Department of Health and Human Services

Office of Inspector General

Semiannual Report to Congress

April 1, 2024–September 30, 2024

Contents

A Message From the Inspector General

I am pleased to submit this *Semiannual Report to Congress* summarizing the activities of the Department of Health and Human Services (HHS or the Department), Office of Inspector General (OIG) for the 6-month period ending on September 30, 2024.

OIG provides independent, objective oversight for HHS's more than $2 trillion in annual expenditures and more than 100 health and human services programs. OIG's investigators, auditors, evaluators, attorneys, data scientists, and other professionals focus on identifying improper payments, ensuring high-quality and safe care, and holding wrongdoers accountable. Our work helps ensure that taxpayers are getting good value for their investments in HHS programs.

OIG's dedicated workforce continues to deliver exceptional results for the American public in achieving the mission set for us by Congress: to detect and prevent fraud, waste, and abuse and to promote the economy, efficiency, and effectiveness of HHS programs. For fiscal year 2024, OIG identified $7.13 billion in expected recoveries and receivables through our investigative and audit work. OIG achieved 1,548 civil and criminal results and excluded 3,234 individuals and entities from participating in Federal health care programs.

OIG is the Nation's leading health care fraud investigative agency. In June, OIG participated in the 2024 National Health Care Fraud Enforcement Action with the Department of Justice and other Federal, State, and local law enforcement partners. This Enforcement Action resulted in criminal charges against 193 defendants in 32 Federal districts for alleged participation in fraud schemes, including kickbacks and fraudulent billing for expensive amniotic wound grafts and addiction treatment, unlawful distribution of stimulants over the internet, distribution of adulterated and misbranded HIV medication, and fraudulent telemedicine and genetic testing schemes. The conduct charged involved approximately $2.75 billion in intended losses to Government programs and taxpayers.

In this reporting period, OIG continued to tackle the most pressing and complex issues facing the Department's programs using our full range of authorities and resources. We use a risk-based approach to identify, prioritize, and mitigate evolving threats and maximize the return on American taxpayers' investment in OIG. We endeavor to prevent fraud before people and programs can be harmed. We use sophisticated data analytics and modern investigative techniques to detect fraud and stop it faster. Our audits and evaluations uncover program vulnerabilities and make recommendations for meaningful improvements to reduce risk and improve program operations.

For example, OIG has continued to prioritize investigations in areas particularly vulnerable to criminal schemes, such as durable medical equipment. During this reporting period, our investigators worked with the Department of Justice to prosecute two brothers who used aggressive telemarketing strategies and bribed doctors to order unnecessary durable medical equipment. The brothers were sentenced to jail and ordered to

pay more than $424 million in restitution. We also excluded a nurse practitioner who had been convicted of a $192 million durable medical equipment fraud scheme from participating in Federal health care programs. Additionally, our audit work identified key vulnerabilities in CMS's oversight of durable medical equipment and recommended actions CMS should take to reduce risks of fraud, waste, and abuse and protect the health of Medicare enrollees.

HHS is the Federal Government's largest grant-making agency and the fourth largest contracting agency. During this reporting period, OIG published a Strategic Plan titled *Safeguarding the Integrity of HHS Grants and Contracts* that describes our strategy for vigorous oversight using data and advanced analytics to safeguard taxpayer dollars, hold poor performers accountable, and protect the people that HHS programs serve. We also identified gaps in the Department's oversight of grants and contracts that allowed HHS funds to be misspent and put people at risk. For example, OIG pursued bad actors who diverted funds from a Substance Abuse and Mental Health Services Administration grant intended to prevent youth substance abuse. Our actions helped protect Federal grant dollars and ensured that the program could better serve this population.

OIG's innovative, data-driven, technology-savvy workforce produces outsized impacts for the American people. OIG's work consistently yields a positive health care return on investment of around $10 returned for every $1 invested, including expected and actual recoveries of funds to HHS programs. As evidenced by this report, our work identifies misspent taxpayer funds, stops fraud, and finds opportunities to improve the quality and efficiency of HHS programs. OIG stands ready to do even more. With additional resources, we have in place the infrastructure and expertise to deliver even greater results for the American people.

We appreciate the continued support of Congress and HHS for OIG's important work.

Christi A. Grimm
Inspector General

At a Glance: OIG Accomplishments

The Department of Health and Human Services (HHS or the Department), Office of Inspector General (OIG) oversees more than 100 health and human services programs to ensure that more than $2.5 trillion in taxpayer funds are responsibly spent and that the more than 150 million Americans who rely on those programs are well served. OIG focuses on the most significant and high-risk issues in health care and human services. OIG also remains at the forefront of the Nation's efforts to fight fraud in HHS programs and hold wrongdoers accountable for their actions. The graphic below features a few of our fiscal year (FY) 2024 accomplishments.

Reporting Period Specific Accomplishments

During the semiannual reporting period of April 1, 2024, through September 30, 2024 (reporting period), our investigative and audit efforts identified $4.36 billion in expected recoveries and receivables. We also issued 53 audits and 22 evaluations to HHS in which we identified systemic weaknesses and opportunities for improvement. See Appendix A for a full list of these audits and evaluations, including the identified questioned costs, funds put to better use, and unsupported costs.

The scope of our work extended beyond identifying concerns; during the reporting period, we issued 239 new recommendations that, if implemented, will foster sustainable program improvements and safeguard taxpayer funds. Further, HHS and non-HHS entities implemented 187 recommendations to address problems we identified in previous audits and evaluations. Our enforcement efforts through our investigative and counsels' offices resulted in more than 836 civil and criminal actions during this reporting period, which includes settlements resulting from using OIG's civil monetary penalty authorities and criminal convictions. Additionally, we identified and excluded 1,439 bad actors from participation in Federal health care programs during this reporting period, ensuring that untrustworthy actors don't receive Federal health care program payment.

Introduction

The Inspector General Act of 1978 (Public Law 95-452), as amended, requires that the Inspector General report semiannually to the head of the Department and to Congress on the activities of the office. The semiannual reports are intended to keep the Secretary and Congress fully informed of significant current findings and recommendations.

Semiannual Report Restructure

Beginning with the Spring 2024 semiannual report, we have restructured these reports based on recent congressional reforms that streamline and modernize reporting requirements and allow inspectors general to focus on the most significant activities and critical issues facing the departments they oversee. This revised semiannual report highlights OIG's oversight work completed during the reporting period focused on the most significant issues facing HHS. OIG identifies these significant issues every year in its *Top Management and Performance Challenges Facing HHS* (TMCs). OIG identified five TMCs in its 2024 report:

1) Public Health
2) Financial Integrity
3) Medicare and Medicaid
4) Beneficiary Safety
5) Data and Technology Security

Having identified these TMCs for the Department, OIG makes its own investments, using its suite of oversight and enforcement tools and authorities, to better understand and address these issues. Our mission is to protect the integrity of HHS programs as well as the health and welfare of the people they serve. We do that, in part, by strategically focusing our efforts on the areas of greatest vulnerability. The summaries of OIG's work in this semiannual report identify key findings, information, and recommendations that could help the Department address the TMCs and fulfill its mission to enhance the health and well-being of all Americans.

In addition to highlighting OIG's work related to the TMCs, this report includes a comprehensive overview of all OIG's work completed in this semiannual reporting period. This overview can be found in six appendices that provide detailed information on OIG's oversight, including a full list of OIG audits and evaluations issued to each HHS operating division during the reporting period. Changes to streamline this semiannual report are consistent with statutory amendments for inspector general reporting requirements. Appendix F lists each of the current reporting requirements and the location within this semiannual report where they are met.

Additional Resources

OIG's website offers additional resources to understand the full scope of OIG's oversight and enforcement work, including all reports available by issue area and HHS agency; OIG recommendations to improve Department programs and reduce vulnerabilities, including the status of those recommendations and those OIG has identified as top unimplemented recommendations; and OIG enforcement actions. Additional information on how OIG's work has a positive financial impact on Medicare and Medicaid can be found in the annual Health Care Fraud and Abuse Control Program Report.

