Department of Health and Human Services

Office of Inspector General

Semiannual Report to Congress

October 1, 2022–March 31, 2023

A Message From Christi A. Grimm, Inspector General

I am pleased to submit this *Semiannual Report to Congress* summarizing the activities of the Department of Health and Human Services (HHS), Office of Inspector General (OIG) for the 6-month period ending on March 31, 2023.

HHS-OIG's oversight portfolio is vital, vast, and varied. We are responsible for oversight of more than $2.4 trillion in HHS expenditures and more than 100 health and human services programs. HHS is the Federal Government's largest grant-making agency and the fourth largest contracting agency, with obligations in the hundreds of billions of dollars in grants and tens of billions of dollars in total contracts each year. OIG provides independent, objective oversight of these substantial taxpayer investments to ensure sound fiscal management; prevent fraud, waste, and abuse; enhance transparency; and promote the delivery of high-quality health and human services.

During this reporting period, HHS-OIG's law enforcement arm continued as a formidable force in combating fraud and abuse and protecting patients from harm. OIG and its partners pursued a multi-State, coordinated law enforcement action to apprehend individuals engaged in a brazen scheme to sell more than 7,600 false and fraudulent nursing degree diplomas and transcripts. Further, across the Nation, our investigators worked with Federal and State law enforcement partners to bring to justice perpetrators of detrimental kickback, false billing, and other schemes, including an alarming scheme involving unnecessary prescriptions for opioids. Another disturbing case cataloged in this *Semiannual Report* resulted in a 20-year prison sentence for the medical director of a drug and alcohol addiction treatment facility involved in a $746 million, multiyear scheme to bill for fraudulent tests and treatments. HHS-OIG remains resolute in our commitment to aggressively combat fraud and hold wrongdoers accountable.

This *Semiannual Report* reflects HHS-OIG's critical oversight of the nearly $130 billion in HHS grants awarded each year. In January 2023, HHS-OIG released a report that examined the monitoring of research grants by the National Institutes of Health and EcoHealth Alliance. This work elucidated complex grants oversight issues and underscored the importance of getting the fundamentals of grants management right, especially for risky scientific research. Also during this reporting period, OIG continued critical oversight to ensure that recipients of grant funding complied with Federal requirements. For example, OIG issued a report finding concerning gaps in the reporting of missing foster children to the National Center for Missing and Exploited Children.

As our work during this reporting period demonstrates, from protecting children to improving nursing home care to bolstering the integrity of managed care and more, HHS-OIG delivers positive results for the American people. Our capacity to shine a light on program vulnerabilities, uncover misspent funds, and undertake enforcement actions is limited only by our available resources. Notwithstanding concerted efforts by HHS-OIG and the Department—with strong support from Congress for HHS-OIG's oversight and enforcement—serious fraud, waste, and abuse continue to threaten HHS programs and the people they serve. With current resources, HHS-OIG is unable to keep pace with these threats. For example, we are

turning down 300 to 400 viable criminal and civil health care fraud cases each year due to lack of resources. Each case means unaddressed potential fraud and missed opportunities for deterrence. Currently, HHS-OIG has about 2 cents to oversee every $100 of HHS spending. The FY 2024 President's Budget requests resources for OIG that, if enacted, would substantially help address this shortfall.

Since its 1976 establishment, OIG has worked collaboratively with its partners to protect and oversee HHS programs that touch the lives of every American. The achievements of this office would not be possible without the dedication, professionalism, and adroitness of OIG's workforce. We greatly appreciate the support of Congress and the Department for independent, vigorous oversight and HHS-OIG's important work.

Christi A. Grimm
Inspector General

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Selected Acronyms and Abbreviations

ACF	Administration for Children and Families
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
NCMEC	National Center for Missing and Exploited Children
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
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
PDE	prescription drug event
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.

OIG's Top Unimplemented Recommendations

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

Top Management and Performance Challenges Facing HHS

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

OIG's Semiannual Report to Congress

OIG's *Semiannual Report to Congress* (Semiannual Report) describes OIG's work on identifying significant problems, abuses, deficiencies, remedies, and investigative outcomes relating to the administration of HHS programs and operations that were disclosed during the reporting period. In the report that follows, we present OIG expected recoveries, criminal and civil actions, and other statistics as a result of our work for the semiannual reporting period of October 1, 2022, through March 31, 2023. We also provide data for accomplishments for fiscal year (FY) 2023 to date 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

Statistic	Semiannual Reporting Period (10/1/2022–3/31/2023)
Audit Reports Issued	62
Evaluations Issued	19
Expected Audit Recoveries	$200.1 Million
Questioned Costs	$277.2 Million
Potential Savings	$0
New Audit and Evaluation Recommendations	213
Recommendations Implemented by HHS OpDivs	253
Expected Investigative Recoveries	$892.3 Million
Criminal Actions	345
Civil Actions	324
Exclusions	1,365

Results for the Semiannual Reporting Period

During this semiannual reporting period (October 1, 2022, through March 31, 2023), we issued 62 audit reports and 19 evaluation reports. Our audit work identified $200.1 million in expected recoveries, as well as $277.2 million 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). During this reporting period, OIG made 213 new audit and evaluation recommendations, which are crucial to encourage positive change in HHS programs. Meanwhile, HHS OpDivs implemented 253 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, and local law enforcement agencies—we detect, investigate, and prosecute fraud through a coordinated and data-driven approach. OIG's investigative

work led to $892.3 million in expected investigative recoveries and 345 criminal actions during this reporting period. OIG also took civil actions, such as assessing monetary penalties, against 324 individuals and entities, and excluded 1,365 individuals and entities from Federal health care programs.

OIG continues to focus on the most significant and high-risk issues in health care and human services. Our mission is to provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve. Below we highlight results from selected OIG oversight and enforcement activities from the semiannual reporting period of October 1, 2022, through March 31, 2023, organized by subject area. A comprehensive list of OIG work during the reporting period follows, and Appendices A through F provide data to meet the reporting requirements in the Inspector General Act of 1978.

Responding to the COVID-19 Pandemic and Other Emergencies

OIG has advanced four goals with respect to HHS's COVID-19 response and recovery: (1) protect people; (2) protect funds; (3) protect infrastructure; and (4) promote the effectiveness of HHS programs, now and into the future. While HHS's Public Health Emergency declaration is anticipated to end in May of 2023, these four goals will continue to drive OIG's strategic planning and mission execution in relation to COVID-19. Additional information about the OIG COVID-19 strategic plan, emerging fraud schemes, and work related to COVID-19 is available on our COVID-19 Portal.

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

- *Home Health Agencies Used Multiple Strategies To Respond to the COVID-19 Pandemic, Although Some Challenges Persist* (OEI-01-21-00110), October 2022
- *IHS Did Not Always Provide the Necessary Resources and Assistance To Help Ensure That Tribal Programs Complied With All Requirements During Early COVID-19 Vaccination Program Implementation* (A-07-21-04125), October 2022
- *During the Initial COVID-19 Response, HHS Personnel Who Interacted With Potentially Infected Passengers Had Limited Protections* (OEI-04-20-00360), October 2022
- *Early Challenges Highlight Areas for Improvement in COVID-19 Vaccination Programs* (OEI-04-21-00190), January 2023
- *Challenges With Vaccination Data Hinder State and Local Immunization Program Efforts To Combat COVID-19* (OEI-05-22-00010), January 2023

OIG continues to work with Federal partners such as DOJ to identify and criminally prosecute bad actors exploiting the COVID-19 response. For example, during this reporting period, an individual was sentenced to 3 years of probation for creating false COVID-19 vaccine records. The individual, who worked as a data entry specialist for a company providing vaccinations, created fraudulent vaccination cards and made false vaccination entries to recordkeeping systems for 14 individuals.

Leveraging Oversight To Better Protect Nursing Home Residents

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

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

Currently, OIG has 26 ongoing audits and evaluations of nursing home issues. We are continuing to monitor identified areas of concern, push for implementation of unimplemented recommendations, and issue new recommendations as problems and solutions are identified. Information about ongoing nursing home work can be found on OIG's Nursing Homes website. Significant OIG work completed during this reporting period related to protecting residents in nursing homes includes the following:

- *Long-Term Trends of Psychotropic Drug Use in Nursing Homes* (OEI-07-20-00500), November 2022
- *More Than a Thousand Nursing Homes Reached Infection Rates of 75 Percent or More in the First Year of the COVID-19 Pandemic; Better Protections Are Needed for Future Emergencies* (OEI-02-20-00491), January 2023

Promoting Program Integrity and Good Financial Stewardship in Traditional Medicare

The 2023 Medicare Trustees report projected that assets in the Part A trust fund will be depleted by 2033, adding urgency to efforts to ensure good stewardship and appropriate use of scarce Medicare funds. OIG recognizes the importance of identifying and mitigating fraud risks in the Medicare program and holding accountable those who defraud Medicare, beneficiaries, and taxpayers.

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

- *Labs With Questionably High Billing for Additional Tests Alongside COVID-19 Tests Warrant Further Scrutiny* (OEI-09-20-00510), December 2022
- *Medicare Part B Spending on Lab Tests Increased in 2021, Driven By Higher Volume of COVID-19 Tests, Genetic Tests, and Chemistry Tests* (OEI-09-22-00400), December 2022
- *Medicare Could Have Saved up to $216 Million Over 5 Years if Program Safeguards Had Prevented At-Risk Payments for Definitive Drug Testing Services* (A-09-21-03006), February 2023

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

- An owner and operator of five home health companies was sentenced to serve 30 months in Federal prison followed by 3 years of supervised release for a home health fraud scheme and was also ordered to pay $21,197,440 in restitution. From 2010 to 2015, these home health companies submitted false claims to Medicare for home health services for patients who did not need or were not provided services.
- A sales representative was sentenced to 25 months in prison and ordered to pay, along with yet-to-be-sentenced defendants, a total of $2,954,585.90 for a kickback scheme. The representative paid cash kickbacks to physicians in exchange for referrals and prescriptions directed to select pharmacies and clinical laboratories.

OIG uses the Civil Monetary Penalties Law (CMPL) to settle liabilities with facilities who self-disclose inappropriate billing practices. For example, during this reporting period, OIG entered into a $14,351,283.06 settlement agreement with a facility that submitted incorrect claims to Medicare for inpatient rehabilitation stays that did not meet coverage criteria.

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.

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

- A physician was sentenced to 16.5 years in prison for his role in a "shots-for-pills" scheme, whereby patients were required to receive unnecessary back injections in exchange for prescriptions of medically unnecessary opioids. These unnecessary injections and prescriptions resulted in more than $250 million in false and fraudulent claims being submitted to Medicare, Medicaid, and other health insurance programs.
- A physician was sentenced to 30 months in prison and was ordered to surrender his medical license, pay $2,163,995 in restitution, and pay a $50,000 fine for conspiring with others to increase the number of prescriptions for a specific central nervous system agent. Between October 2011 and April 2016, the physician received kickbacks for presentations, receiving $331,550 and writing 10,088 prescriptions for the drug—the highest in the country.
- A physician was sentenced to 20 years in prison for engaging in a massive multiyear scheme to bill health care benefit programs for fraudulent tests and treatments for vulnerable patients seeking treatment for drug and/or alcohol addiction. The physician, while serving as the Medical Director for the treatment facility, signed standing orders for unnecessary urinalyses and blood tests, along

with other unnecessary addiction treatments.

OIG continues to exclude entities and individuals engaging in fraud and abuse from participation in health care programs. For example, during this reporting period, OIG excluded an advanced practice nurse practitioner for a period of 45 years based on a conviction related to the distribution of controlled substances beyond the practice of medicine.

Ensuring Proper Departmental Management

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

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

- *FDA's Approach to Overseeing Online Tobacco Retailers Needs Improvement* (OEI-01-20-00241), December 2022
- *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies* (A-05-21-00025), January 2023
- *ASPR Could Improve Its Oversight of the Hospital Preparedness Program To Ensure That Crisis Standards of Care Comply With Federal Nondiscrimination Laws* (A-01-21-01502), January 2023

Promoting Integrity and Effectiveness in Medicare Advantage and Medicaid Managed Care

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

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

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

- *CMS Generally Ensured That Medicare Part C and Part D Sponsors Did Not Pay Ineligible Providers for Services to Medicare Beneficiaries* (A-02-20-01027), October 2022
- *Keystone First Should Improve Its Procedures for Reviewing Service Requests That Require Prior Authorization* (A-03-20-00201), December 2022

- *The Inability To Identify Denied Claims in Medicare Advantage Hinders Fraud Oversight* (OEI-03-21-00380), February 2023

Safeguarding Medicaid Program Integrity

Medicaid is the largest Federal health care program, with nearly 93 million individuals enrolled as of December 2022. Medicaid is administered by States per Federal requirements. The program is funded jointly by the Federal Government and States. CMS estimated Federal and State Medicaid expenditures of $734.0 billion in 2021.

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

- *Missouri Claimed Federal Medicaid Reimbursement for Tens of Millions in Consumer-Directed Personal Care Assistance Services That Did Not Comply With Federal and State Requirements* (A-07-20-03243), February 2023

Reducing Prescription Drug Spending for HHS Programs and Enrollees

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

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

- *Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Second Quarter of 2022* (OEI-03-23-00070), November 2022
- *CMS Should Bolster Its Oversight of Manufacturer-Submitted Average Sales Price Data To Ensure Accurate Part B Drug Payments* (OEI-03-21-00390), December 2022
- *Manufacturers May Need Additional Guidance To Ensure Consistent Calculations of Average Sales Prices* (OEI-BL-21-00330), December 2022
- *Technical Assistance Brief: Implementation of Inflation-Indexed Rebates for Part B Drugs* (OEI-BL-23-00170), February 2023
- *Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Third Quarter of 2022* (OEI-03-23-00080), February 2023
- *Some Skin Substitute Manufacturers Did Not Comply with New ASP Reporting Requirements* (OEI-BL-23-00010), March 2023

Ensuring Health and Safety of Vulnerable People Served by HHS

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

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

- *For Medicaid-Enrolled Children Diagnosed With Lead Toxicity in Five States, Documentation Reviewed for Diagnoses and Treatment Services Raises Concerns* (OEI-07-18-00370), December 2022
- *State Agencies Did Not Always Ensure That Children Missing From Foster Care Were Reported to the National Center for Missing and Exploited Children in Accordance With Federal Requirements* (A-07-21-06102), March 2023

Cybersecurity Protection

OIG continues to recognize cybersecurity vulnerabilities as major risks to effectively managing and safeguarding HHS's programs. Oversight of HHS's cybersecurity is being prioritized. Repeated cyberattacks focused on accessing critical information in HHS systems added urgency to the task of developing departmental cybersecurity safeguards—in addition to conducting normal operations—over the course of the COVID-19 pandemic.

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

- *FDA Should Improve Its Management of Contracts for the Acquisition of Information Technology* (A-18-21-11100), January 2023

Medicare and Medicaid Reports and Reviews

Medicare Program Reports and Reviews

Financial Management and Improper Payments

Payments Made to Providers Under the COVID-19 Accelerated and Advance Payments Program Were Generally in Compliance With the CARES Act and Other Federal Requirements (A-05-20-00053), October 2022

CMS generally made COVID-19 Accelerated and Advanced Payments (CAAP) Program payments to providers in compliance with the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) and other Federal requirements. Of the 109 providers in our sample, CMS appropriately made CAAP Program payments to all 100 providers that we randomly selected. For the nine providers under bankruptcy, CMS did not send a CAAP Program payment to six of the providers but did make a CAAP Program payment to three of the providers.

The CAAP Program payments made to the three providers under bankruptcy occurred because two Medicare Administrative Contractors (MACs) did not correctly match the provider's request against their bankruptcy databases, and one MAC did not update its bankruptcy database based on bankruptcy information that was provided by CMS prior to approving the CAAP Program payment request. For the three CAAP Program payments made to providers under bankruptcy, the MACs immediately identified their errors after the payment and recovered the improper payments.

Based on our sample, we found that CMS and its MACs generally made CAAP Program payments to providers in compliance with the CARES Act and other Federal requirements. Although the MACs erroneously approved CAAP Program payments to nine providers under bankruptcy, the MACs immediately identified their errors, stopped payments to six providers, and recovered improper payments made to the other three providers. Therefore, we do not have any recommendations.

CMS Generally Ensured That Medicare Part C and Part D Sponsors Did Not Pay Ineligible Providers for Services to Medicare Beneficiaries (A-02-20-01027), October 2022

CMS generally ensured that sponsors complied with Federal requirements for preventing payments for Medicare services to ineligible providers. However, some sponsors submitted encounter and prescription drug event (PDE) data to CMS indicating that ineligible providers rendered services

and wrote prescriptions for Medicare beneficiaries. We identified 136 Part C sponsors and 62 Part D sponsors that may have paid claims for health care services associated with ineligible providers.

The ineligible providers were able to submit these claims to plan sponsors because some sponsors may not have had effective compliance programs in place to prevent, detect, and correct noncompliance with CMS's program requirements. Also, CMS may not have adequately monitored the sponsors to ensure that their compliance programs were effective. Although Part D regulations expressly require sponsors and their pharmacy benefit managers (PBMs) to reject pharmacy claims unless they contain active and valid provider identification numbers, CMS does not have similar requirements for claims submitted to Part C sponsors. Additionally, CMS system edits did not properly work to identify all ineligible providers after sponsors submitted their encounter and PDE data to CMS. As a result, CMS used data from services associated with ineligible providers in its risk adjustment of capitation payments to the sponsors.

We make a series of recommendations for CMS to direct Part C and Part D sponsors to ensure that only eligible providers receive payments for Medicare services. We also recommend that CMS strengthen its oversight of sponsors and provider identifiers to prevent deactivated and deceased providers from receiving payments for Medicare services. CMS concurred with one of our recommendations and requested that we remove our remaining recommendations.

Medicare Improperly Paid Physicians for Co-Surgery and Assistant-at-Surgery Services That Were Billed Without the Appropriate Payment Modifiers (A-01-20-00503), November 2022

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

We recommend that CMS: (1) recover the portion of the $56,016 in Medicare Part B overpayments that are within the 4-year claim reopening period; (2) instruct the Medicare contractors to notify appropriate providers so that they can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule; (3) strengthen its system controls to detect and prevent improper payments to providers for incorrectly billed co-surgery services, assistant-at-surgery services, and duplicate services—which could have saved approximately $4.9 million during our audit period; and (4) update Medicare requirements and corresponding educational

material. CMS concurred with our recommendations and described actions that it planned to take to address them.

The Number of Beneficiaries Who Received Medicare Part B Clinical Laboratory Tests Decreased During the First 10 Months of the COVID-19 Pandemic (A-09-21-03004), November 2022

During the first 10 months of the COVID-19 pandemic (March through December 2020), the number of beneficiaries who received Medicare Part B clinical laboratory (lab) tests decreased for: (1) all lab tests and (2) lab tests associated with certain chronic medical conditions (i.e., diabetes, kidney disease, and heart disease) common among Medicare beneficiaries. From March through December in 2016, 2017, and 2018, and for the immediate pre-pandemic period (March through December 2019), the number of beneficiaries who received lab tests paid for by Medicare decreased by 1 percent or less in each year. However, for the pandemic period, the number of beneficiaries who received lab tests decreased by about 9 percent.

