ability to assess health disparities. Limited race and ethnicity categories and missing information contribute to inaccuracies in the enrollment data. Although the use of an algorithm improves the existing data to some extent, it falls short of self-reported data. Finally, Medicare's enrollment data on race and ethnicity are inconsistent with Federal data collection standards, which inhibits the work of identifying and improving health disparities within the Medicare population. Advancing health equity is a priority for CMS and the Department. Race and ethnicity data are foundational to identifying and understanding health disparities among Medicare beneficiaries and to assessing the effectiveness of efforts to reduce such disparities. It is critical that these data are accurate, complete, and comprehensive. Therefore, CMS must improve its race and ethnicity data; though a significant undertaking, the need for better data is pressing.

Accordingly, we recommended that: (1) CMS should develop its own source of race and ethnicity data, (2) CMS should use self-reported race and ethnicity information to improve data for current beneficiaries, (3) CMS should develop a process to ensure that the data are as standardized as possible, and (4) CMS should educate beneficiaries about CMS's efforts to improve the race and ethnicity information. CMS did not explicitly concur with the first recommendation and concurred with the other three recommendations.

Review of Medicare Administrative Contractor Information Security Program Evaluations for Fiscal Year 2021 (A-18-22-11300), July 2022

The Social Security Act requires that each MAC have its information security program evaluated annually by an independent entity. CMS contracted with Guidehouse, LLP (Guidehouse), to evaluate information security programs at the MACs.

Guidehouse's evaluations of the contractor information security programs were adequate in scope and sufficiency. Guidehouse identified a total of 95 gaps at the 7 MACs in FY 2021, which was 4 percent less than the number of gaps for the same 7 MACs in FY 2020. The number of high- and moderate-risk gaps decreased by 39 percent from FY 2020. Deficiencies remained in eight of the nine Federal Information Security Modernization Act of 2014 (FISMA) control areas that were tested. The results warrant CMS continuing its oversight visits to ensure that the MACs remediate all gaps to improve the MACs' IT security, especially those with increased gaps from the previous

year. Gaps that were similar to those from prior years should be considered repeat findings to highlight systemic problems and the existence of continued exposure to known weaknesses. This report contains no recommendations.

Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks (OEI-02-20-00720), September 2022

We identified 1,714 providers out of approximately 742,000 whose billing for telehealth services during the first year of the pandemic poses a high risk to Medicare. Each of these 1,714 providers had concerning billing on at least 1 of 7 measures we developed that may indicate fraud, waste, or abuse of telehealth services. In addition, more than half of the high-risk providers we identified are a part of a medical practice with at least one other provider whose billing poses a high risk to Medicare. Further, 41 providers whose billing poses a high risk appear to be associated with telehealth companies. Although these high-risk providers represent a small proportion of all providers who billed for a telehealth service, these findings demonstrate the importance of strong, targeted oversight of telehealth services.

CMS concurred with our recommendation to follow up on the providers identified in this report, but CMS did not explicitly indicate whether it concurred with the other four recommendations. Our recommendations were that: (1) CMS should strengthen monitoring and targeted oversight of telehealth services, (2) CMS should provide additional education to providers on appropriate billing for telehealth services, (3) CMS should improve the transparency of "incident to" services when clinical staff primarily delivered the telehealth service, (4) CMS should identify telehealth companies that bill Medicare, and (5) CMS should follow up on the providers identified in this report.

Drug Spending and Reimbursement

Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Fourth Quarter of 2021 (OEI-03-22-00200), May 2022, and *Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the First Quarter of 2022* (OEI-03-22-00210), August 2022

OIG identified eight drug codes in the fourth quarter of 2021 and eight drug codes in the first quarter of 2022 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 substituted rate 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.

Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2022 (OEI-05-22-00230), June 2022

We found that dual eligibles—that is, beneficiaries who are covered by both Medicare and Medicaid—have access to the majority of commonly used prescription drugs in 2022 via Part D plans, as we also found in previous years. A majority of the 449 Part D plan formularies covered almost all (at least 97 percent) of the 200 drugs most commonly used by dual eligibles. Similarly, among Part D plans with premiums below the regional benchmark, a majority of formularies (95 of 132) covered at least 97 percent of the drugs commonly used by dual eligibles. This is important because when dual eligibles do not select their own Part D plans, CMS randomly assigns them to plans with premiums below the regional benchmark without considering their specific prescription drug needs. If dual eligibles' plans do not cover specific drugs, they have several options (switching plans, using an exceptions and appeals process, finding an alternative drug, or paying out of pocket), but these options require beneficiaries to take administrative actions and do not guarantee access to the drugs.

This report did not make recommendations.

Part D Plan Preference for Higher-Cost Hepatitis C Drugs Led to Higher Medicare and Beneficiary Spending (OEI-BL-21-00200), August 2022

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

Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2020 Average Sales Prices (OEI-03-22-00170), September 2022

Because CMS did not implement all eligible drug price reductions based on 2020 ASPs for Part B drugs, savings that could have totaled $2.8 million over 1 year amounted to only $8,158. (Generally, Part B-covered drugs are those that are injected or infused in physicians' offices or outpatient settings. ASPs generally serve as the basis for reimbursement for Part B drugs. CMS has a price-substitution policy under which OIG's comparisons of ASPs with AMPs can—depending on the difference—result in the substitution of a lower calculated rate. The use of this policy serves as a mechanism for monitoring market prices and limiting potentially excessive payment amounts.)

Although the $8,158 amount is small, Medicare and its beneficiaries have saved $73.1 million for Part B-covered drugs since the price-substitution policy went into effect in 2013. These total savings highlight the impact of OIG's mandated quarterly ASP-AMP comparisons and the implementation of CMS's current price-substitution policy. This data snapshot contains no recommendations. However, OIG continues to support a previous recommendation that CMS expand the price-substitution criteria.

Medicaid Program Reports and Reviews

Financial Management and Improper Payments

California Improperly Claimed at Least $23 Million of $260 Million in Total Medicaid Reimbursement for Opioid Treatment Program Services (A-09-20-02009), April 2022

California claimed Medicaid reimbursement for some opioid treatment program (OTP) services that did not meet Federal and State requirements. Of the 130 sample items, 88 had services that were all allowable, but 42 had services that were unallowable.

On the basis of our sample results, we estimated that California claimed at least $23.1 million in unallowable Federal Medicaid reimbursement for OTP services during our audit period. In addition, we identified deficiencies in three areas that that did not result in unallowable services but could impact the quality of care provided to beneficiaries receiving OTP services.

California agreed with our recommendations that it refund $23.1 million to the Federal Government and take specific actions to address the deficiencies that we identified. In addition, we recommend that California take actions to ensure that OTPs comply with Federal and State requirements for providing and claiming reimbursement for OTP services.

Washington State Did Not Comply With Federal and State Requirements for Claiming Enhanced Federal Reimbursement for Medicaid Managed-Care Health Home Service Expenditures (A-09-20-02008), May 2022

Washington State did not comply with Federal and State requirements for claiming health home service expenditures under Medicaid managed care at the enhanced Federal medical assistance percentage. Specifically, Washington State improperly calculated and claimed enhanced Federal reimbursement for its managed-care health home expenditures, totaling $1,770,860. In addition, of the $1,770,860 that Washington State claimed, $374,579 was not supported by encounter data, and $29,161 was claimed for unallowable encounters. These issues occurred because Washington State did not follow its State plan or Federal guidance and lacked adequate procedures and Medicaid Management Information System (MMIS) edits.

Washington concurred with our recommendations that it: (1) refund to the Federal Government $374,579 for the encounters that were no longer supported and the $29,161 that exceeded the number of allowable encounters; (2) determine the portion of the remaining $1,367,120 that should have been claimed based on the portion of the managed-care capitation rate attributable to health home services and refund any unallowable amounts; (3) review all managed-care health home encounters from July 1, 2013, through March 31, 2017, to determine the amount that should have been claimed based on the portion of the managed-care capitation rate attributable to health home services; (4) implement a procedure to identify whether encounters used to support journal vouchers have been removed from the encounter data; and (5) strengthen its MMIS edits to ensure that encounters comply with State reporting requirements.

Texas Did Not Report and Return All Medicaid Overpayments for the State's Medicaid Fraud Control Unit's Cases (A-06-20-04004), May 2022

Texas did not correctly report and return the Federal share of all MFCU-determined Medicaid overpayments identified for the period October 1, 2016, through September 30, 2018. We determined that Texas should have reported MFCU-determined Medicaid overpayments totaling $24.3 million (at least $13.9 million Federal share) for the 65 cases with Medicaid restitution during the period that we reviewed. In addition, Texas did not report $5.2 million (at least $2.7 million Federal share) for 37 cases within the required timeframe. These issues occurred because Texas did not have adequate internal controls to ensure that it always reported MFCU-determined Medicaid overpayments in accordance with Federal requirements.

Texas agreed with our recommendations that it: (1) report and return the Federal share for the 26 cases, totaling $19 million ($11.1 million Federal share); (2) strengthen internal controls by developing written policies and procedures, including procedures for recording MFCU-determined Medicaid overpayments, and reconciling case files received from the MFCU with the overpayments recorded in the State agency's accounting system; (3) ensure that it reports all MFCU-determined Medicaid overpayments in accordance with Federal regulations and within regulatory timeframes; and (4) review the MFCU-determined Medicaid overpayments for cases after our audit period to ensure that all overpayments were reported on the Form CMS-64.

More Than 90 Percent of the New Hampshire Managed Care Organization and Fee-for-Service Claims for Opioid Treatment Program Services Did Not Comply With Medicaid Requirements (A-01-20-00006), June 2022

New Hampshire claimed Medicaid reimbursement for OTP services that did not comply with Federal and State requirements. Of the 100 OTP services we sampled, 6 complied with Federal and State requirements, but 94 did not meet applicable Federal and State requirements. These deficiencies occurred because New Hampshire did not have the resources to oversee providers and enforce the OTP requirements. Providers said high personnel turnover, difficulty attracting and retaining personnel, and difficulty keeping patients engaged in counseling services contributed to

the lack of adherence to State requirements. Furthermore, New Hampshire did not always provide guidance regarding State OTP requirements.

On the basis of our sample results, we estimated that New Hampshire improperly claimed at least $7.9 million in Federal Medicaid reimbursement for OTP services during our audit period.

New Hampshire agreed with our recommendations that it: (1) refund $7.9 million to the Federal Government, (2) take steps to ensure that providers comply with Federal and State requirements for providing and claiming Medicaid reimbursement for OTP services, and (3) improve communication with providers regarding the State requirements for opioid use disorder treatment and provide written confirmation about whether offsite counseling may be included as a required counseling service.

Montana Claimed Federal Medicaid Reimbursement for More Than $5 Million in Targeted Case Management Services That Did Not Comply With Federal and State Requirements (A-07-21-03246), August 2022

Montana did not always claim Federal Medicaid reimbursement for targeted case management (TCM) services during FYs 2018 through 2020 in accordance with Federal and State requirements. Of the 150 randomly sampled grouped line items, 43 sample items were at least partially unallowable because they had at least 1 error related to case managers lacking required experience or qualifications, unsupported services, unallowable services, or an ineligible recipient.

Montana had policies and procedures in place for the administration of TCM services that, if followed, would have ensured compliance with Federal and State requirements. Based on our sample results, we estimated that Montana claimed at least $7.7 million (more than $5 million Federal share) in unallowable Medicaid reimbursement for these services.

We recommended that Montana refund to the Federal Government the more than $5 million (Federal share) in overpayments. We also made procedural recommendations that Montana always follow its established policies and procedures regarding: (1) TCM providers' case manager hiring practices, (2) verification that billed services were allowable and properly documented, and (3) verification that all individuals receiving services were eligible. Furthermore, we made procedural recommendations that Montana require TCM providers to comply with established policies and procedures. Montana neither concurred nor nonconcurred with our recommendations.

New York Claimed $196 Million, Over 72 Percent of the Audited Amount, in Federal Reimbursement for NEMT Payments to New York City Transportation Providers That Did Not Meet or May Not Have Met Medicaid Requirements (A-02-21-01001), September 2022

Of the 100 sampled non-emergency medical transportation (NEMT) payments, 17 complied with Federal and State requirements. However, for 41 sampled payments, NEMT payments did not comply with Federal and State requirements and were therefore unallowable. For the remaining 42 sampled payments, we could not determine whether the services complied with Federal and State requirements. We estimated that New York improperly claimed at least $84,329,893 in Federal Medicaid reimbursement for payments to NEMT providers that did not comply with certain Federal and State requirements. In addition, we estimated that New York claimed $112,028,279 in Federal Medicaid reimbursement for payments to NEMT providers that may not have complied with certain Federal and State requirements.

New York did not indicate concurrence or nonconcurrence with our recommendations that it refund $84,329,893 to the Federal Government for the payments that did not comply with certain Federal and State requirements and work with the transportation manager to review the $112,028,279 in Federal Medicaid reimbursement for payments to NEMT providers that may not have complied with certain Federal and State requirements and refund to the Federal Government any unallowable amounts. We also made recommendations for New York to improve its monitoring of its NEMT program.

Nearly All States Made Capitation Payments for Beneficiaries Who Were Concurrently Enrolled in a Medicaid Managed Care Program in Two States (A-05-20-00025), September 2022

All 47 States reviewed made capitation payments on behalf of Medicaid beneficiaries who were concurrently enrolled in two States. The significant increase in these payments from August 2019 to August 2020 coincided with an overall increase in Medicaid enrollment during that time, and new Federal requirements and flexibilities that were available to States during the COVID-19 public health emergency.

CMS does not actively monitor beneficiaries' concurrent Medicaid managed care enrollment; instead, it relies on the individual States to identify concurrent enrollments and potential erroneous payments. CMS does not provide States with Transformed Medicaid Statistical Information System (T-MSIS) national enrollment data that would assist them in identifying beneficiaries who were concurrently enrolled in a Medicaid managed care program in two States. Two States often made capitation payments for the same Medicaid beneficiary in part because States did not have full access to data they needed to identify beneficiaries who were concurrently enrolled in another State. Therefore, CMS does not take all available steps, either directly or through the States, to identify and prevent State capitation payments for non-resident beneficiaries.

CMS did not concur with our recommendations that it provide States with matched T-MSIS enrollment data that identify Medicaid beneficiaries who were concurrently enrolled in a Medicaid managed care program in two States, and assist States with utilizing the data as needed to reduce future capitation payments made on behalf of beneficiaries concurrently enrolled in two States.

CMS Has Opportunities To Strengthen States' Oversight of Medicaid Managed Care Medical Loss Ratios (OEI-03-20-00231), September 2022

States' oversight of Medicaid managed care plans' annual reporting of medical loss ratios (MLRs) is critical to improve fiscal transparency, monitor costs, and promote high-quality care in Medicaid managed care. (The Federal MLR is the percentage of premium revenue that a managed care plan spent on covered health care services and quality-improvement activities in a 12-month period.) Although States reported that most of their plans submitted MLR reports, we found that nearly half of plans' MLR reports were incomplete. The data element for non-claims costs, generally defined as plans' expenses for administrative services, accounted for the majority of incomplete MLR reports. In addition, some States did not review selected MLR data elements for accuracy. We made four recommendations to strengthen States' oversight of MLR reporting and better ensure that plans are using Federal dollars for patient care.

CMS concurred with all four recommendations, which were that: (1) CMS should design an annual MLR reporting template for States to provide to their Medicaid managed care plans, (2) CMS should clarify that States should verify the completeness of their plans' MLR reports, (3) CMS should clarify that States should review their plans' MLR reports to verify the accuracy of reported data elements, and (4) CMS should provide additional guidance to States regarding plans' reporting of non-claims costs in MLR reports.

Tennessee Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations (A-07-21-06096), September 2022

Tennessee did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to managed care organization (MCO) enrollees. Tennessee did not invoice for, and collect from manufacturers, rebates totaling $18.4 million ($12 million Federal share) for physician-administered drugs dispensed to MCO enrollees. In addition, Tennessee did not invoice for, and collect from manufacturers, $43.3 million ($28.4 million Federal share) in rebates for physician-administered drugs invoiced on crossover claims, for which beneficiaries are eligible for both Medicare and Medicaid services.

Although its policies required the collection of drug utilization data necessary to invoice for rebates on all claims, Tennessee's internal controls did not always ensure that the data were used to invoice manufacturers and collect rebates for physician-administered drugs dispensed to enrollees of MCOs.

Tennessee generally concurred with our recommendations that it: (1) invoice for and collect manufacturers' rebates and refund to the Federal Government $11 million (Federal share) for single-source and top-20 multiple-source drugs; (2) work with the CMS to determine the portion of the $1 million (Federal share) for other multiple-source drugs that were eligible for rebate, invoice manufacturers, and refund the Federal share; and (3) strengthen internal controls for non-crossover

claims to ensure that all eligible physician-administered drugs are invoiced for rebate. Tennessee did not concur with our recommendation that it consider revising its methodology going forward regarding payments for crossover claims.

New York Generally Determined Eligibility for Its Basic Health Program Enrollees in Accordance With Program Requirements (A-02-20-01028), September 2022

New York generally determined eligibility for its Basic Health Program (BHP) enrollees in accordance with Federal and State requirements. For five sampled policies, New York enrolled individuals who were ineligible or potentially ineligible for the program and received improper monthly payments totaling $8,615. According to New York, system defects prevented controls that were in place from working as intended.

On the basis of our sample results, we estimated that the financial impact of the incorrect or potentially incorrect eligibility determinations made by New York for its BHP during the audit period totaled $69.9 million.

New York did not indicate concurrence or nonconcurrence with our recommendations that it: (1) reimburse its BHP Trust Fund $8,615 associated with the improper monthly payments identified in our sample and (2) identify and reimburse the BHP Trust Fund all improper payments, which we estimate to total $69.9 million, resulting from system defects identified in our report. We also made recommendations for New York to improve its system for enrolling individuals in its BHP.

Texas Claimed or May Have Claimed More Than $30 Million of $9.89 Billion in Federal Funds for Medicaid Uncompensated Care Payments That Did Not Meet Federal and State Requirements (A-06-19-09002), September 2022

Texas claimed $16.90 billion ($9.86 billion Federal share) in uncompensated care payments in accordance with applicable Federal and State requirements. However, Texas incorrectly claimed $18.90 million ($11.05 million Federal share). Specifically, Texas claimed: (1) $12.91 million ($7.51 million Federal share) because it did not refund the full Federal share of overpayments and (2) $5.99 million ($3.54 million Federal share) because it did not collect overpayments it identified. Additionally, the State agency may have incorrectly claimed $33.78 million ($19.66 million Federal share) because it did not reduce hospitals' actual uncompensated care costs by Medicare payments the hospitals received.