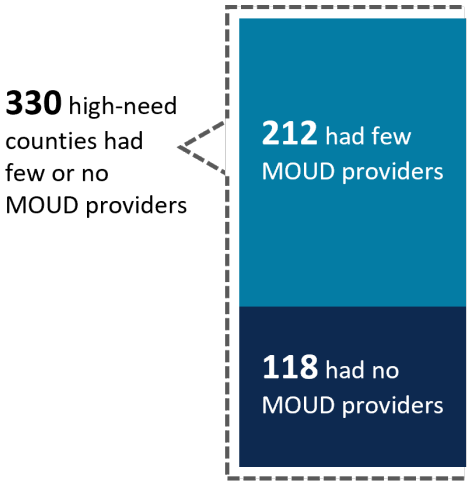
1 | Public Health

Opioid Epidemic

HHS funds a wide range of programs to address the opioid epidemic by increasing access to treatment and reducing overdose-related deaths. OIG's oversight and enforcement related to the opioid epidemic helps foster access to treatment, promote compliance with Federal and State requirements, and deter bad actors from opioid-related drug diversion. Significant OIG work completed during this reporting period related to the opioid epidemic is detailed below.

Access to Treatment

OIG found that hundreds of counties with high needs for medication for opioid use disorder (MOUD) services lacked office-based buprenorphine providers and opioid treatment programs (i.e., MOUD providers). Even in counties where MOUD providers did practice, they often did not treat any Medicare or Medicaid enrollees. Factors that may influence MOUD providers' ability and willingness to treat Medicare and Medicaid enrollees include Medicare Advantage prior authorization requirements, low Medicaid reimbursement rates, and inadequate public information about MOUD provider locations (OEI-BL-23-00160).



See OIG's interactive map for additional detail about these counties (OEI-BL-23-00161).

Oversight of Treatment Programs

OIG found that opioid treatment programs (OTPs) in Washington and Massachusetts did not fully comply with Federal and State requirements for providing and documenting opioid treatment services. Failure to comply with these requirements may lead to poor treatment outcomes for individuals, including relapses, overdoses, or deaths. Specifically, OIG found that Washington OTPs did not adequately document enrollee admissions, treatment plans, opioid treatment services, the results of drug screens, checks of Washington's prescription drug monitoring program data, and enrollee assessments (A-09-21-02001). Additionally, OIG found that OTPs in Massachusetts met many, but not all, Federal and State requirements and that the State could improve its oversight of OTPs. Specifically, OIG found OTPs did not review treatment plans every 3 months and did not document counseling services as required (A-01-23-00002).

Oversight of Opioid Grant Programs

OIG found that West Virginia did not comply with Federal regulations regarding oversight and reporting requirements for its Opioid State Targeted Response and State Opioid Response (SOR) grants. Specifically, West Virginia could not support its annual progress reports and did not adequately monitor subrecipient

spending, nor did it have adequate procedures in place to determine whether it met SOR grant program goals (A-06-22-01005).

Enforcement Actions

OIG excluded multiple bad actors from federally funded health care programs for opioid-related drug diversion. For example, OIG excluded a former advanced nurse practitioner for a minimum period of 56 years following her conviction for illegally prescribing and dispensing opioids outside of the scope of legitimate medical practice, which resulted in the deaths of five people between 2014 and 2019. She was sentenced to 30 years in prison.

In another example of OIG's and other law enforcement partners' work, Endo Health Solutions Inc. (EHSI), an opioid manufacturer, was ordered to pay $1.54 billion in criminal fines and forfeiture, the second-largest set of criminal financial penalties ever levied against a pharmaceutical company, for violations of the Federal Food, Drug, and Cosmetic Act related to the distribution of the opioid medication Opana ER. Specifically, EHSI sales representatives marketed Opana ER to prescribers by touting the drug's purported abuse deterrence and tamper and crush resistance despite a lack of clinical data supporting those claims. EHSI also pled guilty to one misdemeanor count of introducing misbranded drugs into interstate commerce. This was part of a global criminal and civil resolution that included a False Claims Act settlement resolving allegations that EHSI's false marketing scheme caused the submission of false claims for Opana ER to Federal health care programs.

Maternal Health

U.S. rates of pregnancy and postpartum complications exceed those of any other high-income nation. Medicaid finances more than 40 percent of all U.S. births and more than half of pregnancies and deliveries in rural and low-income communities. Most State Medicaid programs require managed care enrollment during pregnancy and use provider coverage rules and network adequacy standards (i.e., requirements that managed care organizations [MCOs] include enough providers in their networks) to help ensure adequate access to care.

OIG found that States could better leverage MCO provider coverage requirements and network adequacy standards to promote access to maternal health care (OEI-05-22-00330). Specifically, OIG found that:

Beyond obstetrician/gynecologist (OB/GYN) physicians and hospitals, many States reported they do not require MCOs to cover important types of maternal health providers and professionals, some of whose services are federally required.

Some States are not using network adequacy standards to address important dimensions of maternal health care access. For example, some measure access to specific provider types such as OB/GYNs, but many do not. Some tailor their standards to maternal health care needs (e.g., by varying appointment wait time requirements by pregnancy stage), while others do not.

All States reported monitoring MCOs' compliance with network adequacy standards, but they may lack data on the standards' impact on access to maternal health care.

Food Safety

The Food and Drug Administration (FDA) is responsible for maintaining the safety of the Nation's food supply. The FDA develops policies and procedures to hold food manufacturers accountable for the safety of the foods they grow, make, and sell—including infant formula. In response to a recall of certain Abbott Laboratories powdered infant formula products and related congressional concerns, OIG conducted work that found that FDA lacked or had inadequate policies and procedures to identify risks to infant formula and respond effectively through its complaint, inspection, and recall processes. For example, FDA had not developed an organizational structure or assigned responsibilities to handle whistleblower complaints in an efficient and effective manner and took more than 15 months to address a February 2021 Abbott facility whistleblower complaint. OIG also found that FDA did not have policies and procedures to establish timeframes for the initiation of mission-critical inspections, nor did it have sufficient policies and procedures on how to initiate an infant formula recall under its FDA-required recall authority (A-01-22-01502).

2 | Financial Integrity

OIG's oversight identifies and reduces improper payments, promotes efficient and effective ways to address costs, and ensures good financial stewardship by recommending program improvements. In addition, OIG recognizes the importance of identifying and holding accountable those who defraud Medicare, Medicaid, other HHS programs, enrollees, and taxpayers. Significant OIG work completed during this reporting period related to improper payments, cost effectiveness, and program integrity in all HHS programs is detailed below.

Improper Payments

OIG found Medicare improperly paid hospitals an estimated $79 million realted to mechanical ventilation. Hospitals attributed the improper billing to incorrectly counting the hours that enrollees had received mechanical ventilation or clerical errors in selecting procedure or diagnosis codes (A-09-22-03002).

CASE EXAMPLE

Pharmacy Owners Sentenced for $18 Million COVID-19 Health Care Fraud and Money Laundering

As a result of OIG's and other law enforcement partners' work, Peter Khaim and his brother Arkadiy Khaimov were sentenced to 8 years and 6 years in prison, respectively, for using pharmacies to submit millions of dollars in fraudulent claims to Medicare and for money laundering. Khaim was ordered to pay more than $18 million in restitution and to forfeit more than $2.7 million. Khaimov was ordered to pay more than $18 million in restitution and to forfeit more than $9.6 million. The brothers and their co-conspirators used COVID-19 related emergency override billing codes to submit claims for cancer medications that were not prescribed or dispensed. They funneled money to shell companies. The funds were then typically sent to companies in China for distribution to individuals in Uzbekistan. The defendants received cash from a co-conspirator, minus a commission. At other times, the funds were sent from the sham companies to the brothers, their relatives, or their designees via certified cashier's checks and cash. The brothers used the proceeds of the scheme to purchase real estate and other luxury items.

Enforcement Action

OIG excluded an unlicensed individual posing as a physican for a minimum of 49 years for his role in a home health care fraud scheme. The individual acted in the role of a physician to qualify patients for home health services. He was convicted in a jury trial of conspiracy to commit health care fraud, ordered to pay more than $11 million in restitution, and sentenced to 168 months in prison. His co-conspirator, an owner of numerous home health agencies, was also convicted of conspiracy to commit health care fraud, excluded for a minimum of 45 years, ordered to pay more than $27 million in restitution, and sentenced to 60 months in prison.