Our comparison of the numbers of beneficiaries who received lab tests during the pandemic and pre-pandemic periods identified, among other trends, the following: (1) The number of beneficiaries who received lab tests had the highest percentage decreases during the first 3 months of the pandemic period when compared with the same months during the pre-pandemic period; and (2) the number of beneficiaries with diabetes, kidney disease, and heart disease who received common lab tests for those conditions decreased during the pandemic period. The results of our data analysis suggest that the COVID-19 pandemic contributed to these decreases. Lab tests are important for beneficiaries with chronic medical conditions, which are associated with hospitalizations, billions of dollars in Medicare costs, and deaths.

The information in this report is provided for informational purposes only and therefore the report does not contain any recommendations.

Medicare Providers Did Not Always Comply With Federal Requirements When Billing for Advance Care Planning (A-06-20-04008), November 2022

Medicare providers that billed for advanced care planning (ACP) services in an office setting did not always comply with Federal requirements. On the basis of our sample results, we estimated that Medicare providers in an office setting were paid approximately $42.3 million for ACP services that did not comply with Federal requirements. These payments occurred because the providers did not understand the Federal requirements for billing ACP services.

We recommend that CMS educate providers on documentation and time requirements for ACP services to comply with Federal requirements. Had the requirements been followed, Medicare could have saved an estimated $42.3 million during our audit period. In addition, CMS should instruct the MACs to recoup $33,332 for ACP services paid in error for claims in our sample. Also, CMS should instruct the MACs to notify appropriate providers so that they can exercise reasonable

diligence in identifying, reporting, and returning any overpayments in accordance with the 60-day rule. Finally, CMS should establish Medicare requirements that address when it is appropriate to provide multiple ACP services for a single beneficiary and how these services should be documented when required to support the need for multiple ACP services.

CMS concurred with our first three recommendations but not our fourth recommendation. After reviewing CMS's comments, we revised our fourth recommendation to address when multiple ACP services are appropriate, and the documentation required to support the need for these services.

National Government Services, Inc., Accurately Calculated Hospice Cap Amounts but Did Not Collect All Cap Overpayments (A-06-21-08004), November 2022

National Government Services, Inc. (NGS) accurately calculated all cap amounts and collected or attempted to collect $211.3 million of the $213.4 million in total cap overpayments in accordance with CMS requirements. However, NGS did not attempt to collect the remaining $2.1 million in net lookback overpayments because of its internal policy of not pursuing lookback cap calculation amounts that were less than a set threshold.

Additionally, against CMS requirements, NGS instructed hospices to wait to submit the overpayments calculated on their cap determination notices until the hospice received a demand letter from NGS, which took an average of more than 2 months after the due date for hospices to file the cap determination notices. Of 30 judgmentally sampled hospices, 13 reported cap overpayments, totaling $8.1 million, on their cap determination notices. Nine of those 13 hospices did not remit their overpayments, totaling $6.1 million, when they filed their cap determination notices as required.

We recommend that NGS: (1) collect $2.1 million in lookback overpayments and return $22,576 in lookback refunds resulting from 2019 hospice cap calculations for lookback years, (2) discontinue its internal policy of waiving certain overpayment collections related to lookback years and start collecting all hospice cap overpayments and paying refunds in accordance with CMS requirements, and (3) change its instructions on the cap determination notices to follow the CMS requirement that hospices remit overpayments at the time they submit their cap determination notice. NGS concurred with our third recommendation but not with our first and second recommendations.

Accuracy of Risk-Adjusted Payments to Medicare Advantage Organizations

CMS makes risk-adjusted payments to Medicare Advantage organizations for which the payment level is higher 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 six audits that were designed 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. Complete recommendations and providers' responses can be found in the final reports summarized here.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross & Blue Shield of Rhode Island (H4152) Submitted to CMS (A-01-20-00500), November 2022

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that Blue Cross & Blue Shield of Rhode Island (BCBS RI) submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. As demonstrated by the errors found in our sample, BCBS RI's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements could be improved. As a result, the Hierarchical Condition Categories for these high-risk diagnosis codes were not validated. Based on our sample results, we estimated that BCBS RI received at least $4.8 million in net overpayments for 2016 and 2017.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That California Physicians' Service, Inc. (Contract H0504) Submitted to CMS (A-09-19-03001), November 2022

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that California Physicians' Service, Inc. (CPS) submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. As demonstrated by the errors in our sample, the policies and procedures that CPS used to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. On the basis of our sample results, we estimated that CPS received at least $2 million of net overpayments for these high-risk diagnosis codes for 2015 and 2016.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring of Tennessee, Inc. (Contract H4454) Submitted to CMS (A-07-19-01193), December 2022

With respect to the 10 high-risk groups covered by our audit, most of the selected diagnosis codes that Cigna-HealthSpring of Tennessee, Inc. submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. As demonstrated by the errors found in our sample, Cigna's policies and procedures to prevent, detect, and correct noncompliance with CMS's program

requirements, as mandated by Federal regulations, could be improved. On the basis of our sample results, we estimated that Cigna received at least $5.9 million in net overpayments for 2016 and 2017.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS (A-09-21-03011), March 2023

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that Geisinger Health Plan submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 224 of the 270 sampled enrollee-years, either the medical records that Geisinger provided did not support the diagnosis codes, or Geisinger could not locate the medical records to support the diagnosis codes, resulting in $566,476 of net overpayments. As demonstrated by the errors found in our sample, Geisinger's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements could be improved. On the basis of our sample results, we estimated that Geisinger received at least $6.5 million of net overpayments for 2016 and 2017. In accordance with recently updated Federal regulations, we recommend that Geisinger refund the $566,476 of net overpayments.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MCS Advantage, Inc. (Contract H5577) Submitted to CMS (A-02-20-01008), March 2023

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes for the sampled enrollee-years that MCS Advantage, Inc., submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 183 of the 280 sampled enrollee-years, the diagnosis codes were not supported in the medical records, resulting in $220,577 of net overpayments. These errors occurred because MCS's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, could be improved. On the basis of our sample results, we estimated that MCS received at least $6.2 million of net overpayments for 2016 and 2017. In accordance with recently updated Federal regulations, we recommend that MCS refund the $220,577 of net overpayments.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring Life & Health Insurance Company, Inc. (Contract H4513) Submitted to CMS (A-07-19-01192), March 2023

With respect to the nine high-risk groups covered by our audit, most of the selected diagnosis codes that Cigna-HealthSpring Life & Health Insurance Company, Inc., submitted to CMS for use in CMS's risk adjustment program did not

comply with Federal requirements. Specifically, for 200 of the 300 sampled enrollee-years, the medical records that Cigna provided did not support the diagnosis codes, resulting in $468,372 in net overpayments. As demonstrated by the errors found in our sample, Cigna's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements could be improved. On the basis of our sample results, we estimated that Cigna received at least $6.24 million in net overpayments for 2016 and 2017. In accordance with recently updated Federal regulations, we recommend that Cigna refund the $468,372 of net overpayments.

Mandated Analysis of Home Health Service Utilization From January 2016 Through March 2022 (A-05-20-00031), December 2022

We determined that, during the audit period, beneficiary utilization of home health services decreased for urban counties and rural counties in the "high utilization" and "all other" categories, while utilization in the "low population density" category remained steady. We further determined that the number of home health episodes decreased for all urban and rural county categories. Many variables during the audit period, including the COVID-19 pandemic, may have affected utilization of services. Therefore, we could not determine the cause of any changes in utilization of services during this period.

Lawmakers designed the new rural add-on methodology to provide higher add-on percentages to rural counties in the "low population density" and "all other" categories. The methodology shifted the distribution of add-on payments from the "high utilization" category to the "low population density" and "all other" categories. We originally planned to use Federal Information Processing Standards (FIPS) data to analyze utilization from January 2016 through March 2022, but we were unable to do so because the FIPS data were incomplete.

We recommend that CMS take the following steps to improve FIPS code reporting: (1) update the home health Pricer logic to check for missing and invalid FIPS codes on all home health claims and work with MACs to ensure that these claims are returned to providers for correction and (2) re-educate providers on the requirement for all home health claims to be submitted with the FIPS code for the county where the service was provided. CMS concurred with our second recommendation but not with our first recommendation.

Providers Did Not Always Comply With Federal Requirements When Claiming Medicare Bad Debts (A-07-20-02825), December 2022

Providers did not always comply with Federal requirements when claiming Medicare reimbursement for Medicare bad debts. Of the 148 Medicare bad debts in our nonstatistical sample, 86 were associated with beneficiaries whom providers had deemed indigent and for whom, therefore, no reasonable collection efforts were required. Providers did not comply with

Federal requirements when claiming 18 of the remaining 62 Medicare bad debts. We identified four additional bad debts for which the amounts that providers claimed did not reflect the amounts owed by the beneficiaries. These 22 bad debts resulted in a total of $29,787 in unallowable Medicare reimbursement. CMS inappropriately reimbursed these amounts because the MACs did not concentrate on reviewing bad debts when performing audits of cost reports during our audit period.

For our second objective, the 67 selected providers' policies and procedures for collecting from beneficiaries Medicare deductible and coinsurance amounts that providers claimed as Medicare bad debts complied with Federal requirements. These policies and procedures were similar to the providers' policies and procedures for collecting non-Medicare bad debts.

We recommend that CMS consider issuing instructions to the MACs that require or encourage more review of Medicare bad debts claimed on cost reports, such as defining thresholds beyond which individual Medicare bad debts would trigger an audit, and that direct the MACs to revise their cost report audit work plans accordingly. CMS concurred with our recommendation and stated that it would consider our findings when issuing future guidance to the MACs.

Medicare Part B Spending on Lab Tests Increased in 2021, Driven By Higher Volume of COVID-19 Tests, Genetic Tests, and Chemistry Tests (OEI-09-22-00400), December 2022

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

Medicare Improperly Paid Physicians for Epidural Steroid Injection Sessions (A-07-21-00618), March 2023

Medicare did not always pay physicians for epidural steroid injection sessions in accordance with Medicare requirements. For our audit period, Medicare improperly paid physicians $3.6 million on behalf of beneficiaries who received more epidural steroid injection sessions than were permitted by the coverage limitations in the applicable local coverage determinations. These improper payments occurred because neither CMS's oversight nor the MACs' oversight was adequate to prevent or detect improper payments for epidural steroid injection sessions.

After our audit period, all 12 MAC jurisdictions updated their local coverage determinations with revised coverage limitations that were specific to epidural steroid injections.

We recommend that CMS: (1) direct the MACs to recover the $3.6 million in improper payments; (2) instruct the MACs, based on the results of this audit, to notify appropriate physicians so that they can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule; (3) assess the effectiveness of oversight mechanisms put in place after our audit period that are specific to preventing or detecting improper payments to physicians for more than the allowed number of epidural steroid injection sessions, and modify the mechanisms if necessary; and (4) direct the MACs (or other designated entities) to review a sample of claims for injection sessions administered after our audit period but before the revised coverage limitations became effective to identify and recover any improper payments. CMS concurred with all of our recommendations and described actions that it had taken or planned to take to address them.

Medicare Improperly Paid Physicians an Estimated $30 Million for Spinal Facet-Joint Interventions (A-09-22-03006), March 2023

Medicare did not pay physicians for some spinal facet-joint interventions in accordance with Medicare requirements and guidance. Of the 120 sampled sessions, 54 complied with Medicare requirements; however, the remaining 66 sessions did not comply with 1 or more of the requirements. As a result, Medicare made improper payments to physicians in the amount of $18,084. On the basis of our sample results, we estimated that Medicare improperly paid physicians $29.6 million for facet-joint interventions for our audit period.

In addition, of the 120 sampled sessions, 43 had claim lines that were billed for at least 1 therapeutic facet-joint injection. Of these 43 sessions, 33 sessions did not meet Medicare guidance, i.e., had claim lines that should have been billed for diagnostic instead of therapeutic facet-joint injections. This improper billing did not result in improper payments because Medicare pays the same amount for diagnostic and therapeutic facet-joint injections.

We recommend that CMS direct the MACs to recover $18,084 in improper payments made to physicians for the 66 sampled sessions. We also recommend that CMS encourage the MACs to: (1) develop collaborative training programs for all of the MAC jurisdictions to use that are specific to Medicare requirements for facet-joint interventions, which could have saved an estimated $29.6 million for our audit period; and (2) develop solutions to prevent the incorrect billing of diagnostic facet-joint injections as therapeutic facet-joint injections, such as developing additional education or updating guidance on how each type of injection should be billed. The report contains one other recommendation. CMS concurred with our recommendations, noting that it will direct the MACs to recover the identified overpayments. In addition, CMS will notify the MACs of this audit so that they can determine whether additional education on proper billing is necessary.

Quality of Care, Safety, and Access

Home Health Agencies Used Multiple Strategies To Respond to the COVID-19 Pandemic, Although Some Challenges Persist (OEI-01-21-00110), October 2022

Home health agencies (HHAs) used their own strategies to help address challenges that the COVID-19 pandemic presented related to staffing and infection control, and HHAs benefited from CMS support such as regulatory flexibilities and expanded telehealth allowances, but challenges with staffing and telehealth persist. Our findings can help CMS identify how to help HHAs prepare for and respond to future emergencies, as well as to evaluate how changes to the home health landscape can better serve patients.

CMS concurred with our recommendations that CMS: (1) evaluate how HHAs are using telehealth—specifically, the types of services and the characteristics of patients who benefit from these services; (2) inform decision making and evaluate how the regulatory flexibilities it has offered in response to the COVID-19 Public Health Emergency affect the quality of home health care; and (3) in collaboration with the Administration for Strategic Preparedness and Response's (ASPR's) Technical Resources, Assistance Center, and Information Exchange, apply lessons learned from the COVID-19 pandemic to update and/or develop emergency preparedness trainings and materials for HHAs on responding to infectious disease outbreaks.

Long-Term Trends of Psychotropic Drug Use in Nursing Homes (OEI-07-20-00500), November 2022

Overall, psychotropic drug use in nursing homes was relatively constant from 2011 through 2019; about 80 percent of Medicare's long-stay nursing home residents were prescribed a psychotropic drug. While CMS focused its efforts on reducing the use of antipsychotics, the use of anticonvulsants increased. Additionally, over time the number of unsupported schizophrenia diagnoses increased and, in 2019, these diagnoses were concentrated in relatively few nursing homes. Our findings identified ways that CMS can enhance its monitoring of the use of psychotropic drugs in nursing homes.

CMS concurred with our recommendations that CMS: (1) evaluate the use of psychotropic drugs among nursing home residents to determine whether additional action is needed to ensure that use among residents is appropriate and (2) use data to identify nursing homes or nursing home characteristics that are associated with a higher use of psychotropic drugs and focus oversight on nursing homes in which trends may signal inappropriate use.

CMS did not concur with our recommendation for CMS to expand the required data elements on Medicare Part D claims to include a diagnosis code.

More Than a Thousand Nursing Homes Reached Infection Rates of 75 Percent or More in the First Year of the COVID-19 Pandemic; Better Protections Are Needed for Future Emergencies (OEI-02-20-00491), January 2023

Nursing homes had an initial surge of COVID-19 cases during the spring of 2020 and then a greater surge during the fall of that year, well after they were known to be vulnerable. More than 1,300 nursing homes had extremely high infection rates during these surges. In each of these nursing homes, 75 percent or more of the Medicare beneficiaries were diagnosed with COVID-19 or likely COVID-19 during the 2-month surge periods. These nursing homes were more common and geographically widespread during the second surge than the first, even though they were known to be vulnerable. Facilities with these extremely high infection rates experienced an average *overall* mortality rate approaching 20 percent—roughly double that of other nursing homes. Our findings indicate that significant changes are needed to protect residents and better prepare for current and future health emergencies. Moreover, our findings lend urgency to the Biden administration's recent initiative to improve safety and quality care in nursing homes.

CMS concurred with our recommendations that CMS: (1) re-examine current nursing staff requirements and revise them as necessary and (2) target nursing homes in most need of infection control intervention and provide enhanced oversight and technical assistance to these facilities as appropriate.

CMS neither concurred nor nonconcurred with our recommendation to improve how surveys identify infection control risks to nursing home residents and strengthen guidance on assessing the scope and severity of those risks.

Program Integrity

CMS Can Use OIG Audit Reports To Improve Its Oversight of Hospital Compliance (A-04-21-08084), October 2022

Of the 387 improperly paid claims identified in our previous 12 hospital compliance audits, 333 were inpatient claims that resulted in $5,260,147 in net overpayments, and 54 were outpatient claims that resulted in $53,729 in net overpayments. Of these 387 improperly paid claims, 229 were appealed at the first level; 22 were overturned. In addition, 126 claims were appealed at the second level; 6 were overturned. As a result, 359 overpayment determinations totaling $5,041,721 remained. After considering the results of the first and second levels of appeal, we determined that the total overpayments received by the 12 hospitals was $82 million. CMS has taken some actions to ensure that the recommendations in our previous 12 audits were implemented. However, CMS provided us with insufficient information regarding our recommendations to repay funds, and we could not determine whether it had implemented our recommendations. In addition, CMS provided us with insufficient information regarding our recommendations to follow

the 60-day rule; therefore, we could not ensure that our recommendations were implemented. With respect to our recommendations to strengthen internal controls, CMS acted on most but not all of these recommendations.

We make several recommendations, including that CMS: (1) continue to follow up on the overpayment recovery recommendations contained in the 12 audits and (2) improve tracking and responding on the status of claims identified in our reports as they proceed through the appeals process. CMS concurred with three of our recommendations but requested we remove two others.

Labs With Questionably High Billing for Additional Tests Alongside COVID-19 Tests Warrant Further Scrutiny (OEI-09-20-00510), December 2022

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

The Inability To Identify Denied Claims in Medicare Advantage Hinders Fraud Oversight (OEI-03-21-00380), February 2023

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

Drug Pricing and Reimbursement

Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Second Quarter of 2022 (OEI-03-23-00070), November 2022, and *Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Third Quarter of 2022* (OEI-03-23-00080), February 2023

OIG identified 7 drug codes in the second quarter of 2022 and 15 drug codes in the third quarter of 2022 that met CMS's criteria for price substitution. OIG compares average sales prices (ASPs) to average manufacturer prices every quarter and identifies Part B–covered drug codes eligible for price substitutions. If OIG finds that the ASP for a drug exceeds the average manufacturer price by a certain percentage—currently, 5 percent—the ASP-based payment amount is substituted with a lower calculated rate. This serves as a mechanism for monitoring market prices and limiting potentially excessive payment amounts. OIG provides these drug codes to CMS for its review. CMS reviews this information and determines whether to implement price substitutions that would limit excessive payments for Part B drugs.