Texas did not concur with our recommendation that it work with CMS to determine whether the $33.78 million in uncompensated care payments hospitals retained should be recouped and refund the related Federal share or redistribute the recouped funds to hospitals that had unmet uncompensated care costs. Texas concurred with our recommendations that it: (1) refund $11.05 million to the Federal Government for the underreported uncompensated care overpayments; (2) follow the CMS-approved methodology for calculating actual uncompensated

care costs when reconciling initial uncompensated care payments with providers' actual uncompensated care costs, including reducing uncompensated care costs by Medicare payments providers receive; and (3) establish review procedures for overpayments to ensure that they are accurately entered into the State agency's accounting system and returned to the Federal Government.

Quality of Care, Safety, and Access

South Carolina Did Not Fully Comply With Requirements for Reporting and Monitoring Critical Events Involving Medicaid Beneficiaries With Developmental Disabilities (A-04-18-07078), April 2022

South Carolina did not fully comply with requirements for reporting and monitoring critical events involving Medicaid beneficiaries with developmental disabilities residing in community-based settings. Specifically, South Carolina did not ensure that providers: (1) reported all critical incidents, (2) reported within 24 hours or the next business day all critical events, or (3) always submitted the results of their internal reviews within 10 working days.

South Carolina concurred with our recommendations that it work with the Department of Disabilities and Special Needs (DDSN) to: (1) ensure that providers follow the reporting requirements for critical events, (2) provide training to providers on recognizing and reporting critical incidents according to reporting requirements, (3) perform analytical procedures such as data matches on Medicaid claims data to identify any unreported critical incidents and investigate as needed, and (4) ensure that providers submit all incident reports to DDSN through the Incident Management System within 24 hours of an incident or the next business day.

Massachusetts Implemented Our Prior Audit Recommendations and Generally Complied With Federal and State Requirements for Reporting and Monitoring Critical Incidents (A-01-20-00003), April 2022; and *Maine Implemented Our Prior Audit Recommendations and Generally Complied With Federal and State Requirements for Reporting and Monitoring Critical Incidents* (A-01-20-00007), June 2022

Massachusetts implemented the five recommendations from our prior audit and generally complied with Federal and State requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities residing in group homes. However, the corrective actions for one recommendation in our prior audit were not effective in addressing one of our previous findings.

Maine implemented the seven recommendations from our prior audit and generally complied with Federal and State requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities. However, Maine's corrective actions for two recommendations were not fully implemented by the conclusion of our current audit period and, therefore, were only partially effective in addressing two of our previous findings.

Massachusetts agreed with our recommendations that it: (1) continue to coordinate with Department of Developmental Services and the Disabled Persons Protection Commission to ensure that all reasonable suspicions of abuse and neglect are properly identified, reported, and investigated as needed; and (2) require periodic training for DDS and group home staff on reporting reasonable suspicions of abuse and neglect.

Maine concurred with our recommendations that it: (1) continue to work with CMS to fully implement the prior recommendation to ensure that followup reports are submitted by community-based providers appropriately and (2) ensure that the Mortality Review Committee reviews Mortality Review Form aggregate data to identify patterns and trends and to make recommendations to improve care.

National Background Check Program for Long-Term Care Providers: An Interim Assessment (OEI-07-20-00181), May 2022

The National Background Check Program (Program) provides grants to States to develop programs for conducting background checks of prospective long-term care employees via State and Federal criminal history records. In our interim assessment of Idaho and Mississippi, OIG found that during the first years of Program participation, both States were unable to implement some requirements and did not consistently report Federal and State funds. Additionally, one State did not report data to accurately assess Program outcomes. We recommended that CMS continue to implement OIG's prior recommendations for it to take appropriate actions to: (1) encourage States to obtain the necessary legislative authority from the State to fully implement Program requirements and (2) require participating States to consistently submit data that allow CMS and each State to calculate determinations of ineligibility. CMS concurred with our new recommendation to ensure that participating States submit accurate quarterly reports.

Drug Spending and Reimbursement

South Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs (A-07-21-07003), August 2022

South Carolina did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. South Carolina did not invoice for, and collect from manufacturers, rebates associated with $14.5 million (Federal share) in physician-administered drugs. Of this amount, $14.3 million (Federal share) was for single-source drugs and $242,000 (Federal share) was for top-20 multiple-source drugs. Further, we were unable to determine whether, in some cases, South Carolina was required to invoice for rebates for other multiple-source physician-administered drug claims. South Carolina did not invoice the

manufacturers for rebates associated with claims totaling $1.3 million (Federal share) for these multiple-source drugs.

We recommended that South Carolina refund to the Federal Government $14.3 million (Federal share) for claims for single-source physician-administered drugs and $242,000 (Federal share) for claims for top-20 multiple-source physician-administered drugs. We also recommended that South Carolina work with CMS to determine the unallowable portion of $1.3 million (Federal share) for other claims for multiple-source, physician-administered drugs that may have been ineligible for Federal reimbursement, refund that amount, and consider invoicing drug manufacturers for rebates for these drugs if CMS determines that the drug claims are allowable. In addition, we recommend that South Carolina work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2019, and continue to review and strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced. South Carolina generally concurred with our recommendations.

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 354 criminal and 413 civil actions against individuals or entities that engaged in offenses related to health care. We also reported more than $929.1 million in investigative receivables due to HHS and more than $357.5 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.

COVID-19 Enforcement Activities

The following case examples involve COVID-19 Enforcement activities:

Maryland—On August 4, 2022, Thomas Connally was sentenced to 37 months in Federal prison, followed by 3 years of supervised release, for making threats against a Federal official, specifically for sending emails threatening harm to Dr. Anthony Fauci, the Director of the National Institute of Allergy and Infectious Diseases (NIAID) at NIH. Connally further admitted to threatening Dr. Francis Collins, the former Director of the NIH; Dr. Rachel Levine, currently the Assistant Secretary for Health at HHS; a Massachusetts public health official; and a religious leader. According to Connally's plea agreement, from December 28, 2020, to July 25, 2021, Connally used an anonymous email account from a provider of secure, encrypted email services based in Switzerland to send a series of emails to Dr. Anthony Fauci threatening to harm and/or kill Dr. Fauci and members of his family. One email threatened that Dr. Fauci and his family would be "dragged into the street, beaten to death, and set on fire." On April 24, 2021, Connally sent Dr. Collins a series of four emails threatening Dr. Collins and his family with physical assault and death if Dr. Collins did not stop speaking about the need for "mandatory" COVID-19 vaccinations. Connally admitted that he sent the threats to Dr. Fauci and Dr. Collins with the intent of intimidating or interfering with the performance of their official duties and with the intent to retaliate against Dr. Fauci and Dr. Collins for performing their official duties, including discussing COVID-19 and its testing and prevention.

Connally also admitted sending emails threatening harm to three other individuals. Specifically, on November 24, 2020, Connally sent a series of six threatening emails to Dr. Rachel Levine, then Secretary of Health for the State of Pennsylvania, at Dr. Levine's email account at the Pennsylvania Department of Health. The subject lines and body of the

emails threatened Dr. Levine with physical violence and death. Similarly, on August 31, 2020, Connally sent an email threatening physical violence and death to a Massachusetts public health official. Finally, on April 21, 2021, Connally sent a series of four threatening emails to four individuals who work for a religious institution in Newark, New Jersey. The four emails threatened physical violence and death to a religious leader at the institution.

Florida—On June 30, 2022, MorseLife Health System Inc. (MorseLife) agreed to pay the United States $1.75 million to resolve its potential liability under the False Claims Act for facilitating COVID-19 vaccinations for hundreds of individuals ineligible to participate in the CDC Pharmacy Partnership for Long-Term Care Program (LTC PPP), a program specifically designed to vaccinate long-term care facility (LTCF) residents and staff when doses of COVID-19 vaccine were in limited supply at the beginning of the CDC COVID-19 Vaccination Program. MorseLife is a not-for-profit corporation located in West Palm Beach, Florida, that oversees health care facilities on its campus, including a nursing home and an assisted living facility.

The CDC announced the launch of the LTC PPP in October 2020. Because the LTCF population was at the highest risk of COVID-19 infections, the CDC created the LTC PPP to prioritize vaccinations for that population as quickly as possible and while vaccine availability was limited. Under this program, the CDC engaged with pharmacy partners to provide "end to end" management of the COVID-19 vaccination process, including conducting on-site vaccination clinics at the nursing homes and other LTCFs. More than 8 million vaccine doses were administered to LTCF residents and staff through this program.

MorseLife enrolled in the LTC PPP and scheduled its first vaccination clinic at MorseLife on Dec. 31, 2020 (the vaccination clinic) for residents and staff of the Joseph L. Morse Health Center, a skilled nursing facility on MorseLife's campus. The settlement resolves allegations that MorseLife knew that the LTC PPP covered only LTCF residents and staff but nevertheless invited and facilitated the vaccination of hundreds of ineligible persons at the clinic by characterizing them as "staff" and "volunteers," many of whom MorseLife targeted for donations. Specifically, the United States alleged that MorseLife: (1) characterized board members as "staff," (2) directed the organization's fundraising arm to invite donors and potential donors to the vaccination clinic, and (3) allowed the Vice Chairman of the MorseLife Health Systems Inc. Board and his brother to invite close to 300 ineligible individuals to receive the vaccine at MorseLife.

MorseLife's chief executive officer (CEO) allegedly directed the MorseLife Foundation, the organization's fundraising arm, to invite donors and potential donors to the vaccination clinic, encouraging Foundation employees to take advantage of the vaccination opportunity to target billionaires and millionaires for donations. For example, in one text message MorseLife's CEO stated: "I'm a little disappointed in the foundations mentality; I have delivered you 350 of the richest people in the country and you're still thinking $25,000

gift…". MorseLife's CEO added: "Do not be weak be strong you have the opportunity to take advantage of everyone who needs the shot…" Ultimately, the United States alleged that, of 976 persons vaccinated at the December 31, 2020, clinic, 567—or more than half—were ineligible to participate in the LTC PPP.

Utah—On July 6, 2022, Dino Rende and Francis Rende II were both sentenced to 36 months of probation and ordered to pay $500 in restitution after pleading guilty to misdemeanor conspiracy to steal or convert Government property charges stemming from the theft of CDC COVID-19 Vaccination Record Cards. In the plea agreement, both defendants admitted that between March 2021 and August 2021, they conspired to defraud CDC by agreeing to sell stolen CDC COVID-19 Vaccination Record Cards to others for $50 each. Both defendants also admitted that defendant Francis Rende II stole at least 20 CDC Vaccination Record Cards in March 2021; that he sent his brother, Dino Rende, some of the stolen vaccination record cards; and that they agreed to use them and sell them to others for $50 each.

Home Health

The following case examples involve home health fraud:

Kentucky—On May 5, 2022, SHC Home Health Services of Florida, LLC and its related entities (collectively, "Signature HomeNow") paid $2.1 million to the United States Government to settle claims of improperly billing the Medicare Program for home health services provided to beneficiaries living in Florida. Signature HomeNow, whose corporate headquarters is located in Louisville, Kentucky, operated home health care services in Florida. According to a complaint filed in the U.S. District Court for the Southern District of Florida against Signature HomeNow and the subsequent settlement agreement, it was alleged that between 2013 and 2017 Signature HomeNow knowingly submitted false or fraudulent claims seeking payment from the Medicare Program for home health services to Medicare beneficiaries who: (1) were not homebound, (2) did not require certain skilled care, (3) did not have a valid or otherwise appropriate plans of care in place, and/or (4) did not have appropriate face-to-face encounters needed to be appropriately certified to receive home health services.

Oklahoma and Florida—On September 27, 2022, the United States entered into two settlements with Carter Healthcare, LLC, an Oklahoma-based for-profit home health provider, and its affiliates. Carter Healthcare agreed to pay $7,175,000 to resolve allegations that it violated the False Claims Act by submitting claims to Medicare for medically unnecessary home health therapy services to Medicare beneficiaries in Florida, and it also agreed to pay $22,948,004 to resolve allegations that it submitted claims to

Medicare in violation of the anti-kickback statute by paying physicians remuneration under the guise of medical directorships in order to induce referrals of home health patients in Oklahoma. Carter Healthcare and its affiliates (CHC Holdings and CHC-FLA) entered into a 5-year CIA with OIG as part of the resolution of the matter. OIG excluded CEO Stanley Carter and Chief Operating Officer Brad Carter from participation in Federal health care programs for 5 years.

Hospital

The following case example involves a hospital:

Washington—On April 12, 2022, Providence Health & Services Washington (Providence) agreed to pay $22,690,458 to resolve allegations that it fraudulently billed Medicare, Medicaid, and other Federal health care programs for medically unnecessary neurosurgery procedures. Providence is a large health care and hospital system that operates 51 hospitals in 7 western U.S. States, including Providence St. Mary's Medical Center (Providence St. Mary's) in Walla Walla, Washington. Between 2013 and 2018, Providence St. Mary's employed neurosurgeons identified in the Settlement Agreement as Dr. A and Dr. B. Providence St. Mary's paid neurosurgeons based on a productivity metric that provided them a financial incentive to perform more surgical procedures of greater complexity. Between 2014 and 2018, Dr. A was one of the highest producing neurosurgeons in the entire Providence system. Between 2014 and 2017, based on the productivity metric, Providence paid Dr. A between $2.5 million and $2.9 million per year. This settlement resolves allegations that Providence falsely billed Medicare, Washington State Medicaid, and other Federal health care programs for deficient and medically unnecessary neurosurgery procedures performed by Dr. A and Dr. B.

As part of the Settlement Agreement, Providence admitted that during the time period in which Dr. A and Dr. B were employed at Providence St. Mary's as neurosurgeons, Providence medical personnel articulated concerns that Dr. A and Dr. B: (1) were endangering the safety of patients, (2) created through their surgeries an excessive level of complications and negative outcomes, (3) performed surgery on candidates who were not appropriate for surgery, and (4) failed to properly document their procedures and outcomes. Providence further admitted that Providence medical personnel articulated additional concerns that Dr. A: (1) completed medical documentation with falsified and exaggerated diagnoses to obtain reimbursement from insurance providers, (2) performed surgical procedures that did not meet the medical necessity requirements set by Medicare and other insurance programs, (3) "over-operated" (i.e., performed surgeries of greater complexity and scope than were medically appropriate), and (4) jeopardized patient safety by attempting to perform an excessive number of overly complex surgeries. Finally, Providence admitted that, while it eventually placed both Dr. B and Dr. A on administrative

leave in February 2017 and May 2018, respectively, it allowed both doctors to resign while on leave, and did not take any action to report Dr. A or Dr. B to the National Practitioner Data Bank or the Washington State Department of Health.

Pharmacies

The following case example involves a pharmacy:

New York—On April 13, 2022, Aleah Mohammed was sentenced to 6.5 years in prison for carrying out multiple schemes to defraud health care programs, including obtaining more than $6.5 million from Medicare Part D plans and Medicaid drug plans. According to court documents, Mohammed was the owner and operator of five pharmacies: Superdrugs Inc., Superdrugs I Inc., Superdrugs II Inc., S&A Superdrugs II Inc., and Village Stardrugs Inc. Between 2015 and2020, Mohammed utilized these pharmacies to engage in schemes that defrauded health care programs, including Medicare and Medicaid, by submitting claims for prescription drugs that were not dispensed, not prescribed as claimed, not medically necessary, or dispensed during a time when the pharmacy was no longer registered with the State of New York. The fraudulent claims included claims for expensive prescription drugs for the treatment of human immunodeficiency virus (HIV). Mohammed and her family used proceeds of the scheme to purchase luxury items such as a Cadillac Escalade SUV, a Mercedes Benz sedan, a Porsche Turbo coupe, as well as jewelry and real property in Queens, New York, and Pocono Pines, Pennsylvania.

Prescription Drugs

The following case examples involve prescription drugs:

Pennsylvania—On May 10, 2022, Andrew Berkowitz was sentenced to 20 years in prison, followed by 5 years of supervised release, and was ordered to pay a $40,000 fine and almost $4 million in restitution for running a prescription "pill mill" from his medical practice, which he operated in Philadelphia under the name "A+ Pain Management." In January 2020, Berkowitz pleaded guilty to 19 counts of health care fraud and 23 counts of distributing oxycodone outside the course of professional practice and without a legitimate medical purpose. The defendant fraudulently billed insurers for medically unnecessary physical therapy, acupuncture, chiropractic adjustments, and prescription drugs. In addition, the defendant fraudulently billed for treatments that were not provided at all. Regardless of their medical complaint, at every visit patients received a "goodie bag," which was a tote bag filled with prescription drugs for which Berkowitz submitted pharmacy claims through his company, Bucks Philadelphia Medical Care Group. The "goodie bags"

typically included a combination of drugs, including topical analgesics such as Relyyt and/or lidocaine, muscle relaxers such as chloroxazon and/or cyclobenzaprine, anti-inflammatories such as celecoxib and/or nalfon, Schedule IV controlled substances such as tramadol for pain, and/or eszopiclone and quazepam for insomnia and anxiety. The defendant obtained payments from insurers of more than $4,000 for each bag by falsely asserting that the drugs were for the benefit of the patient.

As part of the fraud scheme, Berkowitz also prescribed oxycodone to "pill-seeking" patients in exchange for their tacit approval that he would submit excessive claims to the patient's insurer for the "goodie bag" and other medically unnecessary services. From 2015 through 2018, Berkowitz obtained more than $4 million in fraudulent proceeds from his scheme. The defendant is also subject to a civil judgement under which he is obligated to pay approximately $1.8 million as a result of civil False Claims Act liability for false claims submitted to Medicare, and is subject to a permanent prohibition on prescribing, distributing, or dispensing controlled substances.

Washington State—On April 27, 2022, Janet Sue Arnold was sentenced to 48 months in Federal prison for conspiring to distribute and possess with intent to distribute opioid pain medications and other controlled substances without a legitimate medical purpose and outside the usual course of professional practice. According to court documents, Arnold abused her position of trust as a medical doctor by participating in a prescription drug conspiracy with Danielle Corine Mata, David Barnes Nay, Lisa Marie Cooper, and Jennifer Cheri Prichard. As part of their conspiracy, Dr. Arnold and her conspirators pushed thousands of pills on the street that were abused by addicts, and potentially caused others to become addicted to controlled substances. Mata and Prichard, who were both addicts, started out as patients but eventually started working at Dr. Arnold's clinic, Desert Wind Family Practice, in Richland, Washington. In approximately March 2016, Mata became the practice's office manager and one of Arnold's most trusted associates. During the conspiracy, Nay and Cooper also provided Mata with the names of fictitious patients for her to use on several of the blank, pre-signed prescriptions to obtain opioids.