Cost Effectiveness

OIG found that Medicare and some enrollees paid 80 percent more when Stelara injections, a high-cost prescription biologic approved to treat certain autoimmune diseases, were covered under Part D (i.e., self-administered) versus under Part B (i.e., administered by a physician). However, given recent coverage changes, enrollees who once opted to receive Stelara injections in their doctors' offices (i.e., through Part B) must now obtain Stelara through a pharmacy (i.e., through Part D), where they will potentially face much higher out-of-pocket costs. Our findings illustrate how differences in the methods used to set drug payment amounts under Part B (i.e., manufacturers' sales prices) versus under Part D (i.e., negotiations between plan sponsors, manufacturers, pharmacy benefit managers, and pharmacies) result in widely different payment amounts for the same drugs (OEI-BL-19-00500).

In 2021, the annual cost per enrollee for Stelara was 80% more under Part D than Part B

Program Integrity

Contracts Administration

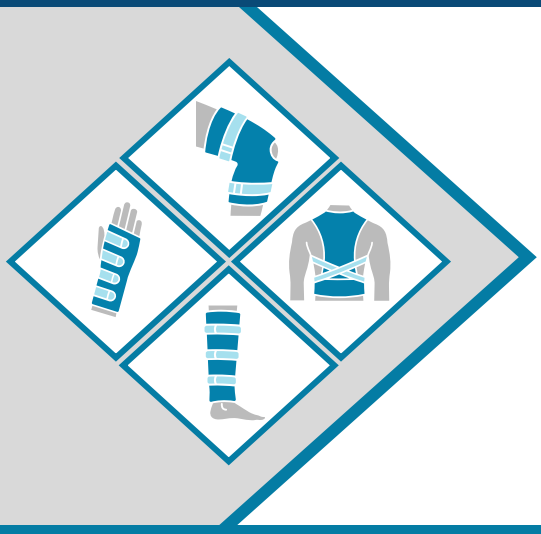
Closing contracts is generally the last chance for the Government to detect and recover improper contract payments. A delayed closeout poses a financial risk to agency funds. OIG found the National Institutes of Health (NIH) did not always close contracts in accordance with Federal regulations and HHS policies and procedures. Specifically, OIG reviewed 30 judgmentally selected contracts totaling $2.1 billion and found that for 29 of the contracts, NIH did not meet one or more administrative closeout requirements (e.g., performing a contract audit) (A-04-23-03585).

Medicare Rules and Compliance

OIG identified three weaknesses in the Centers for Medicare & Medicaid Services' (CMS's) established program safeguards for preventing and detecting improper payments for short inpatient stays and recovering overpayments. Specifically, for claims at risk for noncompliance with the two-midnight rule, CMS did not have: (1) adequate information to identify short inpatient stays, (2) prepayment edits, or (3) adequate policies and procedures to review these claims and recover overpayments (A-09-21-03022).

Service Oversight

OIG identified the need for additional oversight of remote patient monitoring services in Medicare to ensure that it is being used and billed appropriately. The number of Medicare enrollees who received remote patient monitoring was more than 10 times higher in 2022 than in 2019. OIG found Medicare lacks key information for oversight, including who ordered monitoring services for enrollees. The use of remote patient monitoring has the potential to continue expanding in the Medicare population. As a result, there is an increasing need to know how remote patient monitoring is being used, including who is receiving it and for what conditions, as well as a need to identify any vulnerabilities that may limit the oversight of these services (OEI-02-23-00260).



SPOTLIGHT ON ORTHOTIC BRACES

In calendar year 2023, Medicare paid approximately $485 million for orthotic braces provided to Medicare enrollees. Medicare remains vulnerable to fraud, waste, and abuse related to these orthotic braces, which may result in improper payments and impact the health of enrollees. Orthotic braces are consistently among the top 20 durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items with the highest improper payment rates. For example, in 2023, the improper payment rate for orthotic braces was between 36 and 41 percent.

OIG WORK THIS REPORTING PERIOD

OIG identified vulnerabilities related to off-the-shelf orthotic braces (A-09-21-03019).

- Providers ordered braces for enrollees for whom there was no history of a treating relationship.
- New suppliers started doing business in geographic areas with known fraud.
- Medicare paid more than private payers for off-the-shelf braces.
- Suppliers used prohibited solicitation to contact enrollees.

OIG excluded an advanced registered nurse practitioner for 97 years.

OIG excluded Elizabeth Hernandez, an advanced registered nurse practitioner, for 97 years based on her conviction for her role in a scheme to defraud Medicare by submitting more than $192 million in claims for orthotic braces and other items patients did not need and telemedicine visits that did not occur. Hernandez was ordered to pay approximately $111 million in restitution and was sentenced to 20 years in prison.

OIG worked with the Department of Justice to prosecute bad actors for defrauding Medicare by submitting false claims and paying kickbacks to physicians.

Charles Burruss and Ardalaan "Armani" Adams were charged with defrauding Medicare through the submission of claims for medically unnecessary durable medical equipment (DME), mostly braces. Burruss and Adams paid millions in kickbacks and bribes to acquire the DME claims, which were generated using aggressive telemarketing strategies in concert with fraudulent telemedicine involving bribed doctors who rarely spoke to the beneficiaries for whom the DME was ordered. Burruss, Adams, and their co-conspirators submitted the illegal DME claims to Medicare and other programs through a conglomerate of fraudulently established DME companies. The defendants pled guilty before the U.S. District Court and the Southern District of California to one count of conspiracy to commit wire fraud, conspiracy to commit healthcare fraud, and conspiracy to violate the anti-kickback statute.

Burruss and Adams were sentenced to 42 months and 30 months in prison, respectively, and ordered to pay more than $424 million jointly in restitution. Each also had a forfeiture judgment issued against them for more than $424 million.

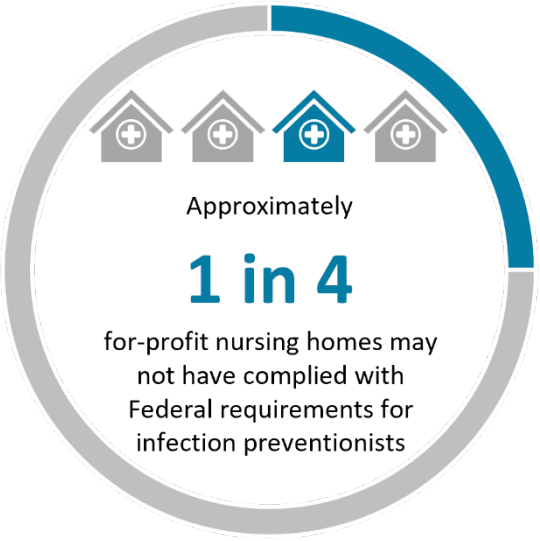
3 | Medicare and Medicaid

Nursing Homes

According to recent CMS data, more than 1.2 million people reside in the approximately 15,000 Medicare and Medicaid certified nursing homes nationwide. Improving nursing home quality of care is a top priority for OIG. To protect residents, OIG continually assesses nursing home performance and oversight and uses our enforcement tools to address misconduct. Significant OIG work completed during this reporting period related to nursing home quality and safety is detailed below.

Infection Prevention and Control

OIG reviewed 100 for-profit nursing homes nationwide and found that 24 potentially did not meet Federal requirements pertaining to infection preventionists. Infection preventionists are responsible for facility infection prevention and control. Based on our sample results, OIG estimates that 2,568 (approximately 1 in 4) for-profit nursing homes nationwide may not have complied with Federal requirements for infection preventionists during our review period. As a result, there may be increased health and safety risks for the residents and staff of these nursing homes (A-01-22-00001).



Enforcement Actions

OIG excluded a certified nursing aide (CNA) for a minimum of 25 years based on his conviction for injuring a nursing home resident, who ultimately died, and tampering and fabricating physical evidence. The resident fell and suffered a head wound and two broken ribs after the CNA tied him to his wheelchair using a bedsheet. The CNA was sentenced to 5 years in prison.