CMS Should Bolster Its Oversight of Manufacturer-Submitted Average Sales Price Data To Ensure Accurate Part B Drug Payments (OEI-03-21-00390), December 2022

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

Manufacturers May Need Additional Guidance To Ensure Consistent Calculations of Average Sales Prices (OEI-BL-21-00330), December 2022

We identified a small number of inconsistencies in how ASPs for Medicare Part B drugs are calculated and nine specific areas for which manufacturers believe additional CMS guidance may be needed to ensure more accurate ASP calculations. The manufacturers we surveyed also expressed concerns that CMS has published comparatively fewer regulations and less overall guidance regarding the calculation of the ASPs used in Medicare compared to the average manufacturer prices and best prices used in Medicaid. As a result, manufacturers say they must rely on reasonable assumptions to a much greater extent when calculating ASP than they do with these other payment benchmarks.

CMS concurred with our recommendation that CMS actively review current guidance related to the nine areas identified in our report and determine whether additional guidance would ensure more accurate and consistent ASP calculations.

Technical Assistance Brief: Implementation of Inflation-Indexed Rebates for Part B Drugs (OEI-BL-23-00170), February 2023

On the basis of our prior oversight work, we anticipate that unless CMS takes action to remedy several administrative issues, it will face the following challenges in implementing inflation-indexed rebates for Part B drugs:

- identifying products subject to Part B rebates and
- excluding claims from Part B rebate calculations that were already subject to:
    - rebates under the Medicaid Drug Rebate Program and
    - discounts under the 340B Drug Discount Program.

We propose potential solutions to mitigate each administrative issue. This technical assistance brief contained no recommendations.

Medicare Could Have Saved up to $216 Million Over 5 Years if Program Safeguards Had Prevented At-Risk Payments for Definitive Drug Testing Services (A-09-21-03006), February 2023

From January 2016 through December 2020 (audit period), Medicare paid $704.2 million for definitive drug testing services that were at risk for noncompliance with Medicare requirements. These payments were for the definitive drug testing service with the highest reimbursement amount (procedure code G0483). These payments were made to 1,062 at-risk providers that routinely billed this procedure code and may not have been reasonable and necessary. Presumptive drug testing preceded most definitive drug testing services billed by both the at-risk and other providers, but the at-risk providers may not have always used presumptive testing to determine the number of drug classes that needed to be tested using definitive drug testing. Although the at-risk providers billed a significantly higher percentage of definitive drug testing services using procedure code G0483 than the other providers, the at-risk and other providers had similar characteristics (such as frequency of testing). This suggests that the at-risk providers may have been able to bill for definitive drug testing services using primarily procedure codes with lower reimbursement amounts, as the other providers did.

We recommend that CMS: (1) expand program safeguards to prevent and detect at-risk payments to at-risk providers for procedure code G0483; (2) review at-risk payments made to at-risk providers during and after our audit period and recover any overpayments; (3) notify appropriate providers to exercise reasonable diligence to identify, report, and return any overpayments; and (4) educate providers that received payments that did not comply with Medicare requirements. CMS

concurred with our first recommendation, did not concur with our second and third recommendations, and did not state whether it concurred with our fourth recommendation.

Medicare Part D Plan Sponsors and CMS Did Not Ensure That Transmucosal Immediate-Release Fentanyl Drugs Were Dispensed Only to Beneficiaries Who Had a Cancer Diagnosis (A-09-20-03033), February 2023

Medicare Part D plan sponsors and CMS did not ensure that all transmucosal immediate-release fentanyl (TIRF) drugs were dispensed in accordance with Medicare requirements. Medicare requires that TIRF drugs be dispensed only for the medically accepted indication of breakthrough cancer pain. For 7,552 PDEs, plan sponsors approved TIRF drugs dispensed to 810 beneficiaries who did not have a cancer diagnosis in their Medicare claims history to support a medically accepted indication for use of these drugs. As a result, plan sponsors paid $86.2 million in unallowable Part D total costs. Plan sponsors also approved 2,023 PDEs totaling $19.7 million for TIRF drugs for 176 beneficiaries whose most recent cancer diagnosis in their Medicare claims history was more than 1 year before the drugs were dispensed. Although we did not determine these PDEs to be unallowable, they were at high risk of being unallowable.

We recommend that CMS work with its plan sponsors to: (1) delete the PDEs related to the $86.2 million of unallowable Medicare Part D total costs and determine after reconciliation the impact to the Federal Government and (2) identify and delete any unallowable PDEs related to the $19.7 million of Part D total costs for beneficiaries whose most recent Medicare claim with a cancer diagnosis was for services provided more than 1 year before the TIRF drugs were dispensed, and determine the impact to the Federal Government. The report contains three other recommendations. CMS did not concur with four of our five recommendations and did not explicitly state whether it concurred with our fifth recommendation.

Some Skin Substitute Manufacturers Did Not Comply with New ASP Reporting Requirements (OEI-BL-23-00010), March 2023.

Despite new legislative requirements, CMS was unable to calculate ASP-based payment amounts in the first quarter of 2023 for 30 of 68 skin substitute billing codes because their manufacturers did not report the required ASP data. According to our analysis, Part B payment amounts would be reduced substantially if ASPs were consistently reported and used, potentially leading to tens of millions of dollars in savings each quarter. However, CMS faces several unique hurdles in implementing ASP-based reimbursement for skin substitutes. For example, because skin substitutes are not actually prescription drugs, CMS cannot employ its usual methods and data sources to corroborate manufacturer-reported data on pricing and packaging. CMS is actively considering changes to the payment methodology for skin substitutes and, in January 2023, conducted a skin substitutes Town Hall to address stakeholder concerns and discuss potential payment approaches.

Medicaid Program Reports and Reviews

Financial Management and Improper Payments

Colorado Did Not Report and Refund the Correct Federal Share of Medicaid-Related Overpayments for 70 Percent of the State's Medicaid Fraud Control Unit Cases (A-07-21-02834), October 2022

Colorado did not report and return the correct Federal share of MFCU-determined Medicaid overpayments identified during the period of October 1, 2014, through December 31, 2020. Colorado reported $5.8 million ($3.1 million Federal share) for this period but should have reported MFCU-determined Medicaid overpayments totaling $13 million ($6.8 million Federal share) for the 179 MFCU cases that we reviewed. Colorado did not report some or all of the correct Federal share for 126 cases (70 percent of the 179 MFCU cases we reviewed). Furthermore, Colorado did not correctly report to CMS MFCU-determined Medicaid overpayments related to fraud, waste, and abuse. Although Colorado had policies and procedures for the reporting of Medicaid overpayments, these policies and procedures were not always adequate.

We recommend that Colorado refund $3.7 million (Federal share) in unreported MFCU-determined Medicaid overpayments that related to paid claims and court-ordered awards that have been recovered and collected. We also recommend that Colorado determine the value of overpayments identified after our audit period that have been recovered and collected but not reported, report them to CMS, and refund the Federal share. We make additional procedural recommendations. Colorado agreed with the amount of unreported MFCU-determined Medicaid overpayments but disagreed with refunding the overpayments. Colorado said that it would review the cases to ensure that the amounts are not uncollectable and return the applicable Federal share by September 30, 2023. Colorado agreed with our other recommendations and described corrective actions.

California Made Almost $16 Million in Unallowable Capitation Payments for Beneficiaries With Multiple Client Index Numbers (A-04-21-07097), October 2022

California made unallowable capitation payments on behalf of Medicaid beneficiaries with multiple Client Index Numbers (CINs). Of the 100 beneficiary matches in our sample, California correctly made capitation payments on behalf of individuals associated with 24 beneficiary matches. However, it incorrectly made capitation payments that totaled $657,057 ($328,529 Federal share) on behalf of individuals associated with the remaining 76 matches. The unallowable capitation payments occurred because the associated beneficiaries had multiple Medicaid CINs. According to California, human error caused it to assign multiple CINs to these beneficiaries. In addition, California used an algorithm to create the Beneficiary Name and Date of Birth Match Report that was too broad and did not require county staff to review training materials. We estimated that

California made unallowable capitation payments totaling approximately $31.4 million ($15.7 million Federal share) on behalf of beneficiaries with multiple CINs.

We recommend that California: (1) refund to the Federal Government approximately $15.7 million in unallowable payments, (2) review capitation payments that fell outside of our audit period and refund any unallowable payments, (3) ensure that the algorithm used to create its revised Beneficiary Name and Date of Birth Match Reports is effective at detecting individuals with multiple records, (4) require county staff to review training materials on the prevention of issuing multiple CINs, and (5) enhance its controls to ensure that no beneficiary is issued multiple CINs. California concurred with our recommendations and described the corrective actions that it has taken or plans to take.

Iowa Implemented Most of Our Prior Audit Recommendations and Generally Complied With Federal and State Requirements for Reporting and Monitoring Major Incidents (A-07-21-06105), November 2022

Iowa implemented the nine recommendations from our prior audit and generally complied with Federal and State requirements for reporting and monitoring critical incidents involving Medicaid members with developmental disabilities residing in group homes. However, Iowa's corrective actions for one recommendation in our prior audit were not completely effective in addressing the associated finding. Iowa did not ensure that community-based providers properly reported all major incidents involving members in waiver programs to the State. Although Iowa achieved significant progress since our prior audit, its internal controls did not ensure that providers properly reported all major incidents because the State did not periodically update the diagnosis code list it used to identify Medicaid claims involving major incidents.

We recommend that Iowa continue to strengthen internal controls to ensure full compliance with Federal and State requirements, to include periodically updating the list of diagnosis codes used when reviewing the Medicaid emergency room claims data to ensure that all Critical Incident Reports for major incidents are submitted as required. Iowa concurred with our findings, agreed with our recommendation, described corrective actions that it has taken or plans to take, and projected the completion dates for the corrective actions.

Puerto Rico MMIS and E&E Systems Security Controls Were Generally Effective, but Some Improvements Are Needed (A-18-20-08005), November 2022

The Puerto Rico Medicaid Management Information System (MMIS) and Eligibility and Enrollment (E&E) system had reasonable security controls 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. Puerto Rico did not correctly implement five security controls required by the National Institute of Standards and Technology (NIST) Special Publication (SP) 800-53, Revision 4. We estimated that the level of sophistication required by an adversary to

compromise the Puerto Rico MMIS and E&E system was significant. Still, some improvements were needed in Puerto Rico detection controls to better identify cyberattacks against its MMIS and E&E system and respond appropriately. Potential reasons why Puerto Rico did not implement these security controls correctly may be that software developers did not follow secure coding standards to prevent security vulnerabilities or system administrators were not aware of Government standards or industry best practices that require securely configuring systems before deployment to production. Puerto Rico's procedures for periodically assessing the implementation of the NIST security controls were not effective.

We recommend that Puerto Rico: (1) remediate the vulnerabilities related to the five security control findings identified by properly implementing and regularly assessing the associated NIST SP 800-53 controls and (2) assess the cryptographic configurations of public servers at least annually and adjust if the requirements have changed. Puerto Rico concurred with our recommendations and stated that it has addressed and remediated our findings.

The Centers for Medicare & Medicaid Services' Review Contractors Generally Conducted Medicaid Fee-for-Service Claim Reviews for Selected States Under the Payment Error Rate Measurement Program in Accordance with Federal and State Requirements (A-04-21-00132), November 2022

CMS's contractors generally conducted Medicaid fee-for-service (FFS) reviews in accordance with Federal and State requirements. Of the 100 sampled Medicaid Payment Error Rate Measurement FFS claims we reviewed, 90 claims were correctly determined and adequately documented. However, claim review determinations for the remaining 10 claims were not documented and therefore may be incorrect. Based on our sample results, we estimated that 10 percent of the sampled Medicaid FFS claims reviewed by CMS's contractors were not documented, and claim review determinations for these claims may not have been correct. We also estimated the total amount paid related to these claims to be $6,411 (Federal share) during our audit period.

CMS's contractors did not always maintain documentation of their claim review determinations because CMS did not include specific contract language requiring its contractors to maintain all documentation to support the contractors' Medicaid FFS claim review determinations for non-error claims.

We are not making recommendations because CMS took action to address the deficiencies we identified.

Illinois Generally Complied With Requirements for Claiming Medicaid Reimbursement for Telehealth Payments During COVID-19 (A-05-21-00035), December 2022

Illinois generally made telehealth payments that were in accordance with Federal and State requirements. Of the 584,492 Medicaid FFS telehealth payments in our population, 583,960 payments were in compliance with the requirements, but the remaining 532 payments were not.

For 249 payments not in compliance, the same provider was paid both the originating site fee and the distant site fee. Additionally, there were 146 payments made as duplicate payments for the same services provided to the same recipient on the same day. Also, 22 of the payments were inaccurately billed as both originating and distant site fees. Finally, providers incorrectly used the telehealth modifier with 35 different procedure codes that are for in-person services. A total of 115 telehealth payments were identified with these codes that could not be performed via telecommunication systems. This noncompliance occurred because the State agency did not adequately monitor compliance. The State agency also did not establish a list of acceptable telehealth procedure codes. Based on our testing, we calculated that the unallowable payments totaled approximately $16,154 ($9,832 Federal share) during our audit period.

We recommend that Illinois: (1) refund up to $9,832 to the Federal Government and enhance the monitoring of provider compliance by conducting periodic reviews of telehealth payments for compliance with requirements and (2) establish a list of acceptable telehealth procedure codes. Illinois agreed with our findings and provided information on actions that it plans to take to address our recommendations.

The Centers for Medicare & Medicaid Services' Review Contractor Did Not Document Medicaid Managed Care Payment Review Determinations Made Under the Payment Error Rate Measurement Program (A-04-21-09003), December 2022

CMS's review contractor conducted the majority of its Medicaid managed care payment reviews in accordance with Federal requirements. Of the 100 sampled Medicaid managed care payments we reviewed, 60 were correctly determined. However, we were not able to determine whether the remaining 40 payment review determinations were correct because the payment reviews were not documented and therefore may be incorrect. Based on the sample results, we estimated 40 percent of the sampled Medicaid managed care payment determinations made by CMS's review contractor may not have been correct. We also estimated the total amount related to these 40 claims to be $229,435 ($123,520 Federal share) during our audit period. CMS's review contractor did not maintain documentation of its payment review determinations because CMS did not include specific contract and statement-of-work language requiring its review contractor to maintain all documentation to support its Medicaid managed care payment review determinations for non-errors.

We are not making recommendations because CMS took action to address the deficiencies we identified. Specifically, after our audit period, for the reporting year 2020, 2021, and 2022 Payment Error Rate Measurement cycles, CMS exercised an optional task for the contract with the review contractor, which added language requiring that the review contractor maintain relevant documentation for non-error (i.e., correct) payments. In its contract renewal occurring in March 2021, CMS replaced the optional task with a permanent requirement for the review contractor to maintain relevant documentation for non-error payments.

Missouri Claimed Federal Medicaid Reimbursement for Tens of Millions in Consumer-Directed Personal Care Assistance Services That Did Not Comply With Federal and State Requirements (A-07-20-03243), February 2023

Missouri did not always ensure that the consumer-directed personal care assistance (PCA) services for which it claimed Federal Medicaid reimbursement during FYs 2018 and 2019 complied with Federal and State requirements. Specifically, 17 of the 150 sampled items were at least partially unallowable. Based on our sample results, we estimated that Missouri claimed at least $52.5 million ($34.2 million Federal share) for unallowable consumer-directed PCA services during FYs 2018 and 2019. In addition, timesheets for 46 of the 150 sampled items did not identify the specific services that were performed in accordance with the plans of care. We are setting aside an estimated $133.8 million ($87 million Federal share) for CMS resolution associated with these 46 items.

Additionally, Missouri did not have established and implemented pandemic emergency preparedness standards and protocols within the consumer-directed PCA program. Most providers for the sampled items did not have any emergency preparedness documentation for a pandemic response.

We recommend that Missouri: (1) refund the $34.2 million (Federal share) in overpayments to the Federal Government and (2) work with CMS to determine the allowability of the $87 million (Federal share) and refund any amount that is determined to be unallowable. We also make procedural recommendations. Missouri disagreed with most of our findings and recommendations and gave us additional documentation. We revised the number of sampled items in error, revised our statistical estimate and the amount conveyed in our first recommendation, and removed one procedural recommendation for this final report.

Florida Made Capitation Payments for Enrollees Who Were Concurrently Enrolled in a Medicaid Managed Care Program in Another State (A-05-21-00028), February 2023

Florida made August 2020 Medicaid managed care capitation payments totaling $15.8 million on behalf of 55,164 enrollees who were concurrently enrolled for Medicaid benefits in another State. Of the 100 enrollees in our stratified random sample, we determined that 56 enrollees were residing and enrolled for Medicaid benefits in Florida. However, Florida made August 2020 capitation payments totaling $22,624 ($15,336 Federal share) on behalf of 44 Florida 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 Florida incurred costs of $6.9 million ($4.7 million Federal share) for August 2020 capitation payments made on behalf of enrollees who were residing and concurrently enrolled in another State.

We recommend that Florida: (1) resume and enhance procedures that are in accordance with Federal requirements and the State's unwinding plan to identify and disenroll enrollees who are residing and enrolled in Medicaid managed care in another State when the Public Health Emergency ends and (2) work with CMS to consider the potential use of CMS's Transformed Medicaid Statistical Information System data to identify potential cases of concurrent enrollment. In written comments on our draft report, Florida concurred with our recommendations and described the actions that it plans to take to address them.

Quality of Care, Safety, and Access

For Medicaid-Enrolled Children Diagnosed With Lead Toxicity in Five States, Documentation Reviewed for Diagnoses and Treatment Services Raises Concerns (OEI-07-18-00370),December 2022

In five States, most of the medical records that our study reviewed for children with a lead toxicity diagnosis in their Medicaid claims lacked adequate information to confirm a diagnosis of lead toxicity, and among children for whom there was sufficient medical record documentation to confirm their diagnosis, many did not receive comprehensive followup testing and treatment services, as recommended, for their identified blood lead level. Our findings can help CMS address concerns related to oversight of the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program and ensure that Medicaid-enrolled children with lead toxicity are given the best possible health care. CMS concurred with our recommendations that CMS: (1) explore the discrepancy between Medicaid claims data and medical documentation for lead toxicity and implement solutions to ensure better oversight of the EPSDT program and (2) issue guidance to reiterate State obligations under the EPSDT benefit to ensure access to services to correct or ameliorate confirmed blood lead levels identified during screenings.

Keystone First Should Improve Its Procedures for Reviewing Service Requests That Require Prior Authorization (A-03-20-00201), December 2022

Keystone First did not comply with Federal and State requirements when denying 76 of the denied service requests in our sample. Specifically, Keystone First should not have denied the overnight care portion of 10 denied pediatric skilled nursing service requests on the basis that it had not received work or school verification documentation for the caregiver. For 72 denied service requests, Keystone First's denial letter, based on Pennsylvania's required form, did not inform beneficiaries of their right to request a State fair hearing after exhausting the managed care organization's (MCO's) appeals process.

