

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

Semiannual Report to Congress

April 1, 2021–September 30, 2021



A Message From Christi A. Grimm, Principal Deputy 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 Department), Office of Inspector General (OIG), for the 6-month period ending on September 30, 2021.

This year marks the 45th anniversary since Congress passed the Inspector General (IG) Act, giving IGs the authority and responsibility for promoting integrity, accountability, and transparency in their respective agencies. Since 1978, IGs have led the fight against fraud, waste, and abuse in Federal programs. Across the Federal Government, IGs perform an essential public service and propel significant change and improvements to help the Government better serve the American people. A strong IG makes a stronger Department and a stronger, more trusted Federal Government.



Through our oversight work, HHS-OIG strives to identify the most critical issues that HHS faces as it pursues its mission of enhancing the health and well-being of all Americans. We protect the Nation's \$2.8 trillion investment in HHS resources and programs, buttressing the Department's ability to operate efficiently and effectively, and to deliver beneficial outcomes for the American public. During this reporting period, OIG focused on protecting the health, safety, and welfare of beneficiaries receiving care in nursing homes, hospitals, and other facilities, which have been particularly affected by the COVID-19 pandemic. For example, we issued a report that illuminated the devastating impact of the pandemic on nursing homes, where almost 1,000 more beneficiaries died per day in April 2020 than in April 2019, and the overall mortality rate increased from 17 percent in 2019 to 22 percent in 2020. This report highlighted the finding that approximately half of all Black, Hispanic, and Asian residents of nursing homes either had or likely had COVID-19 in 2020, compared with 41 percent of White residents.

We aggressively pursue criminals whose schemes jeopardize public health efforts and endanger the public. In May, along with our law enforcement partners, we targeted efforts against schemes designed to exploit the COVID-19 pandemic through genetic testing scams, which resulted in \$143 million in false billings. In September, we pursued charges associated with \$1.4 billion in losses to the Government in health care fraud cases that involved telefraud, COVID-19-related relief, substance abuse treatment facilities, illegal prescription and distribution of opioids, and other schemes.

Our oversight work also focuses on ensuring that HHS programs run effectively and that its beneficiaries see the value of the substantial Federal investment in health and human services programs. As the Nation responds to and recovers from the evolving COVID-19 pandemic, we are committed to providing HHS with insights on gaps in emergency preparedness programs and identifying opportunities for HHS to improve its emergency response capabilities. We remain steadfast in conducting thorough oversight aimed at protecting the financial integrity of HHS programs and ensuring that taxpayer funds are spent for intended purposes. Our oversight work will sharply emphasize reducing improper payments in Medicaid and Medicare. We will also continue to engage in essential work on promoting beneficiary access to opioid treatment programs; ensuring that beneficiaries and taxpayers do not overpay for prescription drugs;

strengthening Medicare and Medicaid managed care programs; and safeguarding children, including those in foster care and the Unaccompanied Children Program. In addition, we remain committed to protecting whistleblowers and investigating whistleblower reprisal allegations.

As health care delivery evolves, and as telehealth and other technologies become increasingly prevalent, HHS must guard against ever-present cybersecurity risks and continue to deliver on its mission in today's changing landscape. As a resourceful and resilient organization, OIG continues to adapt our oversight methods and undertake new work to address novel challenges. We currently seek [public input](#) as part of a new initiative focused on modernizing our program integrity data and resources. Through this initiative, OIG aims to increase the transparency and usability of our data and information to spur improved compliance and innovative approaches that adapt to changes in the health care system.

OIG uses multidisciplinary methods, sophisticated data analysis techniques and technology, and strong partnerships with other law enforcement and oversight entities to maximize the impact of our work. With a team of over 1,600 highly skilled and dedicated analysts, attorneys, auditors, evaluators, investigators, and other professionals, OIG continues to forge a path rooted in independence, objectivity, and transparency to advance our important mission and make a positive difference for the American public. OIG remains committed to sustaining these efforts and innovating toward the future. I would like to express my appreciation to Congress and to the Department for their sustained commitment and support of our important work.

Christi A. Grimm

Principal Deputy Performing Duties of the Inspector General

Table of Contents

OIG’s Approach to Driving Positive Change	4
Highlights of OIG Accomplishments	5
OIG Participation in Congressional Hearings	15
Selected Acronyms and Abbreviations	16
Medicare and Medicaid Reports and Reviews	17
Legal and Investigative Activities Related to Medicare and Medicaid	48
Public Health and Human Service Agency Reports and Reviews	64
Legal and Investigative Activities Related to Public Health and Human Service Agencies	71
Other HHS-Related Reviews and Investigative Activities	72
Appendix A: Questioned Costs and Funds To Be Put to Better Use	78
Appendix B: Savings Decisions Supported by OIG Recommendations	83
Appendix C: Peer Review Results	86
Appendix D: Summary of Sanction Authorities	89
Appendix E: Reporting Requirements in the Inspector General Act of 1978	92
Appendix F: Reporting Requirements in the Inspector General Empowerment Act of 2016	94
Appendix G: Anti-Kickback Statute—Safe Harbors	102

OIG’s Approach to Driving Positive Change

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

OIG Organization

Office of Audit Services

OAS conducts audits of HHS programs and operations either through its own resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or of HHS's grantees and contractors in carrying out their respective responsibilities and provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote the economy, efficiency, and effectiveness of programs and operations throughout HHS.

Office of Evaluation and Inspections

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

Office of Investigations

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

Office of Counsel to the Inspector General

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

Mission Support and Infrastructure

MSI is composed of the Immediate Office of the Inspector General and the Office of Management and Policy. MSI is responsible for coordinating OIG activities and providing mission support, including setting vision and direction for OIG's priorities and strategic planning; ensuring effective

management of budget, finance, human resource management, and other operations; and serving as a liaison with HHS, Congress, and other stakeholders. MSI plans, conducts, and participates in a variety of cooperative projects within HHS and with other Government agencies. MSI provides critical data analytics, data management, and information technology (IT) infrastructure that enables OIG components to conduct their work efficiently and effectively.

OIG Strategic Publications

HHS-OIG Strategic Publications



HHS-OIG Strategic Plan

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

OIG Work Plan

OIG’s [Work Plan](#) sets forth projects that OIG plans to undertake during the fiscal year (FY) and beyond. Projects listed in the Work Plan span HHS’s operating divisions (OpDivs), which include the Centers for Medicare & Medicaid Services (CMS), public health agencies such as the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), and human services agencies such as the Administration for Children and Families (ACF) and the

Administration for Community Living (ACL). The Work Plan also includes oversight of State and local governments' use of Federal funds as well as the administration of HHS. Some of the projects described in the Work Plan are statutorily required.

OIG's Top Recommendations

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

Top Management and Performance Challenges Facing HHS

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

OIG's Semiannual Report to Congress

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

Highlights of OIG Accomplishments

HHS-OIG’S SEMIANNUAL REPORT TO CONGRESS (Semiannual Report) describes OIG’s work identifying significant risks, problems, abuses, deficiencies, remedies, and investigative outcomes relating to the administration of HHS programs and operations that were disclosed during the semiannual reporting period of April 1, 2021, through September 30, 2021. In this highlights section, we present data on OIG reports issued, expected recoveries, criminal and civil actions, and other statistics resulting from our work for both the semiannual reporting period and the entirety of FY 2021. We then highlight significant results from selected audits, evaluations, and enforcement activities completed during the reporting period.

At-a-Glance FY 2021 Highlights

Statistic	FY 2021 (10/1/2020—9/30/2021)
Audit Reports Issued	162
Evaluations Issued	46
Expected Audit Recoveries	\$787.29 million
Questioned Costs	\$1.17 billion
Potential Savings	\$1.24 billion
New Audit and Evaluation Recommendations	506
Recommendations Implemented by HHS OpDivs	432
Expected Investigative Recoveries	\$3.00 billion
Criminal Actions	532
Civil Actions	689
Exclusions	1,689

Results for the Semiannual Reporting Period

During this semiannual reporting period (April 1, 2021, through September 30, 2021), we issued 87 audit reports and 26 evaluation reports. Our audit work identified \$220.82 million in expected recoveries, as well as \$934.21 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). Our audit work also identified \$318.91 million in potential savings for HHS—funds that could be saved if HHS implemented all of OIG’s audit recommendations. During this reporting period, OIG made 276 new audit and evaluation recommendations, which are crucial to encourage positive change in HHS programs. Meanwhile, HHS OpDivs implemented 238 prior recommendations, leading to positive impact for HHS programs and beneficiaries.