CASE EXAMPLE

Strauss Ventures, LLC To Pay $21.3 Million in a False Claims Act Settlement for Fraudulent Rehabilitation Therapy Services

Strauss Ventures LLC, doing business as The Grand Health Care System, and 12 affiliated skilled nursing facilities agreed to pay $21.3 million in a False Claims Act settlement with the United States. The settlement resolved allegations that, from January 1, 2014, through September 30, 2019, twelve of Strauss Ventures' skilled nursing facilities submitted false claims to Medicare Part A and TRICARE for medically unnecessary, unskilled, or not provided rehabilitation therapy. As part of the settlement, Strauss Ventures entered into a 5-year corporate integrity agreement with OIG.

In another example of OIG's work, Supportive Care Holdings, LLC, its related healthcare companies, and its CEO agreed to pay more than $4.5 million in a False Claims Act settlement with the United States. The settlement resolved allegations that between 2019 and 2023, Supportive Care Holdings, LLC, and its CEO fraudulently and improperly billed Medicare and Connecticut Medicaid for telehealth services provided to nursing home residents that should only have been billed by the nursing homes. The settlement also resolved allegations that Supportive Care Holdings, LLC, and its CEO submitted false claims for psychological services for nursing home residents who did not actually reside in a nursing home.

Medicaid

OIG oversight of Medicaid ensures that CMS and States comply with Federal requirements, ensures program integrity, and identifies improper payments. Significant OIG work completed during this reporting period related to Medicaid payments, enrollment data, and eligibility actions is detailed below.

Payment Accuracy

OIG found that State agencies generally did not comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. In the aggregate, State agencies could have invoiced and obtained rebates from the manufacturers for $225.7 million (Federal share) for physician-administered drugs reimbursed on a fee-for-service basis. States also should have collected additional rebates associated with $236.2 million (Federal share) for physician-administered drugs administered to Medicaid MCO enrollees (A-07-23-06111).

Additionally, OIG found New Mexico performed reconciliations of capitated payments for community benefit (CB) services as required under its contracts with MCOs. However, it did not recoup $139.2 million in overpayments for enrollees who did not use CB services within 90 calendar days of their approval for CB services and, as a result, did not return the related Federal share of $98.6 million. Additionally, New Mexico did not provide support that the enrollees on whose behalf MCOs received $35.2 million in capitated payments at the higher nursing facility level-of-care rate were eligible for services at that rate. As a result, it claimed $29.4 million in overpayments for those enrollees and inappropriately received $20.5 million in Federal share for those overpayments (A-06-20-09001).

Enrollment Data Accuracy

State agencies are required to verify the State of residency for enrollees; however, OIG estimates that California incurred costs of approximately $19.9 million ($15.5 million Federal share) for August 2021 capitation payments made on behalf of enrollees who were residing and concurrently enrolled in a Medicaid managed care program in another State (A-05-23-00008). Additionally, OIG found California improperly claimed $52.7 million in Federal Medicaid reimbursement for capitation payments made on behalf of noncitizens with unsatisfactory immigration status (A-09-22-02004).

Eligibility Actions

States ensured most Medicaid enrollees were continuously enrolled for Medicaid benefits during the COVID-19 public health emergency. When the continuous enrollment condition period ended, States had to conduct a variety of Medicaid eligibility actions such as redetermining eligibility status for enrollees during a period known as unwinding. OIG audited four States and determined that all four—Ohio (A-05-23-00019), Utah (A-

07-24-07013), California (A-09-24-02001), and Massachusetts (A-02-24-01001)—generally completed the actions in accordance with Federal and State requirements.

Medicaid Fraud Control Units

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. 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 enrollees in noninstitutional or other settings. During the reporting period, OIG and MFCUs worked together on 1,329 joint investigations. Additionally, our joint work resulted in 237 civil settlements or Civil Monetary Penalty Law outcomes and 426 criminal adjudications. For information about MFCU accomplishments, see our FY 2023 MFCU Annual Report. Additionally, during the reporting period, OIG revised its MFCU performance standards to further support MFCUs operations, performance, and program integrity efforts.

4 | Beneficiary Safety

Access to Services

Access to services is a principle of federally funded health care programs, including Medicaid. Enrollees should have access to providers who administer safe, effective, and equitable screenings and care in a thorough, timely, and efficient manner. Significant OIG work completed during this reporting period related to access to screenings and care is detailed below.

OIG found that Medicaid enrollees may not be screened for intimate partner violence (IPV)—which includes physical, sexual, and psychological abuse perpetrated by a spouse or partner. Primary care clinicians who serve Medicaid enrollees reported a range of challenges to screening for IPV. The most frequently reported challenge was time constraints; other barriers included concerns about patient privacy and safety and inadequate training. Among primary care clinicians who screened patients for IPV, additional challenges hindered their ability to make referrals, such as limitations with IPV support resources for patients who screen positive (OEI-03-21-00310).

OIG identified systemic and operational challenges that hinder efforts to ensure HIV care for Medicaid enrollees. Specifically, States and plans reported that two systemic issues—unmet health-related social needs and provider shortages—impact enrollees' abilities to maintain their care and limit States' and plans' abilities to address resulting gaps in care. Further, States and plans reported that two operational challenges—limited access to data and insufficient administrative staff—impact States' and plans' efforts to monitor enrollees' care needs and take action to connect enrollees to care (OEI-05-22-00242).

States and plans discussed multiple unmet social and economic needs that can affect how enrollees with HIV are able to maintain their health and well-being, known as health-related social needs. Unmet health-related social needs reported included:

- Housing instability
- Lack of transportation
- Lack of child care
- Food insecurity
- Lack of internet or phones
- Stigma

Children in Foster Care

HHS provides or funds services to children through programs such as foster care. OIG oversees these programs to ensure that children receive appropriate services in safe environments free from potential harm. Significant OIG work completed during this reporting period related to the health and safety of children in foster care is detailed below.

OIG found that many State child welfare agencies lack information to monitor maltreatment in residential facilities for children in foster care. States reported missing or incomplete information in the following key areas that could support enhanced oversight of residential facilities for children, although collecting and sharing this information is not required by Federal law (OEI-07-22-00530):

Nearly one-third of States could not identify patterns of maltreatment in residential facilities within their State.

States had limited awareness of maltreatment that occurred across chains of residential facilities operating in multiple States.

States reported challenges monitoring the safety of children placed in out-of-State residential facilities.

Thirteen States did not consistently report to the national maltreatment database whether children who experienced maltreatment were living in a residential facility.

Additionally, OIG found that most children in foster care, who are vulnerable to identity theft, did not receive federally required credit checks and assistance in interpreting and resolving any inaccuracies identified. Specifically, more than half of the children in foster care who should have received credit checks did not receive any credit checks in FY 2021. Further, for 4 percent of children who received at least one credit check, they rarely received assistance in interpreting or resolving credit reports, as required (OEI-07-22-00510).

5 | Data and Technology Security

HHS faces persistent cybersecurity threats that exacerbate the challenges associated with data and technologies used to carry out the Department's vital health and human services missions. OIG oversight helps ensure that HHS's cybersecurity is effective by auditing the Department's systems and operations along with the systems and operations of contractors and others that work with HHS. Significant OIG work completed during this reporting period related to securing data and technology is detailed below.

Cybersecurity Compliance

OIG audits aim to further cybersecurity compliance for HHS programs, grantees, and contractors. For example, OIG found through the annual audit of the Department's compliance with the Federal Information Security Modernization Act of 2014 that HHS's information security program was not effective. However, large disparities exist between the maturity levels at individual operating and staff divisions (A-18-23-11200). In another example, OIG found that despite some identified gaps and deficiencies, the evaluations of seven Medicare Administrative Contractors were adequate in scope and sufficiency (A-18-24-11300).