We recommend that Keystone First coordinate with Pennsylvania to: (1) update Keystone First's administrative process to require that medical directors assess whether overnight care requests meet the medical necessity requirement, even if some documentation is missing; (2) review all pediatric skilled nursing service requests for which overnight care was completely denied and determine whether overnight care requests meet the medical necessity requirement; and (3)

implement a revised initial denial notice to explain that a beneficiary has the right to request a State fair hearing after exhausting the MCO's appeals process. We also recommend that Pennsylvania revise its denial notice template. In written comments on our draft report, Keystone First stated that it concurred with the intent of all three recommendations addressed to it. Pennsylvania also concurred with the recommendation addressed to it and concurred with the first and third recommendations addressed to Keystone First but did not concur with the second recommendation due, in part, to a COVID-19 waiver.

Drug Spending and Reimbursement

During this reporting period, OIG conducted a number of audits that were designed to assess whether States properly billed manufacturers for physician-administered drugs. Prior OIG reviews and investigations have identified areas at risk for noncompliance with Medicaid billing requirements. Complete recommendations and State responses can be found in the final reports summarized here.

Mississippi Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs (A-07-21-06101), October 2022

Mississippi did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Mississippi did not invoice for or collect from manufacturers rebates associated with $2.2 million (Federal share) in physician-administered drugs. Of this amount, $820,732 (Federal share) was for single-source drugs and $395,621 (Federal share) was for top-20 multiple-source drugs.

Further, we were unable to determine whether Mississippi was required to invoice for rebates associated with $1 million (Federal share) for other multiple-source physician-administered drug claims. In addition, Mississippi did not invoice for or collect from manufacturers $35.6 million (Federal share) in rebates for physician-administered drugs invoiced on crossover claims, for which beneficiaries are eligible for both Medicare and Medicaid. Mississippi's internal controls did not always ensure that the drug utilization data it collected were used to invoice manufacturers and collect rebates.

North Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs (A-07-21-07002), February 2023

North Carolina did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. North Carolina did not invoice for or collect from manufacturers rebates associated with $3.1 million (Federal share) in physician-administered drugs. Of this amount, $2.3

million (Federal share) was for single-source drugs and $734,000 (Federal share) was for top-20 multiple-source drugs.

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

Florida Did Not Invoice Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations (A-04-21-07098), March 2023

Florida generally complied with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees. However, Florida did not invoice for or collect from manufacturers an estimated $57,700 ($35,126 Federal share) in rebates for single-source physician-administered drugs. Furthermore, we were unable to determine whether, in some cases, Florida was required to invoice for rebates for other multiple-source physician-administered drug claims. Florida did not invoice manufacturers for rebates totaling $40,635 ($24,772 Federal share) for these multiple-source drugs.

Georgia Did Not Always Invoice Rebates to Manufacturers for Pharmacy and Physician-Administered Drugs (A-04-21-08089), March 2023

Georgia did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for pharmacy and physician-administered drugs. Georgia did not invoice for or collect from manufacturers rebates associated with $953,067 ($644,802 Federal share) in single-source physician-administered drug claims and $13,785 ($9,325 Federal share) in top-20 multiple-source physician-administered drug claims. Further, we were unable to determine whether, in some cases, Georgia was required to invoice for rebates for other multiple-source physician-administered drug claims. Georgia did not invoice the manufacturers for rebates associated with the claims totaling $78,013 ($52,837 Federal share) for these multiple-source drugs. Additionally, OIG identified $1.8 million ($1.2 million Federal share) in single-source pharmacy drug claims and $526,240 ($360,454 Federal share) in multiple-source pharmacy drug claims that were not rebated for prior to our audit.

The District of Columbia Has Taken Significant Steps To Ensure Accountability Over Amounts Managed Care Organizations Paid to Pharmacy Benefit Managers (A-03-20-00200), March 2023

The District of Columbia provided some oversight of its MCOs with the intent of ensuring adequate accountability over amounts paid for prescription benefits to its PBMs. This oversight consisted of guidance requiring MCOs to report spread pricing. However, the amounts reported were aggregated with other amounts and as a result did not provide transparency over the amount of the funds that was attributable to spread pricing. We found that PBMs kept $23.3 million in spread pricing during our audit period. Spread pricing may increase the cost of Medicaid prescriptions for both the MCO and the Medicaid program and, if not correctly accounted for, inflate the cost of the drugs. Limiting spread pricing may decrease Federal and State spending through lower payments to MCOs.

We recommend that the District develop policies and procedures for validating MCO, PBM, and pharmacy transactions on a periodic basis to ensure transparency of costs associated with the prescription drug program. The District concurred with our recommendation and asked for clarification and guidance regarding the amounts or percentages that are deemed appropriate for PBMs to retain under the practice of spread pricing.

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/or negotiated settlement agreements. Investigative outcomes take many forms, including incarceration, restitution, fines, penalties, forfeitures, assessments, and exclusion of individuals or entities from participation in all Federal health care programs. Frequently used exclusion and penalty authorities are described on our Enforcement Actions website.

During this semiannual reporting period, we reported 318 criminal and 318 civil actions against individuals or entities that engaged in offenses related to health care. We also reported more than $626.8 million in investigative receivables due to HHS and more than $207 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:

Connecticut – On November 4, 2022, Zaya Powell, of Waterbury, was sentenced to 3 years of probation for creating false COVID-19 vaccine records for several individuals. Judge Meyer also ordered Powell to pay a $5,000 fine and perform 200 hours of community service. Between August and October 2021, Powell created fraudulent vaccination records in the Vaccine Administration Management System for 14 different individuals. The fraudulent cards included lot numbers of genuine vaccines that were administered to other patients.

Home Health

The following case example involves home health fraud:

Texas – On October 31, 2022, Felix Amos, of Houston, was sentenced to serve 30 months in Federal prison followed by 3 years of supervised release for conspiracy to commit health care fraud. He was further ordered to pay $21,197,440 in restitution. Oluyemisi Amos (Felix Amos's wife), 41, of Houston, previously pled guilty and later received a sentence of 72 months in prison. In addition, on March 22, a jury returned guilty verdicts against Fausat Adekunle, 39, of Richmond, on 10 counts following a 4-day jury trial. Adekunle was later ordered to serve 144 months in Federal prison to be immediately followed by 3 years of supervised release, and to pay restitution of $21,197,440.14. Evidence and testimony revealed that the three conspired to submit claims to Medicare for home health services for patients who did not need services or did not receive services and for whom physicians had not ordered such services. Furthermore, billing emails showed that many of the claims Adekunle submitted were for Medicare beneficiaries who were dead for more than 3 years or incarcerated in prison and were thus not eligible for home health services.

Substance Use Disorder Treatment

The following case example involves a treatment facility:

Florida – On January 9, 2023, Michael Ligotti was sentenced to 20 years in prison for engaging in a massive multiyear scheme to bill health care benefit programs for fraudulent tests and treatments for vulnerable patients seeking treatment for drug and/or alcohol addiction. This case was brought as part of DOJ's Sober Homes Initiative. According to court documents, Ligotti, D.O., of Delray Beach, served as Medical Director or Authorizing Physician for more than 50 sober homes, substance use disorder treatment facilities, and clinical testing laboratories in the Palm Beach County area, often signing standing orders for expensive, medically unnecessary urine drug tests for patients at various addiction

treatment facilities. As a result of this conduct, which took place from 2011 to 2020, health care benefit programs were billed more than $746 million and paid approximately $127 million for fraudulent urine drug tests and addiction treatments. Ligotti pled guilty to conspiracy to commit health care and wire fraud in the Southern District of Florida in October 2022 and was ordered at sentencing to surrender his medical license.

Prescription Drugs

The following case examples involve prescription drugs:

Michigan – On January 30, 2023, Francisco Patino, M.D., was sentenced to 16.5 years in prison for his role in a health care fraud scheme that resulted in more than $250 million in false and fraudulent claims being submitted to Medicare, Medicaid, and other health insurance programs. Patino exploited patients suffering from addiction by administering unnecessary injections, illegally distributed more than 6.6 million doses of medically unnecessary opioids, and engaged in money laundering. Patino played a critical role in developing and implementing a "shots-for-pills" protocol at several pain clinics, whereby patients were required to receive unnecessary back injections in exchange for prescriptions for high doses of medically unnecessary and addictive opioids. In September 2021, Patino was convicted at trial in the Eastern District of Michigan of conspiracy to commit health care fraud and wire fraud, health care fraud, conspiracy to defraud the United States and pay and receive health care kickbacks, conspiracy to commit money laundering, and money laundering.

Pennsylvania – On January 19, 2023, Larry J. Goisse, Jr., was sentenced to 24 months in prison to be followed by 3 years of supervised release on charges of drug diversion and health care fraud. On October 4, 2022, Goisse pled guilty to one count of an indictment charging him with drug diversion and five counts of an information charging him with health care fraud.

In connection with the guilty plea, the court was advised that in September 2018 through January 2019, Goisse, a former certified nurse practitioner, illegally prescribed the scheduled drug Adderall after his State medical license was revoked and he lost his Drug Enforcement Administration registration. In order to continue to receive payments from Medicare, Goisse submitted claims to Medicare for office visits under a coworker's license after suspension.

Kickbacks

The following case examples involve kickbacks:

Florida – On November 1, 2022, Modernizing Medicine, Inc. (ModMed), an electronic health record (EHR) technology vendor located in Boca Raton, Florida, agreed to pay $45 million to resolve allegations that it violated the False Claims Act by accepting and providing unlawful remuneration in exchange for referrals and by causing its users to report inaccurate information in connection with claims for Federal incentive payments. In a complaint filed in conjunction with the settlement, the United States alleged that ModMed violated the False Claims Act and the anti-kickback statute through three marketing programs. First, ModMed solicited and received kickbacks from Miraca Life Sciences, Inc. (Miraca) in exchange for recommending and arranging for ModMed's users to utilize Miraca's pathology lab services. Second, ModMed conspired with Miraca to improperly donate ModMed's EHR to health care providers in an effort to increase lab orders to Miraca and simultaneously add customers to ModMed's user base. Third, ModMed paid kickbacks to its current health care provider customers and to other influential sources in the health care industry to recommend ModMed's EHR and refer potential customers to ModMed. As a result of this conduct, the Government alleged that ModMed improperly generated sales for itself and for Miraca, while causing health care providers to submit false claims for reimbursement to the Federal Government for pathology services and for incentive payments from HHS for the adoption and "meaningful use" of ModMed's EHR technology. In January 2019, Miraca (known as Inform Diagnostics as of 2018) agreed to pay $63.5 million to resolve allegations that it violated the anti-kickback statute and the physician self-referral law (Stark Law) by providing referring physicians with subsidies for EHR systems and free or discounted technology consulting services.

Massachusetts – On January 20, 2023, DePuy Synthes, Inc. (DePuy), a subsidiary of Johnson & Johnson, agreed to pay $9.75 million to resolve allegations that it violated the False Claims Act by paying kickbacks to an orthopedic surgeon based in Massachusetts to induce the use of DePuy products. DePuy violated the anti-kickback statute and caused the submission of false or fraudulent claims to Medicare by paying the orthopedic surgeon kickbacks in the form of free spinal implants and tools for use in surgeries that the surgeon performed overseas to induce that surgeon to use DePuy products in surgeries performed in the United States. DePuy has admitted that from at least July 2013 through February 2018, DePuy, acting through certain former sales representatives, gave the Massachusetts surgeon thousands of dollars' worth of free DePuy implants and instruments, including cages, rods, screws, plates, and surgical instrumentation, that the surgeon used to perform surgeries overseas for patients who were not Federal health care beneficiaries. Of the $9.75 million to be paid by DePuy, approximately $7.23 million will be returned to the Federal Government, and approximately $2.52 million will be returned to Massachusetts, which jointly funded claims for surgeries involving DePuy devices that were submitted to the Massachusetts Medicaid program.

New York – On December 1, 2022, two New York diagnostic testing facility owners were sentenced to 3 years in prison for their roles in a more than $18 million health care fraud

scheme. According to court documents, Tea Kaganovich, 50, and Ramazi Mitaishvili, 62, both of Brooklyn, are a married couple that co-owned several diagnostic testing facilities in Brooklyn. The couple paid more than $18 million in kickbacks for the referral of beneficiaries who submitted themselves to diagnostic testing and other purported medical services. Kaganovich and Mitaishvili also falsely reported to the Internal Revenue Service that the illegal kickback payments were legitimate business expenses and therefore submitted tax forms that underreported business income and claimed deductions to which they were not entitled.

Ohio – On February 3, 2023, Deepak Raheja, of Hudson, was sentenced to 30 months in prison and ordered to surrender his medical license, pay $2,163,995 in restitution, and pay a $50,000 fine. Between February 2011 and July 2016, Raheja and co-defendants Frank Mazzucco, Gregory Hayslette, and Bhupinder Sawhny conspired together to increase the number of prescriptions that Raheja and Sawhny wrote for Nuedexta, a prescription drug that treats pseudobulbar affect (PBA), in exchange for the payment of monetary kickbacks and other items of value. Mazzucco and Hayslette were employed as pharmaceutical sales representatives by Avanir Pharmaceuticals (Avanir) in the region where Raheja and Sawhny practiced medicine. Avanir promoted Nuedexta through a speaker's bureau, under which Avanir representatives engaged doctors to speak about and promote Nuedexta to other medical professionals. Raheja received approximately $1,500 for each of these purported presentations. During this timeframe, Raheja received approximately $331,550 in payments from Avanir and wrote approximately 10,088 Nuedexta prescriptions—the highest in the country. Raheja and Sawhny took steps in return, including writing more Nuedexta prescriptions, which caused the submission of bills to Medicare and Medicaid for Nuedexta prescriptions for patients that did not have PBA, falsely diagnosing patients with PBA, and recording fictitious symptoms in patient records to support a diagnosis of PBA.

Texas – On November 23, 2022, Lindell King and Ynedra Diggs were sentenced for a $1 million Medicare fraud scheme, including violations of the Federal anti-kickback statute. King, of Missouri City, was sentenced to 60 months in prison. Diggs, also of Missouri City, was sentenced to 70 months in prison. King and Diggs were also ordered to pay $537,992.55 in restitution. According to court documents and evidence presented at trial, both Diggs and King were patient recruiters who owned and operated group homes in which Medicare beneficiaries lived. In exchange for sending their group home residents to Behavioral Medicine of Houston (BMH), a community mental health center that purported to provide partial hospitalization services, BMH paid Diggs, King, and other patient recruiters illegal kickbacks in cash and by check, often concealed as payment for "transportation" or other sham services. During the conspiracy, BMH fraudulently billed approximately $1 million to Medicare in claims related to patients it received in exchange for the kickbacks paid to Diggs and King.

Nursing Homes

The following case example involves a nursing home:

California – On November 29, 2022, Tranquility Incorporated, a corporation doing business as San Miguel Villa, a 190-bed nursing home located in Concord, agreed to pay $2.3 million to settle allegations that it submitted false claims by billing the Medicare and Medi-Cal programs for substandard nursing home services. The settlement resolves allegations that from 2012 to 2017 San Miguel Villa submitted, or caused to be submitted, claims to the Medicare and Medi-Cal programs for payment of its services that were grossly substandard and failed to meet minimum required standards of skilled nursing care in multiple ways. The United States alleges that nursing home residents at San Miguel Villa were overmedicated with psychotropic drugs, suffered excessive falls, were exposed to resident-on-resident altercations, and experienced other mental and physical harm.

Durable Medical Equipment

The following case example involves durable medical equipment:

Illinois – On January 4, 2023, Jet Medical, Inc. (Jet) agreed to pay $200,000 to resolve criminal allegations relating to a migraine headache treatment device, and Jet and two related companies agreed to pay another $545,000 in a civil settlement involving the same device. Between April 2014 and April 2019, Jet introduced into interstate commerce devices that were misbranded under the Federal Food, Drug, and Cosmetic Act because Jet did not obtain approval or clearance from the Food and Drug Administration (FDA) prior to distributing the devices. Jet's device, the Allevio SPG Nerve Block Catheter (Allevio), was intended to treat migraine headaches by administering nerve blocks to the sphenopalatine ganglion (SPG), a collection of nerves located deep in the midface of the skull. The information alleges that Jet never sought approval or clearance from FDA to distribute the Allevio for this intended use, nor did Jet conduct an investigational study regarding the Allevio's safety and effectiveness when used as intended.

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 97 individuals or entities, 98 criminal actions, and more than $239 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 examples involve Strike Force cases:

Maryland – On November 18, 2022, Edward T. Buford, III, was sentenced to 30 months in Federal prison followed by 3 years of supervised release for conspiracy to commit mail fraud and health care fraud. Buford was also ordered to pay $1,267,630 in restitution. Buford was a licensed dentist in Washington, DC and the owner and Chief Executive Officer of International Dental Associates, Inc. (IDA), a dental clinic located in Washington, DC. According to his guilty plea, from January 2013 to May 2018, Buford led a scheme to file fraudulent Medicaid claims for dental services to Medicaid beneficiaries and recruited Medicaid beneficiaries to fuel the scheme through the payment of kickbacks and bribes. Buford caused the submission of Medicaid claims for a variety of dental services, including dentures. As part of the conspiracy, Buford paid kickbacks to patient recruiters in exchange for referring Medicaid beneficiaries to IDA for dental services. Buford stored hundreds of undelivered dentures on IDA's premises, many of which had been billed to and paid for by Medicaid. As part of the scheme, Buford maintained a post office box in Silver Spring, Maryland as IDA's billing address and received the fraudulently obtained payments at that location. This was a joint investigation with the FBI, the Social Security Administration-OIG, and the MFCU.

Mississippi – On October 18, 2022, sales representative Logan Power was sentenced to 25 months in prison and ordered to pay a total of $2,954,585.90 in restitution jointly with other yet-to-be-sentenced defendants. Power worked as a sales representative for a pharmacy in Baton Rouge, Louisiana that dispensed "foot bath" medications, as well as a laboratory in Glen Allen, Virginia that performed expensive genetic testing on toenail samples. Power was paid kickbacks for steering referrals and prescriptions from podiatrists with whom he had relationships to select pharmacies and laboratories. Power then paid cash kickbacks to those podiatrists in exchange for their referrals and prescriptions. In total, Power paid approximately $133,000 in cash kickbacks to three Mississippi podiatrists: Dr. Carey Williams, Dr. Marion Lund, and Dr. Jared Spicer. In July 2020, Power was captured on video paying a cash kickback to a cooperating doctor. On October 5, 2021, Power pled guilty to one count of conspiracy to defraud the United States. In August 2022, Dr. Spicer pled guilty to one count of conspiracy to commit health care fraud, and in February 2023 he

was sentenced to 3 years of probation. In September 2022, Dr. Williams pled guilty to one count of conspiracy to commit health care fraud and is awaiting sentencing. In February 2023, Dr. Lund pled guilty to one count of conspiracy to commit health care fraud and is awaiting sentencing. This was a joint investigation with the Department of Defense OIG (DOD-OIG)/Defense Criminal Investigative Service.

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 American Indian/Alaska Native (AI/AN) communities. The training series covers topics such as compliance; fraud, waste, and abuse; and health care quality, including how OIG works with the AI/AN community to combat the opioid epidemic and to protect patients from sexual abuse. The training series includes web-based trainings, job aids, and videos, which can be accessed on OIG's 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 Fugitives website. During this semiannual reporting period, 2 fugitives were captured.