OIG also remains at the forefront of the Nation’s efforts to fight fraud in HHS programs and hold wrongdoers accountable for their actions. Along with our partners DOJ, Medicaid Fraud Control Units (MFCUs or Units), and other Federal, State, and local law enforcement agencies, we detect, investigate, and prosecute fraud through a coordinated and data-driven approach. OIG’s investigative work led to \$1.61 billion in expected investigative recoveries and 311 criminal actions during this reporting period. OIG also took civil actions, such as assessing monetary penalties, against 417 individuals and entities, and excluded 654 individuals and entities from Federal health care programs.

OIG continues to focus on the most significant and high-risk issues in health care and human services. Our mission is to provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve. Below we highlight results from selected OIG oversight and enforcement activities from the semiannual reporting period of April 1, 2021, through September 30, 2021, organized by subject area. A comprehensive list of OIG work during the reporting period follows, and Appendices A through G provide data to meet the reporting requirements in the Inspector General Act of 1978.

Responding to the COVID-19 Pandemic and Other Emergencies

OIG continues to advance the four goals that drive OIG’s strategic planning and mission execution with respect to HHS’s COVID-19 response and recovery. These goals are: (1) to protect people, (2) to protect funds, (3) to protect infrastructure, and (4) to promote effectiveness of HHS programs. To this end, our work encompasses more than 50 audits and evaluations underway, assessing a wide range of urgent issues—from health disparities to vaccine administration to nursing home oversight and preparedness, among others—along with law enforcement efforts, data analytics, and issuance of fraud alerts and other guidance.

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

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

OIG found that COVID-19 had a devastating impact on Medicare beneficiaries in nursing homes in 2020. Two in five Medicare beneficiaries in nursing homes either had or likely had COVID-19 in 2020. Overall mortality in nursing homes increased to 22 percent in 2020 from 17 percent in 2019, with almost 1,000 more beneficiaries dying per day in April 2020 than in April 2019. About half of Black, Hispanic, and Asian beneficiaries in nursing homes either had or likely had COVID-19, compared with 41 percent of White beneficiaries. (See report [OEI-02-20-00490](#).)

OIG found that although CMS's COVID-19 data included required information from nursing homes, CMS could take additional actions to improve the completeness and accuracy of the data. CMS's COVID-19 data for nursing homes included the required data from the vast majority of nursing homes. However, the data were not complete or accurate for some nursing homes. Specifically, for 775 of the 15,388 nursing homes (about 5 percent), CMS's data did not include all of the COVID-19 data that nursing homes were required to report and were not complete or accurate after CMS had performed its quality assurance checks (e.g., the number of confirmed COVID-19 cases among residents may have been under or overreported). (See report [A-09-20-02005](#).)

OIG found that Medicare beneficiaries hospitalized with COVID-19 experienced a wide range of serious, complex conditions. Although almost all of these beneficiaries were treated for acute respiratory issues—such as viral pneumonia—many were treated for other types of serious conditions, including acute kidney failure, heart attacks, and sepsis. More than half of the beneficiaries hospitalized with COVID-19 received intensive care or mechanical ventilation. We also found that beneficiaries who were dually eligible, Black, Hispanic, or older were hospitalized at disproportionately high rates. (See report [OEI-02-20-00410](#).)

OIG found the Indian Health Service (IHS) Critical Care Response Teams (CCRTs) program to be a positive step in IHS's efforts to address the immediate needs of facilities during COVID-19. IHS deployed CCRTs to support facilities in caring for critically ill COVID-19 patients. While onsite, the CCRTs assessed facility needs and provided hands-on training to strengthen staff skills and capacity to handle patient surges. This model also holds promise for addressing some of the longstanding challenges that facilities face related to quality of care and staffing. We made recommendations to IHS to further leverage the successes of the CCRT model in support of IHS's broader care improvement efforts. (See report [OEI-06-20-00700](#).)

OIG investigated pandemic-related schemes to fraudulently bill Medicare for medically unnecessary testing and medical equipment. OIG, along with our law enforcement partners, participated in a strategically coordinated, 6-week nationwide Federal law enforcement action to combat health care fraud nationwide. The efforts resulted in criminal charges against 138 defendants, including more than 42 doctors, nurses, and other licensed medical professionals, for over \$1.4 billion in alleged losses.

OIG found that the Puerto Rico Department of Health (PRDOH) did not effectively implement its emergency preparedness and response activities before and after Hurricane Maria. PRDOH's planning efforts prior to Hurricane Maria did not prepare PRDOH to meet actual needs and PRDOH did not have procedures in place to ensure that activities were in accordance with its Hospital Preparedness Program-Public Health Emergency Preparedness Cooperative Agreement. As a result, PRDOH placed the health and safety of its residents at risk. (See report [A-02-18-02002](#).)

Ensuring Health and Safety of Children Served by HHS

OIG has devoted substantial oversight efforts to protect children served by HHS programs such as the Unaccompanied Children (UC) Program, the Child Care and Development Fund (CCDF), and foster care.

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

OIG found that Colorado’s monitoring process did not ensure provider compliance with State requirements related to criminal background checks for 18 of the 30 child care providers reviewed. OIG found that Colorado did not retain criminal background check records for child care center individuals and also did not require child care providers and associated individuals to receive training on background check requirements. Although Colorado reviewed required background checks during its annual inspections of child care providers, the providers did not always inform the State and properly obtain background checks when hiring individuals or when new individuals began to reside in family homes. (See report [A-07-19-06084](#).)

OIG published a toolkit compiling insights from its oversight of the UC Program. These insights are drawn from audits and evaluations conducted since 2008, including reports issued following site visits at 45 facilities during the 2018 surge of children entering the UC Program. This toolkit outlines immediate actions that HHS program officials and facility administrators can take to ensure the health and safety of children in care, especially children at influx care facilities and emergency intake sites. (See report [OEI-09-21-00220](#).)

OIG conducted a case study of Missouri’s efforts to protect children missing from foster care. In the cases that OIG reviewed in detail, we found that the Missouri foster care agency rarely attempted to reduce children’s risk of going missing. Additionally, the Missouri foster care agency failed to protect all children missing from its care and did not effectively use resources to assist in locating them. As a result, these children were exposed to additional risks associated with being missing from care, such as a heightened risk for sex trafficking, and poorer outcomes related to health, safety, education, and criminal justice system involvement. (See report [OEI-07-19-00372](#).)

Preventing and Treating Opioid Misuse

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

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

OIG found that the Substance Abuse and Mental Health Services Administration (SAMHSA) is missing opportunities to better monitor access to MAT through the Buprenorphine Waiver Program. Less than a quarter of providers in the program required to submit data do so, but SAMHSA has not taken enforcement actions to improve reporting. Data collected from these providers has benefits beyond compliance and enforcement. (See report [OEI-BL-20-00260](#).)

A prescriber was sentenced to 121 months in prison for participating in a scheme to receive bribes and kickbacks from a pharmaceutical company in exchange for prescribing millions of dollars' worth of a potent fentanyl-based spray. Gordon Freedman received the bribes and kickbacks from Insys Therapeutics in the form of fees for sham educational programs. In exchange, Freedman prescribed enormous quantities of Subsys, a fentanyl-based spray manufactured by Insys. Freedman was also sentenced to 210 months in prison, to run concurrently with the other sentence, for distributing oxycodone and fentanyl to a patient for no legitimate medical purpose. (In 2019, Insys entered into a \$225 million global resolution, including a corporate integrity agreement with OIG, related to its promotion of Subsys.)

Protecting Beneficiaries From Abuse, Neglect, and Unsafe Conditions

A top priority for OIG is protecting the health and well-being of HHS beneficiaries, including residents in nursing homes and group homes.

Significant OIG work completed during this semiannual reporting period related to protecting beneficiaries from abuse, neglect, and unsafe conditions includes the following:

OIG found that the data that CMS uses to monitor nursing homes' use of antipsychotic drugs may not always provide complete information. Some residents' use of antipsychotics may not have been detected by CMS's quality measure intended to monitor the use of these drugs, which relies solely on self-reported information from the Minimum Data Set (MDS). CMS could enhance the information it uses to monitor antipsychotics in nursing homes by using additional data sources in its measurement of this complex issue that is critical for resident health and safety. (See report [OEI-07-19-00490](#).)

OIG found that Louisiana and California did not fully comply with Federal Medicaid waiver and State requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities residing in community-based settings. OIG found that Louisiana did not ensure that all hospital emergency room visits were reported as critical incidents, and all critical incidents were reported or followed up on, or both, within required timeframes. (See report [A-06-17-02005](#).) OIG found that California did not ensure that all critical incidents were reported or that all reported critical incidents were reported in a timely manner and followed up on completely to ensure beneficiaries' health and safety. (See report [A-09-19-02004](#).)

