Department of Health and Human Services

Office of Inspector General

Semiannual Report to Congress

April 1, 2023–September 30, 2023

A Message From Christi A. Grimm, Inspector General

I am pleased to submit the *Semiannual Report to Congress* highlighting 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, 2023.

HHS-OIG oversees more than 100 health and human services programs to ensure that more than $2 trillion in taxpayer funds are responsibly spent and that the more than 150 million Americans who rely on those programs are well served. HHS-OIG employs audits, evaluations, inspections, investigations, and enforcement actions to safeguard these critical programs and, ultimately, promote the health and well-being of all Americans. The *Semiannual Report* details enforcement actions and other key oversight work across the scope of HHS programs and operations.

HHS-OIG recognizes that emerging technologies promise tremendous potential benefits for patients and Federal health care programs, but also pose potential risks if corrupted by individuals with malicious intent to perpetrate widespread fraud. To combat such abuses, we perform cutting-edge analyses in evolving and emergent areas, including telehealth and cybersecurity. The 2023 Nationwide Health Care Fraud Enforcement Action conducted by HHS-OIG and our law enforcement partners charged 78 individuals with $2.5 billion in false billing to Federal programs. Part of this alleged fraud involved a novel software platform that facilitated auto-generated orders, misrepresentation of in-person versus remote place-of-service, and false billing on a massive scale. HHS-OIG built on prior experience in investigating robo-dialer scams, manipulation of clinical decision support in electronic health records, and dark web purchasing of patient information to uncover these new abuses.

This *Semiannual Report* includes additional examples of health care fraud that diverts important resources from enrollees. In one case, a laboratory owner and operator was sentenced to 27 years in prison for defrauding Medicare by submitting more than $463 million in claims for unnecessary genetic and other laboratory tests that were procured through the payment of kickbacks and bribes. In another alarming case, a physician was sentenced and fined for requiring Medicare enrollees and other patients to schedule clinic visits multiple times each month and undergo unnecessary steroid injections to obtain prescriptions. Among the most consequential enforcement authorities available to HHS-OIG is the ability to exclude disreputable entities and individuals from participation in Federal health care programs, thereby protecting patients and programs going forward. This report details HHS-OIG's exclusion of a pharmacist who was convicted on 70 counts related to illegal dispensing and distributing of controlled substances from a pill-mill operation.

Another alarming area of abuse involves manipulation of managed care programs to maximize Medicare and Medicaid payments to insurance plan sponsors while minimizing care rendered to enrollees. HHS-OIG vigilantly looks for schemes whereby insurance plans mount barriers to enrollees' ability to access needed care or misrepresent enrollee's health status to game risk adjustments and inflate capitated payments from

the Medicare and Medicaid programs. As Medicare and Medicaid enrollees increasingly rely on managed care, HHS-OIG prioritizes oversight and enforcement to ensure that managed care programs operate as intended. During this reporting period, HHS-OIG published our *Strategic Plan: Oversight of Managed Care for Medicare and Medicaid* outlining how HHS-OIG will oversee contracting with managed care plans, enrollment, payments, and quality and adequacy of services to: (1) promote access to care for people enrolled in managed care, (2) provide comprehensive financial oversight, and (3) promote data accuracy and encourage data-driven decisions. Ultimately, HHS-OIG's work holds managed care plans, and the individual executives who run them, accountable for appropriately serving enrollees' health care needs without overcharging Federal programs and taxpayers.

HHS-OIG employs modern technologies and tools to ensure good financial stewardship of American taxpayers' investment in HHS. Our diligent and innovative workforce leverages deep experience in overseeing complex and consequential initiatives and produces outsized impact. Our capacity to achieve high-impact results is limited only by our resources, which have not kept pace with the growth of HHS programs in recent years. HHS-OIG will continue to pursue the mission of providing independent, objective, standards-based oversight and enforcement to protect HHS's programs and the people they serve. The additional investment in the Health Care Fraud and Abuse Control Program proposed in the President's Fiscal Year 2024 Budget would provide critically needed resources to combat fraud, waste, and abuse and enhance efficiency and effectiveness in the Medicare and Medicaid programs.
We appreciate the continued support of Congress and HHS for this important work.

Christi A. Grimm
Inspector General

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Selected Acronyms and Abbreviations

ACF	Administration for Children and Families
AI/AN	American Indian/Alaska Native
ASA	Assistant Secretary for Administration
ASP	average sales price
ASPR	Administration for Strategic Preparedness and Response
CDC	Centers for Disease Control and Prevention
CIA	corporate integrity agreement
CIGIE	Council of the Inspectors General on Integrity and Efficiency
CIN	Client Index Number
CMP	civil monetary penalty
CMPL	Civil Monetary Penalties Law
CMS	Centers for Medicare & Medicaid Services
DMEPOS	durable medical equipment, prosthetics, orthotics, and supplies
DoD	Department of Defense
DOJ	Department of Justice
DOL	Department of Labor
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
MSI	Mission Support and Infrastructure
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health
OAS	Office of Audit Services
OASH	Office of Assistant Secretary for Health
OCIG	Office of Counsel to the Inspector General
OEI	Office of Evaluation and Inspections
OI	Office of Investigations
OIG	Office of Inspector General

OS	Office of the Secretary
PBM	pharmacy benefit manager
SAMHSA	Substance Abuse and Mental Health Services Administration

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 Organization

OIG's work is conducted by the Office of Audit Services (OAS), the Office of Evaluation and Inspections (OEI), the Office of Investigations (OI), the Office of Counsel to the Inspector General (OCIG), and Mission Support and Infrastructure (MSI).

Office of Audit Services

OAS provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. The audits examine the performance of HHS programs, funding recipients, and contractors in carrying out their respective responsibilities and provide independent assessments of HHS programs and operations to reduce waste, abuse, and mismanagement.

Office of Evaluation and Inspections

OEI's national evaluations provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. To promote impact, OEI reports also provide practical recommendations for improving program operations.

Office of Investigations

OI's criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs and operations often lead to criminal convictions, administrative sanctions, and civil monetary penalties (CMPs). OI's nationwide network of investigators collaborates with DOJ and other Federal, State, and local law enforcement authorities. OI works with public health entities to minimize adverse patient impacts following enforcement operations. OI also provides security and protection for the Secretary and other senior HHS officials.

Office of Counsel to the Inspector General

OCIG provides legal advice to OIG on HHS programs and OIG's internal operations. The law office also imposes exclusions and CMPs, monitors corporate integrity agreements (CIAs), and represents HHS's interests in False Claims Act cases. In addition, OCIG publishes advisory opinions, compliance program guidance documents, fraud alerts, and other resources regarding compliance considerations, 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 infrastructure that enables 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, including audits and evaluations, that are underway or are planned during the fiscal year 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. 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.

Public Recommendations Tracker

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. OIG publishes information about unimplemented recommendations via its Recommendations Tracker.

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 significant problems, abuses, deficiencies, remedies, and investigative outcomes relating to the administration of HHS programs and operations during the reporting period. In this report, 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, 2023–September 30, 2023. We also provide data for accomplishments for fiscal year (FY) 2023 and highlight some of our work completed during this semiannual reporting period.

Highlights of OIG Accomplishments

In this section, we present data on OIG reports issued, expected recoveries, criminal and civil actions, and other statistics resulting from our work during the semiannual reporting period. We then highlight significant results from selected audits, evaluations, and enforcement activities completed during the reporting period.

At-a-Glance Highlights for Fiscal Year 2023

Statistic	FY 2023 (10/1/2022–9/30/2023)
Audit Reports Issued	127
Evaluations Issued	42
Expected Audit Recoveries	$283.5 million
Questioned Costs	$1.5 billion
Potential Savings	$47.2 million
New Audit and Evaluation Recommendations	464
Recommendations Implemented by HHS OpDivs	493
Expected Investigative Recoveries	$3.16 billion
Criminal Actions	707
Civil Actions	746
Exclusions	2,112

Results for the Semiannual Reporting Period

During this semiannual reporting period (April 1, 2023, through September 30, 2023), we issued 65 audit reports and 22 evaluation reports. Our audit work identified $82.7 million in expected recoveries, as well as $1.2 billion in questioned costs (costs questioned by OIG because of an alleged violation, costs not supported by adequate documentation, or the expenditure of funds where the intended purpose is unnecessary or unreasonable). Our audit work also identified $47.2 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 247 new audit and evaluation recommendations, which are crucial to encourage positive change in HHS programs. Meanwhile, HHS OpDivs implemented 228 prior recommendations, leading to positive impact for HHS programs and beneficiaries.

OIG also remains at the forefront of the Nation's efforts to fight fraud in HHS programs and hold wrongdoers accountable for their actions. Along with our partners—including DOJ; Medicaid Fraud Control Units (MFCUs); and other Federal, State, local, and tribal law enforcement agencies—we detect,

investigate, and prosecute fraud through a coordinated and data-driven approach. OIG's investigative work led to $2.26 billion in expected investigative recoveries and 362 criminal actions during this reporting period. OIG also took civil actions, such as assessing monetary penalties, against 422 individuals and entities, and excluded 750 individuals and entities from Federal health care programs.

OIG continues to focus on the most significant and high-risk issues in health care and human services. Our mission is to provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve. Below we highlight results from selected OIG oversight and enforcement activities from the semiannual reporting period of April 1, 2023, through September 30, 2023, organized by subject area. A comprehensive list of OIG work during the reporting period follows, and Appendices A through G provide data to meet the reporting requirements in the Inspector General Act of 1978.

Leveraging Oversight To Better Protect Nursing Home Residents

Improving nursing home quality of care is a top priority for OIG. Decades of OIG oversight of nursing homes has revealed significant challenges and vulnerabilities. A three-part strategy guides our oversight work, with the goal of better understanding contributing factors; identifying fraud, operational inefficiencies, and substandard care; and aiding policymakers:

- **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 effect rapid remediation.

OIG has 29 ongoing audits and evaluations of nursing home issues. We continue to monitor identified areas of concern, promote unimplemented recommendations, and issue new recommendations as we identify problems and solutions. OIG's website provides information about ongoing and completed nursing home work.

Significant OIG work completed during this reporting period to protect residents in nursing homes includes the following:

- *CMS Did Not Accurately Report on Care Compare One or More Deficiencies Related to Health, Fire Safety, and Emergency Preparedness for an Estimated Two-Thirds of Nursing Homes* (A-09-20-02007), April 2023
- *Nursing Homes Reported Wide-Ranging Challenges Preparing for Public Health Emergencies and Natural Disasters* (OEI-06-22-00100), August 2023

OIG continues to exclude entities and individuals who have committed fraud and abuse from participation in Federal health care programs. For instance, during this reporting period, OIG imposed a 40-year exclusion of a nursing assistant who had committed nonconsensual sexual acts upon patients at a skilled nursing facility. Exclusion protects program beneficiaries by preventing these bad actors from working in such capacities going forward.

Promoting Program Integrity and Good Financial Stewardship in Traditional Medicare

The 2023 Medicare Trustees Report projected that the Part A trust fund will run out of funds by 2031 unless congressional action is taken. This adds 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:

- *Toolkit: Analyzing Telehealth Claims to Assess Program Integrity Risks* (OEI-02-20-00723), April 2023
- *Medicare Paid Millions More for Physician Services at Higher Nonfacility Rates Rather Than at Lower Facility Rates While Enrollees Were Inpatients of Facilities* (A-04-21-04084), May 2023
- *2022 Performance Data for the Senior Medicare Patrol Projects* (OEI-02-23-00150), June 2023
- *Medicare Paid $30 Million for Accumulated Repair Costs That Exceeded the Federally Recommended Cost Limit for Wheelchairs During Their 5-Year Reasonable Useful Lifetime* (A-09-22-03003), July 2023

OIG continues to coordinate with DOJ to identify and prosecute bad actors in the Medicare program. The following are two examples of successful criminal prosecutions related to traditional Medicare during this reporting period:

- A physician was sentenced to 84 months in prison and 3 years of supervised release after being ordered to pay more than $1 million in restitution. The physician was also fined $195,000 and must forfeit previously seized assets worth $900,000. The physician required Medicare beneficiaries and other patients to schedule clinic visits multiple times each month and undergo unnecessary steroid injections to obtain prescriptions.
- A clinical laboratory owner and operator was sentenced to 27 years in prison for defrauding Medicare by submitting more than $463 million in genetic and other laboratory tests that patients did not need and were procured through kickbacks and bribes.

OIG uses civil litigation to settle liabilities with facilities who engage in inappropriate billing practices. For example, during this reporting period, a national provider of air medical transport services agreed to pay the Federal Government more than $1 million to resolve allegations that it had failed to return known overpayments for medically unnecessary flights to Medicare and other State and Federal health programs.

Preventing Prescription Drug Misuse and Strengthening Substance Abuse Care

OIG continues to prioritize oversight and enforcement activities to protect enrollees from prescription drug abuse and safeguard health care services for individuals suffering from substance abuse disorder.

Significant OIG work completed during this reporting period related to prescription drug prevention and substance abuse care includes the following:

- *The Risk of Misuse and Diversion of Buprenorphine for Opioid Use Disorder Appears To Be Low in Medicare Part D* (OEI-02-22-00160), May 2023
- *Medicare Made $17.8 Million in Potentially Improper Payments for Opioid-Use-Disorder Treatment Services Furnished by Opioid Treatment Programs* (A-09-22-03005), August 2023
- *Many Medicaid Enrollees With Opioid Use Disorder Were Treated with Medication; However, Disparities Present* (OEI-BL-22-00260), September 2023

OIG continues to coordinate with DOJ to identify and criminally prosecute bad actors in Federal health care programs. The following are two examples of successful criminal prosecutions related to improper prescriptions and distributions during this reporting period:

- A physician was sentenced to 72 months in prison after pleading guilty to illegally prescribing opioids and other controlled substances, illegally distributing controlled substances, and health care fraud.
- A pharmacist was sentenced to 2 years in prison for fraudulently billing Medicare for more than $1 million in compounded drug creams that were never actually dispensed to patients.

OIG continues to exclude entities and individuals engaged in fraud and abuse from participation in Federal health care programs. For example, during this reporting period, OIG imposed a 20-year exclusion on a pharmacist who was convicted on 70 counts related to illegal dispensing and distributing of controlled substances from a pill-mill operation.

Promoting Integrity and Effectiveness in Medicare Advantage and Medicaid Managed Care

More than half of Medicare enrollees are currently enrolled in Medicare Advantage plans. Enrollment is expected to continue to grow to cover 62 percent of enrollees by 2033. Managed care is the predominant payment model in Medicaid. State and Federal expenditures on Medicaid managed care are growing. These expenditures totaled $407 billion and represented 57 percent of all Medicaid benefit expenditures in 2022.

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

- *High Rates of Prior Authorization Denials by Some Plans and Limited State Oversight Raise Concerns About Access to Care in Medicaid Managed Care* (OEI-09-19-00350), July 2023

- *Florida Did Not Refund $106 Million Federal Share of Medicaid Managed Care Rebates It Received for Calendar Years 2015 Through 2020* (A-04-22-04089), August 2023

OIG uses civil litigation to settle liabilities with facilities that engage in inappropriate billing practices. For example, during this reporting period, a health care company agreed to pay more than $22 million to resolve claims that it had violated the False Claims Act by submitting inaccurate diagnosis codes to increase reimbursements from Medicare.

Safeguarding Medicaid Program Integrity

Medicaid is the Federal health care program that covers the most Americans, with nearly 94 million individuals enrolled as of May 2023. Medicaid is administered by States per Federal requirements. The program is funded jointly by the Federal Government and States. Federal and State Medicaid spending was $824.2 billion in FY 2022.

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

- *Four States Reviewed Received Increased Medicaid COVID-19 Funding Even Though They Terminated Some Enrollees' Coverage for Unallowable or Potentially Unallowable Reasons* (A-06-21-09002), September 2023

OIG continues to partner with MFCUs to combat fraud, waste, and abuse in State Medicaid programs. For example, during this reporting period, an owner of a durable medical equipment (DME) company was sentenced to 36 months and nearly $5 million in restitution for involvement in an illegal kickback scheme. The owner paid illegal kickbacks to co-conspirators for referrals or orders sent to DME companies, although the owner knew the orders were fraudulent.

OIG continues to exclude entities and individuals engaged in fraud and abuse from participation in Federal health care programs. For example, during this reporting period, OIG excluded a business owner for a minimum period of 24 years due to a conviction for defrauding the State Medicaid program. OIG's investigation found that the business owner offered unfulfilled promises of housing assistance to Medicaid recipients who were then required to provide their Medicaid identification numbers and submit to medically unnecessary services.

Reducing Prescription Drug Spending for HHS Programs and Enrollees

OIG assesses areas in which HHS programs or enrollees 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:

- *Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Fourth Quarter* (OEI-03-23-00090), May 2023

- *Part D Plans Generally Include Drugs Commonly Used Dual-Eligible Enrollees: 2023* (OEI-05-23-00130), June 2023
- *Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the First Quarter of 2023* (OEI-03-23-00100), August 2023
- *Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2021 Average Sales Prices* (OEI-03-23-00120), August 2023

Ensuring Health and Safety of People Served by HHS

OIG has devoted substantial oversight efforts to protect people who may be at increased risk for negative outcomes—including the elderly, unaccompanied and foster children, and the American Indian/Alaska Native (AI/AN) population—who are served by HHS programs such as Medicaid, the Unaccompanied Children Program, the Child Care and Development Fund, and the Indian Health Service (IHS).

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

- *Crow/Northern Cheyenne Hospital—an IHS-Operated Health Facility—Did Not Timely Conduct Required Background Checks of Staff and Supervise Certain Staff* (A-02-21-02004), April 2023.
- *The Office of Refugee Resettlement Needs To Improve Its Practices for Background Checks During Influxes* (A-06-21-07003), May 2023
- *State Agencies Can Improve Their Reporting of Children Missing From Foster Care to Law Enforcement for Entry Into the National Crime Information Center Database as Required by Federal Statute* (A-07-21-06104), May 2023
- *Florida Did Not Comply With Requirements for Documenting Psychotropic and Opioid Medications Prescribed for Children in Foster Care* (A-05-22-00009), July 2023
- *Widespread Pandemic Disruption Spurred Innovation to State Paternity Establishment Practices* (OEI-06-21-00150), August 2023
- *One Quarter of Medicaid Enrollees with HIV May Not Have Received Recommended Care in 2021* (OEI-05-22-00240), August 2023
- *FDA Could Take Stronger Enforcement Action Against Tobacco Retailers With Histories of Sales to Youth and Other Violations* (OEI-01-20-00240) and *Supplemental Data on Tobacco Retailer Inspections* (OEI-01-20-00242), September 2023

Promoting Cybersecurity

OIG continues to recognize cybersecurity vulnerabilities as major risks to effectively managing and safeguarding HHS's programs. OIG prioritizes oversight of HHS's cybersecurity. Repeated cyberattacks targeting critical information in HHS systems add urgency to the task of developing departmental cybersecurity safeguards.

Significant OIG work completed during this reporting period related to strengthening HHS's cybersecurity posture includes the following:

- *The Centers for Medicare & Medicaid Services Should Improve Preventative and Detective Controls To More Effectively Mitigate the Risk of Compromise* (A-18-20-08001), May 2023

Fostering 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 also works to ensure that HHS programs accurately capture demographic data to enable identification, analysis, and, ultimately, remediation of health disparities.

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

- *A Resource Guide for Using Medicare's Enrollment Race and Ethnicity Data* (OEI-02-21-00101), June 2023
- *Targeted Provider Relief Funds Allocated to Hospitals Had Some Differences with Respect to the Ethnicity and Race of Populations Served* (OEI-05-20-00580), June 2023

OIG continues to coordinate with DOJ to identify and prosecute those who take advantage of flexibilities in Federal health care programs designed to increase access. For instance, during this reporting period, a laboratory owner was sentenced to 60 months in prison and ordered to pay more than $61 million in restitution for involvement in a $73 million conspiracy to defraud Medicare. The scheme exploited temporary amendments to telehealth restrictions by offering telehealth providers access to Medicare beneficiaries for whom they could bill Medicare for consultations. These telehealth providers agreed to refer beneficiaries to the provider for unnecessary genetic testing.

Ensuring Quality of Care and Protecting Patients From Harm

OIG has long prioritized oversight and enforcement work to protect Medicare and Medicaid patients from harm and to help ensure that patients receive high-quality care. This work includes assessing the safeguards in place to ensure quality and safety and examining the incidence and preventability of patient harm.

Significant OIG work during this reporting period includes the following:

- *Adverse Events Toolkit: Medical Record Review Methodology* (OEI-06-21-00030), June 2023
- *Adverse Events Toolkit: Clinical Guidance for Identifying Patient Harm* (OEI-06-21-00031), June 2023
- *Home Health Agencies Failed To Report Over Half of Falls With Major Injury and Hospitalization Among Their Medicare Patients* (OEI-05-22-00290), August 2023

Promoting Proper Departmental Management

OIG reviews HHS programs to ensure that they are being administered effectively, efficiently, and without waste. Opportunities to improve HHS program administration include compliance with requirements, coordination across programs, and dissemination of best practices.

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

- *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 2022* (A-17-23-52000), May 2023
- *Seventeen of Thirty Selected Health Centers Did Not Use or May Not Have Used Their HRSA COVID-19 Supplemental Grant Funding in Accordance With Federal Requirements* (A-02-21-02005), May 2023
- *Medicaid and Marketplace Enrollment Strategies Used During the COVID-19 PHE Could Benefit States Going Forward* (OEI-09-20-00590), September 2023

OIG Participation in Congressional Hearings

Date	*Witness*	*Testimony/Committee*
5/18/2023	Erin Bliss, Assistant Inspector General, Evaluation and Inspections, OIG	"Testimony on Residents at Risk: The Strained Nursing Home Inspection System and the Need To Improve Oversight, Transparency, and Accountability" U.S. Senate Special Committee on Aging
5/17/2023	Megan Tinker, Chief of Staff, OIG	"Testimony on Examining Health Care Denials and Delays in Medicare Advantage" U.S. Senate Homeland Security and Governmental Affairs Committee
4/18/2023	Christi A. Grimm, Inspector General, OIG	"Testimony on Insights From the HHS Inspector General on Oversight of Unaccompanied Minors, Grant Management, and CMS" U.S. House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations

Medicare and Medicaid Reports and Reviews

Medicare Program Reports and Reviews

Financial Management and Improper Payments

Medicare Could Have Saved Up to $128 Million Over 5 Years if CMS Had Implemented Controls To Address Duplicate Payments for Services Provided to Individuals With Medicare and Veterans Health Administration Benefits (A-09-22-03004), April 2023

Medicare paid providers for medical services that were authorized and paid for by the Department of Veterans Affairs' (VA's) community care programs during our audit period, resulting in duplicate payments of up to $128 million. The Veterans Health Administration (VHA), within VA, is solely responsible for paying providers for medical services that it authorized.