The conspiracy operated primarily out of Dr. Arnold's clinic in Richland, Washington. On a regular basis, the conspirators distributed highly addictive and dangerous controlled substances, including fentanyl, oxycodone, methadone, hydromorphone, methylphenidate, an amphetamine mixture, as well as carisoprodol and alprazolam. Dr. Arnold had a pattern and practice of providing office staff and patients with hundreds of blank, pre-signed prescriptions that, after logging into the clinic computer, allowed the conspirators to complete and print prescriptions for opioids and other controlled substances. Text messages recovered by investigators from Arnold's and Mata's phones showed that Dr. Arnold had texted Mata asking whether she needed more "signed paper."

South Dakota—On July 12, 2022, Donna Garnette was convicted of conspiracy to distribute a controlled substance. Garnette, age 29, was sentenced to 9 years in Federal prison, followed by 3 years of supervised release, and was ordered to pay a $100 special assessment to the Federal Crime Victims Fund. Garnette was indicted for the charge by a Federal grand jury in May 2021 and pleaded guilty in December 2021. The conviction stemmed from Garnette obtaining and distributing fentanyl (4-ANPP) and hydrocodone pills with her conspirators on the Pine Ridge Reservation.

The case was investigated by the Badlands Safe Trails Task Force, which includes the Federal Bureau of Investigation (FBI), Bureau of Indian Affairs, Oglala Sioux Tribe Department of Public Safety, South Dakota Department of Criminal Investigation, and HHS-OIG.

Kickbacks

The following case example involves kickbacks:

Washington State—On May 27, 2022, Jae Lee, the CEO of Northwest Physicians Laboratory (NWPL), was sentenced to serve 24 months in prison and ordered to pay $7.6 million in restitution for conspiracy to solicit kickbacks from medical testing laboratories in exchange for referring Government testing business to the laboratories. CEO Lee helped NWPL obtain more than $3.7 million in kickback payments by steering urine drug test specimens to two laboratories that billed the Government for testing, resulting in Government payments to those two laboratories of more than $6.5 million.

According to records filed in the case between January 2013 and July 2015, those two laboratories, which were not physician owned, made payments to NWPL in exchange for referrals of Medicare and TRICARE program business, in violation of the anti-kickback statute. Paying remuneration to medical providers or provider-owned laboratories in exchange for referrals encourages providers to order medically unnecessary services. The anti-kickback statute functions, in part, to discourage such behavior. NWPL was physician-owned, and for that reason could not test urine samples for patients covered by Government health programs such as Medicare, Medicaid, and TRICARE. To conceal the payment of the kickbacks, Lee and other co-conspirators described the fees as being for marketing services; however, no marketing services were performed.

NWPL pleaded guilty in February 2021 and was sentenced to pay $8,114,417 in restitution joint and several with the other criminal defendants. NWPL has been dissolved. To date, the laboratories and individuals involved in this investigation have agreed to pay more than $14 million to settle related civil allegations.

Nursing Homes

The following case example involves a nursing home:

New York—On June 29, 2022, the United States settled a civil False Claims Act lawsuit against TCPRNC, LLC d/b/a Plaza Rehab and Nursing Center (Plaza Rehab Center) and Citadel Consulting Group LLC d/b/a Citadel Care Centers (Citadel). The settlement resolved allegations that Plaza Rehab Center, acting at the direction of Citadel, fraudulently switched the type of Medicare coverage in which elderly residents were enrolled to maximize the Medicare payments that Plaza Rehab Center would receive.

Under the settlement, Plaza Rehab Center and Citadel agreed to pay a total of $7.85 million and made extensive factual admissions regarding their conduct. Specifically, Plaza Rehab Center and Citadel admitted that their staff often did not obtain the consent of residents or authorized representatives before disenrolling the residents from their Medicare Advantage Plan. From September 2016 to February 2019, Citadel exerted pressure on Plaza Rehab Center staff to increase the number of residents enrolled in fee-for-service Medicare to increase Medicare reimbursements. Plaza Rehab Center and Citadel also entered into a CIA with HHS-OIG, which requires that they maintain a compliance program designed to foster adherence to Federal health care program requirements.

Telemarketing

The following case example involves telemarketing

Florida—On June 16, 2022, Marc Sporn was sentenced to 14 years in prison for health care and wire fraud resulting in a loss of more than $20 million to Medicare, and for evading taxes. According to court documents, Marc Sporn owned and operated several telemarketing and telemedicine companies, including CPL Media Group Inc. Medipak, LLC; Real Time Physicians LLC; 24 HR Virtual MD LLC; Medtech Worldwide Inc.; New World Holdings Inc.; and Ins Cov LLC. Sporn used these companies to market medically unnecessary genetic tests to Medicare beneficiaries, and to sell prescriptions (i.e., doctors' orders) for medically unnecessary genetic tests to laboratories in exchange for kickbacks and bribes. Sporn knew these laboratories would use these doctors' orders to bill Medicare for medically unnecessary goods and services.

Through nominee owners, Sporn also operated and controlled Palm Beach companies Medi Biotech LLC and Walmol Holdings LLC. Sporn used Medi Biotech to market compounded prescription creams to customers with certain health conditions. Pharmacies and laboratories associated with Medi Biotech filled the prescriptions, billed the customers' insurance companies, and paid Sporn kickbacks. In addition to opening bank accounts for

Medi Biotech in nominee names, Sporn opened accounts in the name of Walmol Holdings, a shell corporation, and in 2014 and 2015, avoided paying more than $1.6 million in personal income taxes by diverting millions through the company's accounts. Sporn used these company accounts to purchase luxury items such as high-end watches and diamond jewelry, classic and exotic cars, two yachts, and other items. Sporn also evaded paying more than $2.5 million in personal income taxes for other years dating back to 2000. When the IRS attempted to collect back taxes from Sporn, he tried to conceal assets by transferring property to trusts and individuals and by repeatedly opening and closing companies, among other things. In addition to the prison term and Medicare restitution, Sporn was ordered to pay more than $4 million in restitution to the IRS.

Affordable Care Act

The following case example involves the Affordable Care Act (ACA):

California—On August 18, 2022, Ventura County's organized health system and three medical care providers agreed to pay a total of $70.7 million to settle allegations that they broke Federal and State laws by submitting or causing the submission of false claims to California's Medicaid program (Medi-Cal) related to Medicaid Adult Expansion under the ACA. The parties that entered into the three separate settlement agreements are:

- Ventura County Medi-Cal Managed Care Commission, which does business as Gold Coast HealthPlan, a county-organized health system (COHS) that contracts to arrange for the provision of health care services under Medi-Cal in Ventura County;
- Ventura County, which owns and operates Ventura County Medical Center, an integrated health care system that provides hospital, clinic, and specialty services;
- Dignity Health, a San Francisco-based not-for-profit hospital system that operates two acute-care hospitals in Ventura County; and
- Clinicas del Camino Real, Inc. (Clinicas), a non-profit health care organization headquartered in Camarillo.

Pursuant to the ACA, beginning in January 2014, Medi-Cal was expanded to cover the previously uninsured "Adult Expansion" population—adults between the ages of 19 and 64, without dependent children, and with annual incomes up to 133 percent of the Federal poverty level. The Federal Government fully funded the expansion coverage for the first three years of the program.

Pursuant to contracts with California's Department of Health Care Services (DHCS), if a California COHS did not spend at least 85 percent of the funds it received for the Adult Expansion population on "allowed medical expenses," the COHS was required to pay back to the State the difference between 85 percent and what it actually spent. California, in turn, was required to return that amount to the Federal Government.

The three settlements resolve allegations that Gold Coast, Ventura County, Dignity, and Clinicas knowingly submitted or caused the submission of false claims to Medi-Cal for "Additional Services" provided to Adult Expansion Medi-Cal members between January 1, 2014, and May 31, 2015. The United States and California alleged that the payments were not "allowed medical expenses" under Gold Coast's contract with DHCS, were pre-determined amounts that did not reflect the fair market value of any Additional Services provided, and/or the additional services were duplicative of services already required to be rendered. The United States and California further alleged that the payments were unlawful gifts of public funds in violation of Article IV, Section 17, of the Constitution of California.

As a result of the settlements, Gold Coast agreed to pay $17.2 million to the United States; Ventura County agreed to pay $29 million to the United States; Dignity agreed to pay $10.8 million to the United States and $1.2 million to the State of California; and Clinicas agreed to pay $11.25 million to the United States and $1.25 million to the State of California.

Contemporaneous with the False Claims Act settlement, HHS agreed to release its right to exclude Gold Coast and Ventura County from federally funded health care programs in exchange for their agreements to enter into 5-year CIAs. The CIAs require, among other things, that Gold Coast and Ventura County each implement centralized risk assessment programs as part of their compliance programs, and that each hire an independent review organization to complete annual reviews. Gold Coast's annual reviews will focus on its calculation and reporting of MLR data under Medi-Cal, while Ventura County's annual reviews will target hospital claims submitted to Medicare and Medicaid, including claims submitted to Medicaid managed care organizations.

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 100 individuals or entities, 98 criminal actions, and more than $248.2 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:

> Florida—On July 7, 2022, Jose Santeiro was sentenced to 54 months in prison for engaging in a scheme that fraudulently billed approximately $112 million for substance use disorder services that were never provided or were medically unnecessary. According to court documents, Jose Santeiro worked with others to unlawfully bill for approximately $112 million of addiction treatment services that were never rendered and/or were medically unnecessary at two addiction treatment facilities where Santeiro was the medical director. The facilities were Second Chance Detox LLC, d/b/a Compass Detox (Compass Detox), an inpatient detox and residential facility, and WAR Network LLC (WAR), a related outpatient treatment program.
>
> According to court documents and evidence presented at trial, Santeiro and others admitted patients for medically unnecessary detox services, the most expensive kind of treatment the facilities offered. Patient recruiters offered kickbacks to induce patients to attend the programs and then gave them illegal drugs to ensure admittance for detox at Compass Detox. Evidence at trial also showed that Santeiro submitted false and fraudulent claims for excessive, medically unnecessary urinalysis drug tests that were never used in treatment. Santeiro and others then authorized the re-admission of a core group of patients who were shuffled between Compass Detox and WAR to fraudulently bill for as much as possible, even though the patients did not need the expensive treatments for which they were repeatedly admitted. Santeiro also prescribed Compass Detox patients a so-called "comfort drink" to sedate them, ensure they stayed at the facility, and keep them coming back. The evidence further showed that Santeiro's log-in information was used by others, with his knowledge, to sign electronic medical files to make it appear as if Santeiro had provided treatment himself when he had not.

Compliance Trainings

Health Care Provider Compliance Training

OIG provides free training on our website for health care providers, compliance professionals, and attorneys. OIG's Provider Compliance Training was an initiative developed in 2011 that continues to reach the health care community with OIG's message of compliance and prevention via free downloadable comprehensive training materials and podcasts. OIG's provider compliance training resources are available at https://oig.hhs.gov/compliance/compliance-guidance/index.asp.

American Indian/Alaska Native Compliance Trainings

OIG provides a free online training series, *Improving Health and Well-Being in American Indian and Alaska Native Communities Through Compliance*, for grantees and health care providers who serve American Indian/Alaska Native (AI/AN) communities. The training series covers topics such as compliance; fraud, waste, and abuse; and health care quality, including how OIG works with the AI/AN community to combat the opioid epidemic and to protect patients from sexual abuse. The training series includes web-based trainings, job aids, and videos which are available at https://oig.hhs.gov/reports-and-publications/featured-topics/ihs/training.asp.

Whistleblower Protection Training

In addition to training for health care providers, OIG provides training to HHS employees, contractors, and award recipients on Federal whistleblower protections and prohibitions against retaliation. This training is provided by the HHS Whistleblower Protection Coordinator within the OIG Office of Counsel to the Inspector General and is conducted in coordination with HHS OpDivs and Staff Divisions (StaffDivs). OIG also provides training videos, materials, and FAQs about whistleblower protections on its website at https://oig.hhs.gov/fraud/whistleblower/.

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, no fugitives were captured.

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 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 OIG 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 $40,229,634 as a direct result of cases originating from hotline complaints.

OIG Hotline Activity (4/1/2022–9/30/2022)

Contacts to 1-800-HHS-TIPS phone line, including callers seeking information	60,880
Total tips evaluated	19,450
Tips referred for action	10,547
Closed; no basis provided for further action	1,343
Closed; no HHS violation[1]	770
Closed; other administrative reason	6,790

Sources of tips referred for action

Phone	2,930
OIG website	6,112
Letters or faxes	515
Other	990

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.

In addition to an annual recertification review of each MFCU, OIG conducts reviews of a sample of MFCUs. OIG evaluates MFCU operations based on 12 performance standards and assesses compliance with laws, regulations, and OIG policy guidance. During the reporting period, OIG issued reports of onsite reviews of the following MFCUs:

- *Iowa Medicaid Fraud Control Unit: 2021 Inspection* (OEI-07-21-00340), June 2022;
- *Connecticut Medicaid Fraud Control Unit: 2021 Inspection* (OEI-06-21-00360), September 2022; and
- *Michigan Medicaid Fraud Control Unit: 2021 Review* (OEI-06-21-00270), September 2022.

OIG Joint Casework With MFCUs

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

Louisiana—On April 19, 2022, Marty Johnson was sentenced to 60 months in prison, followed by 1 year of supervised release, and Keesha Dinkins was sentenced to 24 months in prison, followed by 1 year of supervised release, in connection with a health care fraud and wire fraud scheme. In addition, Marty Johnson and Keesha Dinkins were ordered to jointly pay restitution in the amount of $3.5 million. According to information presented to the court, Marty Johnson owned and operated Positive Change Counseling Agency (Positive Change) located in Shreveport, Louisiana, from January 2013 to January 2018. Keesha Dinkins was a manager and supervisor at Positive Change, which provided mental health rehabilitation and related services to Medicaid beneficiaries in the Caddo and Bossier Parish areas. From 2014 to January 2018, Johnson submitted and caused to be submitted fraudulent claims for mental health rehabilitation and non-emergency transportation services on behalf of Positive Change. Keesha Dinkins knew that Marty Johnson submitted these fraudulent claims that she and Johnson both knew were not performed or rendered. These fraudulent claims resulted in Positive Change receiving payments from Medicaid to which it was not entitled. Johnson admitted to paying individuals money to enroll with Positive Change, increasing the capacity for Positive Change to bill Medicaid for services that were not rendered. Johnson instructed employees at Positive Change, and Dinkins advised those employees, to create false client files to conceal from Medicaid and insurance company auditors and inspectors that it had not performed the services related to its previously submitted claims which had already been reimbursed by Medicaid. To create these false client files, sections from different client documents were physically cut to form inserts that were glued into blank client log templates. These templates with the glued inserts were then photocopied to create the appearance of legitimate documents. Johnson and Dinkins supervised and knowingly and willfully instructed the employees creating these false client files to place the false and fictitious photocopied, cut-and-pasted documents into the client files. Johnson and Dinkins knew that these false client files were used to conceal from Medicaid officials that Positive Change did not render the services in the claims submitted by it and paid by Medicaid. The case was investigated by HHS-OIG, the Louisiana State Attorney General's Office MFCU, and the FBI.

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 opinions 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 14 requests for advisory opinions, issued 11 advisory opinions, and modified 2 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 (also known 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 1,290 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 1,290 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:

North Carolina—On May 19, 2022, OIG excluded the owner and operator of a billing agency for a minimum period of 30 years based on her conviction for health care fraud conspiracy. Specifically, the individual engaged in a scheme to defraud Medicaid by

submitting claims for fictitious services or services that were never provided. The court ordered her to pay approximately $6,121,600 in restitution, and she was sentenced to 84 months of incarceration.

Georgia—On May 19, 2022, a dietary supplements company and its owner were excluded for a minimum period of 3 years based on their convictions for introducing a misbranded drug into interstate commerce in violation of the Federal Food, Drug, and Cosmetic Act. Specifically, the individual and company pled guilty to selling and distributing a vitamin D product with false and misleading marketing claims that their product would lower consumers' risks of contracting COVID-19.

Louisiana—On May 22, 2022, OIG excluded the owner of seven nursing homes in the State of Louisiana for an indefinite period of time based on his ownership of excluded entities. As background, OIG had previously excluded the seven nursing homes owned by this individual after the State of Louisiana revoked their licenses to operate as nursing homes following a series of documented violations identified in the aftermath of Hurricane Ida. Specifically, the nursing homes evacuated more than 800 residents of the facilities to a single warehouse where subsequent State inspectors observed residents living in inhumane conditions (e.g., some residents were sleeping on mattresses near standing water, some residents were undressed or naked, other residents were calling for help but being left alone with full diapers). During these onsite visits, the owner attempted to threaten, intimidate, and interfere with the assessment of the site, where seven residents eventually died.

Washington—On July 20, 2022, a physician in Seattle was excluded for a minimum period of 18 years based on his conviction by jury verdict of multiple counts of wire fraud, bank fraud, and money laundering. Specifically, the physician submitted false and misleading loan applications as part of a fraud scheme to obtain funding from the Paycheck Protection Program and Economic Injury Disaster Loan Program, authorized by the Coronavirus Aid, Relief, and Economic Security (CARES) Act designed to offset economic hardships caused by the COVID-19 pandemic. In addition, the court ordered him to pay $1,438,000 in restitution and sentenced him to 48 months of incarceration. The Washington Department of Health Medical Commission also suspended his license to practice.

Texas—On August 18, 2022, OIG excluded a physician for a minimum period of 25 years based on his convictions for conspiracy to distribute a controlled substance and commit mail fraud. In addition to illegally dispensing controlled substances (e.g., hydrocodone), this physician conspired with others to unlawfully enrich themselves by submitting fraudulent claims to workers' compensation programs as well as other health insurers for

medical services that were not rendered. The court ordered the physician to pay approximately $376,300 in restitution and serve 144 months of incarceration.

Maine—On September 20, 2022, OIG excluded a physician's assistant for a minimum period of 23 years based on his conviction of unlawful sexual contact with a minor patient. The court also sentenced the physician's assistant to 7 years of incarceration, and the Maine State Board of Medical Licensure revoked his license.

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 examples involve debarment:

Nebraska—Mubanga Chongo-Ofafa, Little Blessings Learning Center, Seth Mock, Mock's Loving Life Learning Center, and Aileen Kogera Njoroge were each debarred for a period of 3 years. The debarment was imposed by the HHS Suspension and Debarment Official based on a referral from OIG. Chongo-Ofafa, Little Blessings, Mock, Mock's Loving Life Learning Center, and Njoroge were criminally convicted for their role in a scheme to defraud child care programs by submitting claims for children who did not attend the child care program. The child care program is funded in part by HHS's Administration for Children and Families' Child Care Development Fund (CCDF). The CCDF provides child care subsidies to low-income families where the parents are employed or engaged in approved job training. A review of timesheets reflected that the State was falsely billed for families whose children did not attend day care on the days and times claimed.