Protecting HHS Data, Systems, and Beneficiaries From Cybersecurity Threats

OIG's cybersecurity investigations and audits verify the operating status of HHS systems, programs, and data; identify gaps in security; and provide recommendations to address vulnerabilities. Moreover, the security of the personal information and data collected and maintained by HHS programs is critically important to the health and well-being of the American people.

Significant OIG work completed during this semiannual reporting period related to protecting data, systems, and beneficiaries from cybersecurity threats includes the following:

OIG found that the Medicare program lacks consistent oversight of cybersecurity for networked medical devices in hospitals. CMS’s survey protocols for overseeing hospitals do not include requirements for networked device cybersecurity capabilities. Additionally, accrediting organizations do not use their discretion when performing surveys to require cybersecurity plans for these devices, although they do sometimes review limited aspects of device cybersecurity. (See report [OEI-01-20-00220](#).)

Protecting Medicare From Fraud, Waste, and Abuse

OIG continues to devote substantial resources to promote strong financial stewardship of Medicare, reduce improper payments, and protect against fraud in the Medicare program. In the 2020 Medicare Trustees report, actuaries projected that assets in the Part A trust fund will be depleted by 2026, adding urgency to ensuring that funds are conserved and used appropriately.

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

In September 2021, a Nationwide Law Enforcement Action resulted in 138 charged defendants across 51 Federal districts, including more than 42 doctors, nurses, and other licensed medical professionals. These defendants were collectively charged with submitting more than \$1.4 billion in allegedly false and fraudulent claims to Federal health care programs and private insurers, including more than \$1.1 billion connected to telemedicine, \$29 million in COVID-19 health care fraud, \$133 million connected to substance abuse treatment facilities, or “sober homes,” and \$160 million connected to other health care fraud and illegal opioid distribution schemes across the country.

OIG found that Medicare paid new hospitals three times more for their capital costs than what they would have been paid under the Inpatient Prospective Payment System (IPPS). OIG identified significant potential cost savings to Medicare if the IPPS exemption for new hospitals were removed and capital payments were made through the IPPS. For the 112 new hospitals reviewed, Medicare paid \$283 million more for capital costs than would have been paid through the IPPS. On average, the IPPS exemption resulted in new hospitals being paid three times more—on average \$1.3 million per cost report. (See report [A-07-19-02818](#).)

OIG found multiple opportunities for CMS to strengthen prevention and detection of improper payments in the Medicare program. In one report, OIG determined that over 5 years, Medicare could have saved up to \$20 million had CMS oversight been adequate to prevent payments for medically unnecessary cholesterol blood tests. In another report, OIG identified opportunities for CMS and its Medicare contractors to strengthen program safeguards to prevent and detect improper payments for drug testing services. OIG found that contractors did not have necessary tools to prevent and detect these improper payments. (See reports [A-09-19-03027](#) and [A-09-20-03017](#).)

The owner and operator of a purported medical clinic, QC Medical Clinic, was sentenced to 25 years in prison and ordered to pay \$250,000 in restitution for participating in an \$11 million Medicare fraud scheme. QC Medical Clinic sold fraudulent medical documents to home health agencies in and around Houston. From October 2012 through August 2015, QC Medical Clinic conspired to defraud Medicare by selling Plans of Care, and other medical documents signed by a doctor to various home health services, resulting in approximately \$11 million in false and fraudulent claims for home health services billed to Medicare.

Promoting Integrity and Effectiveness in Managed Care

Managed care is the primary delivery system for Medicaid, covering at least some services for more than 80 percent of all enrollees. In Medicare, one-third of beneficiaries are currently enrolled in Medicare Advantage organizations (MAOs).

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

OIG found that States reported multiple challenges with using telehealth to provide behavioral health services to Medicaid enrollees in managed care organizations. The challenges included a lack of training for providers and enrollees, limited internet connectivity for providers and enrollees, difficulties with providers' protecting the privacy and security of enrollees' personal information, and the cost of telehealth infrastructure and interoperability issues for providers. Some States also reported other challenges, including a lack of licensing reciprocity and difficulties with providers obtaining informed consent from enrollees. (See report [OEI-02-19-00400](#).)

OIG found that opportunities exist to strengthen oversight and evaluation of telehealth for behavioral health in Medicaid in States that provide services through managed care organizations (MCOs). A few States reported being unable to identify which services are provided via telehealth, limiting their ability to evaluate and oversee telehealth. We also found that only a few States have evaluated the effects of telehealth on behavioral health services, and that despite concerns about fraud, waste, and abuse, many States do not conduct monitoring and oversight specific to telehealth. (See report [OEI-02-19-00401](#).)

OIG found that nationwide almost all Medicaid managed care plans achieved medical loss ratios (MLRs) that met or exceeded the Federal 85-percent standard for MLRs. Although Federal MLR regulations do not require States to set minimum MLRs, 34 States had established minimum MLRs for 434 Medicaid managed care plans. Ninety-one percent of plans met these State-set minimum MLRs. MLR requirements help ensure that Medicaid managed care plans spend most of their revenue on health care services and quality improvements. (See report [OEI-03-20-00230](#).)

OIG found that some MAOs drove disproportionate payments by leveraging chart reviews and health risk assessments. Our analysis found that 20 of 162 MAOs drove a disproportionate share of \$9.2 billion in risk-adjustment payments from diagnoses that were reported only on chart reviews and health risk

assessments (HRAs), more than 25-percent higher than its share of enrolled beneficiaries. These findings raise quality of care and payment integrity concerns and highlight the need for targeted oversight. (See report [OEI-03-17-00474](#).)

OIG found that MAOs are missing opportunities to use ordering provider identifiers to protect program integrity. We identified that almost half of MAOs lack ordering National Provider Identifiers (NPIs) on at least some MA encounter records. Incomplete NPI information hinders program integrity analyses. Among the MAOs that collect ordering NPIs, most use collected NPIs for program integrity, however one in five do not perform program integrity oversight using ordering NPIs. (See report [OEI-03-19-00432](#).)

OIG found that Humana did not submit some diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. Although most of the diagnosis codes that Humana submitted were supported in the medical records and therefore validated 1,322 of the 1,525 sampled enrollees' Hierarchical Condition Categories (HCCs), the remaining 203 HCCs were not validated and resulted in overpayments. We estimated that Humana received at least \$198 million in net overpayments for 2015. (See report [A-07-16-01165](#).)

Ensuring Medicaid Program Integrity

Medicaid is the largest Federal health care program, with over 75 million individuals enrolled, and represents over one-sixth of the national health economy. Medicaid is administered by States in accordance with Federal requirements. The program is funded jointly by the Federal Government and States. In 2019, Medicaid spending grew 2.9 percent to \$613.5 billion.

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

OIG found that New York claimed estimated unallowable Federal funds totaling \$98 million for Medicaid-eligible health services. New York did not follow Federal random moment time study (RMTS) requirements and used an unsupported method to claim Medicaid costs. New York and its contractor developed complex methods that were difficult or impossible to correctly implement and support with documentation. As a result, New York claimed estimated unallowable Federal funds totaling \$98 million. In addition, New York claimed \$32 million in Federal funds because it did not follow Federal RMTS requirements or document that CMS approved its allocation methodology, and \$309 million in Federal funds using ratios that were not supported. (See report [A-02-18-01019](#).)

Four executives of Continuum Healthcare and its various health centers were sentenced to Federal prison for a massive scam perpetrated in the Houston area. Bobby Rouse, Steven Houseworth, Jeffery Parsons, and David Edson, all pleaded guilty to their respective roles in implementation of the various kickback schemes. Numerous people were referred for treatment in exchange for payment. However, the vast majority did not qualify for partial hospitalization program (PHP) services, because they were not experiencing an acute psychotic episode or were actually suffering from mental retardation, dementia or

Alzheimer's. In total, Continuum billed Medicare approximately \$189 million in total for fraudulent PHP services and Medicaid paid approximately \$66 million on those claims.

Oversight of NIH Grant Programs and Operations

NIH's 27 institutes and centers accomplish their mission, in large part, by annually funding over \$30 billion in extramural research through a grantmaking process. OIG oversight and enforcement activities help to ensure the proper stewardship of funds and the integrity of U.S. medical research.

Significant OIG work during this semiannual reporting period related to NIH grant programs includes the following:

OIG found that selected NIH institutes met requirements for documenting peer review but could do more to track and explain funding decisions. NIH has limited insight into the extent and nature of its institutes and centers' decisions to fund less favorably ranked grant applications. This can raise questions about the transparency, impartiality, and fairness of NIH's grantmaking process. OIG made recommendations for NIH to provide better insights into whether and why funding out of rank order is happening. (See [OEI-01-19-00140](#).)