These duplicate payments occurred because CMS did not implement controls to address duplicate payments for services provided to individuals with Medicare and VHA benefits. Specifically, CMS did not establish a data-sharing agreement with VHA for the ongoing sharing of data between the two agencies and did not develop an interagency process to include VHA enrollment, claims, and payment data in CMS's data repository. Furthermore, CMS guidance to providers on VA's responsibility to pay for medical services did not clarify that a provider should not bill Medicare for a medical service that was authorized by VHA.

We recommend that CMS: (1) establish a comprehensive data-sharing agreement with VHA for the ongoing sharing of data; (2) establish an interagency process to integrate VHA enrollment, claims, and payment data into the CMS Integrated Data Repository to identify potential fraud, waste, and abuse under the Medicare program; (3) establish an internal process (such as system edits) to address duplicate payments made by Medicare for medical services authorized and paid for by VHA, which could have saved Medicare up to $128 million during our audit period; and (4) issue guidance to providers on not billing Medicare for a medical service that was authorized by VHA. CMS concurred with all of our recommendations.

Medicare Improperly Paid Providers for Some Psychotherapy Services, Including Those Provided via Telehealth, During the First Year of the COVID-19 Public Health Emergency (A-09-21-03021), May 2023

Providers did not meet Medicare requirements and guidance when billing for some psychotherapy services, including services provided via telehealth. For 84 of the 216 sampled enrollee days, providers met Medicare requirements. However, for 128 sampled enrollee days, providers did not meet these requirements (e.g., psychotherapy time was not documented). In addition, for 54 sampled enrollee days, providers did not meet Medicare guidance (e.g., providers' signatures were

missing). (We did not review 4 sampled enrollee days and treated them as non-errors because they were already part of other OIG reviews.) Based on our sample results, we estimated that of the $1 billion that Medicare paid for psychotherapy services, providers received $580 million in improper payments for services that did not comply with Medicare requirements, consisting of $348 million for telehealth services and $232 million for nontelehealth services.

We also present the information we obtained on providers' experience with providing telehealth services during the public health emergency for the sampled enrollee days. We found that some providers reported challenges in furnishing telehealth services and most providers used approved communication technology to provide those services.

We recommend that CMS: (1) work with Medicare contractors to recover $35,560 in improper payments for the sampled enrollee days, (2) implement system edits for psychotherapy services to prevent payments for incorrectly billed services, and (3) strengthen educational efforts to make providers aware of educational materials on meeting requirements and guidance for psychotherapy services. The report contains three other recommendations. CMS concurred with four of six recommendations and did not state its concurrence or nonconcurrence with the remaining two recommendations.

Medicare Paid Millions More for Physician Services at Higher Nonfacility Rates Rather Than at Lower Facility Rates While Enrollees Were Inpatients of Facilities (A-04-21-04084), May 2023

Medicare sometimes paid higher nonfacility rates rather than lower facility rates for physician services while enrollees were Part A skilled nursing facility (SNF) or hospital inpatients. During the 2-year audit period, Medicare made overpayments totaling $22,463,193 by paying the nonfacility rate for services coded as furnished in a nursing facility or SNF setting without Part A coverage while enrollees were Part A SNF inpatients. Similarly, while enrollees were Part A SNF or hospital inpatients, Medicare paid an additional $22,142,489 for physician services coded as furnished in a nonfacility setting. CMS has expressed reluctance to take enforcement action for these overpayments because neither statute nor CMS's regulation specifically addresses situations in which these overpayments were made.

We recommended that CMS: (1) direct its Medicare contractors to recover the $22.5 million in overpayments; (2) notify the appropriate practitioners so that they can identify, report, and return any overpayments; (3) establish and apply Common Working File edits to detect instances in which practitioners incorrectly use nonfacility place-of-service codes; (4) revise its regulations to ensure that Medicare appropriately pays for the physician services, which could have resulted in the Medicare program paying up to $22.1 million less; (5) consider developing a mechanism for facilities to indicate when an inpatient leaves a facility and returns the same day; and (6) provide additional education to practitioners on the appropriate use of place-of-service codes.

CMS concurred with recommendations one, two, three, and six and described actions that it plans to take to address those recommendations. For recommendations four and five, CMS stated that it will consider OIG's findings and recommendations, along with other available information, to determine whether it should take action.

CMS's Oversight of Medicare Payments for the Highest Paid Molecular Pathology Genetic Test Was Not Adequate To Reduce the Risk of up to $888 Million in Improper Payments (A-09-22-03010), June 2023

CMS and the Medicare Administrative Contractors' (MACs') oversight of Medicare payments for Current Procedural Terminology (CPT) code 81408 did not: (1) ensure that all Medicare enrollees had established relationships with ordering providers, (2) ensure that Medicare payments for CPT code 81408 were related to diseases associated with genes that would generally be tested and billed under that CPT code, and (3) include adequate monitoring of the number of tests billed under CPT code 81408. In addition, not all MACs could identify the specific gene tested by laboratories billing CPT code 81408, and two MACs' Local Coverage Articles guidance did not limit use of this CPT code.

Because there were no longer payments for this CPT code by the end of our audit period (December 31, 2021), we consider the issues identified by this audit corrected. However, based on the results of our audit, up to $888.2 million in Medicare payments made for CPT code 81408 claims that we identified for our audit period were at risk of improper payment.

We recommend that CMS direct the appropriate Medicare contractors to: (1) review claims billed under CPT code 81408 for our audit period to determine whether they complied with Medicare requirements and (2) determine the amount of improper payments for the claims that did not comply with Medicare requirements and recover up to $888.2 million for claims that were at risk of improper payment during our audit period. The report contains the detailed recommendations and one other recommendation. CMS concurred with our first and third recommendations and provided information on actions that it planned to take to address our second recommendation.

Noridian Healthcare Solutions, LLC, Made $8.8 Million in Improper Monthly Capitation Payments to Physicians and Qualified Nonphysician Practitioners in Jurisdiction E for Certain Services Related to End-Stage Renal Disease (A-09-21-03016), June 2023

Noridian did not make some monthly capitation payments (MCPs) to physicians and qualified nonphysician practitioners in Jurisdiction E for certain services related to end-stage renal disease (ESRD) in accordance with Medicare requirements and guidance. Of the sampled 100 enrollee-months, 74 met the requirements; however, the remaining 26 enrollee-months did not meet 1 or more of the requirements. Improper payments occurred because Noridian's oversight was not sufficient to ensure that physicians and qualified nonphysician practitioners met Medicare billing requirements for ESRD-related services. On the basis of our sample results, we estimated that for

our audit period Noridian made approximately $8.8 million in improper MCPs to physicians and qualified nonphysician practitioners for ESRD-related services. We also estimated that Medicare enrollees paid approximately $2.2 million in coinsurance for the improperly paid ESRD-related services.

We recommend that Noridian: (1) recover $4,663 in improper payments made to physicians and qualified nonphysician practitioners for the 26 sampled enrollee-months; (2) notify the physicians and qualified nonphysician practitioners to refund $1,162 in coinsurance that was collected for the 26 sampled enrollee-months; and (3) update the educational material on its website as well as any previously provided webinars to include all Medicare requirements and guidance for billing and documenting ESRD-related services and continue to perform medical record reviews as part of the Targeted Probe and Educate program, which could have saved the Medicare program an estimated $8.8 million and could have saved Medicare enrollees up to an estimated $2.2 million for our audit period. The report contains one other recommendation. Noridian concurred with all of our recommendations.

HRSA Made COVID-19 Uninsured Program Payments to Providers on Behalf of Individuals Who Had Health Insurance Coverage and for Services Unrelated to COVID-19 (A-02-21-01013), July 2023

In the context of unprecedented challenges related to the COVID-19 national emergency, HRSA implemented a program to distribute funds to providers for COVID-19 testing and treatment for uninsured individuals in a fast and effective manner. However, we determined that HRSA made payments to providers through the COVID-19 Uninsured Program (UIP) for claims for COVID-19 testing and treatment services that did not comply with Federal requirements.

We made a series of recommendations to HRSA, including that it recover $294,294 in improper UIP payments identified in our sample and identify additional improper UIP payments for services provided to insured individuals or services unrelated to COVID-19, which we estimate to be nearly $784 million, and take remedial action. We also made procedural recommendations for HRSA to improve future programs of a similar nature. HRSA partially concurred with our first recommendation and concurred with our second and third recommendations. In addition, HRSA provided information on actions that it has taken or plans to take to address our recommendations.

Medicare Paid $30 Million for Accumulated Repair Costs That Exceeded the Federally Recommended Cost Limit for Wheelchairs During Their 5-Year Reasonable Useful Lifetime (A-09-22-03003), July 2023

The accumulated costs of repairs paid by Medicare for some enrollee-owned wheelchairs that were within their 5-year reasonable useful lifetime (RUL) exceeded the federally recommended cost limit. For 504,794 of the 688,948 repairs (73 percent) that we reviewed, Medicare paid suppliers before the accumulated costs of repairing 77,200 wheelchairs had exceeded the federally recommended

cost limit. However, the remaining 184,154 repairs (27 percent) were paid after the accumulated costs of repairing 16,962 wheelchairs had exceeded this cost limit, resulting in $30.1 million in potentially unallowable Medicare payments. Enrollee coinsurance associated with the potentially unallowable payments totaled $7.6 million. Suppliers' billing of these wheelchair repairs may reflect noncompliance with Medicare requirements.

We recommend that CMS work with the DME Medicare administrative contractors to: (1) strengthen Medicare requirements to ensure that the contractors review accumulated costs of repairs made to wheelchairs during their 5-year RUL that exceed a certain cost limit, using this cost limit as a basis for determining when wheelchairs furnished by suppliers will not remain serviceable for their entire RUL; (2) implement system edits to identify for review claims for repairs made to wheelchairs during their 5-year RUL when the accumulated costs of repairs have exceeded a certain cost limit; and (3) take appropriate action for suppliers that consistently bill for repairs made to wheelchairs during their 5-year RUL that exceed the federally recommended cost limit or the cost limit used as the basis for determining when wheelchairs furnished by suppliers will not remain serviceable for their entire RUL. The report contains one other recommendation. CMS concurred with all of our recommendations.

Medicare Paid Independent Organ Procurement Organizations Over Half a Million Dollars for Professional and Public Education Overhead Costs That Did Not Meet Medicare Requirements (A-09-21-03020), August 2023

Not all professional and public education overhead costs reported by independent organ procurement organizations (OPOs) met Medicare requirements. Of the 300 sampled professional and public education overhead costs, 264 costs met Medicare requirements. The remaining 36 costs, totaling $15,852 (with Medicare payments of $6,423), did not meet Medicare requirements and were therefore unallowable. Furthermore, while reconciling the OPOs' general ledgers with the OPOs' Medicare cost reports, we determined that OPOs reported an additional $132,898 of unallowable professional and public education overhead costs (with Medicare payments of $65,785).

Based on our sample results and additional findings that we identified during our reconciliation, we estimated that $664,295 of the $50.9 million paid for professional and public education overhead costs was unallowable. The OPOs reported unallowable costs because: (1) they misunderstood Medicare requirements and (2) their staff made administrative errors or were not aware that costs did not meet Medicare requirements.

We recommend that CMS: (1) instruct the Medicare administrative contractor to recover $72,208 in unallowable Medicare payments by adjusting the applicable OPOs' Medicare cost reports to correct the $148,750 of unallowable professional and public education overhead costs reported, consistent with relevant laws and the agency's policies and procedures; and (2) update applicable Medicare requirements to clarify which types of professional and public education overhead costs

are unallowable, which could have saved Medicare an estimated $664,295 for professional and public education overhead costs during our audit period. CMS concurred with our recommendations.

Medicare Made $17.8 Million in Potentially Improper Payments for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (A-09-22-03005), August 2023

Payments made to opioid treatment programs (OTPs) for opioid use disorder (OUD) treatment services may not have complied with Medicare requirements. Specifically, Medicare made up to $17.8 million in potentially improper payments to OTPs, consisting of the following payments: $10.4 million for claims for which a bundled payment was made for a weekly episode of care (i.e., a weekly bundle) that was covered by a payment for another weekly bundle for the same enrollee at the same OTP, $5.1 million for take-home supplies of medication that were covered by other payments for take-home supplies of medication or by payments for weekly bundles that included medication, $1.3 million for OUD treatment services that were claimed without an OUD diagnosis, and $1 million in payments for intake activities that occurred a total of 14 or more times for the same enrollee during our audit period.

We made six recommendations to CMS, including that it: (1) work with Medicare Administrative Contractors (MACs) and other Medicare contractors to determine whether claims billed by OTPs for OUD treatment services complied with Medicare requirements; (2) instruct MACs, based on the results of this audit, to notify appropriate providers so that the providers can exercise reasonable diligence to identify, report, and return any overpayments, up to $17.8 million, in accordance with the 60-day rule; and (3) instruct MACs to implement edits in their claims processing systems to prevent an OTP from being paid for two weekly bundles with the same service date for the same enrollee at the same OTP. CMS concurred with four of our six recommendations.

Medicare Improperly Paid Acute-Care Hospitals for Inpatient Claims Subject to the Post-Acute-Care Transfer Policy Over a 4-Year Period, but CMS's System Edits Were Effective in Reducing Improper Payments by the End of the Period (A-09-23-03016), September 2023

From 2019 through 2022, Medicare improperly paid $41.4 million to acute-care hospitals for inpatient claims subject to the post-acute-care transfer policy. These hospitals improperly billed these claims by using the incorrect discharge status codes. Specifically, they coded these claims as discharges to home or to certain types of health care institutions rather than as transfers to post-acute care. Medicare makes the full Medicare Severity Diagnosis-Related Group (MS-DRG) payment to an acute-care hospital that discharges an inpatient to home or certain types of health care institutions but pays an acute-care hospital that transfers an enrollee to post-acute care a per diem rate for each day of the enrollee's stay in the hospital. The overpayment of $41.4 million represented the difference between the amount of the full MS-DRG payments and the amount that would have been paid if the per diem rates had been applied.

These improper payments were made because CMS's system edits were not effective in detecting inpatient claims subject to the transfer policy in October and November 2019 and from October 2020 through March 2022. However, after CMS fixed the edits in April 2022, improper payments significantly decreased through the end of the audit period.

We recommend that CMS: (1) direct the Medicare contractors to recover from acute-care hospitals the portion of the $41.4 million in identified overpayments for our audit period that are within the 4-year reopening period; and (2) instruct the Medicare contractors to notify appropriate providers so that the providers can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule. CMS concurred with our recommendations.

Medicare Advantage Compliance Audit of Diagnosis Codes That Health Net of California, Inc. (Contract H0562) Submitted to CMS (A-09-18-03007), September 2023

Health Net 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 Health Net submitted were supported in the medical records and therefore validated 1,103 of the 1,333 sampled enrollees' Hierarchical Condition Categories (HCCs), the remaining 230 HCCs were not validated and resulted in overpayments. These 230 unvalidated HCCs included 46 HCCs for which we identified 46 other, replacement HCCs for more and less severe manifestations of the diseases. Second, there were an additional 123 HCCs for which the medical records supported diagnosis codes that Health Net should have submitted to CMS but did not.

Thus, the risk scores for the 200 sampled enrollees should not have been based on the 1,333 HCCs. Rather, the risk scores should have been based on 1,272 HCCs (1,103 validated HCCs plus 46 other HCCs plus 123 additional HCCs). As a result, Health Net received $69,182 of net overpayments for 2015 for the sampled enrollees. As demonstrated by the errors found in our sample, Health Net's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved.

We recommend that Health Net: (1) refund to the Federal Government the $69,182 of net overpayments; and (2) continue to improve its policies and procedures to prevent, detect, and correct noncompliance with Federal requirements for diagnosis codes that are used to calculate risk-adjusted payments. Health Net stated that it will take appropriate steps for the HCCs that it agrees are unsupported by medical records but requested that we reconsider our recommendations and work with Health Net to address issues identified in its comments before finalizing our report. After considering Health Net's comments and reviewing additional information Health Net provided, we revised our findings and reduced the recommended refund amount for the final report but did not change our second recommendation.

Home Health Agencies Rarely Furnished Services via Telehealth Early in the COVID-19 Public Health Emergency (A-05-21-00026), September 2023

Home health agencies (HHAs) rarely furnished services via telehealth early in the COVID-19 public health emergency (PHE); however, for the few claims in our sample with services furnished via telehealth, HHAs did not fully comply with Medicare requirements for providing them. The errors occurred because the HHAs were unfamiliar with the Medicare requirements for such services, which were new early in the COVID-19 PHE.

Beginning July 1, 2023, CMS now requires HHAs to report the use of telehealth services on home health claims. CMS has instructed HHAs to use one of two G-codes to report the services on claims and to list each service as a separate, dated line item. CMS stated that such reporting will allow it to analyze the characteristics of patients utilizing telehealth and give it a broader understanding of the determinants that affect who benefits most from those services. Furthermore, in their March 2022 Report to the Congress, the Medicare Payment Advisory Commission recommended tracking the use of telehealth on home health claims to improve payment accuracy.

CMS concurred with our recommendation that it monitor HHA reporting of the new G-codes to determine whether further updates to regulations or guidance are necessary.

Accuracy of Risk-Adjusted Payments to Medicare Advantage Organizations

CMS makes risk-adjusted payments to Medicare Advantage organizations for which the payment level varies based on the diagnoses that enrollees receive. CMS relies on Medicare Advantage organizations to collect diagnosis codes from their providers and submit these codes to CMS. Some diagnoses are at higher risk for being miscoded, which may result in overpayments from CMS. During this reporting period, OIG conducted four audits to assess whether selected diagnosis codes that Medicare Advantage organizations submitted to CMS for use in CMS's risk adjustment program complied with Federal requirements. For instances in which the diagnoses were not supported in the medical records, we calculated the net overpayments that the audited Medicare Advantage organizations received. Updated Federal regulations limit the use of extrapolation in Risk Adjustment Data Validation audits for recovery purposes to payment years 2018 and forward. Complete recommendations and providers' responses can be found in the final reports summarized here.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS (A-05-19-00013), April 2023

With respect to the seven 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 157 of the

210 sampled enrollee-years, the diagnosis codes that HumanaChoice submitted to CMS were not supported in the medical records and resulted in $480,295 of net overpayments for the 210 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. Based on our sample results, we estimated that HumanaChoice received at least $27.3 million of net overpayments for 2015 and 2016.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Keystone Health Plan East, Inc. (Contract H3952) Submitted to CMS (A-03-20-00001), May 2023

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that Keystone submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. Specifically, for 205 of the 270 sampled enrollee-years, the medical records that Keystone provided did not support the diagnosis codes and resulted in $550,391 in overpayments. As demonstrated by the errors in our sample, Keystone's policies and procedures to prevent, detect, and correct noncompliance with CMS program requirements could be improved. We estimated that Keystone received at least $11.3 million in overpayments for 2016 and 2017.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS (A-07-20-01202), July 2023

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that Excellus Health Plan, Inc., submitted to CMS for use in CMS's risk-adjustment program did not comply with Federal requirements. Specifically, for 202 of the 210 sampled enrollee-years, the medical records that Excellus provided did not support the diagnosis codes and resulted in $479,487 in overpayments. As demonstrated by the errors found in our sample, Excellus's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements could be improved. We estimated that Excellus received approximately $5.4 million in overpayments for 2017 and 2018.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS (A-07-20-01197), August 2023

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that Presbyterian Health Plan, Inc. (PHP), submitted to CMS for use in CMS's risk adjustment program did not comply with Federal

requirements. Specifically, for 198 of the 211 sampled enrollee-years, the medical records that PHP provided did not support the diagnosis codes and resulted in $442,454 in net overpayments. As demonstrated by the errors found in our sample, PHP's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. We estimated that PHP received at least $2.2 million in net overpayments for 2017 and 2018.

Quality of Care, Safety, and Access

CMS Did Not Accurately Report on Care Compare One or More Deficiencies Related to Health, Fire Safety, and Emergency Preparedness for an Estimated Two-Thirds of Nursing Homes (A-09-20-02007), April 2023

For 67 of the 100 sampled nursing homes, CMS did not accurately report on its website, Care Compare, one or more deficiencies that State surveyors identified during yearly and complaint inspections of Medicare- and Medicaid-certified nursing homes. The surveyors inspected the nursing homes for compliance with Federal health, fire safety, and emergency preparedness requirements. The deficiencies consisted of health deficiencies for 34 nursing homes, fire safety deficiencies for 52 nursing homes, and emergency preparedness deficiencies for 2 nursing homes. In addition, for 42 of the 100 sampled nursing homes, CMS did not report on Care Compare the results of all yearly fire safety and emergency preparedness inspections.

We estimated that 10,303 nursing homes had 1 or more deficiencies identified during inspections that were not accurately reported on Care Compare. In addition, we estimated that for 6,458 nursing homes, CMS did not report on Care Compare the results of all yearly fire safety and emergency preparedness inspections.

We recommend that CMS: (1) correct the inaccurately reported deficiencies that we identified for the sampled nursing homes; and (2) strengthen its processes for reviewing inspection results reported on Care Compare (i.e., require State survey agencies to verify the deficiencies reported, provide technical assistance and additional training to State survey agencies, and verify that nursing home inspection results are accurately reported). The report has three other procedural recommendations. CMS concurred with the second part of our last recommendation—that it provide technical assistance and additional training to survey agencies—but it did not state whether it concurred with our remaining recommendations.