Washington—Sami Anwar and his companies Mid Columbia Research LLC and Zain Research LLC were each debarred for a period of 3 years. The debarment was imposed by the HHS Suspension and Debarment Official based on a referral from OIG. Sami Anwar, through his clinical research companies Mid Columbia and Zain Research, was paid by drug

sponsors and clinical research organizations to conduct clinical research and drug trials. Between 2013 and 2018 Sami Anwar directed a scheme to have his companies pose as legitimate human clinical research sites and provide false clinical research trial data regarding drug safety and efficacy to dozens of drug companies, and through them, to the Food and Drug Administration (FDA). By engaging in this fraud, Sami Anwar bilked millions from drug sponsors, endangered study participants, and provided false data to the FDA and DEA regulators.

Civil Monetary Penalties Law

The 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 $27.7 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:

Georgia—Michael Dalton Hanowell, M.D.; Hanowell Spine Clinic, LLC; and Hanowell Pain Management, LLC (collectively, "Dr. Hanowell") entered into a $409,809.88 settlement agreement with OIG. The settlement agreement resolves allegations that Dr. Hanowell submitted claims to Medicare for facet joint injections and denervations that exceeded the allowable number of sessions in a rolling 12-month period.

New York—Richmond County Ambulance, Inc. (RCA) entered into a $1,578,412 settlement agreement with OIG. The settlement agreement resolves allegations that RCA presented claims to Medicare Part B for ambulance transportation to and from skilled nursing facilities (SNFs) where such transportation was already covered by the SNF consolidated billing payment under Medicare Part A.

Minnesota—Dr. Kenneth P. Martinez and his professional corporation (Kenneth P. Martinez, M.D., a Medical Corporation d/b/a Neurology and Pain Specialty Center) (collectively, "Dr. Martinez"), entered into a $919,644.34 settlement agreement with OIG. The settlement agreement resolves allegations that Dr. Martinez knowingly presented to Medicare claims

for items or services that Dr. Martinez knew or should have known were not provided as claimed and were false or fraudulent. Specifically, Dr. Martinez submitted claims: (1) using CPT code 95937 (neuromuscular junction testing) under the National Provider Identifier (NPI) number of Kenneth P. Martinez, M.D., when the neuromuscular junction testing was either not medically necessary or was not performed at the applicable standard of care; and (2) using CPT Code 95913 (for 13 or more nerve conduction studies) under Kenneth P. Martinez, M.D.'s NPI number when Kenneth P. Martinez, M.D., performed only 12 or fewer nerve conduction studies.

Arizona—Justin Thompson, DC; Physical Medicine of Scottsdale, LLC d/b/a Arizona Pain Relief; Anthem Physical Medicine; and Biltmore Physical Medicine (collectively, "Arizona Pain Relief") entered into a $1,905,070.74 settlement agreement with OIG. The settlement agreement resolves allegations that Arizona Pain Relief submitted false claims to Medicare for: (1) implantable neurostimulator devices using HCPCS Code L8679 when they instead provided auricular peripheral nerve stimulation devices that are not covered by Medicare; (2) CPT Codes 95970, 64555, and 64999 that were associated with the application, monitoring, and removal of the device; and (3) CPT Codes 99211, 99212, and 99213 for evaluation and management (E&M) services billed on the same date of service as HCPCS Code L8679 that were billed for time spent providing and removing the device when no separate and identifiable E&M service was provided.

Self-Disclosure Programs

Health care providers, suppliers, or other individuals or entities subject to CMPs can apply for acceptance into the Health Care Fraud Self-Disclosure Protocol, a program created in 1998 for voluntary disclosure of self-discovered evidence of potential fraud. The Health Care Fraud Self-Disclosure Protocol may give individuals and entities 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 $18.8 million in HHS receivables.

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

Illinois—After they self-disclosed conduct to OIG, Presence Central and Suburban Hospitals Network d/b/a AMITA Health Mercy Medical Center and Presence Chicago Hospitals Network d/b/a AMITA Health Saints Mary and Elizabeth Medical Center (collectively, "AMITA") agreed to pay $6,232,195.50 for allegedly violating the CMPL. OIG alleged that AMITA submitted claims to Medicare Part A for inpatient psychiatric admissions that were not medically necessary.

Maryland—After it self-disclosed conduct to OIG, Corridor Anesthesia, LLC (Corridor) agreed to pay $1,117,684.50 for allegedly violating the CMPL. OIG alleged that Corridor submitted claims to Federal health care programs for services provided by certified registered nurse anesthetists (CRNAs) who were not authorized to bill for their services on behalf of Corridor. Therefore, Corridor billed for these services under the name of another CRNA who was authorized to bill on behalf of Corridor.

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 examples involve CIA enforcement:

Oklahoma—After it disclosed conduct to OIG pursuant to its CIA, Oklahoma Heart Hospital South, LLC entered into a $1,151,770.50 False Claims Act settlement agreement with DOJ and OIG. The United States alleged that the hospital billed Medicare for intensive cardiac rehabilitation that was not provided under a plan established, reviewed, and signed by a physician, or not updated, reviewed, and signed by a physician every 30 days.

Michigan—After it disclosed conduct to OIG pursuant to its CIA, William Beaumont Hospital (WBH) agreed to pay $1,732,548 for allegedly violating the CMPL by paying kickbacks. OIG alleged that WBH: (1) paid remuneration to cardiologists in the form of excess compensation and (2) paid remuneration to a medical practice in the form of free use of medical equipment and personnel.

Public Health and Human Service Agency Reports and Reviews

Public Health Agency Reports and Reviews

Office of the Assistant Secretary for Preparedness and Response

HHS Did Not Fully Comply With Federal Requirements and HHS Policies and Procedures When Awarding and Monitoring Contracts for Ventilators (A-02-20-02002), September 2022

HHS's Administration for Strategic Preparedness and Response (ASPR) did not consistently award and monitor contracts for ventilators for use in responding to the COVID-19 pandemic in accordance with Federal requirements and HHS policies and procedures. Specifically, ASPR did not establish roles and responsibilities for communication with other emergency response teams, did not always accurately report contract data, and did not always properly monitor contractor performance.

As a result, ASPR could not ensure compliance with applicable Federal requirements or that each contract's terms were economically and efficiently achieved; therefore, ASPR could not determine whether the use of taxpayer funds was reasonable. In addition, the Federal Government may have used inaccurate contract data supplied by ASPR to measure and assess the impact of Federal procurements on Coronavirus Aid, Relief, and Economic Security (CARES) Act spending. Finally, ASPR potentially hindered the Strategic National Stockpile's ability to meet anticipated ventilator demand in support of the Federal Government's COVID-19 pandemic response.

ASPR did not indicate concurrence or nonconcurrence with our recommendations, including that it establish written policies and procedures for communicating with federally established emergency response team lead agencies, accurately report contract data, and strengthen its policies and procedures to ensure proper monitoring of contractor performance.

Food and Drug Administration

The Food and Drug Administration's Foreign For-Cause Drug Inspection Program Can Be Improved To Protect the Nation's Drug Supply (A-01-19-01500), June 2022

FDA's timeframes for completing the steps in the foreign for-cause drug inspection process generally improved after it implemented programmatic changes in 2017. However, we found that: (1) FDA did not always follow its policies and procedures for foreign for-cause drug inspections and

(2) FDA could not provide documentation to support that all lead investigators completed the required training before they conducted inspections.

According to FDA, it had limited resources and faced unexpected events and complex circumstances. FDA did not ensure that it recorded certain information in the Establishment Inspection Report (EIR), such as whether an inspection was announced. If FDA does not follow its policies and procedures related to timeliness, regulatory deficiencies may not be corrected in an efficient manner. FDA did not ensure that lead investigators completed required training before they conducted inspections because FDA did not have policies and procedures that required investigators' supervisors to verify that lead investigators completed the required training prior to being assigned to an inspection. FDA officials told us that because of multiple location moves, FDA misplaced records indicating that lead investigators completed training requirements. It is a vulnerability to have lead investigators conduct inspections before ensuring that they are qualified.

FDA concurred with our recommendations that it identify and implement additional ways to improve the timeliness of its foreign for-cause drug inspection process. We also made other procedural recommendations that are listed in the report.

Delays in Confirmatory Trials for Drugs Granted FDA's Accelerated Approval Raise Concerns (OEI-01-21-00401), September 2022

More than one-third of accelerated approval drug applications with incomplete confirmatory trials are past their trials' original planned completion dates, including four drug applications that are more than 5 years past those dates. Additionally, we found that Medicare and Medicaid spent more than $18 billion from 2018 to 2021 for accelerated approval drugs with incomplete confirmatory trials past their trials' original planned completion dates.

FDA Repeatedly Adapted Emergency Use Authorization Policies to Address the Need for COVID-19 Testing (OEI-01-20-00380), September 2022

From January through May 2020, FDA repeatedly adapted its approach to how it used Emergency Use Authorizations (EUAs) to address COVID-19 testing challenges; however, efforts to increase test availability sometimes came at a cost to test quality. Our findings underscore the need to apply insights from FDA's early experiences with the COVID-19 pandemic toward current and future infectious disease emergencies to better balance test availability and quality.

FDA concurred with all six of our recommendations, which were that: (1) FDA should assess and, as appropriate, revise guidance for test EUA submissions; (2) FDA should develop a suite of EUA templates for future emergencies involving novel pathogens; (3) FDA should expand the FDA Center for Devices and Radiological Health's existing device-tracking platform to facilitate EUA submission and monitoring; (4) FDA should expand and improve resources for test developers on the EUA process; (5) FDA should establish formal communication channels between FDA and the

lab community, to be used in emergency testing; and (6) FDA should work with Federal partners to implement lessons learned about a national testing strategy that go beyond the EUA process

FDA's Work With the Tri-Agency Task Force for Emergency Diagnostics Helped Labs Implement COVID-19 Tests (OEI-01-20-00381), September 2022

FDA's engagement with the Tri-Agency Task Force for Emergency Diagnostics demonstrates the value of interagency coordination and collaboration to facilitate emergency test implementation in laboratories. This task force—a joint effort of FDA, CDC, and CMS—was established in 2019 to enhance the effectiveness of the Federal response to emergencies that require laboratories to implement tests. Prior to the COVID-19 pandemic, the task force identified gaps to prepare for future emergencies. During the pandemic, it provided a venue for member agencies to coordinate their responses to pandemic-related challenges. FDA's continued coordination with the task force holds potential for further improvements in emergency test implementation in laboratories.

Indian Health Service

Indian Health Service Capacity To Manage Supplemental $3.5 Billion Allocated to Its Sanitation Facilities Construction Program (OEI-06-22-00320), September 2022

Congress appropriated $3.5 billion to the Indian Health Service (IHS) for Sanitation Facilities Construction projects under the Infrastructure Investment and Jobs Act (IIJA), and allocated 0.5 percent of the supplemental funding to OIG for oversight. As part of a more comprehensive evaluation, OIG conducted preliminary research of IHS's capacity to administer and oversee the $3.5 billion. Through this research, we identified three initial observations about IHS capacity, which we shared with IHS to assist the agency as it continues its planning for how to use and oversee the funds. These observations were that: (1) IHS quickly began preparations to increase capacity and administer the funds using existing, generally supported methods; (2) to administer the IIJA-funded projects and meet sanitation needs, IHS faces financial, capacity, and other challenges that warrant continued attention; and (3) plans are still unclear for IHS assessment of the use of IIJA funds, strategies for future spending, and assisting Tribes with long-term operation of IIJA-funded facilities.

IHS's National Supply Service Center Was Generally Effective in Providing Supplies to Facilities During the COVID-19 Pandemic, but Its Internal Controls Could Be Improved (A-07-20-04124), September 2022

IHS's National Supply Service Center (NSSC) was generally effective in facilitating the distribution of medical supplies and equipment during the COVID-19 pandemic. However, we noted that NSSC's internal controls could be improved. In lieu of written policies and procedures, NSSC relied on the institutional knowledge of key employees in implementing a new medical supply distribution

method as the pandemic developed. NSSC also did not have sufficient warehouse facilities. Finally, NSSC's inventory management system was outdated and could not track the routing of a product that had been shipped or provide necessary information about the shipment to the customer.

Because NSSC did not have written policies and procedures in place that would provide a framework to guide decision making for emergency situations, its current process is not optimal or sustainable, particularly when institutional knowledge is subsequently lost or diminished. As a result, there is an increased risk that NSSC will not be able to respond effectively to future emergencies. NSSC's outdated inventory management system also poses an increased risk to the effectiveness and efficiency of NSSC operations in the future.

IHS concurred with our recommendations that NSSC strengthen internal controls by developing and implementing written policies and procedures for emergency situations; identify feasibly viable options, including seeking additional funding, to prepare for future emergency situations that address additional storage capacity and inventory distribution; and upgrade its inventory management system software to improve its ability to interface with customers and vendors.

IHS Telehealth System Was Deployed Without Some Required Cybersecurity Controls (A-18-21-03100), September 2022

IHS deployed a national telehealth system, which increased the availability of health care services during the pandemic, but it did not complete select IT controls as required prior to deploying its telehealth system nationally. Specifically, IHS did not complete the contingency plan, risk assessment, finalized authorization to operate, and system security plan. Additionally, after deployment of the telehealth system, IHS did not remediate known vulnerabilities on some telehealth system devices in a timely manner. IHS has since completed the controls covered by this audit, and no major incidents or breaches have been reported to HHS.

IHS concurred with our recommendations that it develop a strategy for identifying, implementing, and testing cybersecurity controls for new information systems that are deployed in an expedited fashion to meet an urgent, mission-critical need.

Centers for Disease Control and Prevention

CDC Found Ways To Use Data To Understand and Address COVID-19 Health Disparities, Despite Challenges With Existing Data (OEI-05-20-00540), July 2022

Although CDC's racial, ethnic, and socioeconomic data associated with COVID-19 testing, cases, hospitalizations, and deaths have limitations, CDC found ways to use these and other data to understand and address COVID-19 health disparities. These findings illuminate challenges that

jurisdictions and CDC face in collecting and using public health data and help CDC prioritize efforts to improve the data collected.

CDC concurred with both of our recommendations, which were that: (1) CDC should expand efforts both to improve racial and ethnic data associated with COVID-19 and to supplement them with additional data sources and (2) CDC should ensure that Tribal Epidemiology Centers have timely access to all public health data to which they are entitled.

HHS Should Improve Internal Coordination Regarding Unaccompanied Children, (OEI-BL-20-00670) May 2022

OIG identified a lack of internal coordination during the development and early implementation of a CDC public health order ("Title 42 order") that significantly affected Office of Refugee Resettlement (ORR) programs to serve unaccompanied children. (ORR is a program office within the HHS's Administration for Children and Families.) Effective coordination is critical, because in order to effectively predict programmatic and capacity needs, ORR must have timely access to all relevant information about HHS decision making that affects unaccompanied children.

CDC and ACF concurred with both of our recommendations, which were that: (1) HHS should take steps to improve internal coordination and communication about unaccompanied children; and (2) HHS should ensure that CDC coordinates with ORR when making future decisions that could affect the number of unaccompanied children placed in ORR's care, including any Title 42 order.

CDC's Corrective Actions Improved Program Operations at the National Institute of Health in Mozambique and Facilitated the Institute's Implementation of Prior OIG Audit Recommendations (A-04-20-01019), September 2022

CDC's corrective actions, in response to our November 2016 memorandum, improved program operations at the National Institute of Health in Mozambique (the Institute). Specifically, CDC took the following eight corrective actions, which we confirmed through our current audit:
(1) designated the Institute a high-risk organization, (2) added special award conditions,
(3) conducted a site visit in December 2016, (4) delayed new funding to the Institute,
(5) conducted a risk and business system assessment in March 2018, (6) hired a project officer to manage the Government-to-Government portfolio in Mozambique, (7) worked with the Institute to ensure proper systems and practices are in place, and (8) employed a fiscal agent.

Of our 10 prior audit recommendations, 2 remained unimplemented when the current audit began: (1) refund to CDC $431,458 of unallowable expenditures and (2) work with CDC to obtain value-added tax (VAT) reimbursement from the Government of Mozambique.

The Institute implemented the first recommendation by refunding $5,287 per CDC's instruction. To implement the second, the Institute is seeking a refund from the Government of Mozambique of $546,543 for the VAT it paid with U.S. President's Emergency Plan for AIDS Relief (PEPFAR) funds from September 2012 through December 2015, when a new agreement was reached providing a framework for VAT reimbursement. During our audit period, the Institute tracked VAT payments and reported them to CDC quarterly for reimbursement requests. This report includes no recommendations.

National Institutes of Health

Opportunities Exist To Strengthen NIH Grantees' Oversight of Investigators' Foreign Significant Financial Interests and Other Support (OEI-03-20-00210), May 2022

The integrity and security of research funded by NIH relies, in part, on grantee institutions' (hereafter grantees') oversight of their investigators' significant financial interests and other support. We found that most grantees failed to meet at least one Federal requirement related to investigators' foreign significant financial interests and other support. In addition, many grantees lacked oversight practices that would help ensure that all materials submitted to NIH are complete and accurate. At the same time, grantees reported promising practices that, if more widely adopted, present additional opportunities to strengthen oversight of investigators' foreign significant financial interests and other support.

NIH concurred with all seven of our recommendations, which were that: (1) NIH should ensure that grantees comply with Federal requirements to train investigators regarding disclosure of significant financial interests, (2) NIH should ensure that grantees conduct the required review of investigators' significant financial interests to determine whether conflicts exist, (3) NIH should specifically require grantees to provide trainings and maintain a written policy regarding investigators' disclosure of other support, (4) NIH should modify reporting mechanisms to require grantees to report whether investigators' significant financial interests and other support involve foreign entities, (5) NIH should conduct outreach to grantees with R13 conference grants to clarify requirements regarding the disclosure and review of investigators' significant financial interests and other support, (6) NIH should clarify whether and how grantees should verify investigators' significant financial interests and other support prior to submitting information to NIH, and (7) NIH should establish a method for grantees to share their best practices for identifying and reviewing investigators' foreign significant financial interests and other support.

The National Institutes of Health Administered Superfund Appropriations During Fiscal Year 2021 in Accordance With Federal Requirements (A-04-22-04088), August 2022

During FY 2021, NIH administered Superfund appropriations in accordance with applicable Federal requirements. Specifically, NIH obligated and disbursed Superfund appropriations in accordance

with Federal laws and in similar proportions to prior years. In addition, NIH'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 Did Not Ensure That All Clinical Trial Results Were Reported in Accordance With Federal Requirements (A-06-21-07000), August 2022

NIH did not ensure that all NIH-funded intramural and extramural clinical trials complied with Federal reporting requirements for responsible parties to submit the results of clinical trials to ClinicalTrials.gov. The noncompliance with Federal reporting requirements occurred because NIH did not have adequate procedures for ensuring that responsible parties submitted the results of clinical trials, took limited enforcement action when there was noncompliance, and continued to fund new research of responsible parties that had not submitted the results of their completed clinical trials. For the 47 NIH-funded clinical trials in which the responsible party submitted their results (35 submitted on time and 12 submitted late), NIH complied with the Federal reporting requirements to post the results to ClinicalTrials.gov.