Sensitive Data

OIG oversight work ensures the confidentiality, integrity, and availability of sensitive data. For example, OIG reviewed HHS's cloud information system inventory and its policies and procedures in 2022 and found that not all of its cloud systems had been accurately identified and inventoried in accordance with HHS security requirements. Additionally, several key security controls were not effectively implemented in accordance with Federal requirements and guidelines. These issues occurred because System Security Officers do not always have the skill sets or experience necessary to adequately perform their roles and responsibilities. HHS concurred with our recommendations and is taking steps to implement them (A-18-22-08018). In one audit of State Medicaid information systems, OIG reviewed Illinois's systems for Medicaid eligibility determinations and claims processing and information retrieval, which store protected health information and other sensitive information. OIG found that, although the State's security controls were adequate, its security controls could be improved. Illinois stated it is taking action to make improvements (A-18-22-09009).

Appendix A: Audits and Evaluations

The following table summarizes OIG's audit and evaluation reports issued during the reporting period, including, if applicable, the associated questioned costs, funds put to better use, unsupported costs, and whether a management decision was made during the reporting period. (OIG has not yet received management decisions for most reports listed below because those decisions are not due to OIG until 6 months following the issuance of a report.) OIG issued two nonpublic audits during this reporting period. See Appendix C for more detail about reports with questioned costs and funds put to better use.

Report	Questioned Costs	Funds Put to Better Use	Unsupported Costs	Management Decision Made
Administration for Children and Families (ACF)				
Many States Lack Information To Monitor Maltreatment in Residential Facilities for Children in Foster Care (OEI-07-22-00530), June 2024	-	-	-	-
Most Children in Foster Care Did Not Receive Credit Checks and Assistance (OEI-07-22-00510), September 2024	-	-	-	-
Administration for Community Living (ACL)				
Missouri May Not Have Used All CARES Act Funds for the Older Americans Act Nutrition Services Program in Accordance With Federal and State Requirements (A-07-22-04130), April 2024	-	-	-	-
2023 Performance Data for the Senior Medicare Patrol Projects (OEI-02-24-00260), June 2024	-	-	-	-
Administration for Strategic Preparedness and Response (ASPR)				
Fiscal Year 2018 and 2019 Biomedical Advanced Research and Development Authority Appropriations May Not Have Been Used for Their Intended Purpose in Accordance With Federal Requirements (A-03-20-03002), April 2024	-	-	-	-
ASPR Did Not Consistently Comply With Federal Requirements for Awarding Research and Development Contracts (A-03-20-03003), July 2024*	$28,000	-	$14,000	-
ASPR Established Adequate Controls for Maintaining Physical Security Over Stockpile Site A, but Some Inventory Discrepancies Were Identified (A-04-24-02044), September 2024	-	-	-	-
Centers for Disease Control and Prevention (CDC)				
Selected CDC Racial and Ethnic Approaches to Community Health Program Recipients Generally Complied With Federal Requirements but Did Not Meet All Targets and Charged Some Unallowable Costs (A-02-22-02001), May 2024	$1,613,612	-	-	-
Heluna Health May Not Have Used California's CDC COVID-19 Funds in Accordance With Award Requirements (A-04-22-02037), July 2024	$3,585,834	$366,850,858	-	-

Report	Questioned Costs	Funds Put to Better Use	Unsupported Costs	Management Decision Made
CDC Provided Oversight and Assistance, but Recipients Faced Challenges in Implementing a COVID-19 Vaccine Confidence Strategy (A-06-22-04004), July 2024	-	-	-	-
Centers for Medicare & Medicaid Services (CMS)				
Medicaid Enrollees May Not Be Screened for Intimate Partner Violence Because of Challenges Reported by Primary Care Clinicians (OEI-03-21-00310), April 2024	-	-	-	-
New York Generally Identified and Corrected Duplicate Children's Health Insurance Plan Payments Made to Managed Care Organizations (A-02-23-01017), April 2024	-	-	-	-
Alabama Claimed Federal Medicaid Reimbursement for Millions of Dollars in Targeted Case Management Services That Did Not Comply With Federal and State Requirements (A-07-22-03253), April 2024	$5,039,433	-	-	Yes
CMS Could Improve Its Procedures for Setting Medicare Clinical Diagnostic Laboratory Test Rates Under the Clinical Laboratory Fee Schedule for Future Public Health Emergencies (A-01-21-00506), April 2024	-	-	-	-
Ohio Generally Completed Medicaid Eligibility Actions During the Unwinding Period in Accordance With Federal and State Requirements (A-05-23-00019), April 2024	-	-	-	-
Florida Ensured That Nursing Homes Complied With Federal Background Check Requirements (A-04-23-08100), April 2024	-	-	-	-
Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Fourth Quarter of 2023 (OEI-03-24-00060), May 2024	-	-	-	-
Medicaid Managed Care: States Do Not Consistently Define or Validate Paid Amount Data for Drug Claims (OEI-03-20-00560), May 2024	-	-	-	-
California Generally Completed Medicaid Eligibility Actions During the Unwinding Period in Accordance With Federal and State Requirements (A-09-24-02001), May 2024	-	-	-	-
New Mexico Should Refund Almost $120 Million to the Federal Government for Medicaid Nursing Facility Level-of-Care Managed Care Capitated Payments (A-06-20-09001), May 2024	$119,118,308	-	-	Yes
Potential Vulnerabilities in CMS Oversight of Medicare Add-on Payments for COVID-19 Tests Show That Oversight of Incentive Payments Could Be Improved (A-09-22-03015), May 2024	-	-	-	-
State Agencies Could Be Obtaining Hundreds of Millions in Additional Medicaid Rebates Associated With Physician-Administered Drugs (A-07-23-06111), May 2024	-	-	-	-
Colorado Did Not Report and Refund the Correct Federal Share of Medicaid-Related Overpayments for Some Cases Identified by the State's Program Integrity Section (A-07-19-02816), May 2024	$673,686	-	-	Yes
California Improperly Claimed $52.7 Million in Federal Medicaid Reimbursement for Capitation Payments Made on Behalf of Noncitizens With Unsatisfactory Immigration Status (A-09-22-02004), May 2024	$52,652,689	-	-	Yes
Medicare Remains Vulnerable to Fraud, Waste, and Abuse Related to Off-the-Shelf Orthotic Braces, Which May Result in Improper Payments and Impact the Health of Enrollees (A-09-21-03019), May 2024	-	-	-	-
Washington Medicaid Fraud Control Unit: 2023 Inspection (OEI-09-23-00230), June 2024	-	-	-	-

Report	Questioned Costs	Funds Put to Better Use	Unsupported Costs	Management Decision Made
CMS Could Strengthen Program Safeguards To Prevent and Detect Improper Medicare Payments for Short Inpatient Stays (A-09-21-03022), June 2024	-	-	-	-
North Carolina Did Not Report and Return All Medicaid Overpayments for the State's Medicaid Fraud Control Unit Cases (A-06-23-04004), June 2024	$20,134,402	-	-	Yes
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Independent Health Association, Inc. (Contract H3362) Submitted to CMS (A-07-19-01194), June 2024	$646,217	-	-	Yes
Part D Plans Generally Include Drugs Commonly Used by Dual-Eligible Enrollees: 2024 (OEI-05-24-00210), July 2024	-	-	-	-
West Virginia Medicaid Fraud Control Unit: 2023 Inspection (OEI-09-23-00390), July 2024	-	-	-	-
Alaska Medicaid Fraud Control Unit: 2023 Inspection (OEI-07-23-00240), July 2024	-	-	-	-
California Made Capitation Payments for Enrollees Who Were Concurrently Enrolled in a Medicaid Managed Care Program in Another State (A-05-23-00008), July 2024	-	-	-	-
Medicare and Some Enrollees Paid Substantially More When Stelara Was Covered Under Part D Versus Part B (OEI-BL-19-00500), August 2024	-	-	-	-
Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the First Quarter of 2024 (OEI-03-24-00070), August 2024	-	-	-	-
Opioid Treatment Programs in Washington State Did Not Fully Comply With Federal and State Requirements, Which May Have Put Medicaid Enrollees at Risk for Poor Treatment Outcomes (A-09-21-02001), August 2024	-	-	-	-
Medicare Improperly Paid Hospitals an Estimated $79 Million for Enrollees Who Had Received Mechanical Ventilation (A-09-22-03002), August 2024	$382,032	$79,354,175	-	-
Massachusetts Generally Completed Medicaid Eligibility Actions During the Unwinding Period in Accordance With Federal and State Requirements (A-02-24-01001), August 2024	-	-	-	-
Medicare Advantage Compliance Audit of Diagnosis Codes That MMM Healthcare, LLC, (Contract H4003) Submitted to CMS (A-04-20-07090), August 2024	$165,312	-	-	Yes
Illinois MMIS and E&E System Had Adequate Security Controls in Place, but Some Improvements Are Needed (A-18-22-09009), August 2024	-	-	-	-
Certain For-Profit Nursing Homes May Not Have Complied With Federal Requirements Regarding the Infection Preventionist Position (A-01-22-00001), August 2024	-	-	-	-
Kansas's Implemented Electronic Visit Verification System Could Be Improved (A-07-23-03255), August 2024	-	-	-	-
New Mexico Did Not Ensure Attendants Were Qualified To Provide Personal Care Services, Putting Medicaid Enrollees at Risk (A-06-22-02000), August 2024	-	-	-	-
Utah Generally Completed Medicaid Eligibility Actions During the Unwinding Period in Accordance With Federal and State Requirements (A-07-24-07013), August 2024	-	-	-	-
South Carolina Did Not Always Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations (A-07-22-07010), August 2024	$14,151,294	-	-	-
Massachusetts Opioid Treatment Program Services Met Many of the Federal and State Requirements (A-01-23-00002), August 2024	-	-	-	-