OIG found that the National Heart, Lung, and Blood Institute (NHLBI) did not fully comply with Federal requirements for "other transactions" (OTs). OTs are special award instruments that are generally not subject to Federal laws and regulations that apply to traditional award instruments. They are generally used for high-risk, high-reward research and development projects. NHLBI did not adequately document its compliance with applicable Federal requirements because its internal controls for awarding and administering OTs were ineffective. As a result, NHLBI could not ensure the proper stewardship of Federal funds to award OTs. (See [A-04-20-04078](#).)

The Van Andel Research Institute (VARI) paid \$1.1 million to resolve allegations that it violated the False Claims Act. Van Andel Research Institute failed to disclose foreign research support for two VARI researchers who served as principal investigators on NIH awards. By failing to disclose a foreign component of an NIH award, Van Andel Research institute violated the requirement for NIH grant recipients to disclose and obtain prior agency approval if a significant scientific element or segment of an NIH-funded project will be performed outside of the United States.

Promoting Payment Integrity in Departmental Programs

The Payment Integrity Information Act of 2019 (PIIA) requires OIG to review and report on agencies' annual improper payment information included in their Agency Financial Reports (AFRs) to determine compliance with PIIA.

Significant OIG work during this semiannual reporting period related to payment integrity include the following:

OIG found that HHS met many requirements but did not fully comply with PIIA. OIG found that HHS did not report an improper payment estimate for the Temporary Assistance for Needy Families (TANF) program and reported improper payment rates in excess of 10 percent for Medicaid and Children’s Health Insurance Program (CHIP). OIG also found that HHS did not conduct recovery audits for the Medicare Advantage program. Finally, OIG found that HHS did not report an improper payment estimate for the Advanced Premium Tax Credit and CDC and Office of Head Start disaster relief programs. (See report [A-17-21-52000](#).)

Insights in the Orphan Drug Designation Program

The Orphan Drug Act (ODA) provides financial incentives to encourage the development of drugs for rare diseases or conditions for which treatments might not be developed otherwise.

Significant OIG work during this semiannual reporting period related to ODA include the following:

OIG found that the majority of high-expenditure Medicare drugs often received ODA financial incentives. Moreover, we found with some drugs generating significant Medicare expenditures and billions of dollars in annual revenue while treating only rare diseases or conditions and others being primarily used to treat relatively common conditions. Orphan drug exclusion from the 340B Drug Pricing Program may provide significant financial incentives for manufacturers to seek orphan designation for drugs approved to treat common diseases or conditions. The findings may illustrate the ODA functioning as intended by encouraging manufacturers to study whether existing drugs could also be used to treat rare diseases or conditions. From another perspective, however, our findings raise questions for further consideration. (See report OEI-BL-20-00080.)

OIG Participation in Congressional Hearings

9/22/2021	Christi A. Grimm, Principal Deputy Performing Duties of the Inspector General	<u>"Hearing to Consider the Nomination of Christi A. Grimm, of Colorado, To Be Inspector General, Department of Health and Human Services," U.S. Senate Committee on Finance</u>
4/22/2021	Gary Cantrell, Deputy Inspector General for Investigations, Office of Inspector General	<u>"Protecting U.S. Biomedical Research: Efforts To Prevent Undue Foreign Influence," U.S. Senate Committee on Health, Education, Labor, and Pensions</u>

Selected Acronyms and Abbreviations

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

Medicare and Medicaid Reports and Reviews

Medicare Program Reports and Reviews

Financial Management and Improper Payments

Hospital Compliance

During this reporting period, OIG conducted a number of audits that were designed to assess compliance with selected inpatient and outpatient billing requirements at acute care hospitals with claims that may be at risk for overpayments. Prior OIG reviews and investigations have identified areas at risk for noncompliance with Medicare billing requirements. Complete recommendations and hospital responses can be found in the final reports.

Medicare Hospital Provider Compliance Audit: Virtua Our Lady of Lourdes Hospital ([A-02-18-01018](#)), May 2021

Virtua Our Lady of Lourdes Hospital complied with Medicare billing requirements for 60 of the 100 inpatient and outpatient claims we audited. However, the hospital did not fully comply with Medicare billing requirements for the remaining 40 claims, resulting in overpayments of \$666,021 for the audit period. Specifically, 37 inpatient claims and 3 outpatient claims had billing errors. On the basis of our sample results, we estimated that the hospital received overpayments of approximately \$4.8 million for the audit period. As of the publication of this report, this amount included claims outside of the Medicare 4-year claim-reopening period.

Medicare Hospital Provider Compliance Audit: Staten Island University Hospital ([A-02-18-01025](#)), June 2021

Staten Island University Hospital complied with Medicare billing requirements for 63 of the 100 inpatient and outpatient claims we audited. However, the hospital did not fully comply with Medicare billing requirements for the remaining 37 claims, resulting in overpayments of \$830,291 for the audit period. Specifically, 34 inpatient claims and 3 outpatient claims had billing errors. On the basis of our sample results, we estimated that the hospital received overpayments of nearly \$11.8 million for the audit period. As of the publication of this report, this amount included claims outside of the Medicare 4-year claim-reopening period.

Medicare Hospital Provider Compliance Audit: Lake Hospital System ([A-05-19-00024](#)), June 2021

Lake Hospital System complied with Medicare billing requirements for 49 of the 100 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 51 claims, resulting in overpayments of \$862,429 for the audit

period. On the basis of our sample results, we estimated that the Hospital received overpayments of approximately \$4.4 million for the audit period. As of the publication of this report, this amount included claims outside of the Medicare 4-year claim-reopening period.

Medicare Hospital Provider Compliance Audit: Jewish Hospital (A-04-19-08077), August 2021

Jewish Hospital complied with Medicare billing requirements for 62 of the 100 inpatient and outpatient claims we reviewed. However, the hospital did not fully comply with Medicare billing requirements for the remaining 38 claims, resulting in overpayments of \$705,976 for the audit period. Specifically, 34 inpatient claims and 4 outpatient claims had billing errors. On the basis of our sample results, we estimated that the hospital received overpayments of at least \$13.5 million for the audit period.

Home Health Compliance

During this reporting period, OIG conducted a number of audits that were designed to assess compliance with selected billing requirements at home health agencies with claims that may be at risk for overpayments. Prior OIG reviews and investigations have identified areas at risk for noncompliance with Medicare billing requirements. Complete recommendations and provider responses can be found in the final reports.

Medicare Home Health Agency Provider Compliance Audit: Visiting Nurse Association of Maryland (A-03-17-00009), April 2021

Visiting Nurse Association of Maryland (VNA) did not comply with Medicare billing requirements for 19 of the 100 home health claims that we audited. For these claims, VNA received overpayments of \$25,295 for services provided in calendar years 2015 and 2016. Specifically, VNA incorrectly billed Medicare for: (1) services provided to beneficiaries who were not homebound, (2) services provided to beneficiaries who did not require skilled services, (3) services that were not delivered in accordance with the beneficiary's plan of care, and (4) claims that were assigned with incorrect Health Insurance Prospective Payment System payment codes. On the basis of our sample results, we estimated that VNA received overpayments of at least \$2.1 million for the audit period. All 100 claims in our sample were outside of the Medicare 4-year claim-reopening period.

Medicare Home Health Agency Provider Compliance Audit: Caretenders of Jacksonville, LLC (A-04-16-06195), May 2021

Caretenders of Jacksonville did not comply with Medicare billing requirements for 39 of the 100 home health claims that we reviewed. For these claims, Caretenders received overpayments of \$92,345 for services provided during our audit period. Specifically, Caretenders incorrectly billed Medicare for services provided to beneficiaries who were not homebound, services provided to beneficiaries who did not require skilled services, and claims that were assigned with incorrect

Health Insurance Prospective Payment System (HIPPS) payment codes. These errors occurred primarily because Caretenders did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas. On the basis of our sample results, we estimated that Caretenders received overpayments of approximately \$4.4 million for the audit period. All 100 claims in our sample are outside of the Medicare 4-year claim-reopening period.

Medicare Home Health Agency Provider Compliance Audit: Catholic Home Care (A-02-19-01013), August 2021

Catholic Home Care did not comply with Medicare billing requirements for 17 of the 100 home health claims that we reviewed. For these claims, Catholic Home Care received overpayments of \$25,742 for services provided during our audit period. Specifically, Catholic Home Care incorrectly billed Medicare for services provided to beneficiaries who did not require skilled services and for some dependent services that did not meet coverage requirements. On the basis of our sample results, we estimated that Catholic Home Care received overpayments of at least \$4.2 million for the audit period.

Hospice Compliance

During this reporting period, OIG conducted a number of audits that were designed to assess compliance with selected billing requirements at hospice providers with claims that may be at risk for overpayments. Prior OIG reviews and investigations have identified areas at risk for noncompliance with Medicare billing requirements. Complete recommendations and providers responses can be found in the final reports.