The following case examples involve a captured fugitive:

Florida – On November 16, 2022, Jeyker Herrera Felipe (Herrera), the owner of AD Pharmacy, was sentenced to 24 months in prison and 3 years of supervised release for one count of health care fraud. Herrera was also ordered to pay $615,725 in restitution plus $100 in court assessments. Herrera was indicted on October 2, 2012, in the Southern District of Florida and was charged with five counts of health care fraud. Herrera had already left the United States when HHS-OIG and FBI agents executed Herrera's arrest warrant and were unable to locate him. On March 2, 2022, Herrera was arrested entering the United States in El Paso, Texas based on the outstanding arrest and indictment from 2012. On September 13, 2022, Herrera pled guilty to one count of health care fraud; all other counts were dismissed by the United States.

Florida – On February 22, 2023, Emilio Mendez, the owner of Complete Pharmacy, was sentenced to 34 months in prison followed by 3 years of supervised release after pleading guilty to conspiracy to commit health care fraud and wire fraud. Mendez was also ordered to pay $1,779,246 in restitution and $100 in court assessments. On January 23, 2014, Mendez was indicted by a Federal Grand Jury in the Southern District of Florida on 12 counts of health care fraud for his role in submitting more than $1.7 million in false claims to Medicare. After the indictment, Mendez fled to Cuba. On July 24, 2022, Mendes was arrested in the Western District of Texas as he tried to reenter the United States.

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 $8,622,602 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	61,804
Total tips evaluated	20,347
Tips referred for action	12,576

Closed; no basis provided for further action	533
Closed; no HHS violation	636
Closed; other administrative reason	6,602

Sources of Tips Referred for Action

Phone	4,120
OIG website	6,789
Letters or faxes	542
Other	1,125

Medicaid Fraud Control Units

OIG Oversight of Medicaid Fraud Control Units

MFCUs are key partners with OIG in the fight against fraud, waste, and abuse in State Medicaid programs. OIG has oversight responsibility for MFCUs and administers grants that provide Federal funding for their operations. Currently, all 50 States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands operate MFCUs. The Federal Government reimburses 90 percent of a MFCU's total expenditures during the first 3 years of operation and 75 percent thereafter. MFCUs investigate and prosecute Medicaid provider fraud as well as abuse or neglect of residents in health care facilities and board and care facilities and of Medicaid beneficiaries in noninstitutional or other settings.

Medicaid Fraud Control Units Fiscal Year 2022 Annual Report (OEI-09-23-00190), March 2023

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

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:

Rhode Island Medicaid Fraud Control Unit: 2022 Inspection (OEI-07-22-00370), March 2023

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 16 requests for advisory opinions and issued 16 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 1,435 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 1,365 individuals and entities from Medicare, Medicaid, and other Federal health care programs. Most of the exclusions resulted from convictions for crimes relating to Medicare or Medicaid, patient abuse or neglect, financial misconduct, controlled substances, or as a result of license revocation. OIG completed the

deployment of a new service for MFCUs to report convictions through a central web-based portal for exclusions. OIG is also responsible for reinstating providers who apply and have met the requirements of their exclusions. For a list of excluded individuals and entities, see OIG's Exclusions website.

The following are case examples of program exclusions:

California – On November 20, 2022, OIG excluded an owner of an ambulatory surgery center that specialized in plastic and cosmetic surgery for 40 years based on her conviction for conspiracy to commit health care fraud. From 2008 until 2013, this business owner convinced patients that they could use Preferred Provider Organization health care benefits to pay for cosmetic procedures (e.g., tummy tucks, liposuction, breast lifts, varicose vein treatment) when in fact she submitted false claims for medically unnecessary procedures using fictitious company names and addresses to defraud private insurance companies. Some patients even suffered severe medical complications after being forced to undergo multiple cosmetic procedures in a short timeframe. The court sentenced the owner to 97 months in prison and ordered her to pay approximately $14,025,900 in restitution.

Florida – On December 20, 2022, OIG excluded a registered nurse for 45 years based on his conviction of sexual battery on a helpless victim. The nurse administered medication to the hospitalized victim before raping her. As a result, the court sentenced the nurse to 30 years in prison, and the Florida Board of Nursing revoked his license to practice as a registered nurse.

Illinois – On November 20, 2022, OIG excluded the owner of a licensed childcare business for 20 years due to her conviction for wire fraud and money laundering. From 2009 until 2019, this individual participated in a scheme to defraud the State of Illinois of its general revenue funds as well as block grant funding received from HHS intended to assist low-income families with affordable childcare by submitting false records and eligibility information. The court sentenced her to 22 months in prison and ordered her to pay approximately $421,800 in restitution.

Pennsylvania – On December 20, 2022, OIG excluded a medical doctor for 23 years based on his conviction for conspiracy to commit health care fraud. Between 2016 and 2018, the doctor conspired with a telemedicine company to defraud Medicare by submitting false and fraudulent claims for medically unnecessary services as well as claims for items or services that were not eligible for Medicare reimbursement in order to divert the proceeds for his own personal use. The court sentenced the provider to 6 months of home detention with electronic monitoring and ordered him to pay approximately $3,354,000 in restitution. Moreover, the North Carolina Board of Medicine suspended his license while the West Virginia Board of Medicine, the Pennsylvania Board of Medicine, and the Washington State Board of Medicine accepted the surrender of his licenses.

Wisconsin – On October 20, 2022, OIG excluded an advanced practice nurse practitioner for 45 years based on a conviction related to the distribution of controlled substances beyond the practice of medicine. From 2015 through 2016, this individual owned and operated a medical clinic that only accepted cash or credit card payments from patients in order to prescribe excessive amounts of controlled substances (e.g., oxycodone, morphine) without insurance oversight. These excessive prescriptions lacked legitimate medical purposes and caused widespread distribution and addiction to controlled substances throughout the State of Wisconsin, leading to the death of one patient. As a result of this conviction, a court sentenced the practitioner to 240 months in prison. The excluded provider also lost nursing licenses by revocation, suspension, and surrender in three different states.

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:

Tennessee – Patrick Martin, the former executive director of the Community Prevention Coalition of Jackson County, Tennessee (CPCJC), was debarred for 3 years. The debarment was imposed based on a referral from OIG. CPCJC received a Federal grant from the Substance Abuse and Mental Health Services Administration (SAMHSA) for the purpose of preventing and reducing underage alcohol abuse and substance use among youth in Jackson County. Martin was convicted of wire fraud, willful failure to collect or pay over tax, and willful filing of false tax returns related to theft of grant monies, and he was sentenced to 15 months in prison after an OIG investigation found that Martin embezzled CPCJC funds by overpaying himself, duplicating payments, and paying for personal expenses including travel and supplies. Martin also diverted CPCJC funds to a personal bank account. Martin made materially false statements and misrepresentations to SAMHSA to obtain continued

funding of the grant and caused SAMHSA to wire $375,000 to CPCJC in 30 separate requests to draw down funds.

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 $39.4 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 Jersey – Gem Ambulance, LLC, entered into a $1,060,513.82 settlement agreement with OIG. The agreement settled its liability under the CMPL arising from its submission of claims to Medicare Part B with dates of service from January 2, 2014, through December 28, 2018, for ambulance transportation to and from skilled nursing facilities, where such transportation was covered by the skilled nursing facility consolidated billing payment under Medicare Part A.

Texas – Vi Dang, M.D., entered into a $132,078.00 settlement agreement with OIG. The agreement resolved allegations that he solicited and received remuneration from various telemedicine and staffing companies in the form of monetary payments related to purported telemedicine consultations. Specifically, that he solicited and received the remuneration in exchange for ordering medically unnecessary durable medical equipment and prescription medications for Medicare beneficiaries with whom he had no physician–patient relationship and never examined.

Self-Disclosure Programs

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

Disclosure Protocol may give individuals and entities the opportunity to avoid costs or disruptions associated with Government-directed investigations and civil or administrative litigation.

Application processes for two additional self-disclosure programs were recently added to the OIG website for HHS contractors and grantees. The OIG contractor self-disclosure program provides contractors the opportunity to self-disclose when they have potentially violated the False Claims Act or other Federal criminal laws prohibiting fraud, conflict of interest, bribery, or gratuity. This self-disclosure process is only available to those with a 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 $38.6 million in HHS receivables.

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

Connecticut – Andrew J. Parker, M.D., LLC, entered into an agreement with OIG in the amount of $985,385.10 to resolve allegations that, between January 1, 2012, and April 1, 2018, the medical practice submitted claims for outpatient services as if those services were rendered by Dr. Parker when in fact those services were provided by employee practitioners that were not enrolled in the applicable Federal health care program at the time the claims were submitted.

Washington State – Kadlec Regional Medical Center (Kadlec) entered into a $14,351,283.06 settlement agreement with OIG. The agreement settled its liability under the CMPL arising from its submission of claims to Medicare Part A, during the period of October 24, 2015, through October 26, 2021, for inpatient rehabilitation stays that did not meet Medicare coverage criteria. This self-disclosure was based on conduct Kadlec identified after a related audit by OAS.

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

During the Initial COVID-19 Response, HHS Personnel Who Interacted With Potentially Infected Passengers Had Limited Protections (OEI-04-20-00360), October 2022

As a result of CDC's initially limited protections, HHS personnel may have been at increased risk of COVID-19 exposure and may have inadvertently spread COVID-19. Though CDC's understanding of COVID-19 was evolving and the protections improved during our review period, they still contained some vulnerabilities. Our findings can help CDC strengthen its protections for personnel interacting with potentially infected passengers during future infectious disease outbreaks.

CDC concurred with our recommendations that CDC: (1) update its guidance recommending protections for personnel who interact with potentially infected passengers, (2) ensure that its personal protective equipment trainings meet standards set by the Occupational Safety and Health Administration, and (3) develop a comprehensive plan for recommending travel-related containment measures that weighs the risks relative to the public health benefits.

Early Challenges Highlight Areas for Improvement in COVID-19 Vaccination Programs (OEI-04-21-00190), January 2023

State and local immunization programs that are funded by CDC to distribute COVID-19 vaccines faced numerous challenges, including achieving logistical efficiency, obtaining complete vaccine data, combating vaccine hesitancy with public health messaging, and overseeing vaccine providers. (We refer to these CDC-funded programs as "awardees.") While CDC addressed some of these challenges during the early stages of the COVID-19 vaccination program, there are still areas for improvement. Our findings can help CDC strengthen the COVID-19 vaccination program and improve future pandemic vaccination programs.

CDC concurred with our recommendations that CDC: (1) update its plans for mass vaccination programs with strategies that address awardee-reported logistical challenges, (2) strengthen reporting of vaccine allocation data and administration data, (3) clarify roles and responsibilities within HHS for vaccine public health messaging during a pandemic, and (4) work with awardees to enhance current and future capabilities for provider training and oversight.

Challenges With Vaccination Data Hinder State and Local Immunization Program Efforts To Combat COVID-19 (OEI-05-22-00010), January 2023

Many State and local immunization programs reported having incomplete individual-level data for the more than 250 million COVID-19 vaccine doses administered by Federal agencies and retail pharmacy partners (retail pharmacies that receive vaccines directly from CDC). Without complete individual-level vaccination data, immunization programs reported that they struggled to accurately measure vaccination coverage and target outreach to unvaccinated and vulnerable populations. Because State and local immunization databases contain data on all types of vaccinations, if left unresolved, these challenges will likely hinder the ongoing COVID-19 vaccination campaign, responses to future public health emergencies, and routine vaccination campaigns (e.g., flu shots).

CDC concurred with our recommendation for it to provide educational outreach to ensure that State and local immunization programs are aware of existing tools to address vaccination campaign needs. CDC did not concur with our recommendation for it to work with State and local immunization programs and retail pharmacy partners to mitigate reported data gaps and timeliness challenges.

Administration for Strategic Preparedness and Response

ASPR Could Improve Its Oversight of the Hospital Preparedness Program To Ensure That Crisis Standards of Care Comply With Federal Nondiscrimination Laws (A-01-21-01502), January 2023

Although ASPR has taken steps to improve its oversight of the Hospital Preparedness Program (HPP) by promoting the adoption of nondiscriminatory Crisis Standards of Care (CSCs) that comply with Federal nondiscrimination laws, it can take additional steps. The HPP cooperative agreement did not previously specify that States should consider Federal nondiscrimination laws when developing CSCs because prior to the COVID-19 pandemic, ASPR did not identify CSC compliance with Federal nondiscrimination laws as a high-risk area. Additionally, ASPR stated that it is not required to review CSCs for legal and regulatory compliance. CSCs that do not comply with Federal nondiscrimination laws increase the risk that individuals could be denied access to lifesaving care during a public health emergency.

We recommend that ASPR consider additional updates to the current HPP cooperative agreement to promote that HPP recipients adopt CSCs that comply with Federal nondiscrimination laws. We acknowledge that ASPR has taken steps in previous HPP updates to promote compliance with Federal nondiscrimination laws; however, we believe that additional steps can be taken. Such steps could include an additional update to the HPP cooperative agreement to encourage recipients to engage with advocacy groups in decision making related to crisis care planning. ASPR said that it accepts our recommendation to include additional updates in the HPP cooperative agreement to promote the adoption of CSCs that comply with Federal nondiscrimination laws.

Food and Drug Administration

FDA's Approach to Overseeing Online Tobacco Retailers Needs Improvement (OEI-01-20-00241), December 2022

For the 16,000 online tobacco websites that FDA's contractor flagged for review from 2010 through 2020, FDA issued warning letters to 899 websites but took no enforcement actions. FDA faces challenges, many unique to the online retailer environment, but also has not taken certain steps that could help it address gaps in its oversight. This review raises questions about the effectiveness of FDA's efforts to prevent youth access to tobacco products online.

FDA concurred with our recommendations that FDA: (1) collaborate with the Bureau of Alcohol, Tobacco, Firearms and Explosives on oversight of online tobacco retailers; and (2) publish information and performance data on its oversight of online tobacco retailers.

FDA neither concurred nor nonconcurred with our recommendations that FDA: (1) complete its rulemaking on non–face-to-face sales of tobacco products, as required by the Family Smoking Prevention and Tobacco Control Act; and (2) collect data to support process and outcome measures for its oversight of online tobacco retailers.

FDA Should Improve Its Management of Contracts for the Acquisition of Information Technology (A-18-21-11100), January 2023

FDA contracting officers generally administered the delivery and call orders we reviewed for the acquisition of information technology in accordance with Federal regulations and policies. However, we identified areas within FDA's management of these orders that were not conducted consistent with applicable Federal and HHS acquisition regulations and policies. Specifically, the contracting officers did not: (1) properly designate a contracting officer's representative or complete all required duties for contracts for which there was no designated contracting officer's representative, (2) complete required contractor performance evaluations, (3) properly document all key contracting decisions or activities and obtain all required signatures on key documents, and (4) include the required acquisition strategy statement in the orders' acquisition plans. Additionally, FDA did not fully comply with the HHS Competition Advocacy Directive for FYs 2018 and 2019.

These conditions occurred because FDA did not always: (1) follow existing FDA acquisition and procurement policies and procedures, including ensuring the completeness of contract documents; or (2) work with HHS to meet its obligation to comply with an HHS directive.

We make procedural and administrative recommendations to improve compliance with Federal acquisition requirements related to contracting officer's representative duties, contractor

performance assessments, documentation of contracting decisions and activities, and acquisition strategies. The full recommendations are in the report. In written comments on our draft report, FDA concurred with all of our recommendations and described actions it has taken or plans to take to address the findings.

Indian Health Service

IHS Did Not Always Provide the Necessary Resources and Assistance To Help Ensure That Tribal Programs Complied With All Requirements During Early COVID-19 Vaccination Program Implementation (A-07-21-04125), October 2022

Indian Health Service (IHS) did not fulfill all of the provisions outlined in a Memorandum of Agreement that specified the conditions for receiving COVID-19 vaccines from CDC and in its Vaccine Plan for operationalizing delivery of the vaccines to help ensure that the vaccination program was implemented appropriately at Tribal programs. Consequently, Tribal programs did not always comply with all program requirements during early program implementation. Specifically, IHS did not always provide the necessary resources and assistance to help ensure that Tribal programs: (1) met reporting requirements for vaccine administration data, (2) used billing practices that conformed to CMS and CDC requirements and American Medical Association guidance regarding reimbursement for vaccine administration fees, and (3) did not enter into unallowable dual-program agreements with both a State jurisdiction and IHS.

We recommend that IHS: (1) ensure that Tribal programs comply with vaccine program requirements by establishing formal reconciliation processes to ensure that the data that the Tribal programs submit on doses administered are correct and by addressing data management system incompatibilities, (2) work with CMS to disseminate guidance to Tribal programs on vaccine coding and billing, (3) work with CDC and one Tribal program to ensure that it returns funds to individuals who were billed inappropriately, and (4) work with CDC to develop and disseminate additional guidance related to dual enrollment and together implement a formal monitoring process to help ensure that Tribal programs do not enter into unallowable dual-program agreements for Federal programs. IHS concurred with all of our recommendations and described corrective actions that it has taken and plans to take.

Three Tribes in New England and Their Health Programs Did Not Conduct Required Background Investigations on All Individuals in Contact With Indian Children (A-01-20-01504), November 2022

The 3 New England Tribes and their health programs did not comply with Federal and Tribal requirements for performing background investigations on 65 employees, 12 contractors, and 1 volunteer in contact with Indian children. IHS officials stated that they recalled providing background investigation training prior to 2015 but could not produce documentation to support their recollections. Current Tribal officials said they were not aware of, or misinterpreted, their obligations under the Indian Child Protection and Family Violence Prevention Act (the Act).

Because the three Tribes and their health programs did not always collect the necessary employment information and did not conduct the required criminal history investigations, they could not compare complete criminal history results to the minimum standards of character for individuals in contact with Indian children. As a result, Indian children faced an increased risk of harm.

We recommend that the three Tribes: (1) perform background investigations on individuals who currently have contact with Indian children and (2) develop and implement policies and procedures to ensure that each Tribe conducts required background investigations and assesses results to verify that applicants meet the required minimum character standards. We also recommend that IHS provide additional training and technical assistance to help Tribes comply with the background investigation and character assessment requirements of the Act. Two Tribes concurred with our findings and the third generally concurred with our findings. IHS concurred with our recommendations.

National Institutes of Health

The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies (A-05-21-00025), January 2023

Despite identifying potential risks associated with research being performed under the EcoHealth Alliance awards, we found that NIH did not effectively monitor or take timely action to address EcoHealth's compliance with some requirements. Using its discretion, NIH did not refer the research to HHS for an outside review for enhanced potential pandemic pathogens because it determined the research did not involve and was not reasonably anticipated to create, use, or transfer an enhanced potential pandemic pathogen. However, NIH added a special term and condition in EcoHealth's awards and provided limited guidance on how EcoHealth should comply with that requirement. We found that NIH was only able to conclude that research resulted in virus growth that met specified benchmarks based on a late progress report from EcoHealth that NIH failed to follow up on until nearly 2 years after its due date. We conclude that NIH missed opportunities to monitor research more effectively.