Adverse Events Toolkit: Medical Record Review Methodology (OEI-06-21-00030), June 2023 and *Adverse Events Toolkit: Clinical Guidance for Identifying Patient Harm* (OEI-06-21-00031), June 2023

These toolkits provide considerations to assist the health care community, government agencies, and researchers in identifying and measuring patient harm events in hospitals or other inpatient

settings. These toolkits are based on methodologies we developed for our extensive work on patient harm and include: (1) a summary of our methodological approach to identifying and categorizing patient harm and (2) clinical guidance we used to decide whether events counted as patient harm. We provide this information to assist others in developing or updating medical record review procedures to identify patient harm and improve patient safety. The toolkits contained no recommendations.

Nursing Homes Reported Wide-Ranging Challenges Preparing for Public Health Emergencies and Natural Disasters (OEI-06-22-00100), August 2023

In June 2022, an estimated 77 percent of nursing homes located in areas at greater risk for natural disasters reported challenges with emergency preparedness activities intended to ensure that resident care needs are met during an emergency. Nursing homes reported concerns across seven topic areas, with preparedness activities related to ensuring proper staffing during emergencies and transporting residents during evacuations being the most problematic. Of the nursing homes that reported a challenge, only about a quarter received a deficiency for emergency preparedness in their most recent compliance survey by CMS. The findings in this report align with our prior work and highlight the vulnerabilities in nursing homes' preparedness efforts that may not always be identified during CMS's compliance surveys. CMS efforts to implement our existing recommendations will help address some of the emergency preparedness challenges identified in this report. This data brief contained no recommendations.

Telehealth During 2020 Helped Ensure End-Stage Renal Disease Patients Received Care, but Limited Information Related to Telehealth Was Documented (A-05-22-00015), August 2023

Providers documented limited information related to telehealth services in the medical records, but the end-stage renal disease (ESRD)-related telehealth service claim lines generally met certain Medicare requirements. Most medical records for sampled claim lines included documentation identifying that the service was provided via telehealth but did not include documentation that would allow us to determine whether the services were provided using: (1) audiovisual interactive technology and (2) technology that was non-public-facing. CMS does not oversee or enforce whether the telecommunications systems used to provide telehealth services are non-public-facing; the HHS Office for Civil Rights (OCR) has responsibility for oversight of this requirement.

Although we did not make any recommendations, we believe it would be beneficial for the medical records to document the type of telecommunications system used to perform the telehealth visit. This information may be beneficial to CMS and OCR when considering future oversight mechanisms or changes regarding remote communication products.

Home Health Agencies Failed To Report Over Half of Falls With Major Injury and Hospitalization Among Their Medicare Patients (OEI-05-22-00290), August 2023

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

The Risk of Misuse and Diversion of Buprenorphine for Opioid Use Disorder Appears To Be Low in Medicare Part D (OEI-02-22-00160), May 2023

Almost all Medicare Part D enrollees who received buprenorphine to treat their opioid use disorder received the recommended amounts in 2021; a very small number received very high average daily dosages of buprenorphine or received buprenorphine at the same time as they received high amounts of opioids indicated for pain. Most prescribers ordered buprenorphine for a limited number of Part D enrollees and very few had patterns that raise concern. CMS concurred with our recommendations for it to: (1) inform providers about buprenorphine use and the low risk of diversion to encourage providers to treat more Part D enrollees who have opioid use disorder; (2) take steps to inform providers about the availability of buprenorphine combination products in Part D, which can minimize the risk of misuse and diversion; and (3) follow up on the prescribers with concerning patterns identified in this report.

Although CMS did not indicate whether it concurred with our recommendation for it to monitor the use of buprenorphine and share information, as appropriate, with Departmental partners, it did indicate ongoing activity it felt was responsive.

Program Integrity

Toolkit: Analyzing Telehealth Claims To Assess Program Integrity Risks (OEI-02-20-00723), April 2023

This toolkit provides detailed information on methods to analyze telehealth claims to identify program integrity risks associated with telehealth services. It is based on the methodology that we developed for the report *Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks* (OEI-02-20-00720), which identified Medicare providers whose billing for telehealth services poses a high risk to Medicare. The toolkit is intended to assist public and

private sector partners—such as Medicare Advantage plan sponsors, private health plans, State Medicaid Fraud Control Units, and other Federal health care agencies—in analyzing their own telehealth claims data to assess program integrity risks in their programs. The toolkit contained no recommendations.

A Resource Guide for Using Medicare's Enrollment Race and Ethnicity Data (OEI-02-21-00101), June 2023

This resource guide provides an explanation of the origins and limitations of Medicare enrollment race and ethnicity data and offers considerations for the use of these data. It is based on information derived from our data brief *Inaccuracies in Medicare's Race and Ethnicity Data Hinder the Ability To Assess Health Disparities* (OEI-02-21-00100). This guide is for public and private-sector users of Medicare data, such as researchers, managed care organizations, Congress, and others involved in health equity work. This resource guide contained no recommendations.

2022 Performance Data for the Senior Medicare Patrol Projects (OEI-02-23-00150), June 2023

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 2022, the 53 reporting SMP projects had a total of 5,365 active team members who conducted a total of 18,274 group outreach and education events, reaching an estimated 1,000,240 people. In addition, the projects had 246,722 individual interactions with, or on behalf of, a Medicare enrollee. The projects reported $153,812 million in expected Medicare recoveries. Cost avoidance totaled $31,122, while savings to beneficiaries and others totaled $74,459. This report contained no recommendations.

Drug Pricing and Reimbursement

Part D Plans Generally Include Drugs Commonly Used by Dual-Eligible Enrollees: 2023 (OEI-05-23-00130), June 2023

Dual-eligible enrollees—individuals who are covered by both Medicare and Medicaid—have access to the majority of commonly used drugs in 2023 via their Part D plans, consistent with OIG's findings from previous years. A majority of the 445 Part D plan formularies covered almost all (at least 97 percent) of the drugs most commonly used by dual-eligible enrollees. Similar to all formularies, a majority of formularies used by Part D plans with premiums below the regional benchmark (92 of 130) covered at least 97 percent of the drugs commonly used by dual-eligible enrollees. Dual-eligible enrollees have several options if their plans do not cover specific drugs; however, these options may be burdensome and do not guarantee access to the drugs. This data snapshot contained no recommendations.

Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2021 Average Sales Prices (OEI-03-23-00120), August 2023

Since 2013, Medicare and its enrollees have saved $73.4 million as a result of CMS's price-substitution policy for Part B-covered drugs. Based on 2021 data, CMS lowered Medicare payment amounts for 13 drugs, resulting in $273,000 in savings. Medicare and its enrollees could realize an additional $889,000 in Medicare savings if CMS expanded the price-substitution criteria. This issue brief contained no recommendations.

*Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Fourth Quarter of 2022 (*OEI-03-23-00090*), May 2023, and Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the First Quarter of 2023* (OEI-03-23-00100), August 2023

We identified 16 drug codes in the fourth quarter of 2022 and 14 drug codes in the first quarter of 2021 that met CMS's criteria for price substitution. We compare average sales prices (ASPs) to AMPs every quarter and identify Part B-covered drug codes eligible for price substitutions. If we find 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 comparison process serves as a mechanism for monitoring market prices and limiting potentially excessive payment amounts. We provide 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. These memos contained no recommendations.

Medicaid Program Reports and Reviews

Financial Management and Improper Payments

Virginia Made Capitation Payments to Medicaid Managed Care Organizations After Enrollees' Deaths (A-03-22-00203), July 2023

Virginia made unallowable capitation payments after enrollees' deaths. For 67 of the 100 capitation payments in our sample, Virginia made unallowable capitation payments totaling $76,939 ($51,062 Federal share). For 30 of the remaining capitation payments in our sample, Virginia adjusted the capitation payments before our audit. We could not confirm that the remaining 3 enrollees associated with 3 of the 100 capitation payments were deceased.

We estimated that Virginia made unallowable capitation payments totaling at least $21.8 million ($15.7 million Federal share) to managed care organizations (MCOs) on behalf of 12,054 deceased enrollees during our audit period.

Virginia made unallowable capitation payments on behalf of deceased enrollees because it did not have adequate controls in place to enable it to identify all deceased enrollees and properly cancel their enrollment.

We recommend that Virginia: (1) refund $15.7 million to the Federal Government; (2) identify and recover unallowable capitation payments, which we estimate to be at least $21.8 million, made to MCOs during our audit period on behalf of deceased enrollees; and (3) identify and recover unallowable capitation payments made on behalf of deceased enrollees in 2018 and 2022 and repay the Federal share of amounts recovered. We also recommend that Virginia continue to pursue development and implementation of an automated matching and eligibility update process and implement additional supervisory review. The full recommendations are in the report.

Virginia did not specifically indicate whether it concurred with our recommendations, but it provided information about actions it has taken or plans to take to address them.

New York Improved Its Monitoring of Medicaid Community Rehabilitation Services but Still Claimed Improper Federal Medicaid Reimbursement Totaling $20 Million (A-02-22-01011), July 2023

New York generally complied with Medicaid requirements for claiming Federal reimbursement for community rehabilitation services. For 111 of the 120 sampled claims, New York properly claimed Medicaid reimbursement for all community rehabilitation services. However, New York claimed reimbursement for some unallowable community rehabilitation services for the remaining nine sampled claims. Specifically, services were provided although service plans were not timely signed

or maintained, claims did not meet Medicaid reimbursement standards, and services were not appropriately authorized.

We recommend that New York refund $19.9 million to the Federal Government. We also recommend that New York improve its monitoring activities by increasing the number of case files reviewed when conducting monitoring visits at providers, and by providing formal guidance or training to providers to clarify Medicaid requirements related to providing community rehabilitation services. New York partially agreed with both of our recommendations and described actions that it had taken or planned to take to increase its oversight of its community rehabilitation services program.

Texas Inappropriately Claimed Nearly $1.8 Million in Federal Medicaid Funds for Private Medicaid Management Information System Contractor Costs (A-06-19-09003), August 2023

Texas followed applicable Federal and State requirements related to claiming Federal Medicaid reimbursement for $126.8 million ($96 million Federal share) in private Medicaid Management Information System (MMIS) contractor costs. However, Texas incorrectly claimed the remaining $2.5 million and inappropriately received $1.8 million in Federal funds. In addition, Texas did not have adequate policies and procedures in place to ensure that MMIS private contractor costs were tracked to the correct advance planning documents. Texas was not able to prevent or detect when it claimed inadequately supported costs, costs allocated to Medicaid using a methodology that was not approved in a Public Assistance Cost Allocation Plan, costs that were approved for the 50- or 75-percent rate but were claimed at the 90-percent rate, and costs that were claimed twice.

We recommend that Texas refund the $1.8 million Federal share to the Federal Government. We also made some procedural recommendations. Texas did not directly concur or nonconcur with our findings and recommendations. However, Texas described actions it has taken in response to one of our findings and our third recommendation.

Florida Did Not Refund $106 Million Federal Share of Medicaid Managed Care Rebates It Received for Calendar Years 2015 Through 2020 (A-04-22-04089), August 2023

Florida calculated and received the required MCO rebates totaling $448.9 million ($292.5 million Federal share) for our audit period in accordance with Florida statutes and the terms of the Medicaid MCO contracts. However, Florida did not properly refund the Federal share of MCO rebates in accordance with Federal requirements. Florida reported only calendar year 2020 rebates on Form CMS-64, which totaled $274.9 million ($186.3 million Federal share). It did not report rebates for calendar years 2015 through 2019, which totaled $174 million ($106.2 million Federal share). Florida did not report the rebates because officials erroneously believed that they were not required to do so before CMS added a provision to the special terms and conditions in January 2021 requiring Florida to refund the Federal share.

We recommended that Florida refund to the Federal Government the $106.2 million in rebates for calendar years 2015 through 2019. Florida did not concur with our recommendation.

Puerto Rico Claimed More Than $500 Thousand in Unallowable Medicaid Managed Care Payments for Enrollees Assigned More Than One Identification Number (A-02-21-01004), September 2023

The Puerto Rico Department of Health (DOH) improperly claimed Federal Medicaid funds for capitation payments to MCOs on behalf of enrollees assigned more than one ID number. Specifically, for all 115 enrollee-matches in our sample, DOH claimed unallowable Federal Medicaid funds. The assignment of more than one ID number occurred because DOH case workers did not effectively use search capabilities within DOH's electronic eligibility system to identify whether an applicant was already assigned an ID number, or the process was insufficient to prevent or detect errors. Also, DOH lacked policies and procedures to ensure the Puerto Rico Health Insurance Administration (known by its Spanish acronym ASES) identified and recovered unallowable payments. On the basis of our sample results, we estimated that DOH claimed at least $516,762 in unallowable Federal Medicaid funds during our audit period.

We recommend that DOH: (1) refund $516,762 to the Federal Government, (2) strengthen its process for ensuring that no person is issued more than one ID number, and (3) establish policies and procedures with ASES to ensure that ASES recovers unallowable payments made on behalf of enrollees assigned more than one ID number. DOH partially concurred with our first and third recommendations and concurred with our second recommendation.

Puerto Rico Claimed Over $7 Million in Federal Reimbursement for Medicaid Capitation Payments Made on Behalf of Enrollees Who Were or May Have Been Deceased (A-02-21-01005), September 2023

The Puerto Rico Department of Health (DOH) claimed Federal Medicaid funds for capitation payments to MCOs on behalf of enrollees who were deceased or potentially deceased. Three of the 105 sampled capitation payments were for enrollees who were not deceased during the month covered by the capitation payment. For 90 sampled payments, we confirmed that the associated enrollees were deceased prior to the month covered by the capitation payment. For the remaining 12 sampled payments, the enrollees had a date of death recorded in the Social Security Administration's Death Master File (DMF); however, we could not confirm the enrollees' month and year of death. These unallowable and potentially unallowable payments occurred because DOH's controls were not sufficient to identify deceased enrollees. Also, DOH lacked a process to ensure that the Puerto Rico Health Insurance Administration identified and made adjustments to correct unallowable capitation payments.

On the basis of our sample results, we estimated that DOH claimed at least $6,979,822 in unallowable Federal Medicaid funds and $885,123 in potentially unallowable Federal Medicaid funds. We made a series of recommendations to DOH, including that it: (1) refund $6,979,822 to

the Federal Government and (2) review potentially unallowable payments (estimated at $885,123) and refund the Federal share of any unallowable amounts to the Federal Government. We also made other procedural recommendations to ensure that Puerto Rico does not make capitation payments on behalf of deceased enrollees. DOH generally concurred with our recommendations but partially concurred with our recommended refund.

Texas Made Capitation Payments for Enrollees Who Were Concurrently Enrolled in a Medicaid Managed Care Program in Another State (A-05-22-00018), September 2023

Texas made August 2021 Medicaid managed care capitation payments totaling $30.9 million on behalf of 61,065 enrollees who were concurrently enrolled for Medicaid benefits in Texas and another State. Of the 100 enrollees in our stratified random sample, we determined that 62 enrollees were residing and enrolled for Medicaid benefits in Texas. However, Texas made August 2021 capitation payments totaling $31,939 ($21,744 Federal share) on behalf of 38 Texas Medicaid managed care enrollees who were residing and concurrently enrolled for Medicaid in another State. On the basis of our sample results, we estimated that Texas incurred costs of $12.8 million ($8.7 million Federal share) for August 2021 capitation payments made on behalf of enrollees who were residing and concurrently enrolled in another State.

We recommend that Texas resume and enhance procedures that are in accordance with Federal requirements and the State's unwinding process to identify and disenroll enrollees who are residing and enrolled in Medicaid managed care in another State, and work with CMS to consider the potential use of Transformed Medicaid Statistical Information System (T-MSIS) data to identify potential cases of concurrent enrollment.

Texas concurred with our recommendations and described the actions that it plans to take to address them.

Four States Reviewed Received Increased Medicaid COVID-19 Funding Even Though They Terminated Some Enrollees' Coverage for Unallowable or Potentially Unallowable Reasons (A-06-21-09002), September 2023

The four States we reviewed did not meet all the requirements to receive the increased COVID-19 Federal medical assistance percentage (FMAP). All four States terminated Medicaid enrollees' coverage for unallowable or potentially unallowable reasons. Two States (Texas and Minnesota) terminated Medicaid coverage for 26,915 total enrollees for unallowable reasons, and three States (New York, Florida, and Minnesota) terminated Medicaid coverage for 220,113 total enrollees for potentially unallowable reasons due to a lack of support or documentation.

Additionally, Minnesota may have inappropriately charged some enrollees cost-sharing for COVID-19 testing, services, and treatment. Minnesota could not determine whether Medicaid enrollees

were responsible for any cost-sharing, and enrollees may have been charged up to $951,202 for COVID-19-related testing, services, and treatment.

CMS concurred with our recommendations that CMS: (1) work with the four States to determine what amount, if any, of the funding they received because of the increased COVID-19 FMAP should be refunded to the Federal Government; and (2) work with Minnesota to determine whether Medicaid enrollees were responsible for any cost-sharing for COVID-19 testing, services, or treatments and, if any cost-sharing is identified, work with Minnesota to ensure that enrollees are reimbursed for any out-of-pocket expenses incurred.

Security of State Medicaid Information Systems

State Medicaid Management Information Systems (MMISs) are automated systems of claims processing and information retrieval used in State Medicaid programs. State eligibility and enrollment (E&E) systems support all processes related to determining Medicaid eligibility. With significant increases in cyberattacks against the health care industry, including email phishing, denial of service, and ransomware attacks, State MMISs and E&E systems are likely targets for hackers. During this reporting period, OIG conducted two penetration test audits of State MMISs and E&E systems in accordance with guidelines outlined by the National Institute of Standards and Technology (NIST). Complete recommendations and providers' responses can be found in the final reports, which are summarized below.

Massachusetts MMIS and E&E System Security Controls Were Generally Effective, but Some Improvements Are Needed (A-18-20-08003), May 2023

The Massachusetts MMIS and E&E system had generally effective security controls in place to prevent our simulated cyberattacks from resulting in a successful compromise; however, some of those security controls could be further enhanced to better prevent certain cyberattacks. Massachusetts did not correctly implement three security controls required by NIST Special Publication (SP) 800-53, Revision 4. We estimated that the level of sophistication needed by an adversary to compromise the Massachusetts MMIS and E&E system was moderate. Based on the results of certain simulated cyberattacks that we conducted, we determined that some improvements were needed in Massachusetts's detection controls to better identify cyberattacks against its MMIS and E&E system and respond appropriately.

A potential reason why Massachusetts did not implement these security controls correctly may be that system administrators were not aware of certain published vendor security advisories or mitigation guidance. Massachusetts's procedures for periodically assessing the implementation of the weak NIST security controls we identified were not effective. Because Massachusetts did not correctly implement these controls, an attacker could

potentially collect sensitive server information to facilitate exploitation of an application or web server or cause a denial of service.

Maryland MMIS and E&E System Security Controls Were Partially Effective and Improvements Are Needed (A-18-21-09003), May 2023

The Maryland MMIS and E&E system had security controls in place that were partially effective to prevent our simulated cyberattacks from resulting in a successful compromise; however, improvements are needed to better prevent certain cyberattacks. Maryland did not correctly implement seven security controls from NIST SP 800-53, Revision 4. We estimated that the level of sophistication needed by an adversary to compromise the Maryland MMIS and E&E system was limited. Maryland demonstrated a partial ability to detect some of our cyberattacks against its MMIS and E&E system and respond appropriately.

A potential reason why Maryland did not implement these security controls correctly may be that system administrators were not aware of Government standards or industry best practices that require securely configured systems before deployment to production. Maryland also may not have considered the latest email phishing tactics used by cyber adversaries in developing the cybersecurity awareness training provided to its employees and contractors. Additionally, Maryland's procedures for periodically assessing the implementation of the NIST security controls above were not effective.

Quality of Care, Safety, and Access

Montana Generally Complied With Requirements for Telehealth Services During the COVID-19 Pandemic (A-07-21-03250), May 2023

Montana and Medicaid providers generally complied with Federal and State requirements when claiming Medicaid reimbursement for telehealth services during the COVID-19 pandemic. More than 99.9 percent of the Medicaid telehealth paid claim lines (lines) we reviewed complied with Federal and State requirements. However, some Medicaid providers claimed services that did not comply with requirements for telehealth services. Specifically, we identified 121 lines totaling $9,589 (Federal share), each of which had 1 of the following types of errors: documentation did not support that services were performed; services were required to be face-to-face but were instead performed and billed as telehealth; or services were performed but providers incorrectly added a modifier or place of service code to indicate that the services were performed via telehealth.

These errors occurred because Montana's claim payment system did not have edits to ensure that only specific procedure codes eligible to be performed via telehealth were billed as telehealth.

We recommend that Montana develop and implement edits in its claim payment system so that it pays only telehealth claims whose procedure codes denote the associated services as eligible to be performed via telehealth. Montana did not provide formal comments on our draft report. However, a Montana official told us that Montana did not have any disagreements with our findings.

CMS Should Strengthen Requirements for State Oversight and External Medical Reviews of Prior Authorization Denials in Medicaid Managed Care (OEI-09-19-00350), June 2023

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

One Quarter of Medicaid Enrollees with HIV May Not Have Received Critical Services in 2021 (OEI-05-22-00240), August 2023

In 2021, more than a quarter of Medicaid enrollees with human immunodeficiency virus (HIV) did not have evidence in their claims data of receiving one or more critical services—medical visits, viral load tests, and antiretroviral therapy (ART) prescriptions. These findings demonstrate that further action is needed to ensure that enrollees are receiving appropriate HIV care. Of particular concern, more than 11,000 enrollees did not have evidence of receiving any of the 3 services we reviewed. These services are recommended by HHS for all people with HIV and are vital to their overall health as well as the prevention of HIV transmission within the general population. This data brief contained no recommendations.

Key Strategies That States Used for Managing Medicaid and Marketplace Enrollment During the COVID-19 PHE (OEI-09-20-00590), September 2023

State Medicaid agencies and State-based Marketplaces used several strategies to address challenges in maintaining key enrollment functions as a result of the COVID-19 public health emergency, including: (1) expanding outreach efforts, (2) improving applications and support, (3) simplifying eligibility determination processes, and 4) adapting program operations. The strategies

can inform other States' efforts to improve their current processes and help them prepare for future local, State, or Federal emergencies. This issue brief contained no recommendations.