Medicare Hospice Provider Compliance Audit: Suncoast Hospice (A-02-18-01001), May 2021

Suncoast Hospice did not comply with Medicare requirements for 49 of the 100 claims in our sample. For these claims, Suncoast claimed Medicare reimbursement for hospice services for which the clinical record did not support the beneficiary's terminal prognosis or the level of care claimed and for services that were not provided. These improper payments occurred because Suncoast's policies and procedures for ensuring that claims for hospice services met Medicare requirements were not always effective. On the basis of our sample results, we estimated that Suncoast received at least \$47.4 million in Medicare reimbursement for hospice services that did not comply with Medicare requirements.

Medicare Hospice Provider Compliance Audit: Ambercare Hospice, Inc. (A-09-18-03017), May 2021

Ambercare Hospice received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 48 claims complied with Medicare requirements. However, for the remaining 52 claims, the clinical record did not support the beneficiary's terminal prognosis. Improper payment of these claims occurred because

Ambercare’s policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis. On the basis of our sample results, we estimated that Ambercare received at least \$24.6 million in unallowable Medicare reimbursement for hospice services.

Medicare Hospice Provider Compliance Audit: Alive Hospice, Inc. ([A-09-18-03016](#)), May 2021

Alive Hospice received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 76 claims complied with Medicare requirements. However, the remaining 24 claims did not comply with the requirements. Specifically, for 16 claims, the clinical record did not support the beneficiary’s terminal prognosis, and for the remaining 8 claims, the clinical record did not support the level of care claimed for Medicare reimbursement. Improper payment of these claims occurred because Alive’s policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis and that the appropriate level of care was provided. On the basis of our sample results, we estimated that Alive received at least \$7.3 million in unallowable Medicare reimbursement for hospice services.

Medicare Hospice Provider Compliance Audit: Franciscan Hospice ([A-09-20-03034](#)), May 2021

Franciscan received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 79 claims complied with Medicare requirements. However, the remaining 21 claims did not comply with the requirements. Specifically, for 19 claims, the clinical record did not support the beneficiary’s terminal prognosis, and for the remaining 2 claims, there was no documentation to support the hospice services that Franciscan billed to Medicare. Improper payment of these claims occurred because Franciscan’s policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis and the hospice services billed to Medicare. On the basis of our sample results, we estimated that Franciscan received at least \$13 million in unallowable Medicare reimbursement for hospice services.

Medicare Hospice Provider Compliance Audit: Professional Healthcare at Home, LLC ([A-09-18-03028](#)), June 2021

Professional Healthcare received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 79 claims complied with Medicare requirements. However, for the remaining 21 claims, the clinical record did not support the beneficiary’s terminal prognosis. In addition, for 1 of these 21 claims, there was no documentation that a hospice physician or hospice nurse practitioner had a required face-to-face encounter with the beneficiary. Improper payment of these claims occurred because Professional Healthcare’s policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis. On the basis of our sample results, we

estimated that Professional Healthcare received at least \$3.3 million in unallowable Medicare reimbursement for hospice services.

Medicare Hospice Provider Compliance Audit: Northwest Hospice, LLC (A-09-20-03035), June 2021

Northwest Hospice (NW Hospice) received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 81 claims complied with Medicare requirements. However, for the remaining 19 claims, the clinical record did not support the beneficiary's terminal prognosis. Improper payment of these claims occurred because NW Hospice's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis. On the basis of our sample results, we estimated that NW Hospice received at least \$3.9 million in unallowable Medicare reimbursement for hospice services.

Medicare Hospice Provider Compliance Audit: Mission Hospice & Home Care, Inc. (A-09-18-03009), July 2021

Mission Hospice received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 66 claims complied with Medicare requirements. However, the remaining 34 claims did not comply with the requirements. Specifically, for 33 claims, the clinical record did not support the beneficiary's terminal prognosis, and for 1 claim, the clinical record did not support the level of care billed to Medicare. In addition, for a few claims, there was no evidence that beneficiaries elected hospice care before the periods covered by the sampled claims, or there was no support for physician services billed to Medicare. Improper payment of these claims occurred because Mission's policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis, election statements were signed before the periods covered by the sampled claims, the appropriate level of care was billed, and physician services were supported. On the basis of our sample results, we estimated that Mission received at least \$10.5 million in unallowable Medicare reimbursement for hospice services.

Medicare Hospice Provider Compliance Audit: Partners In Care, Inc. (A-09-18-03024), July 2021

Partners Hospice received Medicare reimbursement for hospice services that did not comply with Medicare requirements. Of the 100 hospice claims in our sample, 53 claims complied with Medicare requirements. However, the remaining 47 claims did not comply with the requirements. Specifically, for 43 claims the clinical record did not support the beneficiary's terminal prognosis, and for the remaining 4 claims, the clinical record did not support the level of care claimed for Medicare reimbursement. Improper payment of these claims occurred because Partners' policies and procedures were not effective in ensuring that the clinical documentation it maintained supported the terminal illness prognosis and that the appropriate level of care was provided. On

the basis of our sample results, we estimated that Partners received at least \$11.2 million in unallowable Medicare reimbursement for hospice services.

Other Compliance

Medicare Could Have Saved up to \$20 Million Over 5 Years if CMS Oversight Had Been Adequate To Prevent Payments for Medically Unnecessary Cholesterol Blood Tests (A-09-19-03027), May 2021

Payments made to providers for direct low-density lipoprotein (LDL) cholesterol tests that were billed in addition to lipid panels did not comply with Medicare requirements. Under certain circumstances, it may be medically necessary for a provider to perform both tests for the same beneficiary on the same date of service. However, CMS and Medicare contractors explained that these circumstances should happen with only limited frequency. We determined that some providers billed LDL tests in addition to lipid panels for the same beneficiary on the same date of service more than 75 percent of the time. (We refer to such providers as "at-risk providers.") In total, we identified \$20.4 million of Medicare payments made to at-risk providers for direct LDL tests.

Because the claim lines for the \$20.4 million in payments to at-risk providers for direct LDL tests had characteristics similar to the claim lines in the judgmental sample, we determined that up to \$20.4 million in payments were improper. If CMS had had oversight mechanisms to prevent such payments, Medicare could have saved up to \$20.4 million for our audit period.

CMS did not concur with our recommendation that it direct the Medicare contractors to develop oversight mechanisms to identify at-risk providers and prevent improper payments to these providers, which could have saved up to \$20.4 million for our audit period. CMS said that it had complied with our recommendation to educate providers on the billing of direct LDL tests in addition to lipid panels.

Sleep Management, LLC: Audit of Claims for Monthly Rental of Noninvasive Home Ventilators (A-04-18-04066), May 2021

Most Medicare claims submitted by Sleep Management for the monthly rental of noninvasive home ventilators (NHVs) did not comply with Medicare requirements. Of the 100 sampled claim lines with payments totaling \$75,694, 2 complied with Medicare requirements; however, 98 claim lines with payments totaling \$74,288 did not. Based on our sample results, we estimated that Medicare made overpayments to Sleep Management of at least \$29.1 million for the monthly rental of NHVs that did not comply with Medicare requirements.

These overpayments occurred because Sleep Management did not follow its policies and procedures to ensure that it obtained sufficient documentation to support the medical necessity of the NHV or discontinued service for lack of beneficiary usage.

Sleep Management generally did not concur with our recommendations that it: (1) refund the portion of the estimated \$29.1 million in Medicare overpayments for claim lines incorrectly billed that are within the 4-year reopening period, (2) exercise reasonable diligence to identify, report, and return any similar overpayments in accordance with the 60-day rule, and (3) follow existing policies and procedures to help ensure that it complies with Medicare requirements.

Medicare Made Millions of Dollars in Overpayments for End-Stage Renal Disease Monthly Capitation Payments (A-07-19-05117), May 2021

CMS did not always make Medicare monthly capitation payments (MCPs) to physicians for monthly end-stage renal disease (ESRD)-related services provided in CYs 2016 through 2018 in accordance with Federal requirements. Specifically, 23,695 claims were for services for which physicians reported monthly ESRD-related billing codes more than once for the same beneficiary for the same month, including \$4 million in overpayments for instances in which different physicians reported codes for services and \$291,813 in overpayments for instances in which the same physician reported codes for services. Beneficiaries were responsible for up to \$1.1 million in cost sharing related to these 23,695 claims. We are setting aside potential overpayments related to an additional 1,598 claims totaling \$289,169 and \$74,563 in beneficiary cost sharing for CMS's review and determination. CMS did not have adequate claims processing controls in place, including system edits, to identify and prevent these overpayments.