We identified several other deficiencies in the oversight of the awards, including NIH's improper termination of a grant; EcoHealth's inability to obtain scientific documentation from Wuhan Institute of Virology (WIV); and EcoHealth's improper use of grant funds, resulting in $89,171 in unallowable costs. Although WIV cooperated with EcoHealth's monitoring for several years, WIV's lack of cooperation following the COVID-19 outbreak limited EcoHealth's ability to monitor its subrecipient.

We make several recommendations, including that NIH: (1) ensure that EcoHealth accurately and in a timely manner report award and subaward information; (2) implement enhanced monitoring,

documentation, and reporting requirements for recipients with foreign subrecipients; (3) consider whether it is appropriate to refer WIV to HHS for debarment; and (4) ensure any future NIH grant awards to EcoHealth address the deficiencies noted in the report. NIH stated that it concurred or generally concurred with our recommendations and provided actions it has taken or plans to take to address them.

We also recommend EcoHealth submit progress reports by the required due dates, comply with immediate notification requirements, ensure access to all subrecipient records, properly account for subawards, and refund to the Federal Government $89,171 in unallowable costs. EcoHealth concurred with our recommendation to prepare accurate subaward and consultant agreements but did not directly state whether it concurred with the other recommendations.

Drug Control Attestation Reports

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

Independent Attestation Review: National Institutes of Health Fiscal Year 2022 Detailed Accounting Submission and Budget Formulation Compliance Report for National Drug Control Activities, and Accompanying Required Assertions (A-03-23-00351), January 2023

This report provides the results of our review of NIH's National Institute on Drug Abuse (NIDA) and National Institute on Alcohol Abuse and Alcoholism (NIAAA) ONDCP Detailed Accounting Reports, which include the table of Drug Control Obligations, related disclosures, and management's assertions for the fiscal year ended September 30, 2022. We also reviewed the Budget Formulation Compliance Reports, which include budget formulation information for the fiscal year ending September 30, 2024, and the Chief Financial Officer's or accountable senior executive's assertions relating to the budget formulation information.

Based on our review, we are not aware of any material modifications that should be made to NIDA and NIAAA's Detailed Accounting Reports for FY 2022 and NIDA and NIAAA's Budget Formulation Compliance Reports for FY 2024 and management's assertions for them to be in accordance with the ONDCP Compliance Reviews Circular.

Independent Attestation Review: Centers for Disease Control and Prevention Fiscal Year 2022 Detailed Accounting Submission and Budget Formulation Compliance

Report for National Drug Control Activities and Accompanying Required Assertions (A-03-23-00352), January 2023

This report provides the results of our review of CDC's ONDCP Detailed Accounting Report, which includes the table of Drug Control Obligations, related disclosures, and management's assertions for the fiscal year ended September 30, 2022. We also reviewed the Budget Formulation Compliance Report, which includes budget formulation information for the fiscal year ending September 30, 2024, and the Chief Financial Officer's or accountable senior executive's assertions relating to the budget formulation information.

Based on our review, we are not aware of any material modifications that should be made to CDC's Detailed Accounting Report for FY 2022 and CDC's Budget Formulation Compliance Report for FY 2024 and management's assertions for them to be in accordance with the ONDCP Compliance Reviews Circular.

Independent Attestation Review: Food and Drug Administration Fiscal Year 2022 Detailed Accounting Submission and Budget Formulation Compliance Report for National Drug Control Activities and Accompanying Required Assertions (A-03-23-00353), January 2023

This report provides the results of our review of FDA's ONDCP Detailed Accounting Report, which includes the table of Drug Control Obligations, related disclosures, and management's assertions for the fiscal year ended September 30, 2022. We also reviewed the Budget Formulation Compliance Report, which includes budget formulation information for the fiscal year ending September 30, 2024, and the Chief Financial Officer's or accountable senior executive's assertions relating to the budget formulation information.

Based on our review, we are not aware of any material modifications that should be made to FDA's Detailed Accounting Report for FY 2022 and FDA's Budget Formulation Compliance Report for FY 2024 and management's assertions for them to be in accordance with the ONDCP Compliance Reviews Circular.

Human Services Agency Reports and Reviews

Administration for Children and Families

The Municipality of Manati Did Not Always Manage Its Head Start Disaster Assistance Awards in Accordance With Federal and Commonwealth Requirements (A-04-20-02032), December 2022

The Municipality of Manati did not always manage its Head Start disaster assistance awards in accordance with Federal and Commonwealth requirements. Specifically, the Municipality claimed unallowable costs totaling $153,052 related to the purchase of four vehicles and did not comply with all requirements related to criminal background checks for 25 employees hired with award funds. These deficiencies occurred because the Municipality did not have written procurement policies and procedures for determining the most reasonable approach for making vehicle purchases or for ensuring that criminal background checks were conducted within required timeframes. As a result, the Municipality did not show that the purchase of the four vehicles was necessary or reasonable and it potentially jeopardized the safety of children by not complying with background check requirements.

We recommend that the Municipality: (1) work with ACF to develop a viable plan for refunding $153,052 in unallowable costs to the Federal Government; (2) develop and implement procurement policies and procedures, including a requirement to perform analyses to determine the most reasonable approach for vehicle acquisitions; and (3) develop and implement written policies and procedures to ensure that criminal background checks are completed within required timeframes. In written comments on our draft, the Municipality did not indicate concurrence or nonconcurrence with our recommendations. However, the Municipality stated it did not concur with our findings. We maintain that our findings and recommendations are valid.

Greater Bergen Community Action, Inc., Did Not Manage Its Head Start Awards in Accordance With Federal and State Requirements (A-02-19-02008), January 2023

Greater Bergen Community Action, Inc. (GBCA) drew down Head Start funds in excess of immediate cash needs and used the funds to temporarily cover non-Head Start expenditures. In addition, GBCA claimed unallowable costs totaling $394,733 for: (1) rental income that was not properly credited as program income, (2) unallowable rent costs, (3) unallowable salary and fringe benefit costs, and (4) non-Head Start program costs. GBCA also claimed $92,678 in potentially unallowable vehicle costs. Further, GBCA overstated its non-Federal share contributions (e.g., volunteer services) and did not perform required background checks and health screenings on some of its volunteers. These deficiencies occurred because GBCA had inadequate policies in place to ensure that: (1) its Head Start grant funds were used to reimburse current, allowable Head Start expenses; (2) its financial reports to ACF accurately accounted for non-Federal contributions to its Head Start program; and (3) background checks and health screenings were performed.

We recommend that GBCA: (1) refund $394,733 to the Federal Government for unallowable costs charged to the Head Start awards, (2) work with ACF to determine the amount of allowable vehicle costs or refund $92,678 to the Federal Government for potentially unallowable vehicle costs, and (3) strengthen its policies and procedures to address the issues identified in the report. GBCA concurred with some of our findings, did not concur with others, and disagreed with our recommendation that it refund $394,733.

Maryland's Child Support Administration Generally Claimed Administrative Costs That Were Allowable and Allocable (A-01-22-02500), March 2023

Maryland generally claimed Maryland Administrative Office of the Courts (AOC) administrative costs for the Child Support Enforcement Program (CSE Program) that were allowable and allocable, and the overall effect of the errors we identified during our audit period were immaterial. However, we determined that Maryland did not have an adequate invoice review process to ensure that AOC salary and fringe benefits allocated to the CSE Program were accurate and supported and that the AOC properly calculated indirect costs charged to the CSE Program.

We recommend that Maryland: (1) periodically review the allocation and support of payroll costs invoiced by the AOC and (2) verify that the AOC calculates indirect costs charged to the CSE Program by applying the de minimis rate of 10 percent to the correct allocation base.

In written comments on our draft report, Maryland concurred with our recommendations. Maryland also described the actions it will take to address the recommendations. For example, Maryland said it would periodically conduct site reviews, beginning April 1, 2023, and evaluate the AOC billing process, internal controls, and supporting documentation to verify the allocation and support of payroll costs that AOC invoiced.

Safety of Children in Foster Care

Michigan Did Not Comply With Requirements for Documenting Psychotropic and Opioid Medications Prescribed for Children in Foster Care (A-05-21-00030), February 2023

Michigan 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, we found that: (1) the electronic case records for 18 of the 115 children in the sample who were prescribed psychotropic or opioid medications did not contain the required medical information, (2) the electronic case records for 14 of the 85 children in the sample who were prescribed psychotropic medications did not include consent forms for psychotropic medications, and (3) opioid medications prescribed for 60 children in the sample were not recorded in the Michigan Statewide Automated Child Welfare Information System (MiSACWIS).

We make multiple recommendations, including that Michigan ensure that electronic case records for children in foster care are maintained in accordance with requirements by: (1) modifying procedures for the monitoring of caseworkers to ensure that the required medical information is maintained in MiSACWIS; (2) implementing policies to document when consent forms are not required in non-emergency situations, monitoring Medicaid claim data to ensure consent forms are obtained and documented, and implementing procedures to monitor other medications prescribed for children, including opioids, for potential medication interaction and adverse side effects for children who are prescribed psychotropic medications; and (3) implementing

procedures to monitor Medicaid claim data for opioid medications prescribed for children and providing training for documenting the opioid medications prescribed for children due to medical procedures or emergency treatment. Michigan generally agreed with our recommendations and described actions it has taken or plans to take to address our recommendations.

State Agencies Did Not Always Ensure That Children Missing From Foster Care Were Reported to the National Center for Missing and Exploited Children in Accordance With Federal Requirements (A-07-21-06102), March 2023

During our audit period, State agencies did not always ensure that children missing from foster care were reported to the National Center for Missing and Exploited Children (NCMEC) as required by Federal statute. Of the 100 missing children episodes in our sample, the State agencies reported 33 episodes to NCMEC 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, 45 missing children episodes were never reported to NCMEC, and 22 missing children episodes were not reported in a timely manner. On the basis of our sample results, we estimated that the State agencies did not report 51,115 of the 74,353 missing children episodes in accordance with Federal requirements. Specifically, an estimated 34,869 missing children episodes during our audit period were never reported to NCMEC, and an additional estimated 16,246 missing children episodes during our audit period were not reported within 24 hours after the State agencies were notified that the child was missing.

State agencies generally lacked adequate systems to readily identify whether or not they had correctly reported missing children episodes to NCMEC. The opportunity exists for ACF to improve outcomes for missing children by working with State agencies to ensure compliance with Federal reporting requirements and guidance.

We recommend that ACF work with State agencies to ensure compliance with Federal requirements to report missing children episodes to NCMEC in a timely manner. ACF concurred with our recommendation and described corrective actions.

Health Resources and Services Administration

The Health Resources and Services Administration Should Improve Preventive and Detective Controls To More Effectively Mitigate the Risk of Compromise (A-18-20-08200), February 2023

Although the Health Resources and Services Administration (HRSA) implemented some security controls for detecting and preventing threats on its network, HRSA's cybersecurity controls needed improvements to better detect and prevent cyber threats on its network. We found multiple security controls at HRSA that were not operating effectively. Although we did not identify evidence of a past breach, we found three active threats on the HRSA network. We promptly shared these significant findings with HRSA during our audit period. We concluded that HRSA was

able to detect certain breaches and respond appropriately. We based this conclusion on the fact that HRSA was already in the process of investigating two of the three active threats that we had identified before we notified it of our findings.

The security control failures that we identified occurred because HRSA had not updated security configurations to align with the most recent National Institute of Standards and Technology (NIST) Special Publication (SP) 800-53 security controls and had not implemented procedures to assess and monitor the NIST controls on its endpoints. As a result of HRSA not correctly implementing these controls, these threats could increase the endpoint or network attack surfaces, or they could bypass current organizational security policies and controls.

We recommend that HRSA: (1) remediate the security control findings we identified, (2) update security configurations to align with the most current NIST SP 800-53 security controls, and (3) implement policies and procedures to periodically identify and assess whether security controls are in place and operating effectively in accordance with the most current NIST SP 800-53 and remediate weak controls timely.

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.

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

Child Support Enforcement Activities

OIG Investigations

OIG investigates noncustodial parents who violate 18 U.S.C. § 228 by failing to pay court-ordered child support. OIG works with ACF's Office of Child Support Enforcement; DOJ; U.S. Attorneys' Offices; the U.S. Marshals Service; and Federal, State, and local partners to address egregious child support enforcement cases with appropriate law enforcement and prosecutorial action. During this semiannual reporting period, OIG investigations of child support enforcement cases nationwide resulted in one criminal action and court-ordered restitution and settlements of $5,600.

The following case example involves child support enforcement:

Puerto Rico – On or about 2019 through May 2022, Yamil Fonseca Salgado willfully failed to pay his child support obligation to his child who resides on the State of Florida. Such obligation remained unpaid for a period longer than 2 years and amounted to more than $107,000.00. With the purpose of executing a scheme to defraud his minor child and the Court who imposed the child support obligation, Salgado concealed assets, resources, and income. In order to execute said scheme, Salgado made false and fraudulent representations concerning and in relation to a proceeding under Title 11 in the United

States Bankruptcy Court in multiple occasions. Salgado was arrested on August 2, 2022, after a grand jury indicted him on July 28, 2022, in the United States Court, District of Puerto Rico, for charges related to failure to pay child support and bankruptcy fraud. On November 3, 2022, Salgado pled guilty to one count of willful failure to pay child support and five counts of bankruptcy fraud. This case was worked jointly with the United States Trustee's Office.

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

General Departmental

U.S. Department of Health and Human Services Met the Requirements of the Digital Accountability and Transparency Act of 2014, With Areas That Require Improvement (A-17-22-54000), October 2022

Ernst & Young, under its contract with HHS-OIG, determined that HHS generally complied with the requirements for completeness, timeliness, quality, and accuracy of the data, as well as the requirements for implementation and use of the Governmentwide financial data standards established by the Office of Management and Budget and Treasury. Overall, HHS is in compliance with the Digital Accountability and Transparency Act requirements.

Ernst & Young recommended that HHS focus on refreshing the OpDivs' understanding of Departmental guidance and identifying those areas for which OpDiv training would be developed to prevent and detect future accuracy issues related to the performance dates, award types, and award descriptions. Ernst & Young identified the following: (1) 33 accuracy exceptions for data element 26, the period of performance start date; (2) 25 accuracy exceptions for data element 22, Award Description; (3) 18 accuracy exceptions for data element 16, Award Type; and (4) 12 accuracy exceptions for data element 37, Business Types. In these exceptions, the information in Files D1/D2 did not agree with the supporting documentation provided.

Report on the Financial Statement Audit of the Centers for Medicare & Medicaid Services for Fiscal Year 2022 (A-17-22-53000), November 2022

Based on its audit, Ernst & Young, under its contract with HHS-OIG, found that the FY 2022 CMS consolidated balance sheets and the related consolidated statements of net cost and changes in net position and combined statement of budgetary resources were presented fairly, in all material respects, in conformity with U.S. generally accepted accounting principles. Ernst & Young was unable to obtain sufficient audit evidence for the amounts presented in the statements of social insurance as of January 1, 2022, 2021, 2020, 2019, and 2018, and the related statements of changes in social insurance amounts for the periods ended January 1, 2022, and 2021. As a result, Ernst & Young was not able to, and did not, express an opinion on the financial condition of the CMS social insurance program and related changes in the social insurance program for the specified periods.

Ernst & Young also noted two matters involving internal controls with respect to the financial reporting. Under the standards established by the American Institute of Certified Public Accountants and GAO's *Government Auditing Standards*, Ernst & Young identified significant deficiencies in CMS's financial reporting processes and information systems controls. Ernst & Young also identified several instances of noncompliance with laws and other matters.

Financial Statement Audit of the Department of Health and Human Services for Fiscal Year 2022 (A-17-22-00001), November 2022

Based on its audit, Ernst & Young, under its contract with HHS-OIG, found that the FY 2022 HHS consolidated balance sheets and the related consolidated statements of net cost and changes in net position and combined statements of budgetary resources were presented fairly, in all material respects, in conformity with U.S. generally accepted accounting principles. Ernst & Young was unable to obtain sufficient audit evidence for the amounts presented in the statements of social insurance as of January 1, 2022, 2021, 2020, 2019, and 2018, and the related statements of changes in social insurance amounts for the periods ended January 1, 2022, and 2021. As a result, Ernst & Young was not able to, and did not, express an opinion on the sustainability statements for the specified periods.

Ernst & Young also noted two matters involving internal controls with respect to financial reporting. Under the standards established by the American Institute of Certified Public Accountants and GAO's *Government Auditing Standards*, Ernst & Young did not identify any deficiencies in internal control that it considered a material weakness. Ernst & Young noted improvements over internal controls but continued to identify two significant deficiencies related to HHS's Financial Reporting Systems, Analyses, and Oversight, and HHS's Financial Information Systems.

Grants and Contracts

HHS is the largest grantmaking organization and one of the largest contracting agencies in the Federal Government. In FY 2022, HHS awarded more than $792 billion in grants and more than $33 billion in contracts across all program areas. OIG's direct annual discretionary appropriation funding is used to conduct program integrity and enforcement activities with regard to the more than 100 public health and human services programs carried out by more than 80,000 employees worldwide. The size and scope of departmental awards make their operating effectiveness crucial to the success of programs designed to improve the health and well-being of the public.

Grant Fraud Investigations

The following case example relates to misuse of grant funds:

California – On December 18, 2022, the United States entered into a False Claims Act settlement agreement with iSense, LLC (iSense), Specific Diagnostics, Inc. (Specific), and Dr. Paul Andrew Rhodes. The settlement agreement resolves allegations that between July 1, 2014, and June 30, 2019, iSense submitted costs for employee hours that the United States contends were at a salary rate in excess of the applicable salary cap. The total amount of the settlement to be paid is $10,068,875. Of that amount, iSense will pay $4,000,000, Specific will pay $4,000,000, and Dr. Rhodes will pay $2,068,875. The United States also contends that iSense knowingly overcharged costs for employee hours at a salary rate not reduced for uncompensated overtime. These allegations pertain to claims submitted for payment under multiple grants awarded by NIH. All of the grants at issue were Small Business Innovation Research (SBIR) grants. This settlement agreement also resolves allegations that between February 1, 2017, and December 31, 2018, Specific submitted costs for employee hours that the United States contends were a salary rate in excess of the applicable salary cap. Additionally, the United States contends that Specific knowingly overcharged costs for employee hours at a salary rate not reduced for uncompensated overtime. The allegations pertain to claims submitted for payment under two grants awarded by NIH. These two grants were SBIR grants. The settlement agreement further resolves allegations that between February 1, 2018, and July 28, 2020, Specific and Dr. Rhodes knowingly submitted a services agreement between Specific and iSense as properly dated, which were knowingly backdated. These allegations pertain to claims for payment that were caused to be submitted under an award from ASPR. Specific was a subrecipient of this award, which is known as Combating Antibiotic-Resistant Bacteria (CARB-X). Lastly, the settlement agreement resolves allegations that between January 1, 2015, and December 31, 2019, Dr. Rhodes and iSense submitted as accurately dated to the United States cost-sharing agreements between Specific and iSense that were knowingly backdated.