NIH concurred with our recommendations that it: (1) improve its procedures to ensure that responsible parties of NIH-funded clinical trials comply with requirements to submit results to ClinicalTrials.gov in a timely manner, (2) take enforcement actions against responsible parties that are late in submitting trial results or do not submit results, and (3) work with the responsible parties to understand their challenges related to ClinicalTrials.gov and implement procedures to address these challenges.

National Institutes of Health Grant Program Cybersecurity Requirements Need Improvement (A-18-20-06300), September 2022

CliftonLarsonAllen (CLA) completed this audit on behalf of OIG and found that NIH did not have: (1) an adequate pre-award risk assessment process because it does not consider cybersecurity and does not include a special term and condition addressing cybersecurity risk in the Notice of Award; (2) adequate policies because the NIH Grants Policy Statement (NIHGPS) does not include specific, risk-based provisions on cybersecurity; and (3) adequate post-award monitoring to ensure that grantees maintain effective cybersecurity to protect sensitive and confidential data and NIH's intellectual property.

NIH did not concur with CLA's recommendations that NIH: (1) assess its grant award programs to determine which grants should require additional cybersecurity protections; (2) based on results of NIH's risk assessment of grant awards, include cybersecurity controls that should be implemented; (3) strengthen the NIHGPS to establish clear and measurable standards for cybersecurity protections; (4) strengthen the pre-award process to identify and address how cybersecurity risk

will be assessed; and (5) strengthen the NIH post-award process to confirm that cybersecurity protections to adequately safeguard sensitive and confidential data have been implemented.

Human Services Agency Reports and Reviews

Administration for Children and Families

National Snapshot of Trends in the National Domestic Violence Hotline's Contact Data Before and During the COVID-19 Pandemic (A-09-21-06000), April 2022

Although our analysis showed little change in total contact volume for the National Domestic Violence Hotline from the period before to the period during the pandemic, we identified notable changes in the contact data for some subcategories of data that we analyzed. Furthermore, our analysis showed notable fluctuations in the number of contacts for some subcategories of data in certain months during the pandemic. Although the Hotline provided explanations for what could have contributed to these fluctuations, it could not determine whether they were a result of the pandemic. The Hotline believed that the full impact of the pandemic may not be reflected in the contact data until more time has passed.

The Hotline identified four challenges that it faced during the pandemic: (1) connecting victims to providers and resources that were operating at a limited capacity because of the pandemic, (2) tracking the unique impact of the pandemic on victims to better serve contacts' needs, (3) addressing a decrease in contact volume from victims who may have needed help but did not contact the Hotline because they were in closer proximity to their abusers as a result of shelter-in-place orders, and (4) fostering meaningful connections among Hotline staff to carry its mission forward. To address these challenges, the Hotline took actions to help ensure that it continued to support those affected by domestic violence. This report includes no recommendations.

National Snapshot of State Agency Approaches to Reporting and Locating Children Missing From Foster Care (A-07-20-06095), May 2022

There were 110,446 missing children episodes during our audit period, from July 1, 2018, through December 31, 2020. The average number of days that the children were missing ranged from 7 to 96 days; the number of children who were still missing as of December 31, 2020, was 6,619; and the majority (65 percent) of missing children were between 15 and 17 years old. The data also showed that among the missing children, 51 percent were females, 48 percent were males, and 1 percent were reported without gender data, or reported as transgender or undecided.

All 50 State agencies said that they had implemented policies and procedures regarding measures to report and locate missing children. Some State agencies reported enhanced procedures when a high-risk child went missing, or created special units or had specifically designated staff to help locate missing children.

We identified several barriers and other deficiencies in State agencies' policies and procedures. These barriers included limitations in State agencies' data systems, lack of oversight to ensure timeliness when reporting missing children, and issues involving the collaboration and exchange of information with Federal agencies and law enforcement.

The most frequently identified challenges were: (1) locating children who repeatedly go missing from foster care, (2) obtaining cooperation from missing children's families and friends and from law enforcement, (3) finding correct placements for children to prevent them from running away, and (4) lack of awareness of the support and technical assistance that ACF provides. This report makes no recommendations.

California Collected and Disbursed Stimulus Payments and Income Tax Refunds Under the Federal Tax Refund Offset Program in Accordance With Federal and State Requirements (A-01-21-01501), June 2022

California collected and disbursed stimulus payments and income tax refunds under the Federal Tax Refund Offset (FTR Offset) program in accordance with Federal and State requirements during our audit period. For all 115 noncustodial parents sampled, we found that California collected and disbursed $144,262 in FTR Offset payments.

Specifically, California complied with Federal and State requirements by having in its records a copy of the support order and modifications that specifies the date of issuance and amount of support. California maintained a copy of the payment record and provided written notices of the FTR Offset to noncustodial parents. In addition, California accurately and timely disbursed FTR Offset payments to custodial parents and updated the noncustodial parents' arrears balances. This report contains no recommendations.

Office of Refugee Resettlement's Influx Care Facility and Emergency Intake Sites Did Not Adequately Safeguard Unaccompanied Children From COVID-19 (A-06-21-07002), June 2022

During our site visits, we found that most facilities could have done more to meet CDC and HHS recommendations and requirements designed to keep children safe and protect against the spread of COVID-19. We found that these facilities lacked: (1) procedures for COVID-19 testing of children, employees, and volunteers; (2) measures to protect against the spread of COVID-19; and (3) procedures to report required testing and results to ORR and State and local health entities.

These issues occurred, in part, because ORR was rapidly expanding capacity, setting up emergency intake sites (EISs), and developing COVID-19 protocols and guidance for their use. However, ORR did not have a process in place for widely disseminating the guidance and frequent updates to appropriate staff at the EISs. Moreover, ORR did not effectively monitor facilities to ensure compliance with guidance on COVID-19 testing, mitigation, and reporting requirements. As a

result, facilities did not fully implement procedures related to COVID-19, thereby potentially placing the health and safety of children, employees, and volunteers at risk.

ACF concurred with our recommendations that ORR: (1) develop a process to clearly communicate COVID-19 guidance and updates to the appropriate staff at the EISs, (2) reiterate to facilities that they must comply with ORR's COVID-19 testing and reporting requirements and with State reporting requirements, (3) improve and increase training provided to facilities regarding COVID-19 mitigation strategies, and (4) perform routine oversight of facilities to reinforce implementation and compliance with all requirements related to COVID-19.

Nevada's Monitoring Did Not Ensure Child Care Provider Compliance With State Criminal Background Check Requirements at 9 of 30 Providers Reviewed (A-09-21-01000), August 2022

Nevada's monitoring of child care providers did not ensure provider compliance with State requirements related to criminal background checks for 9 of the 30 child care providers we reviewed. These deficiencies occurred because providers did not notify Nevada of a new household member or newly hired staff, and Nevada officials stated that they misinterpreted the State regulations on completing criminal background checks for minors. Additionally, Nevada did not have an explicit requirement or policy to conduct an in-State sex offender registry check for all child care staff members.

We recommended that Nevada: (1) ensure that child care providers notify Nevada when a new household member is added or a new employee is hired so that the State may conduct the required criminal background checks; (2) ensure that all required criminal background checks are conducted for the 21 individuals we identified who did not have all of the required checks at the time of our audit; (3) ensure that all required criminal background checks are conducted for all employees who are under the age of 18; (4) revise its policies and procedures to ensure that all child care staff members, regardless of age, are fingerprinted and have background checks completed immediately after being hired; and (5) add a written requirement and policy to conduct the in-State sex offender registry check for all child care staff members. Nevada agreed with our findings and provided information on actions that it had taken or planned to take to address our recommendations.

The Municipality of Barceloneta Did Not Always Manage Its Head Start Disaster Assistance Awards in Accordance With Federal and Commonwealth Requirements (A-02-20-02003), August 2022

The Municipality of Barceloneta (the Municipality) did not always manage Head Start disaster assistance awards in accordance with Federal and Commonwealth requirements. Specifically, the Municipality's financial management system did not always ensure compliance with requirements for: (1) submitting timely and accurate Federal financial reports, (2) maintaining support for award drawdowns, and (3) timely completing bank reconciliations. Additionally, the Municipality did not conduct timely criminal background checks for nine individuals associated with our sampled

expenditure transactions. These deficiencies occurred because the Municipality did not have adequate controls in place to ensure proper financial management and compliance with criminal background checks. As a result, the Municipality did not minimize the risk of fraud, waste, and abuse of Federal funds, and potentially jeopardized the safety of children.

The Municipality did not indicate concurrence or nonconcurrence with our recommendations, including that it reinforce existing financial management policies and procedures and ensure that criminal background checks are completed within required timeframes.

Operational Challenges Within ORR and the ORR EIS at Fort Bliss Hindered Case Management for Children (OEI-07-21-00251), September 2022

We found that operational challenges within the Office of Refugee Resettlement (ORR)—which is part of ACF—and at the ORR EIS at Fort Bliss, Texas, hindered case management from the facility's opening in March 2021 through June 2021. (This EIS is one of 14 that ORR opened in 2021 to handle the substantial increase in unaccompanied children arriving at the U.S. southern border.) These challenges may have adversely affected children's well-being while in ORR care and their safety following their release to sponsors (i.e., parents, guardians, or relatives or other parent-designated individuals).

ACF concurred with all five of our recommendations, which were that: (1) ACF should develop and issue a plan that supports ORR and its contractors in securing qualified case managers during an influx to help ensure children's safe and timely release to sponsors, (2) ACF should provide case managers with timely and comprehensive training and support to help ensure children's safe and timely release to sponsors, (3) ACF should create an emergency policy development protocol that ensures that ORR field guidance developed during an influx receives adequate input from career staff with expertise in child welfare, (4) ACF should ensure that ORR's case management system addresses challenges regarding usability and search capabilities, and (5) ACF should ensure that ORR's employees and employees of ORR's contractors and recipients are informed about Federal whistleblower protections.

ACF Should Improve Oversight of Head Start To Better Protect Children's Safety (OEI-BL-19-00560), September 2022

ACF is not aware of all incidents in which children in the care of a Head Start center are abused, left unsupervised, or released to an unauthorized person, impeding ACF's efforts to protect children's safety. Head Start grant recipients did not always comply with Federal requirements to self-report all incidents of child abuse, lack of supervision, or unauthorized release. Furthermore, using data from 2 States, OIG identified 130 such incidents that occurred in Head Start centers but of which ACF was not aware. Our findings can help ACF ensure that it is aware of all significant incidents and can take appropriate action to protect children's safety.

ACF concurred with all four of our recommendations, which were that: (1) ACF should improve Head Start grant recipients' self-reporting of incidents of child abuse, lack of supervision, and unauthorized release through better guidance and stronger consequences for failure to report; (2) ACF should extend the reporting requirement to include incidents of child abuse, lack of supervision, and unauthorized release in blended classrooms in which the victim is not a Head Start-funded child; (3) ACF should improve data-sharing with States about incidents of child abuse, lack of supervision, and unauthorized release in Head Start centers; and (4) ACF should disseminate information about innovative practices that Office of Head Start regional offices have developed to better identify and prevent incidents that threaten children's safety.

Indiana Did Not Comply With Requirements for Documenting Psychotropic and Opioid Medications Prescribed for Children in Foster Care (A-05-21-00020), September 2022

Indiana did not always comply with State requirements related to the psychotropic and opioid medications prescribed for children in foster care who were eligible for assistance under Title IV-E of the Act. Specifically, we found that: (1) the health care records for 109 of the 115 children in the sample did not contain medical passports, (2) the psychotropic or opioid medications prescribed for 76 of the 115 children were not recorded in the Management Gateway for Indiana's Kids system, (3) the health care records for 49 of the 85 children in the sample who were prescribed psychotropic medications did not include authorizations for those medications, and (4) the health care records for 13 of the 21 children residing in residential facilities and prescribed psychotropic medications did not contain the required written reports and medical reviews from the prescribing health care providers.

Indiana concurred with our recommendations, including that it: (1) ensure that health care records for the children under its care and supervision are maintained in accordance with State requirements by providing training, technical assistance, and implementing additional controls and procedures; (2) obtain the psychotropic medication authorizations for the children in the sample who are currently in foster care and did not have the authorizations documented; and (3) continue efforts with the Indiana Family and Social Services Administration to obtain access to Medicaid claim history.

Safety of Children in Foster Care

In Five States, There Was No Evidence That Many Children in Foster Care Had a Screening for Sex Trafficking When They Returned After Going Missing (OEI-07-19-00371), July 2022

In five States, we found that the case file documentation for two-thirds of children lacked evidence that they were screened to identify whether they were victims of sex trafficking when they returned to foster care after going missing, as required by Federal law. For some of the children who were screened, their case file documentation lacked information to ensure that the children were

accurately identified as possible victims of sex trafficking. As a result, many children's risks and potential needs may have gone unidentified and unaddressed, and ACF cannot be assured that children in foster care are protected from the dangers of sex trafficking, or that victims of sex trafficking are identified and are provided with needed support services.

ACF concurred with all recommendations, which were that: (1) ACF should work with States to improve compliance with requirements to screen children who return to foster care after going missing to identify whether they are victims of sex trafficking, (2) ACF should encourage all States to evaluate the value of adding an assessment of risk for sex trafficking when children return to foster care after going missing, and (3) ACF should conduct oversight activities to identify States that may not screen all children for sex trafficking when they return to foster care after going missing.

Health Resources and Services Administration

The Health Resources and Services Administration Should Improve Its Oversight of the Cybersecurity of the Organ Procurement and Transplantation Network (A-18-21-11400), August 2022

The Health Resources and Services Administration (HRSA) had ensured that most of the general IT controls that we selected to test were implemented for the Organ Procurement and Transplantation Network (OPTN) by the United Network for Organ Sharing (UNOS) to protect the confidentiality, integrity, and availability of transplant data in accordance with Federal requirements. However, we identified areas for which HRSA could improve its oversight of UNOS to ensure that all Federal cybersecurity requirements are being met in a timely manner. We noted that HRSA could improve its oversight of UNOS to ensure that UNOS performs adequate reviews of local user access of the OPTN, and that certain key cybersecurity policies and procedures were finalized and in place.

We recommend that HRSA develop additional oversight controls and procedures (e.g., deliverable schedules, compliance assessments, and monitoring) to ensure that the OPTN contractor complies with all Federal cybersecurity requirements and implements security controls over the OPTN in an effective and timely manner. HRSA stated that it has made efforts to continuously strengthen its oversight and controls over OPTN.

HHS's and HRSA's Controls Related to Selected Provider Relief Fund Program Requirements Could Be Improved (A-09-21-06001), September 2022

In the context of unprecedented challenges from the COVID-19 national emergency, HHS and HRSA developed controls related to selected Provider Relief Fund (PRF) program requirements designed to ensure that providers received the correct PRF payments from the Phase 1 General Distribution in a fast, fair, and transparent manner. However, we determined that some of these controls could be improved.

Because of statutory requirements, HHS and HRSA prioritized rapid disbursement of payments over the risk of making improper payments, because HHS and HRSA determined that activities to lower the risk would have delayed the payments. As HRSA fully implements postpayment quality control review processes, it should consider the information and recommendations in this report. In addition, HHS should use the information and recommendations when determining lessons learned and look for additional ways to safeguard taxpayers' money when rapidly disbursing assistance payments to health care providers in response to future national emergencies.

HRSA concurred with all of our recommendations, including that it continue to perform postpayment quality control reviews of selected providers, consider reviewing 189 providers that were identified for manual review, and seek repayment of any overpayments from providers. We also recommended that HRSA ensure that the HHS Program Support Center collects payments made to selected providers that did not return their rejected payments as of March 9, 2022. Furthermore, we recommended that HRSA could conduct a cost-benefit analysis for manual review of additional providers and, if the benefit outweighs the cost, it could select additional providers for review.

Substance Abuse and Mental Health Services Administration

Louisiana Faced Compliance and Contracting Challenges in Implementing Opioid Response Grant Programs (A-06-20-07003), April 2022

Louisiana implemented State Targeted Response (STR) grant programs by expanding prevention, treatment, and recovery services for opioid use disorder. However, we found that Louisiana faced challenges in complying with Federal regulations related to reporting and oversight. Additionally, Louisiana met program goals of the STR grant for prevention, treatment, and recovery services, but did not adequately address challenges it faced meeting grant terms.

During the first year of the State Opioid Response (SOR) grant, Louisiana implemented a collaborative approach to enhance and expand the capacity of treatment providers. Louisiana created crisis mobile teams to increase outreach to community programs by partnering with the local governing entities (LGEs) and expanded access to recovery support services by increasing safe recovery housing. Louisiana complied with Federal regulations related to the SOR grant. However, we found that Louisiana did not meet treatment services and naloxone distribution goals during the first year of its SOR grant.

Louisiana concurred with our recommendations that it: (1) develop a process to ensure accurate reporting on the Annual Progress Reports, (2) improve monitoring of subrecipients to ensure that distribution of naloxone kits are tracked and distribution requirements are met, (3) work with the LGEs and OTPs to identify ways to support clients' access to transportation to obtain treatment and

determine how transportation could be addressed in each specific region of the State, and (4) review the contracting process to determine whether there are ways to expedite the process to provide funds to subrecipients and outside organizations in a timely manner.

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 zero criminal actions and no court-ordered restitution or settlements.

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

Cross-Cutting Medicare and Medicaid

Selected Dialysis Companies Implemented Additional Infection Control Policies and Procedures To Protect Beneficiaries and Employees During the COVID-19 Pandemic (A-05-20-00052), May 2022

The nine selected dialysis companies surveyed (representing 83 percent of the ESRD facilities that had a Medicare or Medicaid certification at any point during 2020) implemented additional infection control policies and procedures in accordance with CMS and CDC recommendations to protect high-risk ESRD beneficiaries and employees during the COVID-19 pandemic. We found that all nine companies had infection control policies and procedures in place to protect beneficiaries and employees, and when recommended by CMS and CDC, the companies implemented additional policies and procedures. However, although two companies provided education about the importance of hand hygiene, they did not emphasize the importance of hand hygiene immediately before and after any contact with a face mask or cloth face covering, as recommended by CDC.

Because the nine selected companies implemented additional infection control policies and procedures as recommended by CMS and CDC, this report contains no recommendations.

An Estimated 91 Percent of Nursing Home Staff Nationwide Received the Required COVID-19 Vaccine Doses, and an Estimated 56 Percent of Staff Nationwide Received a Booster Dose (A-09-22-02003), June 2022

On the basis of our sample results, as of the week ended March 27, 2022, we estimated that 91 percent of staff nationwide had received the required vaccine doses, 56 percent of staff nationwide had received a booster dose, and 6 percent of staff nationwide had been granted a religious exemption. We did not estimate the percentages among the small number of staff members (i.e., 38) in our nationwide sample results who were partially vaccinated, who were granted a medical exemption, who applied for an exemption that was being reviewed, or for whom the vaccination status could not be determined.