CMS did not concur with our recommendation that it recover the \$4 million for claims that are within the reopening period. CMS concurred with our recommendations that it: (1) recover the \$291,813 for claims that are within the reopening period; (2) instruct the physicians to refund the \$1.1 million in beneficiary cost-sharing amounts; (3) review the 1,598 claims for potentially duplicate claims, determine which should have been denied, and take followup actions; (4) based on the results of this audit, notify physicians so that they can exercise reasonable diligence to identify, report, and return overpayments in accordance with the 60-day rule and identify any returned overpayments as according with this recommendation; and (5) implement improved claims processing controls, including improved system edits, to prevent and detect overpayments.

University of Michigan Health System: Audit of Medicare Payments for Polysomnography Services (A-04-20-07088), June 2021

The University of Michigan submitted Medicare claims for some polysomnography services that did not comply with Medicare billing requirements. Of the 100 randomly selected beneficiaries in our sample, the University of Michigan submitted Medicare claims for polysomnography services that complied with Medicare billing requirements for 96 beneficiaries associated with 161 lines of service. However, the University of Michigan submitted Medicare claims for the remaining four beneficiaries associated with five lines of service that did not comply with Medicare requirements, resulting in overpayments of \$3,127.

On the basis of our sample results, we estimated that the University of Michigan received overpayments of at least \$12,520 for polysomnography services during our audit period.

The errors occurred because the University of Michigan's policies and procedures did not address the processing of Medicare claims for polysomnography services to ensure that services billed to Medicare were adequately documented and coded correctly.

The University of Michigan generally disagreed with our findings and did not comment on our recommendations that it: (1) refund to the Medicare program the estimated \$12,520 overpayment for claims that it incorrectly billed that are within the 4-year reopening period; (2) based on the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule; and (3) implement policies and procedures to ensure that Medicare claims for polysomnography services comply with Medicare requirements.

Medicare Payments for Transitional Care Management Services Generally Complied With Federal Requirements, but Some Overpayments Were Made (A-07-17-05100), July 2021

Payments made to physicians for transitional care management (TCM) services provided during CYs 2015 and 2016 generally complied with Federal requirements, but we identified almost \$1.7 million in overpayments associated with 13,577 claims (that were outside the reopening and recovery period) for instances in which multiple physicians billed for TCM services for a beneficiary's same 30-day TCM service period and for instances in which a physician billed on different dates for TCM and overlapping care management services provided during the same 30-day TCM service period for the same beneficiary. We also identified at least \$74,275 in unallowable services for instances in which a physician submitted claims on the same date for TCM and overlapping care management services that were rendered for the same beneficiary during a single 30-day TCM service period. CMS did not have controls in place, including claim system edits, to prevent and detect multiple TCM services provided to beneficiaries and to identify instances of overlapping care management.

CMS concurred with our recommendations that it: (1) notify appropriate providers so that the providers can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation; and (2) implement claims processing controls, including system edits, to prevent and detect overpayments for TCM services.

Palmetto GBA, LLC, Accurately Calculated Hospice Cap Amounts but Did Not Collect All Cap Overpayments (A-06-19-08003), July 2021

Palmetto GBA, LLC (Palmetto), accurately calculated cap amounts but did not collect all cap overpayments or pay refunds associated with lookback years due to two internal policies. As a

result, Palmetto did not collect lookback overpayments totaling \$545,639 or send refunds to hospices totaling \$17,513.

Additionally, Palmetto departments did not effectively communicate about issues that affect hospice cap oversight because it did not require such communication. Although Palmetto followed CMS debt collection timing requirements for processing Extended Repayment Schedule requests and referring balances to the Department of the Treasury, \$9.8 million of the \$49.1 million (20 percent) in total overpayments for cap year 2017 was uncollected as of August 2020. Better communication might have resulted in less uncollected debt.

Palmetto concurred with our recommendations that it: (1) collect \$545,639 in lookback overpayments and return \$17,513 in lookback refunds resulting from 2017 hospice cap calculations for lookback years, (2) discontinue using its internal policies 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) develop processes for communication between the departments directly and indirectly involved in hospice cap oversight.

Medicare Paid New Hospitals Three Times More for Their Capital Costs Than They Would Have Been Paid Under the Inpatient Prospective Payment System (A-07-19-02818), August 2021

We identified significant potential cost savings to Medicare if the IPPS exemption were removed and capital payments to new hospitals were made through the IPPS. For the 112 new hospitals that we reviewed, Medicare paid \$283 million more for capital costs than it would have paid if these hospitals had been paid through the IPPS. The IPPS exemption resulted in new hospitals being paid three times more—or an average of almost \$1.3 million more per cost report—under the reasonable cost methodology than if they had been paid for their capital costs under the IPPS.

With respect to the reasons for the IPPS exemption, we compared the first 2 years of operation with the subsequent 2 years of operation of the 35 new hospitals for which such data were available and determined that in the first 2 years of operation, average Medicare-related capital costs were only 3 percent higher, and average Medicare utilization was 15 percent lower.

Most of these new hospitals (approximately 59 percent) were also part of chain organizations that might have been able to provide reserve capital to their new hospitals if needed.

CMS concurred with our recommendation that it review our findings and, if it determines that a separate payment methodology for capital costs at new hospitals is no longer warranted, change its regulations to require new hospitals to have their Medicare capital costs paid through the IPPS with an option for payment adjustments or supplemental payments if necessary.

An Ophthalmology Clinic in Florida: Audit of Medicare Payments for Eye Injections of Avastin, Eylea, and Lucentis (A-09-19-03025), September 2021

An ophthalmology clinic in Florida (the Clinic) complied with Medicare requirements when billing for intravitreal injections of Avastin, Eylea, and Lucentis. (Injections of Lucentis were not included in our sample.) However, the Clinic did not always comply with Medicare requirements when billing for other services provided on the same day as the intravitreal injections (e.g., injections of an anesthesia drug).

The Clinic did not have policies and procedures to ensure that it: (1) did not bill for services that were not separately payable from intravitreal injections of Avastin, Eylea, and Lucentis; and (2) billed only for services that were reasonable and necessary. On the basis of our sample results, we estimated that at least \$215,606 of the \$2.1 million paid to the Clinic for intravitreal injections of Avastin, Eylea, and Lucentis, and for other services provided on the same day as the injections was unallowable for Medicare reimbursement.

The Clinic concurred in part with our recommendation that it refund to the Medicare contractor \$215,606 in estimated overpayments for other services provided on the same day as intravitreal injections of Avastin, Eylea, and Lucentis. The Clinic concurred with our remaining recommendations, including that it implement policies and procedures to ensure that it: (1) does not bill for services that are not separately payable from intravitreal injections of Avastin, Eylea, and Lucentis; and (2) bills only for services that are reasonable and necessary.

Quality of Care, Safety, and Access

CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes ([OEI-07-19-00490](#)), May 2021

CMS has taken important steps to reduce the use of antipsychotic drugs in nursing homes and could further that progress by collecting more complete data on residents' use of these drugs. We found that CMS's use of the MDS as the sole data source to count the number of nursing home residents receiving antipsychotic drugs may not always provide complete information. This means that some residents' use of antipsychotics may not have been detected by CMS's quality measure intended to monitor the use of these drugs. Our findings suggest that CMS could enhance the information it uses to monitor antipsychotics in nursing homes by using additional data sources in its measurement of this complex issue that is critical for resident health and safety. CMS concurred with both of our recommendations, which were for it to take additional steps to validate the information reported in MDS assessments; and supplement the data it uses to monitor the use of antipsychotic drugs in nursing homes.

Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2021 ([OEI-05-21-00170](#)), June 2021

We found that overall, the rate at which Part D plan formularies include the drugs commonly used by dual eligibles (i.e., individuals who are eligible for both Medicare and Medicaid) is high, with some variation. The 453 unique formularies used by the 5,128 Part D plans include 97 percent of the 195 drugs most commonly used by dual eligibles and covered by Part D. In addition, 74 percent of the commonly used drugs are included by all Part D plan formularies. On average, formularies applied utilization management tools to 29 percent of the unique drugs we reviewed in 2021.

Because some variation exists in formularies' inclusion of these drugs and in their application of utilization management tools to the drugs, some dual eligibles may need to use alternative methods to access the drugs they take. This report did not make recommendations.