Many Medicaid Enrollees With Opioid Use Disorder Were Treated With Medication; However, Disparities Present Concerns (OEI-BL-22-00260), September 2023

Treating opioid use disorder with medication (referred to as MOUD) is essential to reducing overdose deaths. However, we found that one-third of the 1.5 million Medicaid enrollees with opioid use disorder did not receive MOUD in 2021. Certain demographic groups—including Black or African-American enrollees, enrollees 18 years and younger, and enrollees with a disability and/or blindness—were less likely to receive MOUD. In 10 States, less than half of enrollees with opioid use disorder received MOUD. These findings underscore the need for continued efforts to increase the use of MOUD in Medicaid. We recommended that CMS: (1) encourage and support States' efforts to reduce barriers to MOUD, especially among groups who may be underserved; and (2) encourage States and work with Federal partners to educate Medicaid and CHIP enrollees about access to MOUD.

Amerigroup Iowa's Prior Authorization and Appeal Processes Were Effective, but Improvements Can Be Made (A-07-22-07007), September 2023

Amerigroup complied with Federal and State requirements when it denied, through its prior authorization and appeal processes, 80 of the 100 sampled prior authorization denials and appeals for medical services that members had requested during 2018 and 2019. However, it did not comply with Federal and State requirements when it denied the remaining 20 prior authorization requests and appeals that we sampled.

For 19 of the 20 sampled prior authorization denials and appeals that did not comply with Federal and State requirements, Amerigroup did not provide correct or any information to members regarding their State fair hearing rights. For the other 1 of the 20 sampled prior authorization denials and appeals that did not comply with requirements, Amerigroup was unable to locate or provide documentation to support a prior authorization denial.

Although Amerigroup denied only 3 percent of requested medical services during its prior authorization process, we noted that of the 2,572 prior authorization requests that Amerigroup denied in 2018 and 2019 and that were subsequently appealed, a total of 1,605 (62 percent) of those denials were overturned through Amerigroup's appeal process.

We recommend that Amerigroup coordinate with Iowa to improve its prior authorization and appeal processes to ensure that members receive correct information regarding prior authorizations, the appeal process, and State fair hearing rights, procedures, and timeframes. We also recommend that Amerigroup review and update its prior authorization process to improve

communication with providers. Amerigroup concurred with our recommendations and described actions that it had taken or planned to take.

New York Did Not Ensure That a Managed Care Organization Complied With Requirements for Denying Prior Authorization Requests, (A-02-21-01016), September 2023

For 35 of 70 sampled denials, New York's oversight of Centers Plan for Healthy Living (CPHL) ensured that CPHL complied with Federal and State requirements when it initially denied prior authorization requests for services and items. For the remaining 35 sampled denials, we determined that CPHL justified the denials by citing incorrect information in denial notices issued to the associated Medicaid enrollees. Ultimately, the enrollees' access to requested services associated with these sampled claims were delayed a median of 75 days and, in one case, as many as 282 days, which may have significantly impacted the health and safety of Medicaid enrollees.

We determined that New York's monitoring was not effective to ensure that CPHL complied with requirements for denying prior authorization requests. New York relied on its retrospective review of a sample of prior authorization denials during its biennial operational surveys and other data. Without obtaining and reviewing information related to MCOs' initial denials and internal appeals, New York had limited ability to conduct effective oversight of CPHL's prior authorization practices.

We recommend that New York: (1) use the findings in this report to determine whether CPHL was noncompliant and determine whether a corrective action plan or other sanctions are appropriate, (2) review CPHL's appeal process and ensure that CPHL makes any necessary changes to comply with requirements for denying services, and (3) implement procedures to obtain and review information related to MCOs' initial denials and internal appeals. New York did not indicate concurrence or nonconcurrence with our findings or recommendations; however, it described actions it has taken or plans to take to address them.

Review of Personnel Shortages in Federal Health Care Programs During the COVID-19 Pandemic (PRAC Report), September 2023

In conjunction with other Federal OIGs and the PRAC, we examined shortages in Federal health care programs during the COVID-19 pandemic. Although personnel shortages existed in the health care community before the pandemic, the pandemic exacerbated these shortages. Maintaining an appropriate level of personnel in health care facilities is essential to providing a safe work environment for health care personnel and quality care to patients. This report provides Congress, Federal and State agencies, health care organizations, and other policymakers with information to inform and raise awareness on health care shortages across four Federal health care programs providing health care services to approximately 20 million individuals: Medical Treatment Facilities (DOD); Federal Bureau of Prisons (DOJ); Veterans Health Administration Facilities (VA); and Medicare- and Medicaid-Certified Nursing Homes (HHS). Specifically, this report summarizes the types of personnel shortages most commonly reported, factors that contributed to personnel

shortages, impacts most commonly encountered, and the incentives and strategies used to recruit and retain personnel and minimize burnout for existing personnel across the four Federal health care programs.

New Jersey Could Better Ensure That Nursing Homes Comply With Federal Requirements for Life Safety, Emergency Preparedness, and Infection Control (A-02-22-01004), September 2023

New Jersey could better ensure that nursing homes that participate in Medicare or Medicaid programs comply with Federal requirements for life safety, emergency preparedness, and infection control if additional resources were available. During our onsite inspections, we identified deficiencies related to life safety, emergency preparedness, or infection control at all 20 nursing homes we audited, totaling 363 deficiencies. As a result, the health and safety of residents, staff, and visitors at the 20 nursing homes are at an increased risk during a fire or other emergency, or in the event of an infectious disease outbreak.

The identified deficiencies occurred because of frequent management and staff turnover, which contributed to a lack of awareness of, or failure to address, Federal requirements. New Jersey also had limited resources to conduct surveys of all nursing homes more frequently than CMS required. Finally, although not required by CMS, New Jersey does not require relevant nursing home staff to participate in standardized life safety training programs despite CMS having a publicly accessible online learning portal with appropriate content on life safety requirements.

New Jersey disagreed with some of our deficiencies and our conclusions and did not indicate concurrence or nonconcurrence with our recommendations that New Jersey follow up with the 20 nursing homes we reviewed to ensure that they have taken corrective actions regarding the deficiencies and instruct all nursing homes to install carbon monoxide detectors. We also recommended New Jersey work with CMS to develop and implement a plan to identify and conduct more frequent surveys at nursing homes and to develop standardized training for nursing home staff.

Drug Spending and Reimbursement

States With Separate Children's Health Insurance Programs Could Have Collected an Estimated $641 Million Annually if States Were Required To Obtain Rebates Through the Medicaid Drug Rebate Program (A-07-22-06106), August 2023

Under current Federal requirements for the Medicaid Drug Rebate Program (MDRP), States must obtain drug rebates for Medicaid-covered outpatient prescription drugs that are provided through Medicaid or an expansion of its Medicaid program (Medicaid expansion). However, for separate Children's Health Insurance Program (CHIP) drugs, those Federal Medicaid drug rebate requirements do not apply.

As of the preparation of this data brief, 40 States operate separate CHIPs, whether in combination with Medicaid expansion or on a stand-alone basis. Separate CHIP is a program under which a State receives Federal funding to provide child health assistance to uninsured, low-income children and which meets the requirements of section 2103 of the Social Security Act.

If Federal law were to require States to obtain rebates under the MDRP for separate CHIP drugs, the 40 States that operated separate CHIPs could, according to our estimates, have invoiced, collected, and directly received $641.2 million from the drug manufacturers for calendar year 2020. These estimated rebates totaled $125.5 million for the States and $515.7 million for the Federal Government. This data brief contains no recommendations.

Kentucky Did Not Always Invoice Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations (A-04-22-07102), September 2023

Kentucky did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to Medicaid MCO enrollees. Kentucky did not file invoices for and collect from manufacturers, rebates totaling $21.6 million ($15.5 million Federal share) for physician-administered drugs dispensed to MCO enrollees. Of this amount, $15.6 million ($11.2 million Federal share) was for drugs that were required to be rebated. In addition, Kentucky did not invoice for rebates associated with $6.0 million ($4.3 million Federal share) in other multiple-source physician-administered drugs that were eligible for rebates.

Although Kentucky's managed care contracts with its MCOs required the collection of drug utilization data necessary to invoice for rebates on all claims, Kentucky'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.

We recommend that Kentucky: (1) files invoices for and collect from manufacturers rebates totaling $15,611,770 ($11,209,642 Federal share) for single-source and top-20 multiple-source physician-administered drugs and refund the Federal share of rebates collected; (2) work with CMS to determine whether the other claims for multiple-source physician-administered drugs, totaling $5,967,128 ($4,281,678 Federal share), were eligible for rebate and, if so, determine the rebates due and, upon receipt of the rebates, refund the Federal share of the rebates collected; (3) strengthen its internal controls to ensure that all eligible physician-administered drugs are invoiced for rebate; and (4) ensure that all physician-administered drugs eligible for rebates after our audit period are processed for rebates. Kentucky concurred with our findings and recommendations and described actions that it had taken to address them.

Alabama Did Not Always Invoice Rebates to Manufacturers for Pharmacy and Physician-Administered Drugs (A-04-21-08090), September 2023

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

We made several recommendations, including that Alabama refund to the Federal Government $14.9 million for claims for single-source physician-administered drugs and $43,981 for claims for top-20 multiple-source physician-administered drugs and work with CMS to determine and refund the unallowable portion of $290,455 for other claims for multiple-source physician-administered drugs that may have been ineligible for Federal reimbursement and consider invoicing drug manufacturers for rebates for those drug claims that CMS determines are allowable. Alabama did not concur with our first four recommendations, but officials said they will be invoicing for, and collecting from manufacturers, rebates associated with those recommendations. The officials also said they would ensure that rebate eligible physician-administered drugs are invoiced for rebates after December 31, 2019, and that they would strengthen their internal controls.

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 at a level higher than warranted); illegal billing, sale, and diversion of prescription drugs; marketing 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 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 Enforcement Actions website.

During this semiannual reporting period, we reported 333 criminal and 414 civil actions against individuals or entities that engaged in offenses related to health care. We also reported more than $1.79 billion in investigative receivables due to HHS and more than $460.2 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 that follows.

COVID-19 Enforcement Activities

The following case example involves COVID-19 enforcement activities:

Arkansas—On June 8, 2023, Billy Joe Taylor was sentenced to 15 years in prison followed by 3 years of supervised release and ordered to pay $29,835,825.99 in restitution for conspiracy to commit health care fraud and money laundering. Taylor pleaded guilty to conspiracy to commit health care fraud and money laundering on October 27, 2022. According to court documents, Taylor and co-conspirators submitted more than $134 million in false and fraudulent claims to Medicare in connection with diagnostic laboratory testing, including urine drug testing and tests for respiratory illnesses during the COVID-19 pandemic, that were medically unnecessary, not ordered by medical providers, and not provided as represented. Taylor and co-conspirators obtained medical information and private personal information for Medicare beneficiaries, and then misused that confidential information to repeatedly submit claims to Medicare for diagnostic tests. According to court documents, Taylor and co-conspirators received more than $38 million from Medicare on those fraudulent claims.

Home Health

The following case example involves home health fraud:

Texas—On May 30, 2023, Akintunde Oyewale, a home health company owner, was sentenced to 57 months in Federal prison followed by 3 years of supervised release and ordered to pay $1,467,719.92 in restitution after being convicted of conspiracy to commit health care fraud. Oyewale operated Grace Healthcare Services LLC through September 2017. At time of plea, Oyewale admitted to and caused the home health company to bill Medicare for home health services that were not medically necessary and not provided. Oyewale also acknowledged furthering the scheme by unlawfully paying medical clinics for fraudulent home health certifications and unlawfully paying for patient referrals. Oyewale admitted to using the fraudulently obtained funds for personal financial benefit and for the benefit of family members.

Laboratory

The following case example involves a laboratory:

Georgia—On August 18, 2023, Minal Patel, was sentenced to 27 years in prison for being involved in a scheme to defraud Medicare by submitting more than $463 million in genetic and other laboratory tests that patients did not need, and that were procured through the payment of kickbacks and bribes.

According to court documents, Minal Patel, owner of LabSolutions LLC, a laboratory enrolled with Medicare that performed sophisticated genetic tests. Patel conspired with patient brokers, telemedicine companies, and call centers to target Medicare beneficiaries with telemarketing calls falsely stating that Medicare covered expensive cancer genetic tests. After the Medicare beneficiaries agreed to take a test, Patel paid kickbacks and bribes to patient brokers to obtain signed doctors' orders authorizing the tests from telemedicine companies. To conceal the kickbacks and bribes, Patel required patient brokers to sign sham contracts that falsely stated that the brokers were performing legitimate advertising services for LabSolutions, when, as Patel well knew, the brokers were deceptively marketing to Medicare beneficiaries and paying kickbacks and bribes to telemedicine companies for genetic testing prescriptions.

Patel knew the telemedicine doctors robo-signed prescriptions for expensive genetic testing even though they were not treating the beneficiaries, often did not even speak with them, and made no evaluation of medical necessity. From July 2016 through August 2019, LabSolutions submitted more than $463 million in claims to Medicare, including for thousands of medically unnecessary genetic tests, of which Medicare paid more than $187 million. In that timeframe, Patel personally received more than $21 million from Medicare in connection with the fraud.

Managed Care

The following case example involves managed care:

Maine—On July 31, 2023, Martin's Point Health Care Inc. (Martin's Point), agreed to pay $22,485,000 to resolve allegations that it violated the False Claims Act by submitting inaccurate diagnosis codes for its Medicare Advantage Plan enrollees to increase reimbursements from Medicare.

Under Medicare Advantage, also known as the Medicare Part C program, Medicare beneficiaries have the option of enrolling in managed care insurance plans called Medicare Advantage Plans (MA Plans). MA Plans are paid a per-person amount to provide Medicare-covered benefits to beneficiaries who enroll in one of their plans. The Centers for Medicare and Medicaid Services (CMS), which oversees the Medicare program, adjusts the payments to MA Plans based on demographic information and the diagnoses of each plan enrollee. The adjustments are commonly referred to as "risk scores." In general, a enrollee with diagnoses more expensive to treat will have a higher risk score, and CMS will make a larger risk-adjusted payment to the MA Plan for that enrollee.

Martin's Point operates MA Plans for beneficiaries living in Maine and New Hampshire. The United States alleged that, from 2016 to 2019, Martin's Point engaged in chart reviews of their Medicare Advantage beneficiaries to identify additional diagnosis codes that had not

been submitted to Medicare. Many of the additional codes submitted, however, were not properly supported by the patients' medical records. The Government alleged that Martin's Point nevertheless submitted those diagnosis codes, which resulted in higher payments from CMS.

The civil settlement includes the resolution of claims brought under the *qui tam* or whistleblower provisions of the False Claims Act by Alicia Wilbur, a former manager in Martin's Point's Risk Adjustment Operations group. Under those provisions, a private party can file an action on behalf of the United States and receive a portion of any recovery.

Physician

The following case example involves a physician:

Tennessee—On August 25, 2023, Dr. Samson K. Orusa was sentenced to 84 months in Federal prison and 3 years of supervised release after being convicted of more than a dozen felony health care fraud charges. Orusa was ordered to pay more than $1 million in restitution. Orusa was also fined $195,000 and must forfeit previously seized assets worth approximately $900,000. Orusa, through their medical clinic in Clarksville, billed Federal health insurance programs for hundreds of medically unnecessary services, including unnecessary office visits and steroid injections. The evidence at trial showed that Orusa required Medicare beneficiaries and other patients to visit Orusa's clinic as many as six times each month and to undergo unnecessary steroid injections to obtain their prescriptions. The evidence also showed that the defendant altered progress visit notes in patients' medical records to justify higher billing rates.

Prescription Drugs

The following case examples involve prescription drugs:

Ohio—On May 23, 2023, Jeffrey Sutton was sentenced to 72 months in prison after pleading guilty to illegally prescribing patients' opioids and other controlled substances, illegally distributing controlled substances and health care fraud. Sutton was also sentenced to 3 years of supervised release, a $5,200 special assessment, a $20,000 fine, and restitution of $148,870.79. According to court documents, from January 2015 through January 2022, Sutton knowingly prescribed medically unnecessary controlled substances to patients outside of the usual course of professional practice and without legitimate medical purpose. In doing so, Sutton fraudulently billed health care benefit programs for office visits and the controlled substances illegally dispensed.

Sutton also admitted to engaging in sexual acts with patients to whom Sutton directly prescribed controlled substances, including during office visits. Sutton also admitted to

delivering dozens of oxycodone pills to the home of a patient with whom Sutton was engaged in a relationship, outside the course of `treatment and without a valid prescription.

Florida—On June 6, 2023, Ronald A. Beasley II was sentenced to 2 years in prison for involvement in a scheme to defraud Medicare of more than $1 million in prescription drug benefits. According to court documents, Beasley was the pharmacist in charge at NH Pharma, a pharmacy located in Lake Mary, Florida. Through NH Pharma, Beasley and co-conspirators billed Medicare for expensive compound drug creams that they never actually purchased or dispensed, instead providing Medicare patients an inexpensive compound drug cream that Medicare did not cover. In fact, NH Pharma did not buy enough of the expensive prescription drugs to fill all the prescriptions NH Pharma billed to Medicare. In total, Beasley and co-conspirators received more than $1 million in fraudulent Medicare proceeds.

Kickbacks

The following case example involves kickbacks:

Massachusetts—On May 24, 2023, Massachusetts Eye and Ear Infirmary, Massachusetts Eye and Ear Associates, Inc., and the Foundation of the Massachusetts Eye and Ear Infirmary, Inc. (collectively "Massachusetts Eye and Ear") agreed to pay more than $5.7 million to resolve allegations that 7 of their physician compensation plans, involving 44 doctors, violated Federal law.

The Government alleges that Massachusetts Eye and Ear compensated 44 physicians in a manner that violated the Physician Self-Referral Law (sometimes referred to as the Stark Law). Mass General Brigham, which has owned and operated Massachusetts Eye and Ear since April 2018, disclosed this issue to the Government in connection with the Government's investigation into related allegations. The Stark Law prohibits physicians from referring patients to receive "designated health services" payable by Medicare from entities, like hospitals, with which the physician has a financial relationship, unless the arrangement falls into the exceptions provided for by law. The law also prohibits the entity from billing Medicare for those services. The law is intended to ensure that physicians' medical judgments are not compromised by improper financial inducements.

All seven physician compensation models at issue began before Mass General Brigham acquired Massachusetts Eye and Ear. One physician compensation model ended before Mass General Brigham took control of Massachusetts Eye and Ear. Mass General Brigham voluntarily terminated the remaining six physician compensation models on October 1, 2019. The Government's investigation was prompted by False Claims Act allegations brought in a lawsuit filed by a whistleblower under the qui tam provisions of the False Claims Act.

Identity Theft

The following case example involves identity theft:

Massachusetts—On May 15, 2023, Jack Massarsky, a Massachusetts dentist, was sentenced to 2 years in prison and 3 years of supervised release for embezzling more than $1.2 million from his employer and fraudulently obtaining Government benefits in the employer's name. Massarsky also paid more than $1.2 million in restitution prior to sentencing. On January 25, 2023, Massarsky pleaded guilty to one count of mail fraud and one count of wire fraud.

Between 2015 and 2021, Massarsky worked as a dentist and bookkeeper for a general dentistry practice in Massachusetts. In 2015, Massarsky opened a secret bank account in the name of the dentistry practice. Massarsky then intercepted insurance reimbursement checks sent to the dentistry practice in the mail and deposited those checks in the secret bank account. Massarsky continued this practice for more than 5 years and embezzled more than $1.2 million.

Additionally, Massarsky used the dentistry practice's name to defraud the United States. In July 2020, Massarsky submitted a fraudulent application to the Health Resources and Services Administration Provider Relief Fund (HRSA PRF) in the name of the dentistry practice. The HRSA is an HHS agency that provides health care to people who are geographically isolated or economically or medically vulnerable. During the COVID-19 pandemic, the HRSA PRF provided economic assistance to qualifying health care providers, including certain dentistry practices. By submitting the fraudulent application to the HRSA PRF, Massarsky obtained more than $52,000 in pandemic relief funds that were deposited in the secret bank account that Massarsky had opened in the employer's name.

Ambulance Services

The following case example involves ambulance services:

Kentucky—On August 8, 2023, Air Methods Corporation, a national provider of air medical transport services, agreed to pay the Federal Government $1,050,873 to resolve civil allegations that it had failed to return known overpayments received from Medicare, Kentucky Medicaid, Tricare, and the VA.

The United States alleged that Air Methods violated the False Claims Act by improperly retaining overpayments for more than 100 flights that it knew to be medically unnecessary and, therefore, ineligible for reimbursement by Federal health care programs. Federal health care programs, including Medicare and Kentucky Medicaid, only provide

reimbursement for air ambulance transportation if the enrollee's medical condition requires air transport, and transport by ground ambulance is not appropriate. The United States alleged that Air Methods' internal review process identified flights that did not meet these coverage requirements, including instances where patients were flown despite not meeting trauma criteria. The False Claims Act, a Federal law that prohibits causing the submission of false or fraudulent claims to the Federal Government, also forbids knowingly concealing, avoiding, or decreasing an obligation to pay the Government. As such, health care providers also face False Claims Act liability when they fail to return known overpayments to Federal health care programs. The settlement resolves a lawsuit brought by a private citizen under the qui tam provisions of the False Claims Act.

Medical Devices

The following case example involves a medical device:

Michigan—On May 3, 2023, Vasso Godiali was sentenced to 80 months in prison for orchestrating a multimillion-dollar scheme to defraud health care programs by submitting claims for the placement of vascular stents and for thrombectomies that were never performed and was ordered to pay $19.5 million in restitution collectively to Medicare, Medicaid, and Blue Cross Blue Shield of Michigan (BCBSM). Additionally, Godiali agreed to pay the United States up to $43,419,000 to resolve related civil allegations that Godiali's fraudulent billings to Federal health care programs violated the False Claims Act (FCA).

According to a plea agreement, Godiali began to knowingly defraud medical insurers, including Medicare and Medicaid, in approximately 2009. Godiali billed for the placement of multiple vascular stents in the same blood vessel and prepared medical records purporting to document the medical necessity justifying that billing. In fact, however, Godiali did not place those stents and admitted to billing for services never rendered while preparing materially inaccurate medical records to justify the fraudulent billings.