Small Business Innovative Research Program

The National Defense Authorization Act for Fiscal Year 2012, § 5143, requires OIG to report annually on the number of cases referred to OIG for fraud, waste, or abuse in the Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) program. OIG must also report on: (1) the actions taken in each case; (2) justification for not taking action on a case; and (3) an accounting of funds used to address waste, fraud, and abuse in this program. From October 1, 2021, through September 30, 2022, OIG received one referral related to potential fraud, waste, or abuse with respect to SBIR/STTR programs, and no cases were opened. For FY 2022, there was one SBIR civil settlement for $541,531. In FY 2022, OIG spent approximately $316,800 in salaries on auditing, investigating, and training activities related to fraud, waste, and abuse in the SBIR/STTR programs. At the end of FY 2022, OIG was working on two SBIR/STTR investigations.

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 265 reports covering $2.1 trillion in audited costs. Federal dollars covered by these audits totaled $678.3 billion, of which about $298.3 billion were HHS funds.

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

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

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

Non-Federal Audits, October 1, 2022, Through March 31, 2023

Not requiring changes or having minor changes	254
Requiring major changes	10
Having significant technical inadequacies	1
Total Number of Non-Federal Audits	**265**

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's Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs* describes priority findings and recommendations from past periods that remain to be implemented.
- Our Work Plan provides citations to laws and regulations that are the subject of ongoing or future reviews.

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

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

The following tables summarize OIG's monetary recommendations and HHS'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	Number of Reports	Dollar Value Questioned	Dollar Value Unsupported
Section 1			
Reports for which no management decisions had been made by the beginning of the reporting period[1]	50	$1,600,255,000	$558,210,000
Issued during the reporting period[2]	28	$277,236,000	$89,769,000
Total Section 1	**78**	**$1,877,491,000**	**$647,979,000**
Section 2			
Reports for which management decisions were made during the reporting period[3]			
Disallowed costs	9	*$200,828,000	$0
Costs not disallowed	14	$757,365,000	$559,212,000
Total Section 2	**23**	**$958,193,000**	**$559,212,000**

* Audit receivables (expected recoveries).

Section 3			
Reports for which no management decisions had been	**55**	**$919,298,000**	**$88,767,000**

Section 4			
Reports for which no management decisions were made within 6 months of issuance[4]	31	$650,607,000	$0

Table 1 End Notes

[1] The opening balance was adjusted upward by $4,000 because of a reevaluation of previously issued recommendations.

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

[3] Revisions to previously reported management decisions:

A-05-18-00040, *Medicare Hospital Provider Compliance Audit: St. Vincent Hospital*. CMS's subsequent review determined that disallowed costs should be reduced by $802,000.

A-06-20-04003, *Vanderbilt University Medical Center: Audit of Outpatient Outlier Payments*. CMS's subsequent review determined that disallowed costs should be increased by $124,865.

[4] Because of administrative delays, some of which were beyond management control, resolution of the following 31 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*, SEPT 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*, SEPT 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*, JULY 2022, $9,212,531
A-01-20-00006	*More Than 90 Percent of the New Hampshire Managed Care Organization and Fee-for-Service Claims for Opioid Treatment Program Services Did Not Comply With Medicaid Requirements*, JUNE 2022, $7,943,271
A-07-19-01195	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That BlueCross BlueShield of Tennessee, Inc. (Contract H7917) Submitted to CMS,* SEPT 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,* SEPT 2022, $6,227,005
A-05-18-00020	*Medicare Advantage Compliance Audit of Diagnosis Codes That Inter Valley Health Plan, Inc. (Contract H0545), Submitted to CMS,* SEPT 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-01-19-00500	*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*, JULY 2018, $2,567,604
A-09-20-03009	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Regence BlueCross BlueShield of Oregon (Contract H3817) Submitted to CMS*, SEPT 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-07-17-01173	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health Care of Missouri, Inc. (Contract H2663) Submitted to CMS*, OCT 2021, $548,852
A-03-18-00002	*Medicare Advantage Compliance Audit of Diagnosis Codes That Cigna HealthSpring of Florida, Inc. (Contract H5410) Submitted to CMS*, AUG 2022, $39,612
A-03-16-00250	*Youth for Tomorrow – New Life Center, Inc., an Administration for Children and Families Grantee, Did Not Comply With All Applicable Federal Policies and Requirements*, SEPT 2020, $16,851
TOTAL CINS: 31	

Audit Reports With Funds Recommended To Be Put to Better Use

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

Table 2: Audit Reports With Funds Put to Better Use

Description	Number of Reports	Dollar Value
Section 1		
Reports for which no management decisions had been made by the beginning of the reporting period	8	$17,121,659,000
Reports issued during the reporting period[1]	5	$328,116,000
Total Section 1	**13**	**$17,449,775,000**
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	0	$0
Based on proposed legislative action	0	$0
Value of recommendations not agreed to by management	5	$2,089,668,000
Total Section 2	**5**	**$2,089,668,000**
Section 3		
Reports for which no management decisions had been made by the end of the reporting period[1] (Section 1 - Section 2)[2,3]	**8**	**$15,360,107,000**

Table 2 End Notes

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

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

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

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

Audit CIN	Audit Title
A-03-13-03002	*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*, SEPT 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-17-22-54000	*U.S. Department of Health and Human Services Met the Requirements of the Digital Accountability and Transparency Act of 2014, With Areas That Require Improvement*	10/12/2022	-	-
A-07-21-04125	*IHS Did Not Always Provide the Necessary Resources and Assistance To Help Ensure That Tribal Programs Complied With All Requirements During Early COVID-19 Vaccination Program Implementation*	10/17/2022	-	-
A-05-20-00053	*Payments Made to Providers Under the COVID-19 Accelerated and Advance Payments Program Were Generally in Compliance With the CARES Act and Other Federal Requirements*	10/24/2022	-	-
A-02-20-01027	*CMS Generally Ensured That Medicare Part C and Part D Sponsors Did Not Pay Ineligible Providers for Services to Medicare Beneficiaries*	10/25/2022	-	-

A-04-21-07097	*California Made Almost $16 Million in Unallowable Capitation Payments for Beneficiaries With Multiple Client Index Numbers*	10/25/2022	$15,722,587	-
A-07-21-02834	*Colorado Did Not Report and Refund the Correct Federal Share of Medicaid-Related Overpayments for 70 Percent of the State's Medicaid Fraud Control Unit Cases*	10/25/2022	$3,669,738	-
A-04-21-08084	*CMS Can Use OIG Audit Reports To Improve Its Oversight of Hospital Compliance*	10/26/2022	-	-
A-07-21-06101	*Mississippi Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs*	10/27/2022	$2,218,202	$35,611,451
A-01-20-01504	*Three Tribes in New England and Their Health Programs Did Not Conduct Required Background Investigations on All Individuals in Contact With Indian Children*	11/4/2022	-	-
A-17-22-53000	*Report on the Financial Statement Audit of the Centers for Medicare & Medicaid Services for Fiscal Year 2022*	11/7/2022	-	-
A-07-21-06105	*Iowa Implemented Most of Our Prior Audit Recommendations and Generally Complied With Federal and State Requirements for Reporting and Monitoring Major Incidents*	11/9/2022	-	-
A-09-21-03004	*The Number of Beneficiaries Who Received Medicare Part B Clinical Laboratory Tests Decreased During the First 10 Months of the COVID-19 Pandemic*	11/9/2022	-	-
A-09-19-03001	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That California Physicians' Service, Inc. (Contract H0504) Submitted to CMS*	11/10/2022	$2,033,039	-
A-17-22-00001	*Financial Statement Audit of the Department of Health and Human Services for Fiscal Year 2022*	11/14/2022	-	-
A-01-20-00500	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross & Blue Shield of Rhode Island (H4152) Submitted to CMS*	11/16/2022	$4,894,595	-
A-04-21-00132	*The Centers for Medicare & Medicaid Services' Review Contractors Generally Conducted Medicaid Fee-for-Service Claim Reviews for Selected States Under the Payment Error Rate Measurement Program in Accordance with Federal and State Requirements*	11/17/2022	-	-
A-06-21-08004	*National Government Services, Inc., Accurately Calculated Hospice Cap Amounts but Did Not Collect All Cap Overpayments*	11/17/2022	$2,138,011	-
A-18-20-08005	*Puerto Rico MMIS and E&E Systems Security Controls Were Generally Effective, but Some Improvements Are Needed*	11/18/2022	-	-

A-01-20-00503	*Medicare Improperly Paid Physicians for Co-Surgery and Assistant-at-Surgery Services That Were Billed Without the Appropriate Payment Modifiers*	11/22/2022	$56,016	$4,883,570
A-06-20-04008	*Medicare Providers Did Not Always Comply With Federal Requirements When Billing for Advance Care Planning*	11/22/2022	$33,332	$42,233,599
A-04-21-09003	*The Centers for Medicare & Medicaid Services' Review Contractor Did Not Document Medicaid Managed Care Payment Review Determinations Made Under the Payment Error Rate Measurement Program*	12/8/2022	-	-
A-07-20-02825	*Providers Did Not Always Comply With Federal Requirements When Claiming Medicare Bad Debts*	12/15/2022	-	-
A-03-20-00201	*Keystone First Should Improve Its Procedures for Reviewing Service Requests That Require Prior Authorization*	12/20/2022	-	-
A-05-20-00031	*Mandated Analysis of Home Health Service Utilization From January 2016 Through March 2022*	12/20/2022	-	-
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*	12/21/2022	$153,052	-
A-05-21-00035	*Illinois Generally Complied With Requirements for Claiming Medicaid Reimbursement for Telehealth Payments During COVID-19*	12/21/2022	$9,832	-
A-07-22-00624	*National Government Services, Inc., Claimed Some Unallowable Medicare Postretirement Benefit Plan Costs Through Its Incurred Cost Proposals*	12/21/2022	$636,197	-
A-07-22-00625	*National Government Services, Inc., Claimed Some Unallowable Medicare Supplemental Executive Retirement Plan Costs Through Its Incurred Cost Proposals*	12/21/2022	$209,543	-
A-07-22-00628	*National Government Services, Inc., Claimed Some Unallowable Medicare Nonqualified Plan Costs Through Its Incurred Cost Proposals*	12/21/2022	$657,765	-
A-07-19-01193	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Cigna-HealthSpring of Tennessee, Inc. (Contract H4454) Submitted to CMS*	12/22/2022	$5,987,509	-
A-07-22-00620	*National Government Services, Inc., Understated Its Plan A Medicare Segment Pension Assets and Overstated Medicare's Share of the Medicare Segment Excess Pension Liabilities as of December 31, 2018*	1/5/2023	$54,544	-
A-07-22-00621	*National Government Services, Inc., Overstated Its Plan B Medicare Segment Pension Assets and Overstated Medicare's Share of the Medicare Segment Excess Pension Assets as of December 31, 2018*	1/5/2023	-	-

A-07-22-00622	*National Government Services, Inc., Overstated Its United Government Services, LLC, Medicare Segment Pension Assets and Understated Medicare's Share of the Medicare Segment Excess Pension Liabilities as of December 31, 2018*	1/6/2023	-	-
A-07-22-00623	*National Government Services, Inc., Claimed Some Unallowable Medicare Pension Costs Through Its Incurred Cost Proposals*	1/7/2023	$73,307	-
A-01-21-01502	*ASPR Could Improve Its Oversight of the Hospital Preparedness Program To Ensure That Crisis Standards of Care Comply With Federal Nondiscrimination Laws*	1/13/2023	-	-
A-18-21-11100	*FDA Should Improve Its Management of Contracts for the Acquisition of Information Technology*	1/13/2023	-	-
A-03-23-00351	*Independent Attestation Review: National Institutes of Health Fiscal Year 2022 Detailed Accounting Submission and Budget Formulation Compliance Report for National Drug Control Activities, and Accompanying Required Assertions*	1/18/2023	-	-
A-03-23-00352	*Independent Attestation Review: Centers for Disease Control and Prevention Fiscal Year 2022 Detailed Accounting Submission and Budget Formulation Compliance Report for National Drug Control Activities, and Accompanying Required Assertions*	1/18/2023	-	-
A-03-23-00353	*Independent Attestation Review: Food and Drug Administration Fiscal Year 2022 Detailed Accounting Submission and Budget Formulation Compliance Report for National Drug Control Activities, and Accompanying Required Assertions*	1/18/2023	-	-
A-05-21-00025	*The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*	1/25/2023	$89,171	-
A-02-19-02008	*Greater Bergen Community Action, Inc., Did Not Manage Its Head Start Awards in Accordance With Federal and State Requirements*	1/26/2023	$487,411	-
A-07-21-07002	*North Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs*	2/7/2023	$3,742,833	-
A-05-21-00030	*Michigan Did Not Comply With Requirements for Documenting Psychotropic and Opioid Medications Prescribed for Children in Foster Care*	2/8/2023	-	-
A-05-21-00028	*Florida Made Capitation Payments for Enrollees Who Were Concurrently Enrolled in a Medicaid Managed Care Program in Another State*	2/16/2023	-	-
A-18-20-08200	*The Health Resources and Services Administration Should Improve Preventive and Detective Controls To More Effectively Mitigate the Risk of Compromise*	2/22/2023	-	-

A-07-20-03243	*Missouri Claimed Federal Medicaid Reimbursement for Tens of Millions in Consumer-Directed Personal Care Assistance Services That Did Not Comply With Federal and State Requirements*	2/23/2023	$121,189,991	-
A-09-21-03006	*Medicare Could Have Saved up to $216 Million Over 5 Years if Program Safeguards Had Prevented At-Risk Payments for Definitive Drug Testing Services*	2/27/2023	-	$215,839,412
A-09-20-03033	*Medicare Part D Plan Sponsors and CMS Did Not Ensure That Transmucosal Immediate-Release Fentanyl Drugs Were Dispensed Only to Beneficiaries Who Had a Cancer Diagnosis*	2/28/2023	$105,951,927	-
A-07-21-06102	*State Agencies Did Not Always Ensure That Children Missing From Foster Care Were Reported to the National Center for Missing and Exploited Children in Accordance With Federal Requirements*	3/2/2023	-	-
A-04-21-07098	*Florida Did Not Invoice Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations*	3/3/2023	$59,898	-
A-06-17-09004	*Texas Could Not Support the Permissibility of the Funds Used as the State Share of the Medicaid Delivery System Reform Incentive Payment Program*	3/8/2023	-	-
A-18-20-08004	*Michigan MMIS and E&E Systems Security Controls Were Generally Effective, but Some Improvements Are Needed*	3/9/2023	-	-
A-07-21-00618	*Medicare Improperly Paid Physicians for Epidural Steroid Injection Sessions*	3/10/2023	$3,585,422	-
A-04-21-08089	*Georgia Did Not Always Invoice Rebates to Manufacturers for Pharmacy and Physician-Administered Drugs*	3/13/2023	$2,308,312	-
A-04-22-00134	*Georgia Did Not Comply With Federal Waiver and State Requirements at All 20 Adult Day Health Care Facilities Reviewed*	3/14/2023	-	-
A-03-20-00200	*The District of Columbia Has Taken Significant Steps To Ensure Accountability Over Amounts Managed Care Organizations Paid to Pharmacy Benefit Managers*	3/16/2023	-	-
A-09-21-03011	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Geisinger Health Plan (Contract H3954) Submitted to CMS*	3/16/2023	$566,476	-
A-07-21-03247	*Missouri's Oversight of Certified Individualized Supported Living Provider Health and Safety Could Be Improved in Some Areas*	3/21/2023	-	-
A-09-22-03006	*Medicare Improperly Paid Physicians an Estimated $30 Million for Spinal Facet-Joint Interventions*	3/22/2023	$18,084	$29,548,088
A-01-22-02500	*Maryland's Child Support Administration Generally Claimed Administrative Costs That Were Allowable and Allocable*	3/23/2023	-	-

A-02-20-01008	*Medicare Advantage Compliance Audit of Specific Diagnosis Codes That MCS Advantage, Inc. (Contract H5577) Submitted to CMS*	3/24/2023	$220,577	-
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*	3/28/2023	$468,372	-
	Total Reports: 62		**$277,235,743**	**$328,116,120**

Evaluation Reports by Operating Division

Report Number	Title	Operating Division	Issue Date
OEI-04-20-00360	*During the Initial COVID-19 Response, HHS Personnel Who Interacted With Potentially Infected Passengers Had Limited Protections*	CDC	Oct-22
OEI-05-22-00010	*Challenges With Vaccination Data Hinder State and Local Immunization Program Efforts To Combat COVID-19*	CDC	Jan-23
OEI-04-21-00190	*Early Challenges Highlight Areas for Improvement in COVID-19 Vaccination Programs*	CDC	Jan-23
OEI-01-21-00110	*Home Health Agencies Used Multiple Strategies To Respond to the COVID-19 Pandemic, Although Some Challenges Persist*	CMS	Oct-22
OEI-07-20-00500	*Long-Term Trends of Psychotropic Drug Use in Nursing Homes*	CMS	Nov-22
OEI-03-23-00070	*Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Second Quarter of 2022*	CMS	Nov-22
OEI-07-18-00370	*For Medicaid-Enrolled Children Diagnosed With Lead Toxicity in Five States, Documentation Reviewed for Diagnoses and Treatment Services Raises Concerns*	CMS	Dec-22
OEI-09-20-00510	*Labs With Questionably High Billing for Additional Tests Alongside COVID-19 Tests Warrant Further Scrutiny*	CMS	Dec-22
OEI-03-21-00390	*CMS Should Bolster Its Oversight of Manufacturer-Submitted Average Sales Price Data To Ensure Accurate Part B Drug Payments*	CMS	Dec-22
OEI-BL-21-00330	*Manufacturers May Need Additional Guidance To Ensure Consistent Calculations of Average Sales Prices*	CMS	Dec-22
OEI-09-22-00400	*Medicare Part B Spending on Lab Tests Increased in 2021, Driven By Higher Volume of COVID-19 Tests, Genetic Tests, and Chemistry Tests*	CMS	Dec-22
OEI-02-20-00491	*More Than a Thousand Nursing Homes Reached Infection Rates of 75 Percent or More in the First Year of the COVID-19 Pandemic; Better Protections Are Needed for Future Emergencies*	CMS	Jan-23
OEI-03-21-00380	*The Inability To Identify Denied Claims in Medicare Advantage Hinders Fraud Oversight*	CMS	Feb-23
OEI-03-23-00080	*Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Third Quarter of 2022*	CMS	Feb-23
OEI-BL-23-00170	*Technical Assistance Brief: Implementation of Inflation-Indexed Rebates for Part B Drugs*	CMS	Feb-23

OEI-BL-23-00010	*Some Skin Substitute Manufacturers Did Not Comply with New ASP Reporting Requirements*	CMS	Mar-23
OEI-01-20-00241	*FDA's Approach to Overseeing Online Tobacco Retailers Needs Improvement*	FDA	Dec-22
OEI-09-23-00190	*Medicaid Fraud Control Units Fiscal Year 2022 Annual Report*	MFCU	Mar-23
OEI-07-22-00370	*Rhode Island Medicaid Fraud Control Unit: 2022 Inspection*	MFCU	Mar-23

Total Reports: 19

Appendix B: Peer Review Results

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

Office of Audit Services

During this semiannual reporting period, no peer reviews involving OAS were completed. As such, information concerning OAS's peer review activity during prior reporting periods is listed here.