Medicare Lacks Consistent Oversight of Cybersecurity for Networked Medical Devices in Hospitals (OEI-01-20-00220), June 2021

Medicare accreditation organizations (AOs), which derive their requirements from the Conditions of Participation, rarely use their discretion to examine the cybersecurity of networked devices during their hospital surveys. Our findings can help CMS identify ways to add consistent oversight of networked medical device cybersecurity in hospitals. CMS stated that it concurred with considering additional ways to appropriately highlight the importance of cybersecurity of networked medical devices for providers in consultation with its HHS partners that have specific oversight authority regarding cybersecurity. We ask that, in its Final Management Decision, CMS share its plan for responding to our specific recommendation, which is for it to identify and implement an appropriate way to address cybersecurity of networked medical devices in its quality oversight of hospitals, in consultation with HHS partners and others.

COVID-19 Had a Devastating Impact on Medicare Beneficiaries in Nursing Homes During 2020 (OEI-02-20-00490), June 2021

Two in five Medicare beneficiaries in nursing homes either had or likely had COVID-19 in 2020. Overall mortality in nursing homes increased to 22 percent in 2020 from 17 percent in 2019, with almost 1,000 more beneficiaries dying per day in April 2020 than in April 2019. About half of Black, Hispanic, and Asian beneficiaries in nursing homes had or likely had COVID-19, compared with 41 percent of White beneficiaries. Understanding the pandemic's effects on nursing home residents is necessary if tragedies like this are to be averted. Analyzing Medicare claims data may help CMS in its efforts. These data are important to understanding the effects of the pandemic and, moving forward, could play an integral part in understanding health disparities within the nursing home population and preparing for and dealing with future public health crises.

States' Backlogs of Standard Surveys of Nursing Homes Grew Substantially During the COVID-19 Pandemic (OEI-01-20-00431), July 2021

States' backlogs of standard nursing home surveys grew substantially during the COVID-19 pandemic, even after August 2020 when CMS lifted its suspension of those surveys (which it had suspended due to the pandemic). Nationally, 71 percent of nursing homes had gone at least 16 months without a standard survey as of May 31, 2021, an increase from June 2020, when 8 percent of nursing homes had gone at least 16 months without a standard survey. The rising backlogs of standard surveys add urgency to our recommendation from our previous report, *Onsite Surveys of Nursing Homes During the COVID-19 Pandemic: March 23–May 30, 2020*, that CMS clarify expectations and provide guidance to States on completing these important surveys.

Medicare Beneficiaries Hospitalized With COVID-19 Experienced a Wide Range of Serious, Complex Conditions (OEI-02-20-00410), September 2021

The wide-ranging and complex conditions of Medicare beneficiaries hospitalized with COVID-19 can create substantial challenges in meeting the needs of these patients, particularly during surges in hospitalizations. Although almost all of these beneficiaries were treated for acute respiratory issues—such as viral pneumonia—many were treated for other types of serious conditions, including acute kidney failure, heart attacks, and sepsis. More than half of the beneficiaries hospitalized with COVID-19 received intensive care or mechanical ventilation. We also found that beneficiaries who were dually eligible, Black, Hispanic, or older were hospitalized at disproportionately high rates. Gaining a better understanding of Medicare beneficiaries hospitalized with COVID-19—including the conditions for which they were being treated and demographic makeup—can assist Federal, State, and local efforts in the COVID-19 pandemic.

CMS's COVID-19 Data Included Required Information From the Vast Majority of Nursing Homes, but CMS Could Take Actions To Improve Completeness and Accuracy of the Data (A-09-20-02005), September 2021

CMS's COVID-19 data for nursing homes included the required data from the vast majority of nursing homes (e.g., the number of confirmed COVID-19 cases among residents); however, the data were not complete or accurate for some nursing homes. These conditions occurred because, in part, CMS's quality assurance checks were not always effective in ensuring the accuracy and completeness of the COVID-19 data for nursing homes.

In addition, we identified two areas in which CMS could take additional actions to help ensure that its COVID-19 data are complete and accurate. First, CMS could provide technical assistance to all nursing homes that fail its quality assurance checks. Second, CMS could make additional efforts to ensure that: (1) CMS's and States' COVID-19 data elements (e.g., confirmed COVID-19 cases among residents) are comparable (i.e., CMS and States could use the same data elements) and (2) the reported data are not substantially different.

When CMS's COVID-19 data are complete and accurate, Federal and State officials and other stakeholders may be able to more effectively monitor trends in infection rates and develop public

health policies when making decisions about how to ensure the health and safety of nursing home residents and staff.

CMS partly agreed and partly disagreed with our recommendations that it assess the costs and benefits of implementing the six recommendations listed in our report (e.g., our recommendations that it revise its quality assurance checks and contact nursing homes that fail quality assurance checks to verify the accuracy of reported data or to correct inaccurate data), and if CMS determines that the benefits outweigh the costs, take action to implement the recommendations.

Program Integrity

Medicare Advantage Organizations Are Missing Opportunities To Use Ordering Provider Identifiers To Protect Program Integrity (OEI-03-19-00432), April 2021

In Medicare Advantage, encounter data lack NPIs for providers who order and/or refer durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); clinical laboratory services; imaging services; and home health services. (Encounter data are the detailed information that MAOs submit to CMS regarding each service provided to MA beneficiaries.) Almost half of the MAOs that lack ordering NPIs on at least some MA encounter records raised concerns that this hinders their data analysis for program integrity. Among MAOs that collect any ordering NPIs, most use them to conduct oversight activities, but one in five does not—despite having the data to do so. Furthermore, when MAOs collect these ordering NPIs, most do not validate them against CMS's NPI registry. CMS neither concurred nor nonconcurred with our recommendation and stated that it would consider whether additional education is needed for MAOs regarding the role that ordering NPIs can play in program integrity oversight. Our recommendation is for CMS to encourage MAOs to perform program integrity oversight using ordering NPIs.

Some Medicare Advantage Companies Leveraged Chart Reviews and Health Risk Assessments To Disproportionately Drive Payments (OEI-03-17-00474), September 2021

Twenty companies with contracts under MA companies drove a disproportionate share of the \$9.2 billion in payments from diagnoses that were reported only on chart reviews and HRAs, and on no other encounter records in 2016. Each company generated a share of payments from these chart reviews and HRAs that was more than 25 percent higher than its share of enrolled MA beneficiaries. Among these 20 MA companies, 1 company further stood out in its use of chart reviews and HRAs to drive risk-adjusted payments without encounter records of any other services provided to the beneficiaries for those diagnoses. This company accounted for about one-third of all payments from diagnoses reported solely on chart reviews and more than half of all payments from diagnoses reported solely on HRAs. CMS neither concurred nor nonconcurred with our three recommendations, which were for it to provide oversight of the 20 MA companies that had a disproportionate share of the risk-adjusted payments from chart reviews and HRAs; take additional actions to determine the appropriateness of payments and care for the one MA company that

substantially drove risk-adjusted payments from chart reviews and HRAs; and perform periodic monitoring to identify MA companies that had a disproportionate share of risk-adjusted payments from chart reviews and HRAs.

Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS (A-07-16-01165), April 2021

Humana, Inc., did not submit some diagnosis codes to CMS for use in the risk-adjustment program in accordance with Federal requirements. We reviewed, for 200 sampled enrollees, the diagnosis codes that Humana submitted, and although most were supported in the medical records and therefore validated 1,322 of the 1,525 sampled enrollees' HCCs, the remaining 203 HCCs were not validated and resulted in overpayments. These 203 unvalidated HCCs included 20 HCCs for which we identified 22 other, replacement HCCs for more and less severe manifestations of the diseases. Second, there were an additional 15 HCCs for which the medical records supported diagnosis codes that Humana should have submitted to CMS but did not.

Thus, the risk scores for the 200 sampled enrollees should not have been based on the 1,525 HCCs. Rather, the risk scores should have been based on 1,359 HCCs (1,322 validated HCCs + 22 other HCCs + 15 additional HCCs). As a result, we estimated that Humana received at least \$197.7 million in net overpayments for 2015. These errors occurred because Humana's policies and procedures to prevent, detect, and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, were not always effective.

Humana disagreed with our recommendations that it refund to the Federal Government the \$197.7 million of net overpayments and enhance its policies and procedures to prevent, detect, and correct noncompliance with Federal requirements for diagnosis codes that are used to calculate risk-adjusted payments.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS (A-07-19-01187), May 2021

With respect to the seven high-risk groups covered by our audit, most of the selected diagnosis codes that Anthem Community Insurance Company, Inc. (Anthem), submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements. For 123 of the 203 enrollee-years, the diagnosis codes that Anthem submitted to CMS were not supported in the medical records and resulted in \$354,016 of net overpayments for the 203 enrollee-years.

These errors occurred because the policies and procedures that Anthem had to detect and correct noncompliance with CMS's program requirements, as mandated by Federal regulations, were not always effective. On the basis of our sample results, we estimated that Anthem received at least \$3.47 million of net overpayments for these high-risk diagnosis codes in 2015 and 2016.