Godiali also billed for arterial thrombectomies and created medical records stating that occluded arteries were encountered that would justify the performance of the procedures. However, Godiali admitted that such occlusions were infrequent, that no such thrombectomies were performed, that insurers were billed for services never rendered, and that false medical records were prepared to justify the fraudulent claims. Godiali's fraudulent practices resulted in $14,473,000 in damages to the Federal Government and a total of $19.5 million across Medicare, Medicaid, and BCBSM, which Godiali agreed to repay as restitution as part of the plea agreement.

In the related FCA action, in addition to alleging that Godiali submitted false claims for procedures never performed, the United States alleged that Godiali improperly used

Modifier 59 to "unbundle" services that should have been billed together in a single claim to increase reimbursements from Federal health care programs.

A civil forfeiture case resulted in the seizure of approximately $39.9 million from financial accounts controlled by Godiali. Except for $7.5 million, which will be released to Godiali's wife pursuant to an agreement with the United States, all of the seized funds will be used to pay the criminal judgment or the FCA settlement. The civil settlement includes the resolution of claims brought under the qui tam or whistleblower provisions of the False Claims Act by Innovative Solutions Consulting, LLC.

Durable Medical Equipment

The following case example involves durable medical equipment:

New York—On May 25, 2023, Christopher Margait was sentenced to 65 months in prison for conspiracy to commit health care fraud by fraudulently trafficking in orders for durable medical equipment such as back, knee, and wrist braces. According to statements made in court and publicly filed documents in this case, from at least August 2019 through May 2021, Margait and co-defendant Matthew Taylor Witkowski engaged in a scheme to defraud Medicare by illegally obtaining and selling fraudulent orders for DME paid for by Medicare. Using a business jointly owned and operated with Witkowski, and a call center that Witkowski operated in the Dominican Republic, Margait illegally generated and purchased fraudulent orders for DME and then sold those fraudulent orders to pharmacies and DME suppliers, including suppliers in New York City. Those pharmacies and DME suppliers then used those fraudulent orders as the basis for at least $7 million in fraudulent claims to Medicare. Many of these fraudulent orders used names and personal health information of actual Medicare beneficiaries, without the beneficiaries' authorization or prior knowledge. Many of these fraudulent orders also contained professional information of doctors and other health care providers enrolled in the Medicare program, as well as the purported electronic signatures of these providers, which were falsified and created without the authorization or knowledge of these providers.

During the scheme, Margait and Witkowski received more than $3.8 million in illegal kickbacks from DME suppliers, who made these payments to True Prospects Marketing, Inc., a company controlled by Margait and Witkowski.

Margait, pled guilty on June 2, 2022, to a single count of conspiracy to commit health care fraud. In addition, Margait was sentenced to 3 years of supervised release and ordered to pay forfeiture of $3,853,442 and restitution of $7 million to the Medicare program. Witkowski, was sentenced on April 20, 2023, to 60 months in prison and 3 years of supervised release. Witkowski was also ordered to pay forfeiture of $4,065,995 and restitution of $8,131,990 to the Medicare program.

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, the Federal Bureau of Investigation (FBI), and State and local law enforcement agencies 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 71 individuals or entities, 77 criminal actions, and more than $465.9 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, 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 the Medicare Strike Force:

> Florida—On June 23, 2023, Michael Stein was sentenced to 60 months in prison and ordered to pay more than $61 million in restitution for involvement in a $73 million conspiracy to defraud Medicare by paying kickbacks to a telemedicine company to arrange for doctors to authorize medically unnecessary genetic testing. The scheme exploited temporary amendments to telehealth restrictions enacted during the COVID-19 pandemic that were intended to ensure access to care for Medicare beneficiaries. According to court documents, Stein, the owner of 1523 Holdings LLC, admitted conspiring with Leonel Palatnik, co-owner of Panda Conservation Group LLC, and others to receive kickbacks from Palatnik in exchange for working to arrange for telemedicine providers to authorize genetic testing orders for Panda's laboratories. Panda's owners and Stein entered into a sham contract for purported IT and consultation services to disguise the true purpose of these payments. Then 1523 Holdings exploited temporary amendments to telehealth restrictions enacted during the pandemic by offering telehealth providers access to Medicare beneficiaries, for whom they could bill Medicare for consultations. In exchange, these providers agreed to refer beneficiaries to Panda's laboratories for expensive and medically unnecessary genetic testing.

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 on OIG's Compliance Guidance website.

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 AI/AN communities. The training series covers topics such as compliance; fraud, waste, and abuse; and health care quality, including how OIG works with the AI/AN community to combat the opioid epidemic and to protect patients from sexual abuse. The training series includes web-based trainings, job aids, and videos, which can be accessed on OIG's IHS Training website.

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 OIG's 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, which can be accessed on OIG's Whistleblower Protection website.

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 on OIG's Fugitive website. During this semiannual reporting period, one fugitive was captured.

The following case example involves a captured fugitive:

Maryland—On July 13, 2023, Atawan Mundu John, a former health care aide at Global Healthcare, Inc. was arrested in Hyattsville, Maryland. On December 18, 2014, John was indicted in the United

States District Court for the District of Columbia with one count of 18 U.S.C. § 1512(b)(3), attempted tampering with a witness. On August 4, 2023, in the District Court for the District of Columbia, John pleaded guilty to one count of tampering with a witness. John is awaiting sentencing.

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 Hotline is to support OIG's oversight responsibilities in safeguarding the integrity of all programs and personnel under HHS's purview and protecting them from fraud, waste, and abuse. The Hotline achieves its mission through its staff's dedication to timely intake and analysis of information received from various sources, such as the "Submit a Complaint" link on the HHS-OIG website. During this semiannual reporting period, the Hotline reported expected recoveries of $117,939,623 as a direct result of cases originating from hotline complaints.

OIG Hotline Activity (10/1/2022–3/31/2023)

Contacts to 1-800-HHS-TIPS phone line, including callers seeking information	84,536
Total tips evaluated	36,244
Tips referred for action	21,740
Closed; no basis provided for further action	1,950
Closed; no HHS violation	537
Closed; other administrative reason	12,017

Sources of Tips Referred for Action

Phone	8,117
OIG website	11,645
Letters or faxes	835
Other	1,143

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.

OIG Onsite Reviews of MFCUs

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:

Minnesota Medicaid Fraud Control Unit: 2022 Inspection (OEI-06-22-00430), September 2023
District of Columbia Medicaid Fraud Control Unit: 2022 Onsite Review (OEI-06-22-00420), September 2023

OIG Joint Casework With MFCUs

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

Missouri—On May 9, 2023, Jackson Preston Siples III was sentenced to 36 months incarceration, 3 years supervised release, restitution of $4,951,639 and a special assessment of $300. On May 11, 2022, Siples pleaded guilty to one count of executing a health care fraud scheme, one count making false statements, and one count paying and receiving illegal kickbacks for referrals. In about April 2017, Siples began employment with AE Wellness, owned by Jamie McCoy. After AE Wellness was suspended by CMS based on allegations of fraud and eventually closed, Siples and another AE Wellness employee and co-conspirator, Brandy McKay, opened three DME companies, all located in Cape Girardeau, MO. Siples was listed as the owner of two of those DMEs (Integrity Medical Supply and Radiance Health Group). To secure business for all the DME companies, Siples paid illegal kickbacks to co-conspirators for referrals or orders sent to DME companies, although Siples knew the orders were fraudulent. As part of the health care fraud scheme, telemarketers in the United States and elsewhere solicited patients through media ads and cold calls. The telemarketers contacted patients to obtain information, including insurance information. Although the telemarketers were not health care professionals, they completed order forms and sometimes encouraged patients to exaggerate the extent of their pain or need for braces and pain creams. The orders were then sent to doctors, who were typically paid $30 to $50 for each order they signed. The doctors did not evaluate or assess the medical necessity for the braces and creams they ordered, and in the majority of cases, the patients did not need, request, or want the items. The two DME companies

owned by Siples were paid $3,110,756 based on the false reimbursement claims that the companies submitted to health care benefit programs. Restitution was increased due to Siple's involvement in AE Wellness and MC Medical Supply. Restitution is joint and several with Brandy McKay and Jamie McCoy.

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, in addition to other OIG health care fraud and abuse sanctions. During this semiannual reporting period, OIG received 14 requests for advisory opinions and issued 4 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 (Stark Law), or the Emergency Medical Treatment and Labor Act, 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 832 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 OIG's Enforcement Actions website.

Program Exclusions

During this semiannual reporting period, OIG excluded 750 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 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 OIG's Exclusions website.

The following are case examples of program exclusions:

Michigan—On May 18, 2023, OIG excluded a pharmacy owner for a minimum period of 35 years based on this individual's conviction for conspiracy to commit wire and mail fraud related to a scheme to defraud pharmaceutical manufacturers. Specifically, the pharmacy owner and co-conspirators worked together to defraud private pharmaceutical manufacturers by submitting false copay assistance reimbursement claims for medications that were neither prescribed nor dispensed. The court also sentenced this pharmacy owner to 72 months of incarceration and ordered that nearly $12 million in restitution be paid to multiple companies.

Georgia—On May 18, 2023, OIG excluded a pharmacist for a minimum period of 20 years due to a jury conviction for 70 counts related to illegal dispensing and distributing controlled substances from a pill-mill pharmacy operation and 1 count of refusing an administrative inspection warrant. The court sentenced the pharmacist to 188 months of incarceration, and the Nevada Board of Pharmacy revoked this individual's pharmacy license. (The pharmacist's license in the State of Georgia lapsed and has not been renewed.)

New York—On May 18, 2023, OIG excluded a respiratory therapist for a minimum period of 16 years based on a conviction for public health law violations, including reckless endangerment as well as physical abuse, neglect, and mistreatment of residents at a nursing and rehabilitation center. Specifically, the respiratory therapist failed to perform required operational verification procedures to ensure that ventilators were providing appropriate respiratory support for two residents, as required by their care plans, resulting in their deaths. The New York Office of the Medicaid Inspector General also excluded this individual from the State Medicaid program.

Florida—On May 18, 2023, OIG excluded a licensed pharmacy technician for a minimum period of 61 years based on a conviction for participating in a multimillion-dollar conspiracy to defraud the United States and pay health care kickbacks through a South Florida compounding pharmacy. Specifically, between July 2014 and March 2016, this individual conspired with others to pay approximately $40 million in kickbacks to patient recruiters in exchange for their referring prescriptions for unnecessary and expensive therapies to the conspirators' compounding pharmacy. These fraudulent prescriptions were issued to DoD's and the VA's health care benefit programs, resulting in approximately $88 million in financial losses to the Government. The court sentenced the pharmacy technician to 60 months incarceration and ordered payment of more than $75 million in restitution.

California—On June 20, 2023, OIG excluded a former nursing assistant for a minimum of 40 years based on a criminal conviction for committing nonconsensual sexual acts upon three dependent adult women while employed at skilled nursing facilities. The court sentenced this individual to prison for a term of 25 years to life, and the California Department of Public Health revoked their Nurse Assistant Credential.

California—On June 20, 2023, OIG excluded the owner of a hospice company for a minimum period of 8 years due to a conviction for theft of Government property after accepting payments under the Provider Relief Fund to which this individual was not entitled. Congress made these funds available under the Coronavirus Aid, Relief, and Economic Security Act to provide emergency assistance to support health care providers that were financially impacted by the cost and care of patients infected by Covid-19. Despite attesting to compliance with the terms and conditions required for retaining these funds, this individual violated those terms by withdrawing payments for personal use and transferring payments to another family member. The court sentenced this individual to 9 months incarceration and ordered payment of nearly $150,000 in restitution.

New York—On September 20, 2023, OIG imposed a minimum exclusion period of 24 years on a business owner convicted of perpetrating a scheme to defraud the New York Medicaid program. Specifically, the owner and business offered housing assistance to Medicaid recipients who were then required to provide their Medicaid identification numbers and submit to medically unnecessary examinations to qualify for the purported housing assistance program. Instead of providing the promised housing assistance, the owner and business used the Medicaid numbers without the recipients' consent to submit for reimbursement from the New York Medicaid program for medically unnecessary and expensive devices (e.g., custom-molded back braces) that were not provided. The court sentenced this individual to prison for a term of 3 to 9 years and ordered payment of more than $4 million in restitution to the New York Medicaid program. This individual was also excluded by the New York Medicaid program.

Florida—On September 20, 2023, OIG excluded a chiropractor for a minimum period of 28 years due to conviction for participating in a multiyear scheme to defraud Medicare by submitting fraudulent claims for expensive DME that Medicare beneficiaries did not want or need and that were procured through the payment of kickbacks. In addition, the chiropractor was sentenced to 97 months in prison and ordered to pay $1,404,200.97 in restitution.

Suspensions and Debarments

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

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

The following case example involves debarment:

> California—Gurgen Israyelyan was debarred for a period of 3 years. The debarment was imposed by the HHS Suspension and Debarment Official based on a referral from OIG. Israyelyan was the owner of Saint Christopher Hospice Inc. (SCH), a hospice agency in North Hollywood, California, which closed around September 2019. SCH, which was never operational during the COVID-19 pandemic, received approximately $89,163 from the HHS Provider Relief Fund, administered by HRSA, and designated for the medical treatment and care of COVID-19 patients. Gurgen Israyelyan admitted to stealing the funds by spending them for personal use and by transferring them to family members, including a family member in Armenia, rather than using the funds in conjunction with pandemic relief efforts as required. In connection with this conduct, in 2022, Israyelyan entered a guilty plea in the U.S. District Court for the Central District of California to three counts of theft of Government property, in violation of 18 U.S.C. § 641.

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 $36.0 million in CMPs and assessments.

Affirmative Litigation

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

The following case examples involve affirmative litigation under the CMPL:

> New York—Chinese-American Planning Council Home Attendant Program entered into a $866,339.25 settlement agreement with OIG. The agreement settled its liability under the CMPL for employing a personal assistant who was excluded from the New York Medicaid program and provided items or services that were billed to New York Medicaid between

August 1, 2016, and January 4, 2022, in connection with the New York State Consumer Directed Personal Assistance Program.

Minnesota—Bridges MN, an adult day care facility, entered into a $150,171.96 settlement agreement with OIG. The agreement settled its liability under the CMPL for, between March 12, 2018, to October 10, 2019, employing an individual as a direct support professional who provided items or services that were billed to Federal health care programs.

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 available only to those with a Federal Acquisition Regulation–based contract with HHS. The OIG grant self-disclosure program is available by application to 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. Self-disclosure guidelines are available on the OIG Self-Disclosure website. During this semiannual reporting period, provider self-disclosure cases resulted in more than $34.4 million in HHS receivables.

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

Illinois—Hearing Screening Associates, LLC, entered into an agreement with OIG in the amount of $4,015,227.04 to resolve allegations that, between January 15, 2015, and December 31, 2020, Hearing Screening Associates submitted claims to Medicaid for audiology services billed under CPT code 92585 that were not provided as claimed because audiologists did not read, interpret, or sign automated test results.

Colorado—Kit Carson County Memorial Hospital entered into an agreement with OIG in the amount of $3,093,850.47 to resolve allegations that, between August 31, 2012, and June 28, 2021, Kit Carson received payment from Federal health care programs for hyperbaric oxygen services and wound care that were not performed or supervised as claimed.

New York—Kaleida Health and Olean General Hospital entered into an agreement with OIG in the amount of $2,702,944.61 to resolve allegations that, between August 1, 2011, and July 31, 2018, Kaleida paid remuneration to certain Kaleida employees and their family members who were Federal health care program beneficiaries in the form of: (1) discounts and reduced deductibles and cost sharing on certain items and services; (2) complimentary local telephone service, television, valet parking, and cafeteria privileges; and (3) room upgrades.

Michigan—Team Rehabilitation Services entered into an agreement with OIG in the amount of $12,256,518.14 to resolve allegations that, between June 1, 2015, and October 6, 2020, Team Rehabilitation improperly billed certain Medicare Part C plans for time-based physical therapy services by improper calculation of 15-minute units when a therapist had not treated a patient for at least 8 minutes, and between June 1, 2015, and June 1, 2021, Team Rehabilitation improperly billed Federal health care programs for routinely performing physical therapy re-evaluations, when routine, continuous assessment of a patient's expected progress in accordance with a therapy plan of care is not considered to be a medically necessary service and is not separately reimbursable as a re-evaluation.

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.

There were no cases involving CIA enforcement during this semiannual reporting period.

Public Health and Human Services Agency Reports and Reviews

Public Health Agency Reports and Reviews

Centers for Disease Control and Prevention

CDC's Vaccines for Children Program Recipients Did Not Conduct Site Visits at Some Providers as Required (A-09-22-01000), September 2023

CDC's Vaccines for Children (VFC) program recipients conducted enrollment site visits for all newly enrolled and reenrolling VFC providers as required. However, recipients did not meet all program requirements for conducting compliance site visits and storage and handling site visits. Specifically, recipients did not: (1) conduct compliance site visits in a timely manner at 11,499 of 39,120 enrolled and active providers (29 percent), (2) conduct storage and handling site visits at either of the 2 CDC-approved depot providers, (3) conduct storage and handling site visits for at least 5 percent of their providers, and (4) verify that providers completed followup actions by the deadlines for 33,316 of 127,594 issues (26 percent) identified during compliance and storage and handling site visits.

CDC officials stated that staffing constraints and the COVID-19 pandemic were reasons that program recipients did not conduct site visits at some providers as required. CDC officials also stated that, during the COVID-19 pandemic, CDC and recipients were focused on the priority of COVID-19 vaccination program development and vaccine distribution, some providers were temporarily closed, and travel was restricted.

We recommend that CDC: (1) work with program recipients to implement a plan and timeline to conduct the required site visits that are overdue and verify the completion of followup actions that had not been completed by the deadlines and (2) develop an action plan to enforce site visit requirements by CDC's planned date of July 1, 2023. The report lists two more procedural recommendations. CDC concurred with our recommendations and described actions that it had taken or planned to take to address our recommendations.

CDC Provided Oversight and Assistance; However, ELC Recipients Still Faced Challenges in Implementing COVID-19 Screening Testing Programs (A-05-22-00010), September 2023

CDC provided oversight and assistance to the Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) Program recipients in implementing the COVID-19 screening testing programs, by utilizing recipient data and conducting periodic outreach through webinars and technical assistance calls, among other things. However, based on

the ELC recipients' responses to the OIG survey, we identified challenges the ELC recipients encountered in implementing the ELC screening testing programs within their jurisdictions. Some of the ELC recipients encountered challenges expending the ELC Reopening Schools funding, such as barriers from schools in implementing the screening testing programs in their districts, while others used alternative sources of Government funding in the implementation of the screening testing programs. In addition, some of the ELC recipients encountered challenges implementing the ELC screening testing programs, including: (1) lack of interest from the schools and communities, (2) limitations on the costs that were allowable under the terms and conditions of the awards, (3) insufficient school staffing and resources, and (4) issues with vendors or contractors. The challenges that were identified in implementing the screening testing programs from the survey of ELC recipients provide CDC with areas to focus on when implementing future ELC programs.

The report includes no recommendations. However, we expect that CDC will use the suggestions and feedback from the ELC recipients' responses to the OIG survey to improve development of ELC programs that are in response to future public health emergencies.

Food and Drug Administration

FDA Could Take Stronger Enforcement Action Against Tobacco Retailers With Histories of Sales to Youth and Other Violations (OEI-01-20-00240), September 2023, and *Supplemental Data on Tobacco Retailer Inspections* (OEI-01-20-00242), September 2023

FDA conducted more than 1 million inspections from 2010 through 2019, inspecting 74 percent of retailers nationwide at least once. Overall, FDA's actions against retailers that violated tobacco laws and regulations were in accord with its policies. In some States, inspection activities were correlated with neighborhoods' socioeconomic conditions, though the direction of the correlation varied. In 18 States, more disadvantaged neighborhoods had more inspection activity, but in 8 States, they had less. FDA uses socioeconomic status to direct its contractor's activities and to fulfill its requirement to ensure enforcement of restrictions against youth access to tobacco products in minority communities. Retailers with histories of violations were often not subject to the strongest enforcement actions. FDA collected the full amount for only 9 percent of the civil money penalties it issued to these retailers. Retailers in our sample that could have been subject to a no-tobacco-sale order, FDA's most stringent enforcement action, usually did not receive one. FDA concurred with our recommendation for it to determine whether variation in inspection activity on the basis of neighborhoods' socioeconomic status is appropriate and the extent to which it is meeting FDA's objective for protecting vulnerable populations (e.g., youth). FDA did not concur or nonconcur with our recommendation for it to give greater weight to retailers' past noncompliance when taking enforcement actions against retailers with histories of violations.

OIG supplemented this report by publishing data on tobacco retailer inspections, including an interactive map, allowing stakeholders to explore geospatial data that provides insights on differences between states; differences by year; and socioeconomic status.

Health Resources and Services Administration

Seventeen of Thirty Selected Health Centers Did Not Use or May Not Have Used Their HRSA COVID-19 Supplemental Grant Funding in Accordance With Federal Requirements (A-02-21-02005), May 2023

Seventeen of 30 selected health centers did not use or may not have used a portion of their COVID-19 supplemental grant funding in accordance with Federal requirements and grant terms. Specifically, 10 health centers charged unallowable costs totaling $787,152 and 13 health centers may not have properly allocated salary and fringe benefits costs totaling $15,056,835 to their COVID-19 supplemental grant funding. (The total exceeds 17 because 6 health centers had more than 1 deficiency.) These funds could have been used to support health centers' activities related to COVID-19 response, including providing essential testing services to monitor and suppress COVID-19.

We made a series of recommendations to HRSA, including that it require health centers in our sample to refund unallowable and improperly allocated costs to the Federal Government. In addition, we recommended that HRSA assist the 17 health centers to implement HRSA's guidance for developing and maintaining financial management systems and internal controls that ensure only allowable, allocable, and documented costs to their HRSA supplemental grant funding. HRSA partially concurred with our recommendations and described actions it plans to take to address them.