Report	Questioned Costs	Funds Put to Better Use	Unsupported Costs	Management Decision Made
Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2022 Average Sales Prices (OEI-03-24-00080), September 2024	-	-	-	-
Medicare and Medicaid Enrollees in Many High-Need Areas May Lack Access to Medications for Opioid Use Disorder (OEI-BL-23-00160), September 2024	-	-	-	-
OIG Companion Product: Medicare and Medicaid Enrollees in Many High-Need Areas May Lack Access to Medications for Opioid Use Disorder (OEI-BL-23-00161), September 2024	-	-	-	-
Additional Oversight of Remote Patient Monitoring in Medicare Is Needed (OEI-02-23-00260), September 2024	-	-	-	-
Systemic and Operational Challenges Hinder Efforts to Ensure HIV Care for Medicaid Enrollees (OEI-05-22-00242), September 2024	-	-	-	-
States Could Better Leverage Coverage and Access Requirements To Promote Maternal Health Care Access in Medicaid Managed Care (OEI-05-22-00330), September 2024	-	-	-	-
Novitas Solutions, Inc., Reopened and Corrected Cost Report Final Settlements With Obvious Errors To Collect Overpayments Made to Medicare Providers (A-06-23-05001), September 2024	-	-	-	-
CMS Recovered Medicare Payments to Providers Under the COVID-19 Accelerated and Advance Payments Program in Compliance With Federal Requirements (A-05-23-00005), September 2024	-	-	-	-
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Humana Health Plan, Inc., (Contract H2649) Submitted to CMS (A-02-22-01001), September 2024	$6,777,385	-	-	-
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That HealthAssurance Pennsylvania, Inc. (Contract H5522) Submitted to CMS (A-05-22-00020), September 2024	$4,256,568	-	-	-
Medicare Advantage Compliance Audit of Diagnosis Codes That EmblemHealth (Contract H3330) Submitted to CMS (A-06-18-02001), September 2024	$551,917	-	-	-
Review of Medicare Administrative Contractor Information Security Program Evaluations for Fiscal Year 2023 (A-18-24-11300), September 2024	-	-	-	-
Food and Drug Administration (FDA)				
The Food and Drug Administration's Inspection and Recall Process Should Be Improved To Ensure the Safety of the Infant Formula Supply (A-01-22-01502), June 2024	-	-	-	-
Health Resources and Services Administration (HRSA)				
A Review of Pandemic Relief Funding and How It Was Used in Six U.S. Communities: Springfield, Massachusetts (OEI-06-22-00440), May 2024	-	-	-	-
A Review of Pandemic Relief Funding and How It Was Used in Six U.S. Communities: Coeur d'Alene, Idaho (OEI-06-22-00450), July 2024	-	-	-	-
A Review of Pandemic Relief Funding and How It Was Used in Six U.S. Communities: Sheridan County, Nebraska (OEI-06-22-00460), September 2024	-	-	-	-
Indian Health Service (IHS)				

Report	Questioned Costs	Funds Put to Better Use	Unsupported Costs	Management Decision Made
Gallup Indian Medical Center—an IHS-Operated Health Facility—Did Not Timely Conduct Required Background Checks of Staff and Supervise Certain Staff (A-02-23-02006), September 2024	-	-	-	-
National Institutes of Health (NIH)				
Plans and Enrollment Often Fell Short for Underrepresented Groups in a Sample of NIH-Funded Clinical Trials (OEI-01-21-00320), May 2024	-	-	-	-
New York Medical College Claimed Unallowable Grant Costs and Did Not Meet Certain Financial Conflict of Interest Requirements (A-04-20-03583), May 2024	$7,542,821	-	-	-
NIH Did Not Close Contracts in Accordance With Federal Requirements, Resulting in the Increased Risk of Fraud, Waste, and Abuse (A-04-23-03585), June 2024*	-	-	-	-
The National Institutes of Health Has Made Progress but Could Further Improve Its Closeout Process for Grants and Similar Awards (A-04-23-08097), June 2024	-	-	-	-
The National Institutes of Health Administered Superfund Appropriations During Fiscal Year 2023 in Accordance With Federal Requirements (A-04-24-02045), August 2024	-	-	-	-
Office of the Secretary (OS)				
The Office of Intergovernmental and External Affairs' Purchase Card Program Did Not Comply With Federal and HHS Requirements (A-03-22-00500), April 2024	-	-	-	-
Department of Health and Human Services Met Many Requirements, but It Did Not Fully Comply With the Payment Integrity Information Act of 2019 and Applicable Improper Payment Guidance for Fiscal Year 2023 (A-17-24-52000), May 2024	-	-	-	-
Review of the Department of Health and Human Services' Compliance With the Federal Information Security Modernization Act of 2014 for Fiscal Year 2023 (A-18-23-11200), June 2024	-	-	-	-
HHS Office of the Secretary Needs to Improve Key Security Controls To Better Protect Certain Cloud Information Systems (A-18-22-08018), July 2024	-	-	-	-
Substance Abuse and Mental Health Services Administration (SAMHSA)				
West Virginia Lacked Effective Oversight of Its Opioid Response Grants (A-06-22-01005), April 2024	-	-	-	-
Total Reports: 73	**$237,319,510**	**$446,205,033**	**$14,000**	**-**

*Contract audit per NDAA 2008 Section 845

OIG issued no investigative reports, which are reports that identify or bring renewed attention to systemic weaknesses or vulnerabilities within HHS programs and recommend administrative, procedural, policy, regulatory, or legislative change to correct or minimize the problems. Additionally, OIG issued no non-public evaluation reports.

Appendix B: Investigative Actions

The following table summarizes OIG's investigative activities during the reporting period.

Description	
Investigative Receivables	
Total	$3,936,240,673
Amount due to HHS	$2,513,086,238
Amount due to non-HHS entities	$1,423,154,435
Investigative Results	
Criminal actions resulting from investigations[1]	401
Civil or Civil Monetary Penalty Law actions resulting from investigations	435
Investigations closed	896
Referrals[2]	
Total	1,553
Made to DOJ	1,307
Indictments and criminal informations resulting from referrals made prior to and during the reporting period	350
Made to State and local authorities	246
Indictments and criminal informations resulting from referrals made prior to and during the reporting period	78
Related to Trafficking in Persons (FY 2024)	
Suspected violations reported	14
Investigations	10
Criminal actions resulting from investigations	3
Recommendations	0
Related to Senior Government Employees	
Investigations conducted	5
Allegations substantiated	0
Resulted in a nonpublic report	0

Description of investigation	Substantiated	Non-public report
OIG investigated two senior Government employees (SES) for allegedly requesting a purchase card transaction to pay for a training that did not occur.	N	N
OIG investigated a senior Government employee (GS-15) for allegedly misusing their personal email to conduct Government business in order to circumvent Freedom of Information Act requirements and for deliberately destroying emails to avoid production according to Federal regulations.	N	N
OIG investigated a senior Government employee (SES) for allegedly sexually assaulting a subordinate employee during international Government travel. The senior Government employee retired from Federal service.	N	N
OIG investigated a senior Government employee (GS-15) for allegedly being charged with criminal trespass and entering or remaining unlawfully in a dwelling.	N	N
OIG investigated a senior Government employee (GS-15) for allegedly having a physical altercation with a subordinate employee.	N	N

[1] Convictions are included among criminal actions.