In addition, the estimated percentages of staff who received the required vaccine doses, staff who received a booster dose, and staff who were granted a religious exemption varied depending on the locations (i.e., HHS regions) of the nursing homes in which they worked. This report includes no recommendations.

The Centers for Medicare & Medicaid Services Had Policies and Procedures in Place To Mitigate Vulnerabilities in a Timely Manner, but Improvements Are Needed (A-18-20-06500), June 2022

CMS had cybersecurity controls in place to remediate known vulnerabilities in accordance with Federal regulations and standards; however, it did not consistently apply security updates to systems with known vulnerabilities and did not consistently upgrade or patch operating systems that had reached the end-of-life period and were no longer supported by the vendor. This occurred because CMS did not have effective management oversight to ensure that CMS mitigated vulnerabilities in a timely manner. As a result, some CMS systems had open vulnerabilities that were vulnerable to exploitation by malicious actors beyond the acceptable limits defined in Binding Operational Directive (BOD) 19-02.

CMS concurred with our recommendations that it: (1) remediate the vulnerabilities identified on internet-facing systems and implement procedures to ensure compliance with BOD 19-02 requirements; (2) implement procedures to ensure that unsupported software that no longer receives security updates, repairs, bug fixes, and threat mitigation is replaced prior to the known end of support or implement compensating controls (if possible) and accept risk in accordance with existing CMS policies and procedures; (3) implement oversight to ensure that corrective actions are performed in accordance with Federal requirements and in the timeframe set forth in CMS policy; and (4) implement a process to centralize the monitoring and reporting of vulnerabilities identified in all CMS systems across all CMS data centers.

Certain Nursing Homes May Not Have Complied With Federal Requirements for Infection Prevention and Control and Emergency Preparedness (A-01-20-00005), July 2022

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

CMS generally agreed with our recommendations that it: (1) instruct SSAs to follow up with the 28 nursing homes that we have identified with potential infection prevention and control and emergency preparedness deficiencies to ensure that they have taken corrective actions, (2) issue updated phase 3 interpretive guidance as soon as feasible, (3) provide training to SSAs on the updated phase 3 interpretive guidance as soon as feasible, and (4) consider updating the regulation to make clear that nursing homes must include emerging infectious diseases as a risk on their facility- and community-based all-hazards risk assessments.

Audits of Nursing Home Life Safety and Emergency Preparedness in Eight States Identified Noncompliance With Federal Requirements and Opportunities for the Centers for Medicare & Medicaid Services To Improve Resident, Visitor, and Staff Safety (A-02-21-01010), July 2022

We identified a total of 2,233 areas of noncompliance with life safety and emergency preparedness requirements at 150 of the 154 nursing homes we visited. As a result, residents, visitors, and staff at the nursing homes were at increased risk of injury or death during a fire or other emergency. CMS subsequently followed up with State survey agencies to determine whether they had addressed the recommendations included in our prior audits. According to CMS, the States had already taken acceptable actions to address our recommendations.

We identified several opportunities for CMS to expand on its life safety requirements for nursing homes to improve the safety of residents, visitors, and staff. Among other findings, CMS could propose regulations requiring nursing homes to install carbon monoxide detectors according to national standards. We also noted areas in which CMS could improve its support for State survey operations and nursing home training. CMS could work with State survey agencies to address issues preventing more frequent surveys of high-risk facilities and require mandatory participation in standardized nursing home staff training.

We made a series of recommendations to CMS to address our findings, including that it propose regulations requiring nursing homes to install carbon monoxide detectors and work with States to encourage mandatory participation in standardized training for nursing home staff. CMS generally agreed with our recommendations and described steps it has taken or plans to take to address them.

UPICs Hold Promise To Enhance Program Integrity Across Medicare and Medicaid, but Challenges Remain (OEI-03-20-00330), September 2022

Although Unified Program Integrity Contractors (UPICs) hold promise for leveraging cross-program consolidation to strengthen oversight across Medicare and Medicaid, improvements are needed to better combat fraud, waste, and abuse—particularly in Medicaid. The UPICs conducted only minimal activities related to Medicaid managed care, even though most Medicaid enrollees receive services through managed care. We also found wide unexplained disparities in program integrity activities across UPICs, even after adjusting for the size of their respective oversight responsibilities.

However, the development of collaborative processes, analytical tools, and new technologies across the UPICs—including the Unified Case Management System and Major Case Coordination initiative—helps to achieve the benefits of unifying program integrity activities. Our findings can help CMS identify ways to strengthen UPICs' abilities to detect and deter fraud, waste, and abuse in both Medicare and Medicaid.

CMS concurred with all of our recommendations, which were that: (1) CMS should implement a plan to increase UPICs' Medicaid program integrity activities, particularly related to managed care; (2) CMS should make improvements to the Unified Case Management System; (3) CMS should implement a plan to help ensure the success of the Major Case Coordination initiative for Medicaid referrals; and (4) CMS should identify the reasons for the unexplained variation in program integrity activities across UPICs.

General Departmental

Review of the Department of Health and Human Services' Compliance With the Federal Information Security Modernization Act of 2014 for Fiscal Year 2021 (A-18-21-11200), April 2022

Overall, through the evaluation of FISMA metrics, it was determined that HHS's information security program was Not Effective. This determination was made based on HHS not meeting the Managed and Measurable maturity level for the Identify, Protect, Detect, and Recover function areas as required by DHS guidance and the FY 2021 Inspector General FISMA Reporting Metrics. However, HHS continues to implement changes to strengthen the maturity of its enterprisewide cybersecurity program. We identified opportunities where HHS can strengthen its overall information security program.

We made recommendations to the Office of the Chief Information Officer that should further strengthen HHS's cybersecurity program and enhance information security controls at HHS. Recommendations specific to deficiencies found at the reviewed HHS OpDivs were provided separately.

Department of Health and Human Services Met Many Requirements, but It Did Not Fully Comply With the Payment Integrity Information Act of 2019 and Applicable Improper Payment Guidance for the Fiscal Year 2021 (A-17-22-52000), May 2022

Ernst & Young (EY), LLP, determined that HHS met many requirements but did not fully comply with the Payment Integrity Information Act of 2019 (PIIA). Among the items required for compliance with PIIA that HHS complied with, EY determined that HHS: (1) published the Agency Financial Report for FY 2021; (2) conducted risk assessments for 38 programs not susceptible to improper payments and determined that the programs were not at risk for improper payments; and (3) published corrective action plans for 8 of the 11 programs that are susceptible to significant

improper payments as determined by HHS management, OMB, or through legislation. EY also determined that HHS developed a plan to meet improper payment and unknown payment reduction targets for 7 of 11 programs, and also reported an improper and unknown payment rate of less than 10 percent for 5 of the 11 programs.

EY concluded that HHS did not comply with several other PIIA requirements. EY found HHS: (1) did not report an improper and unknown payment estimate for the Temporary Assistance for Needy Families program, advanced premium tax credit, and foster care; (2) reported improper and unknown payment rates in excess of 10 percent for Medicaid, the Children's Health Insurance Program, and Medicare Advantage; and (3) had completed minimal recovery audit activities for the identified improper payments for the Medicare Advantage and Medicare Prescription Drug Benefit programs.

Cost Allocation Services Needs To Update Its Indirect Cost Rate-Setting Guidance (A-06-20-01000), June 2022

We found that Cost Allocation Services' (CAS's) indirect cost rate-setting process for nonprofit organizations did not always comply with Federal regulations and its own policies. Specifically, we found that: (1) CAS did not ensure compliance with Federal regulations when negotiating indirect cost rates, (2) CAS did not always follow its Review Guide, (3) CAS did not always follow its internal guidance or negotiate rates in a timely manner, and (4) indirect cost rate proposals included potentially unallowable compensation costs. These errors occurred because CAS had not updated the Review Guide since 2003 to ensure that it reflected Federal requirements and its internal guidance. According to CAS officials, CAS also faced issues with the heavy workload associated with negotiating indirect cost rates and has been unable to fill positions for negotiators and branch chiefs lost through attrition.

CAS generally concurred with our recommendation that it: (1) update its Review Guide to include applicable Federal regulations and CAS internal policies and procedures and (2) provide training to its branch chiefs and negotiators to ensure that its indirect cost rate-setting process conforms with Federal regulations. Additionally, CAS should review its staffing levels and determine whether they are sufficient to meet the agency's objectives and seek clarification on whether the executive compensation policy complies with Federal law and Governmentwide policy.

HHS Made Some Progress Toward Compliance With the Geospatial Data Act (A-18-22-11400), September 2022

HHS made some progress toward compliance with the Geospatial Data Act (GDA), but we identified certain covered agency responsibilities that HHS had yet to meet. Additionally, HHS had not maintained a departmentwide inventory of all geospatial data assets, or accurately reported its achievements in implementing the GDA requirements, as required by GDA section 759(b).

These conditions occurred because there was limited Departmentwide oversight and coordination in HHS's implementation of geospatial-related responsibilities, requirements, policies, and activities. These conditions contributed to HHS's noncompliance with the covered agency responsibilities established in the GDA. As a result, HHS is susceptible to inefficient and ineffective management of geospatial assets, which increases the risk of inconsistent efforts or inability to minimize the costs to acquire, manage, share, and use geospatial data, expertise, technology, and services.

HHS concurred with our recommendations that it: (1) ensure that HHS and its components fully implement the covered agency responsibilities found in GDA section 759(a); (2) ensure that the HHS Senior Agency Official for Geospatial Information or designated official oversee, coordinate, and facilitate HHS's implementation of the geospatial-related requirements, policies, and activities; (3) maintain an inventory of all geospatial data assets, per section 759(b) of the GDA; and (4) prepare the required annual reports or self-assessments based on the status of all of HHS's components.

Grants and Contracts

HHS is the largest grantmaking organization and one of the largest contracting agencies in the Federal Government. In FY 2022, HHS awarded more than $792 billion in grants and more than $33 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 80,000 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:

Tennessee—On August 22, 2022, Patrick Martin was sentenced to 15 months in prison for embezzling approximately $211,000 from the Community Prevention Coalition of Jackson County while serving as the Coalition's Executive Director. Martin was initially charged in May 2019 and pleaded guilty in August 2021 to wire fraud, failure to pay overemployment taxes, and filing a false income tax return. According to court documents, beginning in 2014, Martin submitted applications to an agency of the Department of Health and Human Services for Drug Free Communities program grants and received awards for the Coalition totaling $375,000 over 3 years. Martin was supposed to use the grant funds on behalf of the Coalition, but instead used the money for his own personal benefit, including to make an automobile purchase, pay personal bills, make home renovations, and provide financial support to someone outside of his family. As the Executive Director of the Coalition, Martin also was responsible for paying over certain employment taxes withheld from employees'

paychecks to the IRS. Martin failed to do so and used this money for his own personal benefit as well. Martin also filed false income tax returns with the IRS for tax years 2014 and 2015, failing to report the income from his embezzlement scheme.

Martin was also ordered to pay restitution in the amount of $507,373.76, with $375,000 to be paid to HHS's Substance Abuse and Mental Health Services Administration, the agency that awarded the grant; and $132,373.76 to be paid to the IRS. Martin was also ordered to forfeit $211,795.84.

Small Business Innovative Research Program

The National Defense Authorization Act for Fiscal Year 2012, § 5143, requires OIG to report annually on the number of cases referred to OIG to fraud, waste, or abuse in the Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) program. OIG must also report on the actions taken in each case; justification for not taking action on a case; and an accounting of funds used to address waste, fraud, and abuse in this program. From October 1, 2022, through September 30, 2022, OIG received zero referrals related to potential fraud, waste, or abuse with respect to HHS SBIR/STTR programs, and no cases were opened. For FY 2022, there was approximately one civil action with total money associated at $541,531. The total number of case hours worked was 654.25 for a total cost of case time of $129,214.38. At the end of FY 2022, OIG was working on one SBIR/STTR investigation.

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 Single Audit Division reviewed 261 reports covering $2.1 trillion in audited costs. Federal dollars covered by these audits totaled $994.6 billion, of which about $374.9 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, April 1, 2022, Through September 30, 2022

Not requiring changes or having minor changes	209
Requiring major changes	5
Having significant technical inadequacies	47
Total Number of Non-Federal Audits	**261**

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 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, describes findings and recommendations from recently completed reviews, many of which focus on existing laws and regulations.
- *OIG's Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs* 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.

The lists of issued reports includes all reports and is provided in accordance with the Inspector General Act, §§ 5(a)(6).

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]	42	$1,688,550,000	$1,060,782,000
Issued during the reporting period[2]	27	$612,549,000	$115,075,000
Total Section 1	**69**	**$2,301,099,000**	**$1,175,857,000**
Section 2			
Reports for which management decisions were made during the reporting period[3]			
Disallowed costs	17	*$62,898,000	$687,000
Costs not disallowed	2	$637,950,000	$636,621,000
Total Section 2	**19**	**$700,848,000**	**$637,308,000**

* Audit receivables (expected recoveries).

Section 3			
Reports for which no management decisions had been made by the end of the reporting period (Section 1–Section 2)[4]	**50**	**$1,600,251,000**	**$538,549,000**

Section 4			
Reports for which no management decisions were made within 6 months of issuance[5]	24	$594,970,000	$0

Table 1 End Notes

[1] The opening balance was adjusted upward by $6.5 million because of a reevaluation of previously issued recommendations.

[2] An issued report containing recommendations for both questioned costs and funds put to better use will be counted in Table 1 and Table 2.

[3] Revisions to previously reported management decisions:
A-05-17-00038, *Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs*. CMS subsequent review determined that disallowed cost should be reduced by $431,000.

[4] Included are management decisions submitted during the period on $428,126,000 which are under management review.

[5] Because of administrative delays, some of which were beyond management control, resolution of the following 24 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 for Which No Management Decision Was Received Within 6 Months of Issuance	
Audit CIN	Audit Title
A-07-16-01165	*Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc. (Contract H1036), Submitted to CMS,* APR 2021, $197,720,651
A-02-14-02017	*New York Misallocated Costs to Establishment Grants for a Health Insurance Marketplace*, NOV 2016, $149,654,512
A-07-17-01169	*Medicare Advantage Compliance Audit of Diagnosis Codes That SCAN Health Plan (Contract H5425), Submitted to CMS,* FEB 2022, $54,318,154
A-01-14-02503	*Maryland Misallocated Millions to Establishment Grants for a Health Insurance Marketplace*, MAR 2015, $28,400,000
A-04-14-07050	*Kentucky Misallocated Millions to Establishment Grants for a Health Insurance Marketplace*, FEB 2017, $25,530,429
A-07-18-04111	*Mississippi Needs To Improve Oversight of Its Child Care Payment Program*, APR 2020, $22,284,900
A-02-15-02008	*New York Did Not Comply With Federal Grant Requirements for Allocating and Claiming Marketplace Contract Costs*, DEC 2017, $20,415,344

A-07-15-04226	*Not All of Missouri's Child Care Subsidy Program Payments Complied With Federal and State Requirements*, NOV 2017, $19,076,167
A-07-19-01188	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That UPMC Health Plan, Inc. (Contract H3907) Submitted to CMS, NOV 2021, $6,401,297*
A-02-18-01028	*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
A-06-17-07004	*Southwest Key Programs Failed To Protect Federal Funds Intended for the Care and Placement of Unaccompanied Alien Children*, SEP 2020, $13,130,848
A-01-15-02500	*Vermont Did Not Properly Allocate Millions to Establishment Grants for a Health Insurance Marketplace*, SEP 2016, $11,243,006
A-09-21-03002	*Medicare Improperly Paid Physicians for Spinal Facet-Joint Denervation Sessions,* DEC 2021, $9,528,296
A-02-18-01029	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Healthfirst Health Plan, Inc., (Contract H3359) Submitted to CMS,* JAN 2022, $5,221,901
A-01-19-00500	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Tufts Health Plan (Contract H2256) Submitted to CMS,* FEB 2022, $3,758,335
A-07-19-01187	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS*, MAY 2021, $3,468,954
A-02-16-02013	*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
A-07-17-02808	*The Colorado Health Insurance Marketplace's Financial Management System Did Not Always Comply With Federal Requirements*, JUL 2018, $2,567,604
A-07-11-06013	*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
A-05-14-00045	*The Minnesota Marketplace Misallocated Federal Funds and Claimed Unallowable Costs*, NOV 2016, $1,279,677
A-02-18-02011	*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
A-09-14-01007	*Nevada Misallocated Costs for Establishing a Health Insurance Marketplace to Its Establishment Grants*, FEB 2016, $893,464
A-07-17-01173	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS*, OCT 2021, $548,852
A-03-16-00250	*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

TOTAL CINS: 24
TOTAL AMOUNT: $594,970,000

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	9	$17,247,368,000
Reports issued during the reporting period[1]	2	$40,039,000
Total Section 1	**11**	**$17,287,407,000**
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	$116,992,000
Based on proposed legislative action	0	$0
Value of recommendations not agreed to by management	2	$48,756,000
Total Section 2	**4**	**$165,748,000**
Section 3		
Reports for which no management decisions had been made by the end of the reporting period[1] (Section 1–Section 2)[2,3]	9	**$17,121,659,000**

Table 2 End Notes

[1] An issued report containing recommendations for both questioned costs and funds put to better use will be counted in Table 1 and Table 2.

[2] Included is a management decision submitted during the period on $15 billion which is under management review.

[3] Because of administrative delays, some of which were beyond management control, three of the seven audits open at end of the period were not resolved within 6 months of report issuance. OIG is working with management to reach resolution on these recommendations before the end of the next semiannual reporting period.