HRSA Had an Effective Process To Identify and Monitor High-Risk Health Centers That Received COVID-19 Grant Funds (A-01-21-01503), September 2023

HRSA had effective processes to identify and monitor the health centers that received COVID-19 grant funds. Specifically, we found that for the 37 health centers HRSA identified as high risk, HRSA appropriately performed financial assessments, assigned the correct risk level based on our independent assessment, and added quarterly expenditure report requirements to the applicable grant awards in accordance with its processes. Additionally, we found that for our review sample of 33 moderate or minimal risk health centers, HRSA appropriately assessed the risk level as less than high risk based on the financial information it reviewed.

HRSA had an effective process to identify and monitor high-risk health centers that received COVID-19 grant funds, and as such we do not have a recommendation. During our fieldwork, HRSA provided us with its Risk-Based Recipient Monitoring Framework, dated April 13, 2021, which became effective after the COVID-19 funds were awarded. The framework establishes lower

requirements for assigning high risk to a recipient and lowered five financial risk indicators from high to moderate risk. The lowering of these financial risk indicators may decrease oversight and puts Federal funds at risk. The "Other Matters" section of the report discusses this further.

Indian Health Service

Crow/Northern Cheyenne Hospital—an IHS-Operated Health Facility—Did Not Timely Conduct Required Background Checks of Staff and Supervise Certain Staff (A-02-21-02004), April 2023

The hospital did not fully comply with Federal requirements for conducting background investigations of staff members in contact with Indian children. For 44 of the 50 staff members we reviewed, the hospital did not comply with Federal requirements for conducting background investigations, including failing to initiate or timely initiate and adjudicate certain investigations. Further, the hospital could not document that it supervised certain staff members with pending background investigations (provisional staff) in accordance with Federal requirements. For 47 of the 50 staff members we reviewed, the hospital did not provide evidence documenting complia nce with Federal supervision requirements while their background investigations were pending. These deficiencies generally occurred because the hospital did not monitor compliance with background check requirements for permanent staff or ensure that background checks for temporary staff were performed in accordance with the applicable requirements. Finally, the hospital could not document supervision in accordance with Federal requirements. As a result, Indian children faced an increased risk of harm and abuse.

We made recommendations to the hospital, the Billings Area Office, and IHS Headquarters, including that they work together to: (1) complete and adjudicate necessary background investigations for staff members identified in our report, (2) ensure that provisional staff supervision is adequately documented, and (3) update standard operating procedures and establish monitoring systems for background investigations and provisional staff supervision. IHS, commenting on behalf of the hospital, concurred with our recommendations, and described steps it has taken and plans to take to address them.

Although IHS Allocated COVID-19 Testing Funds To Meet Community Needs, It Did Not Ensure That the Funds Were Always Used in Accordance With Federal Requirements (A-07-20-04123), July 2023

IHS ensured that COVID-19 testing funds from the Families First Act and Paycheck Protection Act used existing allocation methodologies to meet community needs through use of the existing recurring base formulae, which took into consideration programs' populations and health care needs. However, IHS did not ensure that COVID-19 testing funds were always used by Direct, Tribal, and Urban Indian Organization (UIO) programs for testing and testing-related services in accordance with Federal requirements. Direct programs provide services, such as medical care and dental care, through IHS-operated facilities. Five of the 10 sampled programs used a combined $480,437 on expenses that did not support COVID-19 testing or testing-related activities. In

addition, one Tribal program did not spend funds totaling $86,261 because Tribal officials were unaware that the funds expired on September 30, 2022. Finally, two Tribal programs and one UIO program did not track testing funds in accordance with Federal requirements. IHS did not provide adequate guidance to the programs and did not perform oversight specific to testing funds. As a result, the programs did not always have a clear understanding of how the funds could be used.

We made a series of recommendations to IHS, including that it correct the $19,912 in funds not used on COVID-19 testing and other testing-related activities from one Direct program and that it recover the other $460,525 in funds from the applicable sampled Tribal and UIO programs. We also made procedural recommendations that IHS recover any unused, expired funds; strengthen its review and oversight processes; and develop and provide adequate guidance to programs on the proper use and tracking of testing funds. IHS concurred with five of our nine recommendations and described its corrective actions.

National Institutes of Health

Saint Louis University's Management of NIH Grant Awards Did Not Comply With All Federal Requirements but Complied With Financial Conflict of Interest Requirements (A-07-20-05127), June 2023

Saint Louis University did not always manage National Institutes of Health (NIH) awards in accordance with Federal and award requirements. Specifically, of the 31 judgmentally selected costs totaling $426,443 that we reviewed, we determined that 6 costs totaling $42,578 did not comply with Federal and award requirements for allowability of costs. The controls that the university had in place, to include policies and procedures, were inadequate to ensure that it always managed its NIH awards in accordance with Federal and award requirements. We also determined that the university had policies and procedures in place that were designed to meet financial conflict of interest requirements for training and monitoring of outside interest disclosures.

Furthermore, the university's controls, including policies and procedures, were not always sufficient to ensure that it properly monitored subawards to identify possible investigator misconduct that may have impacted the conduct or performance of another NIH award. Of the 31 judgmentally selected costs we reviewed, 1 subrecipient cost was associated with possible subrecipient investigator misconduct in an unrelated NIH award not associated with the university.

We recommend that the university: (1) refund $263 to NIH for unallowable travel costs; (2) ensure that it always manages NIH awards in accordance with Federal and award requirements, by strengthening procedures and controls; (3) enhance its existing controls by developing and implementing policies and procedures to review costs that the university claims for its NIH awards; and (4) strengthen its controls, including policies and procedures, to ensure that it properly

monitors its subaward subrecipients. The university concurred with all of our recommendations and described corrective actions it had taken or planned to take.

NIH Should Improve Its Management of Contracts for the Acquisition of Information Technology (A-18-21-11500), June 2023

NIH contracting officers generally administered the call and task orders that we reviewed for the acquisition of information technology in accordance with Federal regulations and policies. However, we identified areas within NIH's management of these orders that were not always conducted consistent with applicable Federal acquisition regulations and HHS acquisition regulations and policies. Specifically, the contracting officers or contracting officer's representatives (CORs) did not: (1) include all requirements for information security and privacy in appropriate acquisition documents and properly complete information security certification checklists, (2) review invoices and recommend invoice payments for 3 of 24 invoices for 1 order, and (3) complete contractor performance assessments timely. Additionally, NIH did not fully comply with the HHS Competition Advocacy Directive for FYs 2019, 2020, and 2021.

These conditions occurred because NIH did not: (1) adhere to existing NIH acquisition and procurement procedures, (2) have CORs and contracting officers who coordinated and managed their workloads and responsibilities effectively, and (3) work with HHS to meet its obligation to comply with the HHS Competition Advocacy Directive.

We recommend that NIH provide additional training and implement oversight controls to improve compliance with Federal acquisition requirements related to information technology procurements, contractor performance assessments, and competition advocacy reporting. The full recommendations are in the report. NIH concurred with all of our recommendations.

Illinois State University's Management of NIH Awards Complied With Federal and Financial Conflict of Interest Requirements (A-05-20-00033), September 2023

Illinois State University managed NIH awards in accordance with Federal and award requirements. We reviewed 698 expenditures totaling $1,234,300 that the University charged to 5 awards, and we determined that the costs complied with Federal and award requirements.

We determined that the University had policies and procedures in place that were designed to meet Financial Conflict of Interest (FCOI) requirements for training and monitoring of outside interest disclosures. Specifically, the University properly maintained training records and monitored disclosures of significant outside activity to meet FCOI requirements associated with the seven employees in our sample who had received NIH awards as Principal Investigator or Co-Principal Investigator.

This report contains no recommendations. The University accepted the report as written.

Substance Abuse and Mental Health Services Administration

Vermont Complied With Regulations When Implementing Programs Under SAMHSA's Opioid Response Grants, but Claimed Unallowable Expenditures (A-01-20-01501), May 2023

Vermont's program-related activities and its subrecipients responsible for implementing the programs complied with Federal and State regulations and met program goals of the Opioid State Targeted Response (STR) and the State Opioid Response (SOR) grant. However, with regard to its financial related activities, Vermont claimed $282,643 to the STR and SOR grants for unallowable subrecipient expenditures. Vermont reimbursed the unallowable subrecipient expenditures because its internal controls did not identify whether subrecipient expenditures were allowable to the STR and SOR grants. Specifically, Vermont did not: (1) ensure that staff with appropriate training or accounting knowledge conducted pre-award risk assessments, (2) conduct annual site visits as required by the terms and conditions of the grant, and (3) require documentation to support the monthly invoices submitted by the subrecipients of the STR and SOR grant funds.

We recommend that Vermont: (1) refund $282,643 to the Federal Government, (2) require subrecipients to provide and retain supporting documentation for invoices submitted for reimbursement under Federal grants, (3) conduct a periodic review of supporting documentation for any subrecipient expenditures submitted for reimbursement, (4) provide training to the State employees responsible for conducting pre-award risk assessments, and (5) conduct annual site visits as required by the terms and conditions of the grant award that include both a program and fiscal review. Vermont did not indicate concurrence or nonconcurrence with our findings or recommendations; however, it has taken or plans to take to address our recommendations.

Florida Did Not Ensure That Some Providers Complied With Requirements for Determining Eligibility For Its Projects for Assistance in Transition From Homelessness Program (A-02-21-02008), May 2023

Florida complied with Projects for Assistance in Transition From Homelessness (PATH) program requirements related to certain program costs and non-Federal contributions. However, Florida did not comply with certain PATH program requirements when determining consumers' eligibility in its PATH program. Specifically, 6 of the 70 sampled consumers were inaccurately reported as enrolled in the PATH program or ineligible to enroll in the program.

We made several recommendations to Florida, including that it instruct PATH providers to disenroll ineligible consumers from the PATH program and strengthen its oversight of the PATH program to ensure that PATH services are only provided to eligible consumers. In written comments on our draft report, Florida did not indicate concurrence or nonconcurrence with our findings or recommendations; however, it described actions it has taken or plans to take to address them. Among its actions, Florida stated that it instructed the associated providers to confirm that the consumers identified in our report were disenrolled from the PATH program.

The Substance Abuse and Mental Health Services Administration Did Not Ensure That Clinics Fully Complied With Federal Requirements When Awarding and Monitoring Certified Community Behavioral Health Clinic Expansion Grants (A-02-21-02010), September 2023

The Substance Abuse and Mental Health Services Administration's (SAMHSA's) policies and procedures for awarding and monitoring Certified Community Behavioral Health Clinic Expansion (CCBHC-E) grants were not adequate to ensure that clinics complied with Federal requirements. Specifically, for 28 of the 30 CCBHC-E grants in our sample, SAMHSA's policies and procedures related to awarding CCBHC-E grants did not establish: (1) required timeframes for verifying that clinics met certification eligibility requirements or (2) processes to verify that clinics entered into agreements with designated collaborating organizations (DCOs) to provide certain services. Also, SAMHSA's policies and procedures related to monitoring CCBHC-E grants did not establish processes to verify that clinics: (1) filled key personnel positions within established timeframes or ensured that key personnel met level-of-effort requirements, (2) timely submitted financial reports, or (3) properly reported cash on hand.

As a result of SAMHSA's inadequate policies and procedures for awarding and monitoring CCBHC-E grants, there is a risk that clinics awarded CCBHC-E grants may not have used these funds efficiently or for their intended purposes. Also, there is a risk that SAMHSA will award future CCBHC-E grants to clinics that are not eligible to receive these funds. Further, individuals working as key personnel at clinics may not have the necessary qualifications and experiences to oversee and effectively manage grant funds. Also, without proper agreements detailing services performed by DCOs, there is a risk that some clinics may not have provided required clinical services.

We made a series of recommendations to SAMHSA to improve its policies and procedures for awarding and monitoring CCBHC-E grants to ensure that clinics comply with Federal requirements. SAMHSA concurred with our recommendations and described actions that it had taken and planned to take.

Human Services Agency Reports and Reviews

Administration for Children and Families

The Office of Refugee Resettlement Needs To Improve Its Practices for Background Checks During Influxes (A-06-21-07003), May 2023

For some employees, the Office of Refugee Resettlement's (ORR's) influx care facility (ICF) and emergency intake sites (EISs) did not conduct or document all required background checks or did not conduct the checks in a timely manner. Specifically, not all public record checks, FBI fingerprint

checks, child abuse and neglect checks, and DOJ sex offender registry checks were conducted, documented, or conducted in a timely manner. In addition, ORR did not require the transportation services contractor we reviewed to conduct background checks on employees as required by ORR minimum standards.

The issues we identified occurred primarily because the influx of unaccompanied children required ORR to rapidly set up new facilities to expand capacity as well as develop formal policies and procedures related to the EISs. We recommend that ORR take multiple actions related to background checks. ACF, commenting on behalf of ORR, concurred with our recommendations and described the actions it has taken to address our findings.

The Office of Refugee Resettlement Needs To Improve Its Oversight Related to the Placement and Transfer of Unaccompanied Children (A-06-20-07002), May 2023

We found that the Office of Refugee Resettlement (ORR) faced challenges when making initial placements during an influx period. ORR did not consistently make initial placements within 24 hours during influx periods because of capacity issues and lack of intake specialist staff. Additionally, ORR did not adequately document placement decisions or placement designations for children with special concerns or needs. Furthermore, we determined that: (1) for the statistical sample of transfers of unaccompanied children, some were missing supporting documentation; (2) for the judgmental sample of transfers of children into restrictive placements, some of the required documentation was not completed or missing; (3) ORR did not maintain documentation for the reason(s) each child was denied a transfer; and (4) ORR faced challenges transferring children with both behavioral and mental health needs. These errors occurred because ORR had limited quality control procedures, lacked oversight to ensure that documentation was retained by care providers, and did not have a process in place to track denied transfers.

We recommend that ORR make multiple procedural changes related to the placement and transfer of unaccompanied children. ACF, commenting on behalf of ORR, concurred with our recommendations and described actions taken to address our findings.

Widespread Pandemic Disruption Spurred Innovation to State Paternity Establishment Practices (OEI-06-21-00150), August 2023

Paternity establishment services were disrupted by the COVID-19 pandemic in every State, but State child support agencies took numerous actions to maintain services. During the COVID-19 pandemic, hospital visitation restrictions made it difficult for fathers to establish paternity at the time of birth and closures and limited hours for courts and genetic testing sites disrupted post-birth paternity establishment services. State child support agencies took numerous actions to maintain paternity establishment services during the pandemic, including transitioning to telework, assisting hospital staff, and increasing the use of remote court hearings. The Office of Child Support Services (OCSS) temporarily reduced paternity establishment performance requirements,

which protected State agencies from potential financial penalties. State agencies called the OCSS action beneficial, but some said they would have also benefited from additional help in maintaining services. ACF concurred with our recommendations that it: (1) create forums for identifying and sharing State agency best practices in providing paternity establishment services and (2) bolster State agency resilience during emergencies.

Risk Assessment of the Administration for Children and Families' Travel Card Program for Fiscal Year 2021 (A-04-22-06263), August 2023

We assessed the risk of illegal, improper, or erroneous purchases in the ACF travel card program as moderate. Within the 6 risk areas related to ACF's travel card program, we identified 45 sub-risk areas and rated 29 as low risk, 13 as moderate risk, and 3 as high risk. The program was rated as moderate because it: (1) did not provide adequate oversight of employee compliance with travel procedures, (2) did not provide adequate training for proper travel card use, and (3) did not maintain adequate documentation to support employee travel. As a result, ACF reimbursed unallowable travel charges to its employees. Without proper training and policy education, ACF employees could continue to charge the Federal Government for unallowable travel expenditures.

We recommended that ACF develop mitigating controls and strategies to lower the high and moderate risks we identified. In response to our draft report, ACF concurred with our recommendation. ACF stated that it takes its oversight responsibilities seriously and is fully committed to taking the necessary actions to address the identified risks in our report.

Risk Assessment of the Administration for Children and Families' Purchase Card Program for Fiscal Year 2021 (A-04-22-06262), September 2023

We assessed the risk of illegal, improper, or erroneous purchases in the ACF purchase card program as moderate. Within the 6 risk areas related to ACF's purchase card program, we identified 56 sub-risk areas and rated 7 as low risk, 44 as moderate risk, and 5 as high risk. The program was rated as moderate because it: (1) did not provide adequate purchase card training to cardholders, (2) had not corrected prior identified deficiencies, and (3) did not maintain adequate documentation to support purchases. As a result, ACF paid for purchase card expenditures that may not have been allowable. Without proper monitoring of purchase card expenditures, ACF could continue to allow improper purchases.

We recommend that ACF develop mitigating controls and strategies to lower the high and moderate risks we identified. In response to our draft report, ACF concurred with our recommendation. ACF stated that it takes its oversight responsibilities seriously and is fully committed to take the necessary actions to address the identified risks in our report.

Safety of Children in Foster Care

State Agencies Can Improve Their Reporting of Children Missing From Foster Care to Law Enforcement for Entry Into the National Crime Information Center Database as Required by Federal Statute (A-07-21-06104), May 2023

During our audit period, State agencies did not ensure that some children who went missing from foster care were reported to law enforcement for entry into the National Crime Information Center (NCIC) database as required by Federal statute. Of the 100 missing children episodes in our sample, the State agencies reported 86 episodes in a timely manner (i.e., within 24 hours after the State agency received information that the child was missing) in accordance with Federal requirements. However, eight missing children episodes were not reported in a timely manner (i.e., were not reported until 2 calendar days or longer after the State agency received information that the child was missing), and six episodes were never reported to law enforcement for entry into the NCIC database. Based on our sample results, we estimate that the State agencies did not report 13,983 of the 74,353 missing children episodes in accordance with Federal requirements.

State agencies generally lacked adequate systems to readily identify whether or not they had reported missing children episodes to law enforcement accurately and in a timely manner. State agencies that do not properly report missing children episodes to law enforcement for entry into the NCIC database increase the risk that the children may not be safely and swiftly recovered.

We recommend that the ACF work with State agencies to ensure compliance with Federal requirements to report missing children episodes to law enforcement for entry into the NCIC database in a timely manner. ACF concurred with our recommendation and described actions that it had taken and planned to take.

Alaska Experienced Challenges in Meeting Federal and State Foster Care Program Requirements During the COVID-19 Pandemic (A-06-21-07006), June 2023

We did not identify any vulnerabilities or gaps in Alaska's policies or procedures that could place children at risk. However, Alaska did not always comply with State and Federal requirements related to background checks and caseworker visits to foster homes during the COVID-19 pandemic, even when those requirements had been modified to provide flexibility. Specifically, Alaska did not conduct required background checks on all applicants before placing children in homes under emergency conditions and did not document all the required monthly caseworker visits. In addition, Alaska did not complete or document all home inspections as required for licensing foster homes. These issues occurred because Alaska did not consistently follow its policies and procedures for ensuring that background checks were conducted in a timely manner because high turnover limited training of its placement staff. In addition, the State agency faced challenges in conducting and documenting caseworker visits and home inspections.

We recommend that Alaska: (1) ensure that staff are adequately trained on policies and procedures to ensure that required background checks are completed before placing children in foster homes under emergency conditions; (2) continue to identify ways to address the challenges related to meeting the requirements for conducting monthly caseworker visits and home inspections, including consulting with ACF; and (3) complete home inspections in accordance with requirements for the two foster homes identified by our audit as lacking completed inspections and the five foster homes requiring in-person inspections.

Alaska concurred with our recommendations and described actions it had taken related to conducting caseworker visits and home inspections.

Florida Did Not Comply With Requirements for Documenting Psychotropic and Opioid Medications Prescribed for Children in Foster Care (A-05-22-00009), July 2023

Florida 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 the Social Security Act. Specifically, for the 85 sample children who were prescribed psychotropic drugs, we found that: (1) the psychotropic medications prescribed for 36 children were not recorded in Florida's child welfare system, Florida Safe Families Network (FSFN); (2) the medication logs for 56 children were not maintained in FSFN; and (3) the authorization for prescription of psychotropic medications for 33 children were not contained in FSFN. In addition, we found that the opioid medications prescribed for 57 of the 60 children in the sample were not recorded in FSFN.

Florida did not comment on our recommendations that it: (1) provide training to child protective investigators and caseworkers on medication management and administration that addresses requirements for updating case records in FSFN for children who are prescribed psychotropic medications (including related medication logs and authorizations) and opioid medications and (2) coordinate with the Florida Agency for Health Care Administration to obtain access to Medicaid claim data for all children under its care and supervision.

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

Health Education Assistance Loan Program Exclusions

OIG excludes from Federal health care programs individuals who have defaulted on Health Education Assistance Loan (HEAL) Program loans. Under the HEAL Program, which stopped granting loans in 1998, HRSA guaranteed commercial loans to students seeking education in health-related fields. The students could then defer repayment of the loans until after they graduated and began to earn income. Although HHS's Program Support Center takes steps to ensure repayment, some loan recipients do not resolve their debt. After the Program Support Center 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.

A pandemic-related moratorium on student loan collection activities expired in September 2023, and loan payments were to resume in October 2023. During this moratorium, the Program Support Center did not refer individuals in default to OIG for consideration for exclusion, as appropriate under the applicable authority. Accordingly, OIG has no exclusion 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 two criminal actions and court-ordered restitution and settlements of $36,913.

Engaging the Public in Capturing Deadbeat Parents

Because of the success of OIG's Most Wanted Fugitives website, OIG launched its Child Support Enforcement 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.

Other HHS-Related Reviews and Investigative Activities

Cross-Cutting Medicare and Medicaid

The Centers for Medicare & Medicaid Services Should Improve Preventative and Detective Controls To More Effectively Mitigate the Risk of Compromise (A-18-20-08001), May 2023

Although CMS had implemented some security controls for detecting and preventing threats on its network, CMS's cybersecurity controls needed improvements to better detect and prevent cyber threats on its network. Multiple security controls at CMS were not operating effectively, including controls related to monitoring and controlling communications at the CMS boundary, configurations to provide only essential capabilities, and controlling and preventing the installation of unauthorized software by users. Although we did not identify evidence of a past breach, we found one active and one potential threat to the CMS network. Lastly, we concluded that CMS did not consistently detect threat activity that could lead to a potential breach. Specifically, CMS did not identify an active threat and other control weaknesses we found during the audit.