[2] Referrals are presentations of OIG subjects to Federal, State, or local prosecuting jurisdictions for prosecutorial consideration.

Appendix C: Audit Details

The table below summarizes potential cost savings that OIG identified during the reporting period including questioned costs and funds put to better use, as well as OIG's Single Audit oversight.

Description	No. of Reports	Dollar Value Questioned	Dollar Value Unsupported
Audit Reports With Questioned Costs			
Section 1			
Reports for which no management decisions had been made by the beginning of the reporting period	24	$1,253,840,000	$376,695,000
Reports issued during the reporting period	16	$237,320,000	$14,000
Total Section 1	**40**	**$1,491,160,000**	**$376,709,000**
Section 2			
Reports for which management decisions were made during the reporting period			
Disallowed costs	13	$425,424,000*	-
Costs not disallowed	5	$741,151,000	$376,695,000
Total Section 2	**18**	**$1,166,575,000**	**$376,695,000**
Section 3			
Reports for which no management decisions had been made by the end of the reporting period (Section 1 – Section 2)	**22**	**$324,585,000**	**$14,000**
Section 4			
Reports for which no management decisions were made within 6 months of issuance	**13**	**$285,695,000**	-
* Audit receivables (expected recoveries)			
Audit Reports With Funds Put to Better Use			
Section 1			
Reports for which no management decisions had been made by the beginning of the reporting period	7	-	$16,489,698,000
Reports issued during the reporting period	2	-	$446,205,000
Total Section 1	**9**	-	**$16,935,903,000**
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	-	-	-
Based on proposed legislative action	-	-	-
Value of recommendations not agreed to by management	5	-	$1,440,253,000
Total Section 2	**5**	-	**$1,440,253,000**
Section 3			
Reports for which no management decisions had been made by the end of the reporting period (Section 1 – Section 2)	**4**	-	**$15,495,650,000**

OIG Also Oversees Single Audits To Monitor How Recipients Use Federal Funds for HHS Programs		
Single Audit reports reviewed	286	-
Amount of audited costs covered in reviewed reports	-	$3,100,000,000,000
Amount of Federal dollars covered in reviewed reports	-	$891,000,000,000
Amount of HHS funds covered in reviewed reports	-	$479,000,000,000

Read more on OIG's Single Audits website.

Appendix D: Safe Harbor Proposals

OIG annually solicits proposals 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. In December 2023, OIG published its annual solicitation in the *Federal Register*. Below we summarize the 14 proposals OIG received and OIG's response.

Proposal	OIG Response
Modifications to, and guidance regarding, the group purchasing organization (GPO) safe harbor, 42 C.F.R. § 1001.952(j), to address comments and concerns regarding the manner in which GPOs, pharmacy benefit managers (PBMs), and similar entities may be using such safe harbor to protect certain purportedly abusive arrangements and to clarify whether and under what circumstances the GPO safe harbor applies to PBMs and PBM-operated GPOs.	OIG is not adopting these suggestions. We may consider this topic in future rulemaking or in future guidance. OIG has published a response in the Frequently Asked Questions section of our website explaining the potential application of the GPO safe harbor to remuneration paid by pharmaceutical manufacturers to PBMs. Moreover, there is a statutory exception addressing GPOs at section 1128B(b)(3)(C) of the Social Security Act.
New safe harbor to protect arrangements for data analytics provided by a drug, biologic, or device manufacturer (or its agent) to other parties in the health care coverage, delivery, or patient care chain.	OIG is not adopting this suggestion. We believe that existing safe harbors may be utilized to support these types of arrangements, including, for example, the safe harbor for personal services and management contracts and outcomes-based payment arrangements, 42 C.F.R. § 1001.952(d).
New safe harbor for, and guidance regarding, pharmaceutical manufacturer-sponsored patient engagement and product support activities and related tools, outside of the value-based enterprise framework, to facilitate patient support activities.	OIG is not adopting this suggestion. 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; however, we continue to have concerns about the offer of remuneration by pharmaceutical manufacturers to Federal health care program enrollees, which raises many of the traditional fraud and abuse risks under the Federal anti-kickback statute. We may consider this topic in future rulemaking.
New safe harbors to protect certain remuneration from a clinical trial sponsor to a patient who participates in the sponsor's clinical trial. The proposed safe harbors would protect the sponsor's subsidization of certain costs patients incur due to their participation in a trial, including: (1) cost-sharing obligations and (2) indirect costs such as travel, lodging, childcare expenses, and lost wages. According to the proposals, protecting the subsidization of these costs through safe harbors could contribute to increased diversity, equity, and inclusion in clinical trials.	OIG is not adopting these suggestions. OIG appreciates the goal of improving diversity among clinical trial subjects. However, we have longstanding concerns regarding the routine waiver or subsidy of cost-sharing obligations and the provision of other incentives to Federal health care program enrollees. We may consider this topic in future rulemaking.

New safe harbor to protect: (1) 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 (2) the provision of value-based services, such as services that enable parties to evaluate outcome measures associated with value-based price-adjustment arrangements.	OIG is not adopting this suggestion. We appreciate learning about ways in which pharmaceutical manufacturers, medical device manufacturers, and DMEPOS entities believe that they could contribute to the coordination of care and the overall delivery of high-value care for Federal health care program enrollees. However, we continue to have concerns about the offer of remuneration by these entities, which raises many of the traditional fraud and abuse risks under the Federal anti-kickback statute. We may consider this topic in future rulemaking.
New safe harbors for: (1) travel, lodging, and associated expenses and (2) fertility preservation services furnished in connection with cellular and gene therapy treatments.	OIG is not adopting these suggestions at this time. We may consider this topic in future rulemaking.
New safe harbors to protect value-based purchasing arrangements between pharmaceutical manufacturers and payors.	OIG is not adopting this suggestion. 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 value-based arrangements, and we may consider this topic in future rulemaking.
Modification to the patient engagement and support safe harbor, 42 C.F.R. § 1001.952(hh), to remove the requirement that the availability of a tool or support not be determined in a manner that takes into account the type of insurance coverage of the patient in order to address a perception that the existing safe harbor does not sufficiently allow for the promotion of health equity or improvement in health outcomes for different patient populations.	OIG is not adopting this suggestion, as we believe this safe harbor offers sufficient flexibility to address the needs of various patient populations (e.g., by providing a tool or support to primarily a Medicaid population). In the 2020 OIG rulemaking establishing this safe harbor, *Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements* (the 2020 OIG Rulemaking), we stated that: (1) it is possible that a particular tool or support if offered on a neutral basis unrelated to payor type could result in the provision of tools and supports primarily to Federal health care program beneficiaries and (2) a value-based enterprise could define its target patient population—and therefore limit the scope of potential recipients of tools and supports—based on individual or family income, which might overlap substantially with Medicaid or dual-eligible populations but would not be strictly determined based on an individual's enrollment in Medicaid or as dually eligible for both Medicare and Medicaid.[3]
New safe harbor for Indian Health Care Providers (IHCPs) similar to the safe harbor for federally qualified health centers at 42 C.F.R. § 1001.952(w).	OIG is not adopting this suggestion. We may consider this topic in future rulemaking. Although not specific to IHCPs, OIG believes existing regulations, and in particular, the new and modified safe harbors that were finalized in the 2020 OIG Rulemaking, may offer sufficient regulatory flexibility and can facilitate innovative value-based and care coordination arrangements for IHCPs.

[3] OIG, "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," 85 Fed. Reg. 77,684, 77,804 (Dec. 2, 2020).