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

The system of quality control for the audit organization of DOL-OIG in effect for the fiscal year ending September 30, 2021, has been suitably designed and complied with to provide DOL-OIG with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Federal audit organizations can receive a rating of *pass*, *pass with deficiencies*, or *fail*. DOL-OIG received a peer review rating of *pass*.

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

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

Office of Investigations

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

OI	Date	Reviewing Office	Office Reviewed
	February 2023	HHS-OIG, OI	DOD-OIG

The system of internal safeguards and management procedures for the investigative function of DOD-OIG in effect for the year ending December 31, 2022, was in full compliance with the quality standards established by CIGIE and the Attorney General's guidelines.

OI	Date	Reviewing Office	Office Reviewed
	October 2018	Social Security Administration OIG	HHS-OIG, OI

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

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

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

Office of Evaluation and Inspections

During this semiannual reporting period, one peer review involving OEI was completed. Information concerning OEI's peer review activity during a prior reporting period is also listed here.

OEI	Date	Reviewing Office	Office Reviewed
	March 2023	HHS-OIG, OEI	Special Inspector General for Afghanistan Reconstruction (SIGAR) OIG

The SIGAR Audits and Inspections Directorate and the Lessons Learned Program (collectively, SIGAR-OIG) policies and procedures complied with CIGIE's *Quality Standards for Inspection and Evaluation* (known as the Blue Book), December 2020. In addition, each of the three reviewed SIGAR-OIG reports complied with those standards and the SIGAR-OIG's internal policies and procedures. SIGAR concurred with the three recommendations issued in the Letter of Comment regarding the Blue Book standards for independence, competence, and planning.

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

A CIGIE external peer review team assessed the extent to which HHS-OIG, OEI met CIGIE's seven Blue Book standards: Quality Control, Planning, Data Collections and Analysis, Evidence, Records Maintenance, Reporting, and Follow-up. The assessment included a review of OEI's internal

policies and procedures documented in the OEI procedures manual. It also included a review of four reports issued between June 1, 2019, and June 1, 2020, to determine whether the reports compiled with the seven standards and internal policies and procedures. The review team determined that OEI's policies and procedures generally met the seven standards. The four reports reviewed generally met the standards and complied with OEI's internal policies and procedures.

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

The VA Office of Inspector General, Office of Audits and Evaluations, and Office of Healthcare Inspections (collectively, VA-OIG) policies and procedures addressed CIGIE's seven Blue Book standards: Quality Control, Planning, Data Collections and Analysis, Evidence, Records Maintenance, Reporting, and Follow-up. In addition, each of the four reviewed VA-OIG reports complied with those standards and the VA-OIG's internal policies and procedures. As a result of our findings, there are no recommendations associated with this external peer review. The report also noted a VA-OIG beneficial practice of using specialized staff to conduct independent referencing reviews of its reports to achieve greater consistency in its quality assurance processes.

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

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

OEI	Date	Reviewing Office	Office Reviewed
	September 2018	HHS-OIG, OEI	DoD-OIG

The DOD-OIG Inspection and Evaluation component's policies and procedures generally met CIGIE's Blue Book standards. The 10 reports reviewed generally met the applicable Blue Book standards. Onsite visits for these reviews were conducted from October 2, 2017, through November 17, 2017.

Appendix C: Summary of Sanction Authorities

The Inspector General Act of 1978, as amended, specifies requirements for semiannual reports to be made to the 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 the OIG in matters involving HHS grants, contracts, or other agreements.

Patient Dumping

Section 1867 of the Social Security Act (42 U.S.C. § 1395dd) provides that when an individual goes to the Emergency Department of a Medicare-participating hospital, the hospital must provide an appropriate medical screening examination to determine whether that individual has an emergency medical condition. If an individual has such a condition, the hospital must provide either treatment to stabilize the condition or an appropriate transfer to another medical facility when the hospital does not have the capabilities to stabilize the condition.

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

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

Anti-Kickback Statute and Civil False Claims Act Enforcement Authorities

The Anti-Kickback Statute

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

Individuals and entities who engage in conduct prohibited by the anti-kickback statute may be subject to criminal penalties and fines under the anti-kickback statute; CMPs under OIG's authority pursuant to the Social Security Act, 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 $11,181 and $22,363 for each false claim it knowingly submits, or causes to be submitted, to a Federal program. Similarly, a person or an entity is liable under the False Claims Act if 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 D: 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	*OIG's Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs*
(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

Section	Requirement	Location
(a)(12)	Management decisions with which the Inspector General disagrees	None for this reporting period
(a)(13)	Information required by the Federal Financial Management Improvement Act of 1996	Nothing to report
(a)(14)-(16)	Results of peer reviews of HHS-OIG conducted by other OIGs or the date of the last peer review, outstanding recommendations from peer reviews, and peer reviews conducted by HHS-OIG of other OIGs	Appendix C
(a)(17)	Investigative statistical tables	Appendix F
(a)(18)	Metrics description for statistical tables	Appendix F
(a)(19)	Investigations on senior Government employees	Appendix F
(a)(20)	Description of whistleblower retaliation instances	Appendix F
(a)(21)	Description of attempts to interfere with OIG independence	Appendix F
(a)(22)	Description of closed and nondisclosed reports and investigations regarding senior Government employees	Appendix F

Other Reporting Requirements

Section	Requirement	Location
845	Significant contract audits required to be reported pursuant to the National Defense Authorization Act for FY 2008 (P.L. No. 110–181), 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 E: Reporting Requirements in the Inspector General Empowerment Act of 2016

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

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

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

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

For audit and evaluation reports issued from FY 2011 through FY 2022, OIG had a total of 86 reports with overdue final management decisions (FMDs) as of the end of this reporting period. The breakdown of those 86 reports by HHS OpDiv is as follows:

OpDiv	Overdue FMDs
ACF	13
ASA	1
ASPR	1
CMS	52
IHS	14
NIH	2
OASH	1
OS	5

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 1,379 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)	Number of Reports With Unimplemented Recommendations	Number of Unimplemented Recommendations	Dollar Value of Aggregate Potential Cost Savings
2011	12	17	$408,135,515
2012	18	21	$369,932,148
2013	24	36	$232,841,797
2014	22	38	$15,072,080,989
2015	20	32	$296,314,747
2016	16	30	$181,809,287
2017	25	65	$1,100,592,712
2018	32	94	$1,675,138,695
2019	53	151	$718,126,811
2020	66	204	$1,394,187,117
2021	73	171	$834,922,145
2022	94	328	$2,475,128,152
2023	60	192	$505, 914,370
Totals	**515**	**1,379**	**$25,265,124,485**

OIG annually produces *OIG's Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs* which constitutes OIG's response to a specific requirement of the Inspector General Act, as amended (§ 5(a)(3)). The report identifies significant recommendations with respect to problems, abuses, or deficiencies for which corrective actions have not been completed. It also includes an appendix that lists OIG's significant unimplemented

recommendations, which represent opportunities to achieve expected impact through cost savings, improvements in program effectiveness and efficiency, or increasing quality of care and safety for beneficiaries. In OIG's view, these recommendations would most positively impact HHS programs in terms of cost savings and/or quality improvements and should therefore be prioritized for implementation.

(17) Statistical tables showing-

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

(B) the total number of persons referred to the 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]	**1,192**
Total number of persons referred to State and local prosecuting authorities for criminal prosecutions during the reporting period	**130**
Total number of Federal indictments and criminal informations during the reporting period that resulted from any prior referral to prosecuting authorities	**276**
Total number of State and local indictments and criminal informations during the reporting period that resulted from any prior referral to prosecuting authorities	**74**

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

The OIG investigated a senior official (GS-15) for allegedly receiving improper prescription drug medications, which were prescribed by other employees. It was alleged that the senior official directed subordinate employees to provide the senior official with prescriptions for controlled substances without medical examinations. The investigation was presented for Federal prosecution on July 18, 2022, and was initially accepted. After further investigation, criminal prosecution of the senior official was declined on February 8, 2023.

The OIG investigated a senior official (GS-15) for alleged financial conflict of interest. It was alleged that ethics officials directed the senior official to recuse themself from any matters involving a private company in which their spouse was employed; however, the senior official did not. In addition, the senior official did not disclose their spouse's financial interest with the company. This

investigation was referred to the appropriate HHS operational division for evaluation and administrative action. The investigation was not presented for prosecution.

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 (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 two report(s) 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 a complainant at the Orangeburg-Calhoun-Allendale-Bamberg (OCAB) Community Action Agency - Bamberg Head Start Center, an ACF grantee. The complainant alleged that while working in the Bamberg Center, the complainant's supervisors and responsible management officials (RMOs) terminated the complainant for reporting that Federal grant laws were being repeatedly violated by OCAB staff and management. Specifically, investigators found that the complainant made protected disclosures to the RMOs at OCAB and in a written complaint submitted to ACF's Office of Head

Start alleging what the complainant believed to be grant mismanagement and threats to public health and safety. OIG investigators found that the RMOs terminated the complainant in retaliation for making protected disclosures. The OIG investigative report that was issued to the Secretary of Health and Human Services included recommendations to make the complainant whole and to provide whistleblower training for OCAB employees, ACF employees who work in the Head Start program, and Head Start grantee agencies.

OIG conducted an investigation in response to allegations brought forth by a complainant at Jacobs Technologies, a contractor for DOD. DOD entered into an agreement with HHS to provide acquisition assistance under an HHS contract with Jacobs Technologies. The complainant alleged that while working at DOD as a contract employee, the complainant's supervisors and RMOs terminated the complainant for notifying Army personnel of possible security breaches. OIG investigators found that the RMOs terminated the complainant in retaliation for making protected disclosures. The OIG investigative report that was issued to the Secretary of Health and Human Services included recommendations to make the complainant whole and to provide whistleblower training to employees of HHS contractors. A copy of the report was also provided to DOD. The OIG investigative report also included recommendations to DOD to provide whistleblower protection training to management officials and to consider whether DOD employees should be disciplined for committing prohibited personnel actions under applicable laws and/or regulations.

(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, October 1, 2022, Through March 31, 2023

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

(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 five 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 seven senior Government employee(s) for misconduct, but OIG determined the allegations to be unsubstantiated. Descriptions of the investigations follow.

OIG investigated two senior officials (SES) for alleged financial conflict of interest. It was alleged that the senior officials pressured subordinate employees to sign contracts with a company for which one of the senior official's family members had a financial interest. OIG did not find any evidence to support the allegations.

OIG investigated a senior official (GS-15) for alleged fraud and prohibited personnel actions. It was alleged that the senior official retaliated against an employee for reporting fraud and discrimination. The senior official allegedly harassed and terminated the employee after the employee reported administrative fraud, abuse, and sabotage. OIG did not identify any evidence to support the allegation.

OIG investigated a complaint alleging that a senior official (SES) provided false educational credentials for employment. OIG did not identify any evidence to support the allegation. The senior official did in fact have the appropriate and required educational credentials.

OIG investigated a complaint alleging that a senior official (SES) violated Federal law and agency policies. It was alleged that the senior official authorized subordinate employees to commit time and attendance fraud. OIG did not identify any evidence to support the allegation.

OIG investigated two senior officials (GS-15 and SES) for allegedly steering patients to a specific medical air transport company when patients could have been transported at a lesser cost via ground ambulance. OIG did not find any evidence to support these allegations.

Appendix F: Anti-Kickback Statute—Safe Harbors

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

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

Public Proposals for New and Modified Safe Harbors

Annual Solicitation

In December 2021, OIG published its annual solicitation in the *Federal Register* (Annual Solicitation).[1] In response to the Annual Solicitation, OIG received the following proposals related to safe harbors:

Proposal	OIG Response
Repeal or modify existing safe harbors (e.g., the group purchasing organization [GPO] safe harbor, 42 CFR § 1001.952(f)) to address comments and concerns regarding the manner in which GPOs and PBMs may be using such safe harbors to protect purportedly abusive arrangements.	OIG is not adopting commenters' suggestions to repeal or modify the GPO safe harbor, among others, to address their comments and concerns about the financial arrangements for which GPOs and PBMs may be using these safe harbors. We may consider this topic in future rulemaking or in future guidance. OIG highlights that there is a statutory exception addressing GPOs at section 1128B(b)(3)(C) of the Social Security Act.

[1] OIG, *Solicitation of New Safe Harbors and Special Fraud Alerts*, 86 FR 71611 (Dec. 17, 2021). Accessed at https://www.govinfo.gov/content/pkg/FR-2021-12-17/pdf/2021-27314.pdf on April 24, 2023.

Modification of the Cooperative Hospital Services Organization (CHSO) safe harbor, 42 CFR § 1001.952(q), to: (i) protect only CHSO arrangements that involve the provision of items or services that are components of the direct or indirect overhead costs associated with the inpatient or outpatient hospital services of the nonprofit patron-hospitals; and (ii) exclude protection for the creation of revenue-producing joint venture arrangements for nonhospital, postdischarge home care services and the distribution of CHSO revenues to patrons based on referrals.	OIG is not adopting this suggestion. We may consider this topic in future rulemaking.
A new safe harbor to protect: (i) value-based price-adjustment arrangements that are dependent on the achievement of a measurable clinical or cost outcome associated with the value of a seller's reimbursable items or services; and (ii) the provision of value-based services, such as services that enable parties to measure outcome measures associated with value-based price-adjustment arrangements.	OIG is not adopting this suggestion. We appreciate learning about ways in which pharmaceutical manufacturers, medical device manufacturers, and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) entities believe that they could contribute to the coordination of care and the overall delivery of high-value care through, for example, value-based price-adjustment arrangements or value-based services arrangements. However, we continue to have concerns about the offer of remuneration by these entities, which raises many of the traditional fraud and abuse risks under the Federal anti-kickback statute. We may consider this topic in future rulemaking.
A new safe harbor to protect drug copayment assistance in situations in which a less expensive and equally effective alternative drug does not exist.	OIG is not adopting this suggestion. The offer of cost-sharing assistance for a drug, particularly by the manufacturer of such drug (either directly or indirectly), presents many of the traditional risks of fraud and abuse that the Federal anti-kickback statute is designed to prevent.
New safe harbors to protect: (i) value-based purchasing arrangements between pharmaceutical manufacturers and payors or PBMs; and (ii) the provision of data analytics by a drug, biologic, or device manufacturer.	OIG is not adopting these suggestions. We continue to evaluate the ways in which pharmaceutical manufacturers may be able to contribute to the coordination of care and the overall delivery of high-value care through, for example, value-based purchasing arrangements or data-sharing arrangements. However, we continue to have concerns about the offer of

	remuneration through these programs, which raises many of the traditional fraud and abuse risks under the Federal anti-kickback statute. We may consider this topic in future rulemaking.
Modifications to the safe harbors for value-based arrangements, including the safe harbors for arrangements for patient engagement and support to improve quality, health outcomes, and efficiency, 42 CFR § 1001.952(hh), to protect the exchange of remuneration by certain entities that currently cannot use the safe harbors (e.g., pharmaceutical manufacturers, medical device manufacturers, laboratory companies, and DMEPOS suppliers).	As explained in the preamble to the final rule at 85 Fed. Reg. 77684 (Dec. 2, 2020) (referred to in this appendix as the "2020 final rule"), remuneration exchanged by pharmaceutical manufacturers and, in certain circumstances, medical device manufacturers and DMEPOS entities, are not eligible for protection under the value-based safe harbors due to (among other reasons) concerns that such entities could use the safe harbor to protect arrangements that are intended to market their products or inappropriately tether clinicians to the use of a particular product.[2] Consequently, OIG declines to adopt this suggestion.
New safe harbors to implement the Final Rule for the Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees.	OIG is not adopting this suggestion. Section 11301 of the Inflation Reduction Act of 2022 extended the moratorium on the implementation of the Final Rule for the Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees until January 1, 2032.
New safe harbor for charitable assistance programs to protect the provision of medical products and pharmaceutical products at no charge to patients in financial need.	OIG is not adopting this suggestion. We may consider this topic in future rulemaking.
Modification to existing safe harbor at 42 CFR § 1001.952(h) to define "rebate" to include any service fee paid as a percentage of sales.	OIG is not adopting this suggestion. A rebate is a type of discount, and a discount is a reduction in price charged for an item or service. A discount, including a rebate, does not include

[2] 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 FR 77684, 77709 (Dec. 2, 2020). Accessed at https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26072.pdf on April 24, 2023.

	payment for a service. In a final rule issued in 1991, OIG stated that contracts for personal or management services do not fit within the statutory discount exception or the definition of "discount" in the regulatory safe harbor.[3] We decline to revise the definition of "rebate" to include service fees paid as a percentage of sales.
New safe harbor for manufacturer-sponsored patient engagement and product support programs, including therapy management and medication adherence support to encourage patients to manage and follow their treatment plans.	OIG is not adopting this suggestion. We continue to evaluate the ways in which pharmaceutical manufacturers may be able to contribute to the delivery of quality care for patients through programs such as medication adherence support, but we continue to have concerns about the offer of remuneration to patients through these programs, which raises many of the traditional fraud and abuse risks (e.g., patient steering). We may consider this topic in future rulemaking.
New safe harbor to protect internal cost sharing (or gainsharing) payments or modification to the personal services and management contracts and outcomes-based payment arrangements safe harbor, 42 CFR § 1001.952(d), to expand the definition of "outcomes-based payment" to include internal cost sharing (or gainsharing) payments.	OIG is not adopting the suggestion to create a new safe harbor or modify the personal services and management contracts and outcomes-based payment arrangements safe harbor. We continue to believe, as stated in the preamble to the 2020 final rule, that payments for arrangements that reduce internal costs may pose risks to patient care, among other concerns.[4] At this time, we continue to believe that the risks outweigh any potential benefits of these arrangements such that safe harbor protection is not warranted.
New safe harbor for payments from hospitals to post-acute care providers to transition patients to clinically appropriate, lower cost care settings.	OIG is not adopting this suggestion. We believe that existing regulations, including new and modified safe harbors that were finalized in the 2020 final rule, provide sufficient regulatory flexibility for financial arrangements between referral sources that balance the goals of care

[3] 42 CFR § 1001.952(h)(5)(vi); OIG, *Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions*, 56 FR 35952 (July 29, 1991). Accessed at https://oig.hhs.gov/documents/compliance/857/072991.htm on April 24, 2023.
[4] 85 FR 77845.

	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.
A new safe harbor for the waiver or offset of cost-sharing obligations for items and services provided in connection with: (i) value-based arrangements for care management or remote patient monitoring, and (ii) the Acute Care Hospital at Home program and any follow-on model that may be established by CMS following the expiration of the Section 1135 Public Health Emergency waiver.	OIG has repeatedly expressed concerns regarding routine waivers of Medicare cost-sharing amounts that do not meet an exception to the CMP provision prohibiting inducements to beneficiaries at section 1128A(i)(6)(A) of the Social Security Act. Accordingly, we decline to adopt these suggestions.
A new safe harbor that would protect remuneration between wholly owned subsidiaries and between a parent company and a subsidiary.	OIG is not adopting this suggestion. We may consider this topic in future rulemaking.