Audits for Which No Management Decision Was Received Within 6 Months of Issuance

Audit CIN	Audit Title
A-03-17-00010	*Hospitals Overbilled Medicare $1 Billion by Incorrectly Assigning Severe Malnutrition Diagnosis Codes to Inpatient Hospital Claims*, JUL 2020, $1,024,623,449
A-03-13-03002	*HHS Did Not Identify and Report Antideficiency Act Violations*, MAY 2017, $49,445,025
A-07-17-01176	*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
TOTAL CINS: 3 **TOTAL AMOUNT: $1,088,486,000**	

Audit Reports by Issue Date

Report Number	Title	Issued	Questioned Costs	Funds Put to Better Use
A-04-18-07078	South Carolina Did Not Fully Comply With Requirements for Reporting and Monitoring Critical Events Involving Medicaid Beneficiaries With Developmental Disabilities	4/1/2022	-	-
A-05-20-00005	Posthospital Skilled Nursing Facility Care Provided to Dually Eligible Beneficiaries in Indiana Generally Met Medicare Level-of-Care Requirements	4/7/2022	-	-
A-06-20-07003	Louisiana Faced Compliance and Contracting Challenges in Implementing Opioid Response Grant Programs	4/8/2022	-	-
A-09-20-02009	California Improperly Claimed at Least $23 Million of $260 Million in Total Medicaid Reimbursement for Opioid Treatment Program Services	4/20/2022	$23,139,767	-
A-01-20-00003	Massachusetts Implemented Our Prior Audit Recommendations and Generally Complied With Federal and State Requirements for Reporting and Monitoring Critical Incidents	4/25/2022	-	-
A-18-21-11200	Review of the Department of Health and Human Services' Compliance with the Federal Information Security Modernization Act of 2014 for Fiscal Year 2021	4/25/2022	-	-
A-09-21-06000	National Snapshot of Trends in the National Domestic Violence Hotline's Contact Data Before and During the COVID-19 Pandemic	4/27/2022	-	-
A-17-22-52000	Department of Health and Human Services Met Many Requirements, but It Did Not Fully Comply With the Payment Integrity Information Act of 2019 and Applicable Improper Payment Guidance for Fiscal Year 2021	5/9/2022	-	-
A-09-20-02008	Washington State Did Not Comply With Federal and State Requirements for Claiming Enhanced Federal Reimbursement for Medicaid Managed-Care Health Home	5/13/2022	$403,740	-

A-07-20-06095	National Snapshot of State Agency Approaches to Reporting and Locating Children Missing From Foster Care	5/19/2022	-	-
A-05-20-00052	Selected Dialysis Companies Implemented Additional Infection Control Policies and Procedures To Protect Beneficiaries and Employees During the COVID-19 Pandemic	5/24/2022	-	-
A-06-18-05002	Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Peoples Health Network (Contract H1961) Submitted to CMS	5/25/2022	$3,312,219	-
A-06-20-04003	Vanderbilt University Medical Center: Audit of Outpatient Outlier Payments	5/25/2022	$686,500	-
A-06-20-04004	Texas Did Not Report and Return All Medicaid Overpayments for the State's Medicaid Fraud Control Unit Cases	5/25/2022	$11,122,401	-
A-09-20-03016	Medicare Improperly Paid Durable Medical Equipment Suppliers an Estimated $8 Million of the $40 Million Paid for Power Mobility Device Repairs	5/31/2022	$41,137	$11,687,528
A-01-21-01501	California Collected and Disbursed Stimulus Payments and Income Tax Refunds Under the Federal Tax Refund Offset Program in Accordance with Federal and State Requirements	6/1/2022	-	-
A-06-20-01000	Cost Allocation Services Needs To Update Its Indirect Cost Rate-Setting Guidance	6/1/2022	-	-
A-01-20-00007	Maine Implemented Our Prior Audit Recommendations and Generally Complied With Federal and State Requirements for Reporting and Monitoring Critical Incidents	6/6/2022	-	-
A-07-18-02815	Medicare and Beneficiaries Paid Substantially More to Provider-Based Facilities in Eight Selected States in Calendar Years 2010 Through 2017 Than They Paid to Freestanding Facilities in the Same States for the Same Types of Services	6/10/2022	-	-
A-06-21-07002	Office of Refugee Resettlement's Influx Care Facility and Emergency Intake Sites Did Not Adequately Safeguard Unaccompanied Children From COVID-19	6/22/2022	-	-
A-01-20-00006	More Than 90 Percent of the New Hampshire Managed Care Organization and Fee-for-Service Claims for Opioid Treatment Program Services Did Not Comply With Medicaid Requirements	6/23/2022	$7,943,271	-
A-09-22-02003	An Estimated 91 Percent of Nursing Home Staff Nationwide Received the Required COVID-19 Vaccine Doses, and an Estimated 56 Percent of Staff Nationwide Received a Booster Dose	6/23/2022	-	-
A-01-19-01500	The Food and Drug Administration's Foreign For-Cause Drug Inspection Program Can Be Improved To Protect the Nation's Drug Supply	6/24/2022	-	-
A-18-20-06500	The Centers for Medicare & Medicaid Services Had Policies and Procedures in Place To Mitigate Vulnerabilities in a Timely Manner, but Improvements Are Needed	6/29/2022	-	-

A-05-19-00019	The Reduced Outlier Threshold Applied to Transfer Claims Did Not Significantly Increase Medicare Payments to Hospitals	7/5/2022	-	-
A-02-19-01018	Medicare Hospice Provider Compliance Audit: Vitas Healthcare Corporation of Florida	7/14/2022	$140,370,745	-
A-02-21-01010	Audits of Nursing Home Life Safety and Emergency Preparedness in Eight States Identified Noncompliance With Federal Requirements and Opportunities for the Centers for Medicare & Medicaid Services to Improve Resident, Visitor, and Staff Safety	7/15/2022	-	-
A-02-20-01009	Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS	7/18/2022	$9,212,531	-
A-03-20-00002	Medicare Critical Care Services Provider Compliance Audit: Lahey Clinic Inc.	7/19/2022	$6,015	-
A-04-18-03085	CMS Reported Collecting Just Over Half of the $498 Million in Medicare Overpayments Identified by OIG Audits	7/25/2022	-	-
A-01-20-00005	Certain Nursing Homes May Not Have Complied With Federal Requirements for Infection Prevention and Control and Emergency Preparedness	7/26/2022	-	-
A-18-22-11300	Review of Medicare Administrative Contractor Information Security Program Evaluations for Fiscal Year 2021	7/27/2022	-	-
A-04-22-04088	The National Institutes of Health Administered Superfund Appropriations During Fiscal Year 2021 in Accordance With Federal Requirements	8/10/2022	-	-
A-07-21-07003	South Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs	8/10/2022	$15,851,354	-
A-06-21-07000	The National Institutes of Health Did Not Ensure That All Clinical Trial Results Were Reported in Accordance With Federal Requirements	8/12/2022	-	-
A-17-22-00009	Independent Service Auditor's Report on the Department of Health & Human Services' Program Support Center, Grants Finance and Administrative Services, Payment Management System for the Period October 1, 2021–June 30, 2022	8/15/2022	-	-
A-17-22-00010	Independent Service Auditor's Report on the Department of Health & Human Services, Center for Information Technology at the National Institutes of Health, Information Technology General Controls System for the UNIX and Windows Environments	8/15/2022	-	-
A-03-18-00002	Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS	8/19/2022	$39,612	-
A-09-21-01000	Nevada's Monitoring Did Not Ensure Child Care Provider Compliance With State Criminal Background Check Requirements at 9 of 30 Providers Reviewed	8/23/2022	-	-

A-07-21-03246	Montana Claimed Federal Medicaid Reimbursement for More Than $5 Million in Targeted Case Management Services That Did Not Comply With Federal and State Requirements	8/26/2022	$5,065,966	-
A-04-19-07084	Medicare Advantage Compliance Audit of Specific Diagnosis Codes That WellCare of Florida, Inc., (Contract H1032) Submitted to CMS	8/29/2022	$3,518,465	-
A-18-21-11400	The Health Resources and Services Administration Should Improve Its Oversight of the Cybersecurity of the Organ Procurement and Transplantation Network	8/29/2022	-	-
A-02-20-02003	The Municipality of Barceloneta Did Not Always Manage Its Head Start Disaster Assistance Awards in Accordance With Federal and Commonwealth Requirements	8/30/2022	-	-
A-02-20-02002	HHS Did Not Fully Comply With Federal Requirements and HHS Policies and Procedures When Awarding and Monitoring Contracts for Ventilators	9/1/2022	-	-
A-18-21-03100	IHS Telehealth System Was Deployed Without Some Required Cybersecurity Controls	9/7/2022	-	-
A-02-21-01001	New York Claimed $196 Million, Over 72 Percent of the Audited Amount, in Federal Reimbursement for NEMT Payments to New York City Transportation Providers That Did Not Meet or May Not Have Met Medicaid Requirements	9/12/2022	$196,358,172	-
A-09-20-03009	Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3817) Submitted to CMS	9/13/2022	$1,890,855	-
A-07-21-06096	Tennessee Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations	9/14/2022	$12,028,934	$28,351,111
A-01-20-00004	Certain Nursing Homes May Not Have Complied With Federal Requirements for Infection Prevention and Control and Emergency Preparedness	9/15/2022	-	-
A-07-21-07004	System Review Report: External Quality Control Review of the Audit Organization of the U.S. Department of Labor, Office of Inspector General	9/15/2022	-	-
A-07-20-04124	IHS's National Supply Service Center Was Generally Effective in Providing Supplies to Facilities During the COVID-19 Pandemic, but Its Internal Controls Could Be Improved	9/16/2022	-	-
A-05-20-00025	Nearly All States Made Capitation Payments for Beneficiaries Who Were Concurrently Enrolled in a Medicaid Managed Care Program in Two States	9/19/2022	-	-

A-06-21-05003	Medicare Part B Overpaid and Beneficiaries Incurred Cost-Share Overcharges of Over $1 Million for the Same Professional Services	9/19/2022	$1,188,759	-
A-18-20-06300	National Institutes of Health Grant Program Cybersecurity Requirements Need Improvement	9/19/2022	-	-
A-02-20-01028	New York Generally Determined Eligibility for Its Basic Health Program Enrollees in Accordance With Program Requirements	9/20/2022	$8,615	-
A-05-20-00051	End-Stage Renal Disease Network Organizations' Reported Actions Taken in Response to the COVID-19 Pandemic	9/21/2022	-	-
A-09-22-03007	CMS's System Edits Significantly Reduced Improper Payments to Acute-Care Hospitals After May 2019 for Outpatient Services Provided to Beneficiaries Who Were Inpatients of Other Facilities	9/22/2022	$39,310,499	-
A-02-20-01001	Medicare Hospital Provider Compliance Audit: Hospice of Palm Beach County, Inc.	9/23/2022	$42,336,162	-
A-05-18-00020	Medicare Advantage Compliance Audit of Diagnosis Codes that Inter Valley Health Plan, Inc. (Contract H0545), Submitted to CMS	9/26/2022	$5,372,998	-
A-09-21-06001	HHS's and HRSA's Controls Related to Selected Provider Relief Fund Program Requirements Could Be Improved	9/26/2022	-	-
A-18-22-11400	HHS Made Some Progress Toward Compliance With the Geospatial Data Act	9/26/2022	-	-
A-04-20-01019	CDC's Corrective Actions Improved Program Operations at the National Institute of Health in Mozambique and Facilitated the Institute's Implementation of Prior OIG Audit Recommendations	9/27/2022	-	-
A-05-21-00020	Indiana Did Not Comply With Requirements for Documenting Psychotropic and Opioid Medications Prescribed for Children in Foster Care	9/27/2022	-	-
A-05-20-00010	Medicare Dialysis Services Provider Compliance Audit: Dialysis Clinic, Inc.	9/28/2022	$14,193,677	-
A-03-19-00001	Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (H3916) Submitted to CMS	9/29/2022	$6,227,005	-
A-06-19-09002	Texas Claimed or May Have Claimed More Than $30 Million of $9.89 Billion in Federal Funds for Medicaid Uncompensated Care Payments That Did Not Meet Federal and State Requirements	9/29/2022	$30,719,788	-
A-07-19-01195	Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BlueCross BlueShield of Tennessee, Inc. (Contract H7917) Submitted to CMS	9/29/2022	$7,784,540	-
A-05-19-00039	Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract R5826) Submitted to CMS	9/30/2022	$34,414,828	-
	Total Reports: 68		**$612,548,555**	**$40,038,639**

Evaluation Reports by Operating Division

Report Number	Title	Operating Division	Issue Date
OEI-07-19-00371	In Five States, There Was No Evidence That Many Children in Foster Care Had a Screening for Sex Trafficking When They Returned After Going Missing	ACF	7/05/2022
OEI-07-21-00251	Operational Challenges Within ORR and the ORR EIS at Fort Bliss Hindered Case Management for Children	ACF	9/22/2022
OEI-BL-20-00670	HHS Should Improve Internal Coordination and Better Protect the Wellbeing of Unaccompanied Children	ACF	5/02/2022
OEI-BL-19-00560	ACF Should Improve Oversight of Head Start To Better Protect Children's Safety	ACF	9/26/2022
OEI-05-20-00540	CDC Found Ways To Use Data To Understand and Address COVID-19 Health Disparities, Despite Challenges With Existing Data	CDC	7/13/2022
OEI-02-22-00310	2021 Performance Data for the Senior Medicare Patrol Projects	CMS	6/08/2022
OEI-02-21-00100	Inaccuracies in Medicare's Race and Ethnicity Data Hinder the Ability to Assess Health Disparities	CMS	6/13/2022
OEI-02-20-00522	Certain Medicare Beneficiaries, Such as Urban and Hispanic Beneficiaries, Were More Likely Than Others to Use Telehealth During the First Year of the COVID-19 Pandemic	CMS	8/29/2022
OEI-02-20-00720	Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks	CMS	9/02/2022
OEI-02-22-00390	Opioid Overdoses and the Limited Treatment of Opioid Use Disorder Continue To Be Concerns for Medicare Beneficiaries	CMS	9/13/2022
OEI-03-22-00200	Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Fourth Quarter of 2021	CMS	5/12/2022
OEI-03-22-00210	Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the First Quarter of 2022	CMS	8/11/2022
OEI-03-20-00231	CMS Has Opportunities to Strengthen States' Oversight of Medicaid Managed Care Medical Loss Ratios	CMS	9/19/2022
OEI-03-22-00170	Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2020 Average Sales Prices	CMS	9/23/2022
OEI-03-20-00330	UPICs Hold Promise to Enhance Program Integrity Across Medicare and Medicaid, But Challenges Remain	CMS	9/29/2022
OEI-04-20-00620	Reducing Medicare’s Payment Rates for Intermittent Urinary Catheters Can Save the Program and Beneficiaries Millions of Dollars Each Year	CMS	8/31/2022
OEI-05-22-00230	Part D Plans Generally Include Drugs Commonly used by Dual Eligibles: 2022	CMS	6/21/2022
OEI-06-18-00400	Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018	CMS	5/09/2022

OEI-07-20-00181	National Background Check Program for Long-Term Care Providers: An Interim Assessment	CMS	5/09/2022
OEI-09-18-00260	Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care	CMS	4/27/2022
OEI-BL-21-00200	Part D Plan Preference for Higher-Cost Hepatitis C Drugs Led to Higher Medicare and Beneficiary Spending	CMS	8/09/2022
OEI-01-20-00381	FDA's Work With the Tri-Agency Task Force for Emergency Diagnostics Helped Labs Implement COVID-19 Tests	FDA	9/16/2022
OEI-01-20-00380	FDA Repeatedly Adapted Emergency Use Authorization Policies To Address the Need for COVID-19 Testing	FDA	9/16/2022
OEI-01-21-00401	Delays in Confirmatory Trials for Drugs Granted FDA's Accelerated Approval Raise Concerns	FDA	9/26/2022
OEI-06-22-00320	Initial Observations of IHS Capacity To Manage Supplemental $3.5 Billion Appropriated to Sanitation Facilities Construction Projects	IHS	9/28/2022
OEI-06-21-00360	Connecticut Medicaid Fraud Control Unit: 2021 Inspection	MFCU	9/01/2022
OEI-06-21-00270	Michigan Medicaid Fraud Control Unit: 2021 Review	MFCU	9/26/2022
OEI-07-21-00340	Iowa Medicaid Fraud Control Unit: 2021 Inspection	MFCU	6/15/2022
OEI-03-20-00210	Opportunities Exist To Strengthen NIH Grantees' Oversight of Investigators' Foreign Significant Financial Interests and Other Support	NIH	6/02/2022
	Total Reports	**29**	

Appendix B: Savings Decisions Supported by OIG Recommendations

The table below lists policy decisions reflected in legislation, regulations, or other directives from prior years that are supported by OIG recommendations and for which cost savings were estimated, usually by third parties, such as the Congressional Budget Office (CBO) or HHS actuaries. Of the $23.9 billion in savings estimated for the decisions below, $2.9 billion was attributed to FY 2022. This figure reflects the most recent available savings estimates issued by the third-party appraiser; actual savings may be higher or lower.

After laws involving HHS programs are enacted, OIG analyzes the laws to identify the provisions that comport with our prior recommendations, that is, whether our recommendations support the decisions that were made. A similar process occurs with respect to administrative decisions in regulations or other directives or agreements (e.g., modifications to Medicaid State Plans). Most of the decisions reported in this appendix reflect ways in which funds could be put to better use, such as reductions in Federal spending or the avoidance of unnecessary or inappropriate expenditures, or both.

To quantify the value of administrative decisions, we use estimates developed by, or in consultation with, HHS OpDivs or StaffDivs. To quantify the value of legislative decisions, we generally use estimates developed by CBO. CBO projects the annual increases or reductions in Federal spending that it expects would result from enacting the legislation. The policy decisions shown on the table beginning on the next page mirror both OIG's recommendations and the contributions of others, such as HHS staff and OpDivs, congressional committees, and the GAO.