The security control failures that we identified occurred because CMS did not effectively align some of its security controls with its security policies or NIST SP 800-53, Revision 4, requirements. For certain controls, CMS did not establish effective policies and procedures to periodically assess whether these controls were in place and operating effectively. As a result, cyber threat actors may have been able to carry out a cyberattack.

We recommend that CMS: (1) remediate the seven security control findings OIG identified, (2) update security controls to align with the most current NIST SP 800-53 requirements, and (3) enhance policies and procedures to periodically identify and assess whether security controls are in place and operating effectively. CMS concurred with all of our recommendations and described the actions it has taken.

Georgia Could Better Ensure That Nursing Homes Comply With Federal Requirements for Life Safety, Emergency Preparedness, and Infection Control (A-04-22-08093), September 2023

Georgia could better ensure that nursing homes in Georgia that participate in Medicare or Medicaid programs comply with Federal requirements for life safety, emergency preparedness, and infection control if additional resources were available. During our onsite inspections, we identified deficiencies related to life safety, emergency preparedness, or infection control at 19 of the 20 nursing homes we audited, totaling 155 deficiencies. Specifically, we found 71 deficiencies related to life safety, 66 deficiencies related to emergency preparedness, and 18 deficiencies related to infection control. As a result, the health and safety of residents, staff, and visitors at 19 of the 20

nursing homes are at an increased risk during a fire or other emergency or in the event of an infectious disease outbreak.

The identified deficiencies occurred because of frequent management and staff turnover, which contributed to a lack of awareness of, or failure to address, Federal requirements. In addition, Georgia had limited resources to conduct surveys of all nursing homes more frequently than CMS required.

We recommend that Georgia follow up with the 19 nursing homes in this audit that demonstrated life safety, emergency preparedness, and infection control deficiencies to ensure that they have taken corrective actions. We also make procedural recommendations for Georgia to work with CMS to address foundational issues to implement a risk-based approach to identifying and conducting more frequent surveys at nursing homes and to develop standardized life safety training for nursing home staff. Georgia concurred with our first recommendation and indicated that our other procedural recommendations were beyond its scope and authority.

General Departmental

Review of the Department of Health and Human Services' Compliance with the Federal Information Security Modernization Act of 2014 for Fiscal Year 2022 (A-18-22-11200), May 2023

Overall, through the evaluation of Federal Information Security Modernization Act of 2014 (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 Core Inspector General metrics in the function areas of Identify, Protect, Detect, Respond, and Recover. HHS has continued to implement changes that support progress towards improved maturity of their enterprisewide cybersecurity program across all FISMA domains. We have identified a number of areas that would strengthen the Department's 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. HHS concurred with our Department, OpDiv, and enterprise 1 and 2 recommendations but did not concur with enterprise recommendations 3 and 4.

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 2022 (A-17-23-52000), May 2023

Ernst & Young, under its contract with HHS-OIG, determined that HHS met many requirements but did not fully comply with Payment Integrity Information Act of 2019 (PIIA). Among the items

required for compliance with PIIA that HHS complied with, Ernst & Young determined that HHS: (1) published the Agency Financial Report for FY 2022; (2) conducted risk assessments for 43 programs not susceptible to improper payments and determined the programs were not at risk for improper payments; and (3) published corrective action plans for 9 of the 13 programs that are susceptible to significant improper payments as determined by HHS management, OMB, or through legislation. Ernst & Young also determined that HHS developed a plan to meet improper payment and unknown payment reduction targets for 6 of 13 programs; also reported an improper and unknown payment rate of less than 10 percent for 7 of the 13 programs.

Ernst & Young concluded that HHS did not comply with several other PIIA requirements. Ernst & Young found that HHS: (1) did not conduct improper payment risk assessments for each program with annual outlays greater than $10 million at least once every 3 years; (2) did not report an improper and unknown payment estimate for Covid-19 Uninsured Program, Temporary Assistance for Needy Families, Foster Care, and Head Start programs; (3) reported improper and unknown payment rates in excess of 10 percent for Medicaid and CHIP; (4) had completed minimal recovery audit activities for the identified improper payments for the Medicare Advantage and Medicare Prescription Drug Benefit programs; (5) did not effectively demonstrate improvements to payment integrity for the Medicare Fee For Service program; and (6) has not calculated and reported an improper payment estimate for the State-based exchanges of the Advance Premium Tax Credit program.

Targeted Provider Relief Funds Allocated to Hospitals Had Some Differences with Respect to the Ethnicity and Race of Populations Served (OEI-05-20-00580), June 2023

Communities with greater concentrations of Hispanic/Latino residents were generally associated with less 2020 COVID-19 targeted hospital PRF money per person than communities with lower concentrations. This funding disparity raises concerns because Hispanic/Latino Americans have been more likely to be hospitalized or die from COVID-19 than non-Hispanic White Americans. In nonrural areas, communities with greater concentrations of Non-Hispanic Black residents were associated with more PRF per person than communities with smaller concentrations of Non-Hispanic Black residents, but this pattern did not occur in rural areas. To most effectively use future funding to help reduce health disparities, even in emergencies, we believe HHS would benefit from a framework that prepares it to consider health equity goals when making emergency funding decisions beyond the PRF. This report contained no recommendations.

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 examples relate to misuse of grant funds:

California—On June 14, 2023, the United States entered into a False Claims Act settlement agreement with Capital Technology Information Services, Inc. (CTIS), a health care information technology contractor. The settlement agreement resolves allegations that between July 1, 2013, and June 30, 2018, CTIS knowingly billed NIH for unallowable costs, including for such personal expenses as the costs of luxury vehicles, residential mortgage payments, housekeeping services, the cost of a wedding, and other unreasonable and/or non-contract-related work or for work not actually performed. These costs were falsely represented as incurred specifically in support of the work performed on the NIH grant and Cancer Therapy Evaluation Program Task Order as necessary to the operation of the business of CTIS. The total amount of the settlement to be paid is $1,712,949.44.

Maryland—On March 14, 2023, the United States entered into a False Claims Act settlement agreement with Jelly Bean Communications Design, LLC (Jelly Bean) and Jeremy Spinks, who is Jelly Bean's manager, 50 percent owner, and sole employee. Jelly Bean created the "HealthyKids.org" website for Florida Healthy Kids Corporation, including the online application portal into which parents entered detailed personal data to apply for insurance coverage for their children. However, Jelly Bean did not provide secure hosting of applicants' personal information and instead failed to properly maintain, patch, and update the software systems underlying HealthyKids.org, leaving the site and the data collected from applicants vulnerable to cyberattack. On December 3, 2020, Jelly Bean disclosed that more than 597,414 applications submitted on HealthyKids.org had been hacked. A forensic analysis of the IT system showed that Jelly Bean was running multiple outdated and vulnerable applications, including some software that Jelly Bean had not updated or patched since November 2013. The total amount of the settlement to be paid is $293,771.

Recovery Act Retaliation Complaint Investigations

The American Recovery and Reinvestment Act, § 1553 (Recovery Act) 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 $2.7 trillion in audited costs. Federal dollars covered by these audits totaled $912 billion, of which about $430.3 billion were HHS funds.

Uniform guidance at 2 CFR 200 Subpart F establishes audit requirements for State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards. Under the uniform guidance, covered entities must conduct annual organization wide "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, 2023–September 30, 2023

Not requiring changes or having minor changes	251
Requiring major changes	8
Having significant technical inadequacies	2
Total No. 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 to Congress*, describes findings and recommendations from recently completed reviews, many of which focus on existing laws and regulations.
- *OIG maintains a public Recommendations Tracker that includes characteristics of unimplemented recommendations. This information was previously presented in OIG's Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs,*, which described 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's 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	No. 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	55	$919,298,000	$88,768,000
Issued during the reporting period[1]	27	$1,197,227,000	$38,599,000
Total Section 1	**82**	**$2,116,525,000**	**$127,367,000**
Section 2			
Reports for which management decisions were made during the reporting period[2]			
Disallowed costs	16	*$82,710,000	$55,000
Costs not disallowed	4	$201,628,000	$88,620,000
Total Section 2	**20**	**$284,338,000**	**$88,675000**

* 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)	**62**	**$1,832,187,000**	**$38,692,000**

Section 4			
Reports for which no management decisions were made within 6 months of issuance[3]	37	$657,458,000	$93,000

Table 1 End Notes

[1] Three issued reports containing recommendations for both questioned costs and funds put to better use are counted in Table 1 and Table 2.

[2] Revisions to previously reported management decisions:

- A-05-17-00018, *Minnesota Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations.* CMS's subsequent review determined that disallowed costs should be increased by $79,744,808.
- A-02-19-01018, *Medicare Hospice Provider Compliance Audit: Vitas Healthcare Corporation of Florida.* CMS's subsequent review determined that disallowed costs should be reduced by $2,517,905.
- A-09-19-03010, *Visionquest Industries, Inc.: Audit of Medicare Payments for Orthotic Braces*. CMS's subsequent review determined that disallowed costs should be reduced by $1,447,115.
- Not detailed are reductions to previously disallowed management decisions totaling $1.8 million.

[3] Because of administrative delays, some of which were beyond management control, resolution of the following 37 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-05-19-00039	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract R5826) Submitted to CMS*, SEP 2022, $34,414,828
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-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-01-15-02500	*Vermont Did Not Properly Allocate Millions to Establishment Grants for a Health Insurance Marketplace*, SEP 2016, $11,243,006
A-02-20-01009	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cariten Health Plan, Inc., (Contract H4461) Submitted to CMS*, JUL 2022, $9,212,531
A-07-19-01195	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BlueCross BlueShield of Tennessee, Inc. (Contract H7917) Submitted to CMS,* SEP 2022, $7,784,540
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-03-19-00001	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Highmark Senior Health Company (H3916) Submitted to CMS*, SEP 2022, $6,227,005
A-07-19-01193	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring of Tennessee, Inc. (Contract H4454) Submitted to CMS*, DEC 2022, $5,987,509
A-05-18-00020	*Medicare Advantage Compliance Audit of Diagnosis Codes That Inter Valley Health Plan, Inc. (Contract H0545), Submitted to CMS,* SEP 2022, $5,372,998
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-01-20-00500	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross & Blue Shield of Rhode Island (H4152) Submitted to CMS*, NOV 2022, $4,894,595
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-04-19-07084	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That WellCare of Florida, Inc., (Contract H1032) Submitted to CMS,* AUG 2022, $3,518,465
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-06-18-05002	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Peoples Health Network (Contract H1961) Submitted to CMS,* MAY 2022, $3,312,219
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-09-19-03001	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That California Physicians' Service, Inc. (Contract H0504) Submitted to CMS*, NOV 2022, $2,033,039

A-09-20-03009	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3817) Submitted to CMS*, SEP 2022, $1,890,855
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-09-21-03011	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS*, MAR 2023, $566,476
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-02-19-02008	*Greater Bergen Community Action, Inc., Did Not Manage Its Head Start Awards in Accordance With Federal and State Requirements*, JAN 2023, $487,411
A-07-19-01192	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring Life & Health Insurance Company, Inc. (Contract H4513) Submitted to CMS*, MAR 2023, $468,372
A-02-20-01008	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MCS Advantage, Inc. (Contract H5577) Submitted to CMS*, MAR 2023, $220,577
A-04-20-02032	*The Municipality of Manati Did Not Always Manage Its Head Start Disaster Assistance Awards in Accordance With Federal and Commonwealth Requirements*, DEC 2022, $153,052
A-03-18-00002	*Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS*, AUG 2022, $39,612
TOTAL CINS: 37 **TOTAL AMOUNT: $657,458,398**	

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	No. of Reports	Dollar Value
Section 1		
Reports for which no management decisions had been made by the beginning of the reporting period	8	$15,360,162,000
Reports issued during the reporting period[1,2]	5	$747,102,000
Total Section 1	**13**	**$16,107,264,000**
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	$47,173,000
Based on proposed legislative action	0	$0
Value of recommendations not agreed to by management	3	$373,369,000
Total Section 2	**5**	**$420,542,000**
Section 3		
Reports for which no management decisions had been made by the end of the reporting period[1] (Section 1 - Section 2)[3,4]	**8**	**$15,686,722,000**

Table 2 End Notes

[1] The opening balance was adjusted upward by $55,000 because of a reevaluation of a previously issued recommendation.

[2] Three issued reports containing recommendations for both questioned costs and funds put to better use are counted in Table 1 and Table 2.

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

[4] Because of administrative delays, some of which were beyond management control, three of the eight audits open at the 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-03-13-03002	*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
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*, MAY 2022, $3,739,346
TOTAL CINS: 3 **TOTAL AMOUNT: $67,601,904**	

Audit Reports by Issue Date

Report Number	Title	Issued	Questioned Costs	Funds Put to Better Use
A-05-19-00013	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HumanaChoice (Contract H6609) Submitted to CMS*	4/4/2023	480,295	-
A-09-20-02007	*CMS Did Not Accurately Report on Care Compare One or More Deficiencies Related to Health, Fire Safety, and Emergency Preparedness for an Estimated Two-Thirds of Nursing Homes*	4/10/2023	-	-
A-02-21-02004	*Crow/Northern Cheyenne Hospital—an IHS-Operated Health Facility—Did Not Timely Conduct Required Background Checks of Staff and Supervise Certain Staff*	4/21/2023	-	-
A-09-22-03004	*Medicare Could Have Saved Up To $128 Million Over 5 Years if CMS Had Implemented Controls To Address Duplicate Payments for Services Provided to Individuals With Medicare and Veterans Health Administration Benefits*	4/24/2023	-	127,981,462
A-06-21-07003	*The Office of Refugee Resettlement Needs To Improve Its Practices for Background Checks During Influxes*	5/2/2023	-	-
A-09-21-03021	*Medicare Improperly Paid Providers for Some Psychotherapy Services, Including Those Provided via Telehealth, During the First Year of the COVID-19 Public Health Emergency*	5/2/2023	35,560	579,631,950
A-18-22-11200	*Review of the Department of Health and Human Services' Compliance with the Federal Information Security Modernization Act of 2014 for Fiscal Year 2022*	5/9/2023	-	-

A-07-21-06104	*State Agencies Can Improve Their Reporting of Children Missing From Foster Care to Law Enforcement for Entry Into the National Crime Information Center Database as Required by Federal Statute*	5/12/2023	-	-
A-18-20-08003	*Massachusetts MMIS and E&E System Security Controls Were Generally Effective, but Some Improvements Are Needed*	5/16/2023	-	-
A-07-21-03250	*Montana Generally Complied With Requirements for Telehealth Services During the COVID-19 Pandemic*	5/17/2023	-	-
A-02-21-02005	*Seventeen of Thirty Selected Health Centers Did Not Use or May Not Have Used Their HRSA COVID-19 Supplemental Grant Funding in Accordance With Federal Requirements*	5/18/2023	15,843,987	-
A-17-23-52000	*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 2022*	5/19/2023	-	-
A-06-20-07002	*The Office of Refugee Resettlement Needs To Improve Its Oversight Related to the Placement and Transfer of Unaccompanied Children*	5/23/2023	-	-
A-01-20-01501	*Vermont Complied With Regulations When Implementing Programs Under SAMHSA's Opioid Response Grants, but Claimed Unallowable Expenditures*	5/24/2023	282,643	-
A-18-20-08001	*The Centers for Medicare & Medicaid Services Should Improve Preventative and Detective Controls To More Effectively Mitigate the Risk of Compromise*	5/24/2023	-	-
A-18-21-09003	*Maryland MMIS and E&E System Security Controls Were Partially Effective and Improvements Are Needed*	5/25/2023	-	-
A-02-21-02008	*Florida Did Not Ensure That Some Providers Complied With Requirements For Determining Eligibility For Its Projects for Assistance in Transition From Homelessness Program*	5/26/2023	-	-
A-04-21-04084	*Medicare Paid Millions More for Physician Services at Higher Nonfacility Rates Rather Than at Lower Facility Rates While Enrollees Were Inpatients of Facilities*	5/30/2023	22,463,193	-
A-03-20-00001	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Keystone Health Plan East, Inc. (H3952) Submitted to CMS*	5/31/2023	550,391	-
A-07-20-05127	*Saint Louis University's Management of NIH Grant Awards Did Not Comply With All Federal Requirements but Complied With Financial Conflict of Interest Requirements*	6/1/2023	263	-

A-06-21-07006	*Alaska Experienced Challenges in Meeting Federal and State Foster Care Program Requirements During the COVID-19 Pandemic*	6/2/2023	-	-
A-18-21-11500	*NIH Should Improve Its Management of Contracts for the Acquisition of Information Technology*	6/5/2023	-	-
A-09-22-03010	*CMS's Oversight of Medicare Payments for the Highest Paid Molecular Pathology Genetic Test Was Not Adequate To Reduce the Risk of up to $888 Million in Improper Payments*	6/21/2023	888,169,038	-
A-09-21-03016	*Noridian Healthcare Solutions, LLC, Made $8.8 Million in Improper Capitation Payments to Physicians and Qualified Nonphysician Practitioners in Jurisdiction E for Certain Services Related to End-Stage Renal Disease*	6/27/2023	4,663	8,844,899
A-07-20-01202	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Excellus Health Plan, Inc. (Contract H3351) Submitted to CMS*	7/10/2023	3,103,290	-
A-02-21-01013	*HRSA Made COVID-19 Uninsured Program Payments to Providers on Behalf of Individuals Who Had Health Insurance Coverage and for Services Unrelated to COVID-19*	7/13/2023	294,294	-
A-05-22-00009	*Florida Did Not Comply With Requirements for Documenting Psychotropic and Opioid Medications Prescribed for Children in Foster Care*	7/14/2023	-	-
A-03-22-00203	*Virginia Made Capitation Payments to Medicaid Managed Care Organizations After Enrollees' Deaths*	7/19/2023	37,551,985	-
A-07-20-04123	*Although IHS Allocated COVID-19 Testing Funds To Meet Community Needs, It Did Not Ensure That the Funds Were Always Used in Accordance With Federal Requirements*	7/20/2023	480,437	-
A-02-22-01011	*New York Improved Its Monitoring of Medicaid Community Rehabilitation Services But Still Claimed Improper Federal Medicaid Reimbursement Totaling $20 Million*	7/31/2023	19,888,031	-
A-09-22-03003	*Medicare Paid $30 Million for Accumulated Repair Costs That Exceeded the Federally Recommended Cost Limit for Wheelchairs During Their 5-Year Reasonable Useful Lifetime*	7/31/2023	-	30,051,107
A-05-22-00015	*Telehealth During 2020 Helped Ensure End-Stage Renal Disease Patients Received Care, But Limited Information Related to Telehealth Was Documented*	8/1/2023	-	-
A-07-22-00626	*First Coast Service Options, Inc., Did Not Claim Some Allowable Medicare Supplemental Executive Retirement Plan Costs*	8/2/2023	-	-
A-07-23-00629	First Coast Service Options, Inc., Overstated Its Medicare Segment Postretirement Benefit Assets as of January 1, 2019	8/2/2023	-	-

A-07-23-00630	*First Coast Service Options, Inc., Did Not Claim Allowable Medicare Postretirement Benefit Costs*	8/2/2023	-	-
A-07-23-00632	*First Coast Service Options, Inc., Claimed Some Unallowable Medicare Nonqualified Plan Costs Through Its Incurred Cost Proposals*	8/2/2023	73,194	-
A-07-20-01197	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Presbyterian Health Plan, Inc. (Contract H3204) Submitted to CMS*	8/3/2023	1,302,682	-
A-06-19-09003	*Texas Inappropriately Claimed Nearly $1.8 Million in Federal Medicaid Funds for Private Medicaid Management Information System Contractor Costs*	8/8/2023	1,776,003	-
A-07-22-06106	*States With Separate Children's Health Insurance Programs Could Have Collected an Estimated $641 Million Annually If States Were Required To Obtain Rebates Through the Medicaid Drug Rebate Program*	8/9/2023	-	-
A-09-21-03020	*Medicare Paid Independent Organ Procurement Organizations Over Half a Million Dollars for Professional and Public Education Overhead Costs That Did Not Meet Medicare Requirements*	8/9/2023	72,208	592,087
A-09-22-03005	*Medicare Made $17.8 Million in Potentially Improper Payments for Opioid-Use-Disorder Treatment Services Furnished by Opioid Treatment Programs*	8/17/2023	17,817,121	-
A-17-23-00009	*Independent Service Auditor's Report on the Department of Health and Human Services' Program Support Center, Grants Finance and Administrative Services, Payment Management Services' Payment Management System for the Period From October 1, 2022, Through June 30, 2023*	8/24/2023	-	-
A-17-23-00010	*Independent Service Auditor's Report on the Department of Health and Human Services, Center for Information Technology at the National Institutes of Health, Information Technology General Controls System for the UNIX and Windows Environments for the Period October 1, 2022, Through June 30, 2023*	8/24/2023	-	-
A-04-22-04089	*Florida Did Not Refund $106 Million Federal Share of Medicaid Managed Care Rebates It Received for Calendar Years 2015 Through 2020*	8/31/2023	106,153,061	-
A-04-22-06263	*Risk Assessment of the Administration for Children and Families' Travel Card Program for Fiscal Year 2021*	8/31/2023	-	-
A-04-22-08093	*Georgia Could Better Ensure That Nursing Homes Comply With Federal Requirements for Life Safety, Emergency Preparedness, and Infection Control*	9/6/2023	-	-