Modifications to the safe harbors for value-based arrangements, including the safe harbors for value-based arrangements with substantial downside financial risk and full financial risk, 42 C.F.R. § 1001.952(ff) and (gg), to protect the exchange of remuneration by entities that currently cannot use one or more of these safe harbors (e.g., pharmaceutical manufacturers, manufacturers of a device or medical supply, entities or individuals that sell or rent DMEPOS [other than a pharmacy; a medical device or supply manufacturer that also sells or rents DMEPOS; or a physician, provider, or other entity that primarily furnishes services, all of whom remain eligible]).	OIG is not adopting this suggestion. As explained in the 2020 OIG Rulemaking, remuneration exchanged by pharmaceutical manufacturers and, in certain cases, DMEPOS entities, is not eligible for protection under the value-based arrangement safe harbors due to (among other reasons) concerns that such entities could use the safe harbors to protect arrangements that are intended to market their products or inappropriately tether clinicians to the use of a particular product.[4]
Modifications to value-based arrangement safe harbors to provide greater clarity in the definitions, including the definition of "value-based purpose."	OIG is not adopting this suggestion for modifications to the existing applicable safe harbors and definitions. The existing regulations are intended to provide health care stakeholders regulatory flexibility for certain value-based arrangements that meet each element of an applicable safe harbor. In the event additional clarity is needed, the advisory opinion process remains available for parties to obtain a formal opinion on the application of the Federal anti-kickback statute and safe harbor provisions to a particular arrangement.
Modify the safe harbor for care coordination arrangements to improve quality, health outcomes, and efficiency, 42 C.F.R. § 1001.952(ee), to: (1) eliminate the requirement that remuneration be in-kind, (2) eliminate the requirement for commercial reasonableness, (3) provide greater flexibility regarding outcome measures, and (4) eliminate the 15 percent contribution requirement.	OIG is not adopting these suggestions. We believe the safe harbor provides sufficient flexibility while balancing against fraud and abuse risk.
Modify the full financial risk safe harbor to allow for protections when entities assume full financial risk for a subset of services or items.	OIG is not adopting this suggestion. The advisory opinion process remains available for parties to obtain a formal opinion on the application of the Federal anti-kickback statute and safe harbor provisions to a particular arrangement, including those involving a subset of services or items.
New safe harbor for items and services furnished to address social determinants of health and to facilitate compliance with Internal Revenue Service community benefit requirements for not-for-profit hospitals.	OIG is not adopting this suggestion. We may consider this topic in future rulemaking. OIG recognizes the potential benefits that social determinants of health have for health and well-being. Existing regulations, including the safe harbor for arrangements for patient engagement and support to improve quality, health outcomes, and efficiency at 42 C.F.R. § 1001.952(hh), provide regulatory flexibility for in-kind remuneration to enrollees to address social determinants of health. Moreover, the advisory opinion process remains available for parties to obtain a formal opinion on the application of the anti-kickback statute and safe harbor provisions to a particular arrangement involving items and services furnished to address social determinants of health.

[4] Id. at 77,782.

Appendix E: Peer Reviews

Peer reviews are conducted by member organizations of the Council of the Inspectors General on Integrity and Efficiency (CIGIE). The CIGIE peer review program provides OIGs and their stakeholders with an assessment of the OIG's compliance with relevant quality standards and its quality control systems (e.g., policies and procedures).

Office of Audit Services

During the reporting period, OIG's Office of Audit Services (OAS) did not receive a peer review. The most recent peer review OAS received was conducted by the Department of Housing and Urban Development (HUD) OIG, the final report of which was issued in March 2024. In that review, OAS received a "pass" rating and HUD-OIG issued no recommendations. OAS has no outstanding peer review recommendations. OAS conducted a peer review of the Department of Defense (DOD) OIG during the reporting period, the final report of which was issued September 2024.

Office of Evaluation and Inspections

During the reporting period, OIG's Office of Evaluation and Inspections (OEI) did not receive a peer review. The most recent peer review OEI received was conducted by the Department of Energy (DOE) OIG, the final report of which was issued in February 2023. In that review, DOE-OIG determined that OEI's policies and procedures and the four reports reviewed generally were consistent and complied with the CIGIE Blue Book standards. OEI has no outstanding peer review recommendations. OEI did not conduct a peer review during the reporting period. The most recent per review OEI conducted was of the Special Inspector General for Afghanistan Reconstruction OIG, the final report of which was issued in March 2023.

Office of Investigations

During the reporting period, the United States Postal Service (USPS) OIG conducted a peer review of OIG's Office of Investigations (OI), the final report of which is not yet issued as of December 2024. OI has no outstanding peer review recommendations. OI did not conduct a peer review during the reporting period. The most recent per review OI conducted was of the DOD-OIG, the final report of which was issued in February 2023.

Appendix F: Reporting Requirements

The National Defense Authorization Act (NDAA) of Fiscal Year 2023, section 5273, amended the Inspector General Act of 1978 and the Inspector General Empowerment Act of 2016 to streamline semiannual reporting requirements for offices of inspectors general, which now appear in the note of 5 U.S.C. § 405. The following table presents the new NDAA requirements and other remaining requirements, along with the location of the information in this report.

Section	Requirement	Location
U.S.C. § 405 (note)		
5(a)(1)	Significant problems, abuses, and deficiencies	Throughout this report
5(a)(2)	Recommendations for which corrective action has not been completed	Introduction and OIG's Recommendations Tracker
5(a)(3)	Significant investigations closed during the reporting period	Throughout this report
5(a)(4)	Convictions during the reporting period	Appendix B: Investigative Actions
5(a)(5)	Information regarding reports issued during the reporting period	Appendix A: Audits and Evaluations
5(a)(6)	Information regarding any management decision made during the reporting period with respect to any report issued during a previous reporting period	At a Glance: OIG Accomplishments and OIG's Recommendations Tracker
5(a)(7)	Information required by the Federal Financial Management Improvement Act of 1996	None this reporting period
5(a)(8)	Results of peer reviews of HHS-OIG conducted by other OIGs	Appendix E: Peer Reviews
5(a)(9)	Outstanding recommendations from peer reviews of HHS-OIG conducted by other OIGs	Appendix E: Peer Reviews
5(a)(10)	Peer reviews of other OIGs conducted by HHS-OIG	Appendix E: Peer Reviews
5(a)(11)	Investigative statistical tables	Appendix B: Investigative Actions
5(a)(12)	Metrics description for investigative statistical tables	Appendix B: Investigative Actions
5(a)(13)	Investigations of senior Government employees	Appendix B: Investigative Actions
5(a)(14)	Description of whistleblower retaliation instances	None this reporting period
5(a)(15)	Description of attempts to interfere with OIG independence	None this reporting period
5(a)(16)	Descriptions of investigations of senior Government employees	Appendix B: Investigative Actions
5(a)(16)	Descriptions of nonpublic reports	Appendix A: Audits and Evaluations
Other Requirements		
NDAA 2008 section 845	Significant contract audits	Appendix A: Audits and Evaluations
Health Insurance Portability and Accountability Act	Public proposals for new and modified safe harbors	Appendix D: Safe Harbor Proposals
American Recovery and Reinvestment Act section 1553	Retaliation complaint investigations OIG decided not to conduct or continue during the period	None this reporting period
Executive Order 14074	No-knock entries	None this reporting period
Trafficking Victims Prevention and Protection Reauthorization Act of 2022	Investigations relating to trafficking in persons	Appendix B: Investigative Actions

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Every complaint helps OIG carry out its mission of overseeing HHS programs and protecting the individuals they serve. By reporting your concerns to the OIG Hotline, you help us safeguard taxpayer dollars and ensure the success of our oversight efforts.

Who Is Protected?

Anyone may request confidentiality. The Privacy Act, the Inspector General Act of 1978, and other applicable laws protect complainants. The Inspector General Act states that the Inspector General shall not disclose the identity of an HHS employee who reports an allegation or provides information without the employee's consent, unless the Inspector General determines that disclosure is unavoidable during the investigation. By law, Federal employees may not take or threaten to take a personnel action because of whistleblowing or the exercise of a lawful appeal, complaint, or grievance right. Non-HHS employees who report allegations may also specifically request confidentiality.