Centers for Medicare & Medicaid Services Programs		
OIG Recommendations	Policy Decisions	Estimated Savings
Calculation of Average Manufacturer Price (AMP) Under the Medicaid Drug Rebate Program Seek legislative change to exclude authorized generic drug transactions to secondary manufacturers from the AMP calculation of the brand name drug. The recommendation reflected findings in OIG report A-06-18-04002.	Section 1603 of the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 amended section 1927(k)(1)(C) of the Social Security Act (the Act) to exclude generic drug transactions to secondary manufacturers in the brand name drug's AMP calculations. CBO estimated savings of $3.15 billion over 10 years.	$280 million
Medicaid Rebate for Generic Drugs	Section 602 of the Bipartisan Budget Act of 2015 (P.L. No. 114-74) (See Tab 2) was enacted and	$134 million

Generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 22 percent of the quarterly AMPs that OIG reviewed. If the provision for brand-name drugs were extended to generic drugs, the Medicaid program would receive additional rebates. This finding was noted in OIG reports A-06-07-00042 and A-06-15-00030.	included provisions extending the additional rebate to generic drugs. The additional rebate for generic drugs will apply to rebate periods beginning with the first quarter of 2017. CBO estimated savings of $1.008 billion over 10 years.	
Hospital Transfer Policy for Early Discharges to Hospice Care Change regulations or pursue a legislative change, if necessary, to establish a hospital transfer payment policy for early discharges to hospice care. The recommendation reflected findings in OIG report A-01-12-00507.	Section 53109 of the Bipartisan Budget Act of 2018 modified existing law to require that, beginning in FY 2019, discharges to hospice care would also qualify as a post-acute-care transfer and be subject to payment adjustments.	$545 million
Reductions in Medicare Bad Debt Reimbursement Seek legislative authority to eliminate (or reduce) Medicare payments to hospitals for bad debt associated with beneficiaries' failure to pay their deductibles and coinsurance. The recommendations reflected findings in OIG report A-14-90-00339 and subsequent reviews.	Section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012 applied percentage reductions in bad debt reimbursement to all providers eligible to receive bad debt reimbursement. CMS estimated savings to Medicare of $10.92 billion over 10 years with $1.39 billion attributed to FY 2020. (77 Fed. Reg. 67450, 67523 (Nov. 9, 2012)).	$1,590 million
Payments for Prescription Drugs Provided to Incarcerated Beneficiaries Work with prescription drug plan sponsors to identify and resolve improper Medicare Part D payments made for prescription drugs provided to incarcerated beneficiaries. The recommendation reflected findings in OIG report A-07-12-06035.	CMS issued a final rule about the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug programs. The eligibility requirements to enroll in Medicare Advantage and Part D are outlined in Sections 1851(a)(3)(B) and 1860D-1(a)(3)(A) of the Act. To enroll in Medicare Advantage, a beneficiary must be entitled to Part A and enrolled in Part B. To enroll in Part D, a beneficiary must be entitled to Part A and/or	$211 million

	enrolled in Part B. An incarcerated beneficiary is not precluded from meeting the eligibility requirements for Part A and Part B, but in general, no Medicare Payment is made for these individuals. CMS promulgated regulations to require Part D plans to disenroll incarcerated beneficiaries. CMS estimated savings of $1.6 billion over 10 years with $172 million attributed to FY 2020. (79 Fed. Reg. 29844, 29953 (May 23, 2014)).	
Medicare Payments for Vacuum Erection Systems Seek legislative authority to include vacuum erection systems (VES) in the Competitive Bidding program and then implement a National Mail-Order Competitive Bidding Program for VES. The recommendation reflected findings in OIG report A-07-12-05024.	Section 203 of the Achieving a Better Life Experience Act of 2014 implements changes to treat VES prosthetic devices and related accessories as statutorily noncovered in the same manner that erectile dysfunction drugs are treated in Medicare Part D. CBO estimated savings of $444 million over 10 years.	$44.4 million
Excessive Medicaid Payments to New York State Ensure that expenditures related to developmental centers and other intermediate care facilities and any revised payment methodology be consistent with efficiency and economy. The recommendation reflected findings in OIG reports A-02-11-01029, A-02-13-01008, and other reviews.	Agreement between CMS and the State of New York, dated March 20, 2015, to repay $1.95 billion over 12 years with $100 million attributed to FY 2020.	$100 million

Appendix C: 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 CIGIE.

Office of Audit Services

During this semiannual reporting period, one peer review involving OAS was completed. Information concerning OAS's peer review activity during prior reporting periods are listed below.

OAS	Date	Reviewing Office	Office Reviewed
	September 2022	HHS-OIG, OAS	Department of Labor OIG

The system of quality control for the audit organization of Labor OIG in effect for the year ending September 30, 2021, has been suitably designed and complied with to provide Labor 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. Labor 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	Social Security Administration 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 compiled 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	Date	Reviewing Office	Office Reviewed
	September 2019	HHS-OIG, OEI	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 D: 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

Section 1128 of the Social Security Act (42 U.S.C. § 1320a-7), provides numerous 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 17 other grounds, including misdemeanors for health care fraud other than Medicare or Medicaid fraud; 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.

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 Federal anti-kickback statute (42 U.S.C. § 1320a-7b(b)).

The 21st Century Cures Act (enacted on December 13, 2016) added more grounds for imposing CMPs, assessments, and exclusions from Federal health care programs for fraudulent and other improper conduct related to HHS grants, contracts, and other agreements. OIG may impose a CMP of up to $10,000 per specified claim, an assessment of up to three times the amount claimed, and an exclusion upon any person who knowingly presents a specified claim under and HHS grant, contract, or other agreement that they know or should know is false or fraudulent. In addition, OIG may impose a CMP of up to $50,000, an assessment of up to three times the amount of funds at issue, and an exclusion upon any person who: (1) knowingly makes a false statement in a document required to be submitted to receive funds under an HHS contract, grant, or other agreement; (2) knowingly makes or uses a false record or statement that is material to a false or fraudulent claim; or (3) knowingly makes or uses a false record or statement material to an obligation to pay or transmit funds or property owed to HHS. OIG may also impose a CMP of up to $10,000 per day, an assessment of up to three times the amount at issue, and an exclusion upon any person who for knowingly conceals, or knowingly and improperly avoids or decreases, an obligation owed to HHS with respect to an HHS grant, contract, or other agreement. Finally, OIG may impose a penalty of up to $15,000 per day and an exclusion upon any person who fails to grant timely access to OIG upon reasonable request for the purpose of audits, investigations, evaluations, or other statutory functions of the OIG in matters involving HHS grants, contracts, or other agreements.

Patient Dumping

Section 1867 of the Social Security Act (42 U.S.C. § 1395dd), provides that when an individual goes to the Emergency Department 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 when the hospital does not have the capabilities to stabilize the condition

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 makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a Federal health care program. The statute's prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program. (Social Security Act, § 1128B(b) (42 U.S.C. § 1320a-7b(b)).

Individuals and entities who engage in conduct prohibited by the anti-kickback statute may be subject to criminal penalties and fines under the anti-kickback statute; CMPs under OIG's authority pursuant to the Social Security Act, § 1128A(a)(7) (42 U.S.C. § 1320a-7a(a)(7)-); 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)). In addition, a conviction under the anti-kickback statute leads to mandatory exclusion under the Social Security Act, §1128(a)(1) (42 U.S.C. § 1320a-7a(a)(1)). Finally, a claim that includes items or services resulting from a violation of the Federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act. (Social Security Act, § 1128B(b)(g) (42 U.S.C. § 1320a-7b(b)(g)).

The False Claims Act

OIG investigates alleged violations of the False Claims Act (31 U.S.C. §§ 3729–3733). Under the False Claims Act, 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. Similar to the CMPL, the False Claims Act defines "knowing" to include instances in which the person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information. 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 in 2009. Among other things, the amendments clarified the reach of the False Claims Act to false claims submitted to contractors or grantees of the Federal Government.

Appendix E: 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 and Appendix A
(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 Financial Management Improvement Act of 1996	Nothing to report
(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 C
(a)(17)	Investigative statistical tables	Appendix F
(a)(18)	Metrics description for statistical tables	Appendix F
(a)(19)	Investigations on senior Government employees	Appendix F
(a)(20)	Description of whistleblower retaliation instances	Appendix F
(a)(21)	Description of attempts to interfere with OIG independence	Appendix F
(a)(22)	Description of closed and nondisclosed reports and investigations regarding senior Government employees	Appendix F

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 *Federal Register* 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 G
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 F: 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 section 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 2022 OIG had a total of 86 reports with overdue final management decisions (FMDs) as of the end of this reporting period. The breakdown of those 86 reports by HHS OpDiv is as follows:

OpDiv	Overdue FMDs
ACF	17
ASPR	4
CMS	46
FDA	1
IHS	10
NIH	3
OASH	1
OS	4

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 zero 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 1,451 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	18	21	$369,932,148
2013	24	37	$234,261,321
2014	22	38	$15,072,080,989
2015	22	36	$304,720,009
2016	18	35	$184,156,192
2017	30	90	$1,100,958,099
2018	38	119	$525,408,004
2019	59	175	$728,613,733
2020	80	249	$2,458,020,804
2021	98	230	$880,662,095
2022	106	404	$2,495,003,205
Totals	527	1,451	$24,761,952,114

OIG annually produces *OIG's Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs*, 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]	**1,041**
Total number of persons referred to State and local prosecuting authorities for criminal prosecutions during the reporting period	**120**
Total number of Federal indictments and criminal information during the reporting period that resulted from any prior referral to prosecuting authorities	**314**
Total number of State and local indictments and criminal information during the reporting period that resulted from any prior referral to prosecuting authorities	**66**

(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 and criminal information during the semiannual reporting period, including sealed indictments and 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 DOJ, the date of the referral; and
(ii) if DOJ declined the referral, the date of the declination;

For this section, OIG describes investigations, both criminal and administrative, involving senior Government employees for whom allegations of misconduct were investigated and substantiated. For the reporting period, the OIG investigation of one senior Government employee for misconduct was substantiated.

Description of Investigation	Status	Disposition	DOJ Referral	DOJ Referral Date	DOJ Declination	DOJ Declination Date
A senior Government official allegedly violated conflict of interest rules applicable to all Executive Branch employees.	Closed	Substantiated	Yes	1/8/2021	Yes	1/8/2021

OIG provides investigative facts for the purpose of referring a matter or allegation to the appropriate deciding authority (Department, OpDiv, DOJ, etc.). OIG does not make findings regarding its investigations of departmental employees. Our reports relay the facts obtained during the investigations (e.g., parties involved, dates of events). At the conclusion of an OIG

investigation related to 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. Although, we request from the agency a copy of an SF-50 documenting a personnel action, if one is taken, there are sometimes settlement agreements that may impact the final action. Therefore, OIG may not have a complete record of the disposition of the investigation.

(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;

OIG conducts investigations into whistleblower retaliation against current and former HHS employees, applicants for HHS employment, HHS contractors, subcontractors, personal services contractors, grantees, and subgrantees who disclose information to OIG, and other protected sources, under the authority of the Whistleblower Protection Act of 1989, 41 U.S.C. § 4712, the Military Whistleblower Protection Act (10 U.S.C. 1034), and Presidential Policy Directive 19. OIG makes a determination as to whether retaliatory action has been taken and includes these findings in reports, along with recommendations for corrective action. OIG provides a summary of any substantiated retaliation report on the OIG website to enhance transparency and employer accountability. In the reporting period, OIG submitted one report to the Office of the Secretary of HHS that included findings of retaliation.

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.

OIG conducted an investigation in response to allegations made by a complainant at the Tennessee Coalition to End Domestic and Sexual Violence (Coalition), a CDC grantee. The complainant alleged that, while working for the Coalition, under Domestic Violence Prevention Enhancement and Leadership Through Alliances (DELTA) program grants, the complainant's supervisors and responsible management officials (RMOs), terminated the complainant for making allegations that Federal grant laws were being repeatedly violated by the Coalition. Specifically, investigators found that the complainant made written and oral protected disclosures to the RMOs and a CDC employee alleging DELTA grant mismanagement. OIG investigators found that the RMOs terminated the complainant's employment in retaliation for making protected disclosures. The OIG investigative report included recommendations for corrective action and was provided to the Office of the Secretary of HHS, which may seek to implement alternative or additional actions as deemed appropriate.

The report included the following recommendations for corrective action: (1) that whistleblower protection training be required for the grantee and its employees, as well as for CDC employees who work in the DELTA program; and (2) that the complainant be made whole in the form of backpay since their constructive discharge.

(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 inspection, evaluation, and audit reports for this semiannual reporting period that did not result in public reports.

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

(B) Investigation conducted by the Office involving a senior Government employee that is closed and was not 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 four

investigations closed during this reporting period involving senior Government employees for whom allegations of misconduct were investigated and not substantiated.

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

Description of Investigation	Status	Disposition	DOJ Referral	DOJ Referral Date	DOJ Declination	DOJ Declination Date
A senior Government employee allegedly inappropriately touched/sexually assaulted another Government employee and a former patient.	Closed	Unsubstantiated	No	N/A	N/A	N/A
A senior Government employee allegedly attempted to pressure employees to contract with a company for which the senior Government employee's family member has a financial interest.	Closed	Unsubstantiated	No	N/A	N/A	N/A
A senior Government employee supervised a contracted employee. The contracted employee allegedly attempted to pull a patient's pants down during an examination despite the patient's objection.	Closed	Unsubstantiated	No	N/A	N/A	N/A
A senior Government employee allegedly retaliated against an employee for reporting violations of law and department policies.	Closed	Unsubstantiated	No	N/A	N/A	N/A

Appendix G: 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 2021, 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
Repeal or modification of existing safe harbors (e.g., the group purchasing organization (GPO) safe harbor, 42 C.F.R. § 1001.952(f)) to address comments and concerns regarding the manner in which GPOs and pharmacy benefit managers (PBMs) may be using such safe harbors to protect purportedly abusive arrangements.	OIG is not adopting commenters' suggestions to repeal or modify the GPO safe harbor, among others, to address their comments and concerns about the financial arrangements for which GPOs and PBMs may be using these safe harbors. We may consider this topic in future rulemaking or in future guidance. OIG highlights that there is a statutory exception addressing GPOs at section 1128B(b)(3)(C) of the Social Security Act.
Modification of the Cooperative Hospital Services Organization (CHSO) safe harbor, 42 C.F.R. § 1001.952(q), to: (i) protect only CHSO	OIG is not adopting this suggestion. We may consider this topic in future rulemaking.

[1] OIG, Solicitation of New Safe Harbors and Special Fraud Alerts, 86 Fed. Reg. 71,611 (Dec. 17, 2021), https://www.govinfo.gov/content/pkg/FR-2021-12-17/pdf/2021-27314.pdf.

arrangements that involve the provision of items or services that are components of the direct or indirect overhead costs associated with the inpatient or outpatient hospital services of the nonprofit patron-hospitals; and (ii) exclude protection for the creation of revenue-producing joint venture arrangements for non-hospital, post-discharge home care services and the distribution of CHSO revenues to patrons based on referrals.	
A new safe harbor to protect: (i) value-based price-adjustment arrangements that are dependent on the achievement of a measurable clinical or cost outcome associated with the value of a seller's reimbursable items or services; and (ii) the provision of value-based services, such as services that enable parties to measure outcome measures associated with value-based price-adjustment arrangements.	OIG is not adopting this suggestion. We appreciate learning about ways in which pharmaceutical manufacturers, medical device manufacturers, and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) entities believe that they could contribute to the coordination of care and the overall delivery of high-value care through, for example, value-based price-adjustment arrangements or value-based services arrangements. However, we continue to have concerns about the offer of remuneration by these entities that raises many of the traditional fraud and abuse risks under the Federal anti-kickback statute. We may consider this topic in future rulemaking.
A new safe harbor to protect drug copayment assistance in situations where a less expensive and equally effective alternative drug does not exist.	OIG is not adopting this suggestion. The offer of cost-sharing assistance for a drug, particularly by the manufacturer of such drug (either directly or indirectly), presents many of the traditional risks of fraud and abuse that the Federal anti-kickback statute is designed to prevent.
New safe harbors to protect: (i) value-based purchasing arrangements between pharmaceutical manufacturers and payors or PBMs; and (ii) the provision of data analytics by a drug, biologic, or device manufacturer.	OIG is not adopting these suggestions. We continue to evaluate the ways in which pharmaceutical manufacturers may be able to contribute to the coordination of care and the overall delivery of high-value care through, for example, value-based purchasing arrangements or data sharing arrangements. However, we continue to have concerns about the offer of remuneration through these programs, which raises many of the traditional fraud and abuse

	risks under the Federal anti-kickback statute. We may consider this topic in future rulemaking.
Modifications to the safe harbors for value-based arrangements, including the safe harbors for arrangements for patient engagement and support to improve quality, health outcomes, and efficiency, 42 C.F.R. § 1001.952(hh), to protect the exchange of remuneration by certain entities that currently cannot use the safe harbors (e.g., pharmaceutical manufacturers, medical device manufacturers, laboratory companies, and suppliers of durable medical equipment, prosthetics, orthotics, or supplies).	As explained in the preamble to the final rule at 85 Fed. Reg. 77,684 (Dec. 2, 2020) (referred to in this Appendix G as the "2020 final rule"), remuneration exchanged by pharmaceutical manufacturers and, in certain circumstances, medical device manufacturers and DMEPOS entities, are not eligible for protection under the 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.[2] Consequently, OIG declines to adopt this suggestion.
New safe harbors to implement the Final Rule for the 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.	OIG is not adopting this suggestion. Section 11301 of the Inflation Reduction Act of 2022 extended the moratorium on the implementation of the Final Rule for the 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 until January 1, 2032.
New safe harbor for charitable assistance programs to protect the provision of medical products and pharmaceutical products at no charge to patients in financial need.	OIG is not adopting this suggestion. We may consider this topic in future rulemaking.
Modification to existing safe harbor at 42 C.F.R. § 1001.952(h) to define "rebate" to include any service fee paid as a percent-of-sales.	OIG is not adopting this suggestion. A rebate is a type of discount, and a discount is a reduction in price charged for an item or service. A discount, including a rebate, does not include payment for a service. In a final rule issued in 1991, OIG stated that contracts for personal or

[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, 77,709 (Dec. 2, 2020), https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26072.pdf.

	management services do not fit within the statutory discount exception or the definition of "discount" in the regulatory safe harbor.[3] We decline to revise the definition of "rebate" to include service fees paid as a percent of sales.
New safe harbor for manufacturer-sponsored patient engagement and product support programs, including therapy management and medication adherence support to encourage patients to manage and follow their treatment plans.	OIG is not adopting this suggestion. We continue to evaluate the ways in which pharmaceutical manufacturers may be able to contribute to the delivery of quality care for patients through programs such as medication adherence support, but we continue to have concerns about the offer of remuneration to patients through these programs, which raises many of the traditional fraud and abuse risks (e.g., patient steering). We may consider this topic in future rulemaking.
New safe harbor to protect internal cost sharing (or gainsharing) payments or modification to the personal services and management contracts and outcomes-based payment arrangements safe harbor, 42 C.F.R. § 1001.952(d), to expand the definition of "outcomes-based payment" to include internal cost sharing (or gainsharing) payments.	OIG is not adopting the suggestion to create a new safe harbor or modify the personal services and management contracts and outcomes-based payment arrangements safe harbor. We continue to believe, as stated in the preamble to the 2020 final rule, that payments for arrangements that reduce internal costs may pose risks to patient care, among other concerns.[4] At this time, we continue to believe that the risks outweigh any potential benefits of these arrangements such that safe harbor protection is not warranted.
New safe harbor for payments from hospitals to post-acute-care providers to transition patients to clinically appropriate, lower-cost care settings.	OIG is not adopting this suggestion. We believe that existing regulations, including new and modified safe harbors that were finalized in the 2020 final rule, provide sufficient regulatory flexibility for financial arrangements between referral sources that balance the goals of care coordination and delivery of value-based care with the need to protect both patients and

[3] 42 C.F.R. § 1001.952(h)(5)(vi); OIG, Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952 (July 29, 1991), https://oig.hhs.gov/documents/compliance/857/072991.htm.
[4] 85 Fed. Reg. at 77,845.

	Federal health care programs. We may consider this topic in future rulemaking.
A new safe harbor for the waiver or offset of cost-sharing obligations for items and services provided in connection with: (i) value-based arrangements for care management or remote patient monitoring; and (ii) the Acute Care Hospital at Home program and any follow-on model that may be established by CMS following the expiration of the Section 1135 public health emergency waiver.	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.
A new safe harbor that would protect remuneration between wholly owned subsidiaries and between a parent company and a subsidiary.	OIG is not adopting this suggestion. We may consider this topic in future rulemaking.