A-04-22-06262	*Risk Assessment of the Administration for Children and Families' Purchase Card Program for Fiscal Year 2021*	9/7/2023	-	-
A-02-21-01004	*Puerto Rico Claimed More Than $500 Thousand in Unallowable Medicaid Managed Care Payments for Enrollees Assigned More Than One Identification Number*	9/8/2023	516,762	-
A-09-22-01000	*CDC's Vaccines for Children Program Recipients Did Not Conduct Site Visits at Some Providers as Required*	9/8/2023	-	-
A-09-23-03016	*Medicare Improperly Paid Acute-Care Hospitals for Inpatient Claims Subject to the Post-Acute-Care Transfer Policy Over a 4-Year Period, but CMS's System Edits Were Effective in Reducing Improper Payments by the End of the Period*	9/8/2023	41,401,244	-
A-02-21-01005	*Puerto Rico Claimed Over $7 Million in Federal Reimbursement for Medicaid Capitation Payments Made on Behalf of Enrollees Who Were or May Have Been Deceased*	9/11/2023	7,864,945	-
A-02-21-02010	*The Substance Abuse and Mental Health Services Administration Did Not Ensure That Clinics Fully Complied With Federal Requirements When Awarding and Monitoring Certified Community Behavioral Health Clinic Expansion Grants*	9/11/2023	-	-
A-05-22-00018	*Texas Made Capitation Payments for Enrollees Who Were Concurrently Enrolled in a Medicaid Managed Care Program in Another State*	9/11/2023	-	-
A-04-22-07102	*Kentucky Did Not Always Invoice Manufacturers for Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations*	9/12/2023	15,491,320	-
A-07-23-00633	*Novitas Solutions, Inc., Claimed Some Unallowable Medicare Nonqualified Plan Costs Through Its Incurred Cost Proposals*	9/12/2023	84,291	-
A-07-22-07007	*Amerigroup Iowa's Prior Authorization and Appeal Processes Were Effective, but Improvements Can Be Made*	9/13/2023	-	-
A-02-21-01016	*New York Did Not Ensure That a Managed Care Organization Complied With Requirements for Denying Prior Authorization Requests*	9/18/2023	-	-
A-01-21-01503	*HRSA Had An Effective Process To Identify And Monitor High-Risk Health Centers That Received COVID-19 Grant Funds*	9/21/2023	-	-
A-04-21-08090	*Alabama Did Not Always Invoice Rebates to Manufacturers for Pharmacy and Physician-Administered Drugs*	9/21/2023	15,457,223	-
A-06-21-09002	*Four States Reviewed Received Increased Medicaid COVID-19 Funding Even Though They Terminated*	9/22/2023	-	-

	Some Enrollees' Coverage for Unallowable or Potentially Unallowable Reasons			
A-09-18-03007	*Medicare Advantage Compliance Audit of Diagnosis Codes That Health Net of California, Inc. (Contract H0562) Submitted to CMS*	9/22/2023	69,182	-
A-05-21-00026	*Home Health Agencies Rarely Furnished Services Via Telehealth Early in the COVID-19 Public Health Emergency*	9/25/2023	-	-
A-05-20-00033	*Illinois State University's Management of NIH Awards Complied With Federal and Financial Conflict of Interest Requirements*	9/26/2023	-	-
A-05-22-00010	*CDC Provided Oversight and Assistance; However, ELC Recipients Still Faced Challenges in Implementing COVID-19 Screening Testing Programs*	9/26/2023	-	-
A-02-22-01004	*New Jersey Could Better Ensure That Nursing Homes Comply With Federal Requirements for Life Safety, Emergency Preparedness, and Infection Control*	9/29/2023	-	-
Total Reports: 65			$1,197,227,306	$747,101,505

Evaluation Reports by OpDiv

Report Number	Title	OpDiv	Issue Date
OEI-06-21-00150	*Widespread Pandemic Disruption Spurred Innovation to State Paternity Establishment Practices*	ACF	8/31/2023
OEI-02-20-00723	*Toolkit: Analyzing Telehealth Claims to Assess Program Integrity Risks*	CMS	4/20/2023
OEI-03-23-00090	*Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Fourth Quarter*	CMS	5/11/2023
OEI-02-22-00160	*The Risk of Misuse and Diversion of Buprenorphine for Opioid Use Disorder Appears to Be Low in Medicare Part D*	CMS	5/16/2023
OEI-02-23-00150	*2022 Performance Data for the Senior Medicare Patrol Projects*	CMS	6/16/2023
OEI-02-21-00101	*A Resource Guide for Using Medicare's Enrollment Race and Ethnicity Data*	CMS	6/27/2023
OEI-05-23-00130	*Part D Plans Generally Include Drugs Commonly Used Dual-Eligible Enrollees: 2023*	CMS	6/30/2023
OEI-06-21-00030	*Adverse Events Toolkit: Medical Record Review Methodology*	CMS	7/6/2023
OEI-06-21-00031	*Adverse Events Toolkit: Clinical Guidance for Identifying Harm*	CMS	7/6/2023

OEI-09-19-00350	*High Rates of Prior Authorization Denials by Some Plans and Limited State Oversight Raise Concerns About Access to Care in Medicaid Managed Care*	CMS	7/17/2023
OEI-03-23-00100	*Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the First Quarter of 2023*	CMS	8/16/2023
OEI-03-23-00120	*Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2021 Average Sales Prices*	CMS	8/29/2023
OEI-05-22-00240	*One Quarter of Medicaid Enrollees with HIV May Not Have Received Recommended Care in 2021*	CMS	8/31/2023
OEI-06-22-00100	*Nursing Homes Reported Wide Ranging Challenges Preparing for Public Health Emergencies and Natural Disasters*	CMS	9/1/2023
OEI-05-22-00290	*Home Health Agencies Failed To Report Over Half of Falls With Major Injury and Hospitalization Among Their Medicare Patients*	CMS	9/5/2023
OEI-09-20-00590	*Medicaid and Marketplace Enrollment Strategies Used During the COVID-19 PHE Could Benefit States Going Forward*	CMS	9/18/2023
OEI-BL-22-00260	*Many Medicaid Enrollees with Opioid Use Disorder Were Treated with Medication; However, Disparities Present Concerns*	CMS	9/26/2023
OEI-01-20-00240	*FDA Could Take Stronger Enforcement Action Against Tobacco Retailers With Histories of Sales to Youth and Other Violations*	FDA	9/18/2023
OEI-01-20-00242	*Supplemental Data on Tobacco Retailer Inspections*	FDA	9/18/2023
OEI-05-20-00580	*Targeted Provider Relief Funds Allocated to Hospitals Had Some Differences with Respect to the Ethnicity and Race of Populations Served*	HRSA	7/12/2023
OEI-06-22-00430	*Minnesota Medicaid Fraud Control Unit: 2022 Onsite Review*	MFCU	9/5/2023
OEI-06-22-00420	*District of Columbia Medicaid Fraud Control Unit: 2022 Onsite Review*	MFCU	9/29/2023
	Total Reports: 22		

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 $13.1 billion in savings estimated for the decisions below, $1.4 billion was attributed to FY 2023. 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.	$300 million

Medicaid Rebate for Generic Drugs 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.	Section 602 of the Bipartisan Budget Act of 2015 (P.L. No. 114-74) (see Tab 2) was enacted and included provisions extending the additional rebate to generic drugs. The additional rebate for generic drugs applies to rebate periods beginning with the first quarter of 2017. CBO estimated savings of $1.008 billion over 10 years.	$141 million
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
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 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	$232 million

	$232 million attributed to FY 2023. (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 2023.	$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 the Council of the Inspectors General on Integrity and Efficiency (CIGIE). During this semiannual reporting period, OIG did not conduct or receive a peer review. For information on OIG's involvement in peer reviews in previous reporting periods, please see previous Semiannual Reports.

Appendix D: Summary of Sanction Authorities

The Inspector General Act of 1978, as amended, specifies requirements for semiannual reports to be made to the Secretary of Health and Human Services 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 an 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 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 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 $59,973 against small hospitals (fewer than 100 beds) and up to $119,942 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 $119,973 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, section 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, section 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, section 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 $13,508 and $27,018 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 they knowingly make or use, or cause 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, along with the location of the required information, are listed in the following table.

Section	Requirement	Location
Section 4		
(a)(2)	Review of legislation and regulations	"Other HHS-Related Reviews and Investigative Activities" 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	Public Recommendations Tracker
(a)(4)	Matters referred to prosecutive authorities	"Legal and Investigative Activities Related to the Medicare and Medicaid" 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—Audit Reports With Questioned Costs	Appendix A
(a)(9)	Statistical Table 2—Audit Reports with Funds 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
(a)(12)	Management decisions with which the Inspector General disagrees	None for this reporting period

Section	Requirement	Location
(a)(13)	Information required by the Federal Financial Management Improvement Act of 1996	None for this reporting period
(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), section 845.	"Other HHS-Related Reviews and Investigative Activities" section
205	Pursuant to HIPAA (P.L. No. 104–191), section 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, section 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, section 1553, OIG reports to Congress the retaliation complaint investigations it decided not to conduct or continue during the period.	"Other HHS-Related Reviews and Investigative Activities" 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 2023, OIG had a total of 75 reports with overdue final management decisions (FMDs) as of the end of this reporting period. The breakdown of those 75 reports by HHS OpDiv is as follows:

OpDiv	Overdue FMDs
ACF	10
ASA	1
ASPR	1
CMS	46
IHS	9
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 the fact 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 . . .

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

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

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

OIG is actively tracking 1,401 unimplemented recommendations made in reports issued since FY 2011. Given the volume of recommendations OIG makes each year, the table below reflects summary data by fiscal year:

FY (2011–2023)	Reports With Unimplemented Recommendations	Unimplemented Recommendations	Dollar Value of Aggregate Potential Cost Savings
2011	12	18	$408,135,515
2012	23	26	$369,932,148
2013	20	35	$232,841,797
2014	17	29	$15,072,080,989
2015	19	31	$296,314,747
2016	18	39	$181,809,287
2017	19	50	$1,090,914,540
2018	27	87	$453,747,262
2019	46	126	$712,277,010
2020	62	178	1,193,134,149
2021	63	159	$797,378,636
2022	87	267	$2,244,228,347
2023	104	356	$2,309,065,799
Totals	**517**	**1,401**	**$25,361,860,226**

OIG maintains a public Recommendations Tracker that includes characteristics of unimplemented recommendations.

(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 Department of Justice 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]	**1178**
Total number of persons referred to State and local prosecuting authorities for criminal prosecutions during the reporting period	**103**
Total number of Federal indictments and criminal informations during the reporting period that resulted from any prior referral to prosecuting authorities	**255**
Total number of State and local indictments and criminal informations during the reporting period that resulted from any prior referral to prosecuting authorities	**62**

(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 in the previous section provides the number of indictments and criminal informations during the semiannual reporting period, including sealed indictments and criminal informations. However, the informations cannot be limited to only those that occurred as a result of a presentation in a previous period. In certain situations, the presentation and charging dates are in the same reporting period.

(19) A report on each investigation conducted by the Office involving a senior Government employee where allegations of misconduct were substantiated, including a detailed description of-
(A) the facts and circumstances of the investigation; and
(B) the status and disposition of the matter, including-
(i) if the matter was referred to the Department of Justice, the date of the referral; and
(ii) if the Department of Justice declined the referral, the date of the declination . . .

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, OIG investigated three senior Government employees for misconduct that was substantiated. Descriptions of the investigations are below:

OIG investigated a senior official (SES) for allegedly obtaining interview questions and providing them to a co-worker, who is also the mother of a job applicant. The investigation was presented for Federal prosecution on June 3, 2022, and declined the same day. This investigation was referred to the appropriate HHS operational division for evaluation and administrative action. The action was a 30-day suspension.

OIG investigated a senior official (GS-15) for allegedly teleworking from China with supervisor awareness but no other required notifications. The investigation found that while the senior official violated telework policies, they did not have a requirement to report foreign travel and did not take Government-furnished equipment with them. Additionally, their supervisor was aware of their travel and allowed them to telework using personal computer devices and logging into the systems. The investigation was not presented for prosecution. This investigation was referred to the appropriate HHS operational division for evaluation and administrative action. It was recommended by the security division of the OpDiv that both the senior official and their supervisor retake the training course related to telework.

OIG investigated a senior official (GS-15) for alleged sexual assault. It was alleged that, while out of the country on official business, the senior official entered the hotel room of another agency's

employee and sexually assaulted them. The investigation was presented for Federal prosecution on June 16, 2023, and declined the same day. This investigation was referred to the appropriate HHS operational division for evaluation and administrative action. The senior official has since resigned.

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; and 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 (5 U.S.C. § 2302), the contractor/grantee whistleblower statute (41 U.S.C. § 4712), the Military Whistleblower Protection Act (10 U.S.C. § 1034), and Presidential Policy Directive 19. OIG determines 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 Health and Human Services 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 brought forth by the complainant, a former employee at Clinicas Del Camino Real, Inc. (Clinicas), a Health Resources and Services Administration (HRSA) grantee. The complainant alleged that while working at Clinicas, the complainant's immediate supervisor and responsible management official (RMO), the interim Chief

Executive Officer (CEO), terminated the complainant for asking the interim CEO to follow Clinicas's fiscal and personnel policies, which the complainant alleged were being violated by the interim CEO and the president of Clinicas's board of directors (board). The complainant further alleged that they were terminated for submitting a conflict-of-interest complaint to the compliance officer at Clinicas concerning violations of Clinicas's fiscal and personnel policies committed by the interim CEO and board president. OIG investigators found that the complainant made protected disclosures to the RMO, board president, and compliance officer alleging violations of Clinicas's fiscal and personnel policies with respect to Federal contracts. OIG investigators further found that the RMO terminated the complainant in retaliation for making these protected disclosures. The OIG investigative report was issued to the Secretary of HHS and included recommendations for making the complainant whole and requiring whistleblower protection training for Clinicas employees, board members, and HRSA employees involved in the health center program. OIG is unaware of the consequences imposed upon the responsible management official.

(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 . . .

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 . . .

The table that follows lists inspection, evaluation, and audit reports for this semiannual reporting period that did not result in public reports.

Nonpublic Reports by Category, April 1, 2023, Through September 30, 2023

Category/Description	No. of Reports
IT security reviews (involve IT systems, e.g., penetration test audits)	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 eight 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 defined above, OIG is mindful of the risk that a detailed description of the investigation could inadvertently reveal the subject's identity. During this reporting period, OIG investigated 10 senior Government employee(s) for misconduct, but OIG determined the allegations to be unsubstantiated. Descriptions of the investigations follow.

OIG investigated three senior officials (one SES and two GS-15s) for alleged violations of travel related regulations. It was alleged that the SES senior official allowed their GS-15 subordinate to work outside of their duty station and improperly approved routine travel to and from the location that was not their duty station. It was also alleged that two senior officials (GS-15s) were not working in their assigned duty station. OIG did not find any evidence to support the allegations.

OIG investigated a senior official (GS-15) for allegedly exhibiting a consistent pattern of abuse of the human resources system and the way in which hiring, and the reassignment of employees are executed. OIG did not find any evidence to support the allegations.

OIG investigated a senior official (GS-15) for allegedly inappropriately collaborating closely with a company before and after the submission of the license application for a drug to treat a disease. OIG did not find any evidence to support the allegations.

OIG investigated a senior official (SES) for alleged violations of improper distribution of drugs to retail pharmacies and the White House. The investigation was presented for Federal prosecution on February 27, 2023, and declined on April 20, 2023.

OIG investigated a senior official (GS-15) for allegedly violating conflict of interest laws and regulations. It was alleged that the senior official would advance grant programs or other policies that would benefit a specific association. The investigation was presented for Federal prosecution in September 2023 and declined. This investigation was referred to the appropriate HHS operational division for evaluation.

OIG investigated a senior official (GS-15) for allegedly being served with a temporary restraining order. OIG did not find any evidence to support any violations of policy or law.

OIG investigated a senior official (SES) for allegedly possessing and trading stocks that conflicted with their official duties and using nonpublic information to further their own private interests. It was alleged that they sold between $195,005 and $500,000 in stocks and bonds between January 2020 and February 2020 and purchased between $2,002 and $30,000 in short term bonds in February 2020 prior to the drop in the stock market associated with the COVID-19 pandemic. It was additionally alleged that they provided pandemic-related information to Congress that influenced pandemic-related legislation. OIG did not find any evidence to support the allegations.

OIG investigated an SES for allegedly possessing and trading stocks that conflicted with their official duties. It was alleged that the SES made more than 170 trades of approximately 70 prohibited companies while serving in their capacity, and the stocks traded were purportedly on a list of companies that senior agency officials may not own because they are significantly regulated by the agency. OIG did not find any evidence to support the allegations.

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 be protected by the proposed safe harbor to understand the 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 Federal health care programs and their beneficiaries from abusive practices.

Public Proposals for New and Modified Safe Harbors

Annual Solicitation

In November 2022, 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
Modifications to, and guidance regarding, the group purchasing organization (GPO) safe harbor, 42 CFR § 1001.952(j), to address comments and concerns regarding the manner in which GPOs, pharmacy benefit managers (PBMs), and similar entities may be using such safe harbor to protect certain purportedly abusive arrangements and to clarify whether and under what circumstances the GPO safe harbor applies to PBMs and PBM-operated GPOs.	OIG is not adopting these suggestions. We may consider this topic in future rulemaking or in future guidance. Note that OIG has published a response in the frequently asked questions section of our website explaining the potential application of the GPO safe harbor to remuneration paid by pharmaceutical manufacturers to PBMs.[2] Finally, OIG highlights that there is a statutory exception addressing GPOs at section 1128B(b)(3)(C) of the Social Security Act.
New safe harbors to protect certain remuneration from a clinical trial sponsor to a patient who participates in the sponsor's clinical trial. The proposed safe harbors would protect the sponsor's subsidization of certain costs patients incur due to their participation in a trial, including: (i) cost-sharing obligations; and (ii)	OIG is not adopting these suggestions. Although OIG appreciates the goal of improving diversity among clinical trial subjects, we have longstanding concerns regarding the routine waiver or subsidy of cost-sharing obligations and the provision of other incentives to Federal

[1] OIG, Solicitation of Proposals for New and Modified Safe Harbors and Special Fraud Alerts, 87 Fed. Reg. 72,953 (Nov. 28, 2022), https://www.govinfo.gov/content/pkg/FR-2022-11-28/pdf/2022-25901.pdf.

[2] See OIG, Frequently Asked Questions, General Questions Regarding Certain Fraud and Abuse Authorities, Question #11, https://oig.hhs.gov/faqs/general-questions-regarding-certain-fraud-and-abuse-authorities/.

indirect costs such as travel, lodging, childcare expenses, and lost wages. According to the proposals, clinical trial sponsors assert that protecting the subsidization of these costs through such safe harbors could contribute to increased diversity, equity, and inclusion in clinical trials.	health care program enrollees. We may consider this topic in future rulemaking.
New safe harbor within the value-based enterprise framework to protect arrangements that test improvements in the delivery of care through individual patient health outcomes.	OIG is not adopting this suggestion. We believe that existing regulations, including new and modified safe harbors that were finalized in the 2020 OIG rulemaking, 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 (the "2020 OIG Rulemaking"),[3] provide sufficient regulatory flexibility for arrangements that test improvements to care delivery.
Modifications to the safe harbors for value-based arrangements, including the safe harbors for value-based arrangements with substantial downside financial risk and full financial risk, 42 CFR § 1001.952(ff) and (gg), to protect the exchange of remuneration by entities that currently cannot use one or more of these safe harbors (e.g., pharmaceutical manufacturers, manufacturers of a device or medical supply, and durable medical equipment, prosthetics, orthotics, or supplies ("DMEPOS") suppliers).	As explained in the 2020 OIG Rulemaking, remuneration exchanged by pharmaceutical manufacturers and, in certain circumstances, medical device manufacturers and DMEPOS suppliers, is 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.[4] Consequently, OIG declines to adopt this suggestion.
Modifications to one or more value-based safe harbors to specify that the safe harbors protect in-kind remuneration to providers, patients, or both in the form of a multifunction device.	OIG is not adopting this suggestion because we believe that the existing value-based safe harbors provide sufficient regulatory flexibility for multi-function devices. As explained in the 2020 OIG Rulemaking, there are several factors that would

[3] OIG, Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77,684 (Dec. 2, 2020), https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26072.pdf.

[4] Id. at 77,709.

	dictate whether in-kind remuneration in the form of a multifunction device would meet safe harbor requirements, such as whether the remuneration is predominantly used to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population. See, e.g., our discussion of multifunction devices in the 2020 OIG Rulemaking.[5]
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 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, which raises many of the traditional fraud and abuse risks under the Federal anti-kickback statute. We may consider this topic in future rulemaking.
New safe harbors to protect: (i) value-based purchasing arrangements between pharmaceutical manufacturers and purchasers (including payors); 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.
New safe harbor to protect manufacturer-sponsored patient engagement and product support programs, including therapy management and medication adherence support	OIG is not adopting this suggestion. We continue to have concerns about the offer of remuneration to Federal health care program enrollees through these programs, which raises

[5] Id. at 77,737.

to encourage patients to manage and follow their treatment plans.	many of the traditional fraud and abuse risks under the Federal anti-kickback statute (e.g., patient steering). We may consider this topic in future rulemaking.
New safe harbor to protect in-kind remuneration to patients in the form of free or low-cost equipment or access to software platforms used for purposes such as data analytics or telehealth.	OIG is not adopting this suggestion. We believe that existing regulations, including the safe harbor for arrangements for patient engagement and support to improve quality, health outcomes, and efficiency at 42 CFR § 1001.952(hh), provide sufficient regulatory flexibility for in-kind remuneration to patients in the form of equipment or access to software platforms.
New safe harbor for the waiver or offset of cost-sharing obligations for items and services provided in connection with value-based arrangements for care management or remote patient monitoring.	OIG has repeatedly expressed concerns regarding routine waivers of Medicare cost-sharing amounts for reasons unrelated to individualized, good faith assessments of financial hardship. Accordingly, we decline to adopt this suggestion.
New safe harbor to protect patient cost-sharing assistance for drugs, including in situations where no alternative product is offered.	OIG is not adopting this suggestion. The offer of cost-sharing assistance for a product, particularly by the manufacturer of such product (either directly or indirectly), may present many of the traditional risks of fraud and abuse that the Federal anti-kickback statute is designed to prevent.
New safe harbors to protect remuneration to transition certain patients to clinically appropriate, lower-cost care settings, from: (i) hospitals to post-acute care providers; and (ii) inpatient mental health facilities to an entity that is a Program of All-Inclusive Care for the Elderly ("PACE") provider.	OIG is not adopting these suggestions. We believe that existing regulations, including new and modified safe harbors that were finalized in the 2020 OIG Rulemaking, 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 Federal health care programs. We may consider this topic in future rulemaking.
New safe harbor for de minimis remuneration between referral sources.	OIG is not adopting this suggestion. Depending on the facts and circumstances, remuneration between referral sources of any amount can violate the Federal anti-kickback statute and raise many of the traditional fraud and abuse risks that the Federal anti-kickback statute is designed to prevent.