Anthem disagreed with our recommendations that it refund to the Federal Government the \$3.47 million of net overpayments; identify, for the high-risk diagnoses included in this report, similar instances of noncompliance that occurred before or after our audit period and refund any resulting overpayments to the Federal Government; and enhance its compliance procedures to focus on diagnosis codes that are at high risk for being miscoded by: (1) determining whether these diagnosis codes (when submitted to CMS for use in CMS's risk adjustment program) comply with Federal requirements and (2) educating its providers about the proper use of these diagnosis codes.

CMS Needs To Strengthen Regulatory Requirements for Medicare Part B Outpatient Cardiac and Pulmonary Rehabilitation Services To Ensure Providers Fully Meet Coverage Requirements (A-02-18-01026), May 2021

CMS regulatory requirements related to Medicare outpatient cardiac and pulmonary rehabilitation services did not contain sufficient information to ensure that claims for these services met Medicare coverage requirements. Specifically, the requirements lacked details related to what patient-specific information should be contained in a beneficiary's medical record and how this information should relate to their individualized treatment. As a result, for all 100 sampled beneficiary-days, we determined that medical record documentation obtained from the selected provider did not contain sufficient evidence to support whether Medicare coverage requirements for reimbursement of cardiac and pulmonary rehabilitation services were met. On the basis of our sample results, we estimated that \$2.7 million in Medicare payments made by CMS to the selected provider for outpatient cardiac and pulmonary rehabilitation services may not have met Medicare coverage requirements, as intended. Further, based on our review, we believe that Medicare payments totaling approximately \$626 million made by CMS to all providers for outpatient cardiac and pulmonary rehabilitation services during our audit period may not have met the requirements.

We recommended that CMS revise its regulations to provide sufficient guidance to ensure that providers meet coverage requirements for outpatient cardiac and pulmonary rehabilitation services. CMS stated that it had updated its manuals to more closely reflect regulatory text and that it will consider our recommendation when determining appropriate next steps regarding the regulations on outpatient cardiac and pulmonary rehabilitation services.

Opportunities Exist for CMS and Its Medicare Contractors To Strengthen Program Safeguards To Prevent and Detect Improper Payments for Drug Testing Services (A-09-20-03017), June 2021

We identified several weaknesses in the Medicare contractors' established program safeguards for preventing and detecting improper payments for drug testing services and promoting provider compliance with Medicare requirements. If CMS and its contractors cannot ensure that laboratories' claims for drug testing services comply with Medicare requirements, laboratories may receive improper payments, and beneficiaries with substance use disorders may receive medically unnecessary drug testing services.

CMS did not concur with our recommendations that it work with its Medicare contractors to: (1) take the necessary steps to determine whether clinical evidence exists to support a single, specific reasonable and necessary standard for drug testing services, and if such evidence exists, establish a National Coverage Determination or develop local coverage determinations (LCDs) with more consistent requirements for drug testing services; (2) clearly indicate in LCDs, Local Coverage Articles, or other instructions how laboratories should determine the number of drug classes for billing definitive drug testing services; and (3) implement a system edit or procedure to identify and limit the frequency of drug testing services per beneficiary across all Medicare jurisdictions.

CMS concurred with our recommendations that it: (1) determine whether a postpayment medical review is necessary for laboratories that have been paid for excessive definitive drug tests (e.g., more than one test) in a 1-week period for the same beneficiary, and (2) consider adding a modifier to claims for definitive drug tests indicating whether a test was based on results obtained from a presumptive drug test.

CMS's Controls Related to Hospital Preparedness for an Emerging Infectious Disease Were Well-Designed and Implemented but Its Authority Is Not Sufficient for It To Ensure Preparedness at Accredited Hospitals (A-02-21-01003), June 2021

CMS's controls were well designed and implemented, but CMS's authority is not sufficient for it to fulfill its responsibility to ensure that accredited hospitals would maintain quality and safety during an emerging infectious disease emergency. Specifically, although CMS announced in February 2019 that it was critical for all hospitals to plan for emerging infectious diseases, CMS could not determine that all accredited hospitals updated their emergency preparedness plans to include this planning until 2022 due to accreditation organizations' quality and safety inspection cycles. Further, when COVID-19 emerged in the United States, CMS requested (but could not require) accreditation organizations to perform special targeted infection control surveys to help accredited hospitals prepare for COVID-19 patients. Accreditation organizations performed no such special surveys and, as of August 17, 2020, State survey agencies only performed these surveys at about 13 percent of accredited hospitals and had not performed any in 13 States because of CMS's limited authority over accredited hospitals. As a result of these limitations, CMS could not ensure that accredited hospitals would continue to provide quality care and operate safely during the COVID-19 emergency and cannot ensure quality and safety at accredited hospitals when a future emerging infectious disease threatens the United States.

CMS concurred with our recommendation that it make regulatory changes to allow it to require accreditation organizations to perform special surveys after it issues new participation requirements or guidance and during a public health emergency to address the risks presented by the emergency.

2020 Performance Data for the Senior Medicare Patrol Projects (OEI-02-21-00180), June 2021

The Senior Medicare Patrol (SMP) projects receive grants from the Administration for Community Living to recruit and train retired professionals and other older adults and community members to prevent, recognize, and report health care fraud, errors, and abuse. In 2020, the 54 SMP projects had a total of 5,720 total active team members who conducted a total of 9,870 group outreach and education events, reaching an estimated 425,103 people. In addition, the projects had 249,134 individual interactions with, or on behalf of, a Medicare beneficiary. The projects reported \$16.8 million in expected Medicare recoveries. Cost avoidance totaled \$53,768, while savings to beneficiaries and others totaled \$33,554.

Review of Medicare Administrative Contractor Information Security Program Evaluations for Fiscal Year 2020 (A-18-21-11300), July 2021

CMS contracted with Guidehouse, LLP (Guidehouse), to evaluate information security programs at the MACs, using a set of agreed-upon procedures (AUPs). HHS OIG must submit to Congress annual reports on the results of these evaluations, to include assessments of their scope and sufficiency. This report fulfills that responsibility for fiscal year 2020. Guidehouse's evaluations of the contractor information security programs were adequate in scope and sufficiency. Guidehouse reported a total of 99 gaps at the 7 MACs for FY 2020, which was 21 percent less than the number of gaps for the same 7 MACs in FY 2019. Deficiencies remained in eight of the nine Federal Information Security Modernization Act of 2014 (FISMA) control areas that were tested. CMS should continue its oversight visits and ensure that the MACs remediate all gaps to improve the MACs' IT security. Similar gaps from prior years should be considered repeat findings to highlight systemic problems and the existence of continued exposure to known weaknesses. This report contains no recommendations.

Medicare Continues To Make Overpayments for Chronic Care Management Services, Costing the Program and Its Beneficiaries Millions of Dollars (A-07-19-05122), August 2021

Not all payments made by CMS to providers for noncomplex and complex chronic care management (CCM) services rendered during CYs 2017 and 2018 complied with Federal requirements, resulting in \$1.9 million in overpayments associated with 50,192 claims. These errors occurred because CMS did not have claim system edits to prevent and detect overpayments.

CMS concurred with our recommendations that it direct the Medicare contractors to: (1) recover the \$1.9 million for claims that are within the reopening period, and instruct providers to refund up to \$540,680, which beneficiaries were required to pay; (2) based on the results of this audit, notify appropriate providers so that they can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation; and (3) implement claim system edits to prevent and detect overpayments for noncomplex and complex CCM services. We also recommended that CMS implement claim system edits at its level.

Six of Eight Home Health Agency Providers Had Infection Control Policies and Procedures That Complied With CMS Requirements and Followed CMS COVID-19 Guidance To Safeguard Medicare Beneficiaries, Caregivers, and Staff During the COVID-19 Pandemic (A-01-20-00508), September 2021

Six of the eight selected home health agency (HHA) providers (three of the largest HHA providers in the country and five HHA providers that were recently cited for infection prevention and control deficiencies) had infection control policies and procedures that complied with CMS requirements and followed CMS guidance to safeguard HHA staff, Medicare beneficiaries, and caregivers during the COVID-19 pandemic. However, one HHA provider did not comply with CMS requirements or follow CMS COVID-19 guidance. In addition, this provider and another HHA provider's COVID-19 screening protocols for patients were not consistent with CMS guidance. As a result, the patients and staff at these two HHA providers were at an increased risk of infection. We did not determine whether these HHA providers had infection prevention and control issues related to the implementation of the policies and procedures. However, State survey agencies identified issues with implementation at several of these HHA providers, as indicated by infection prevention and control deficiencies found during surveys conducted in 2019 and 2020.

CMS concurred with our recommendation that it develop and share with the HHA industry information on COVID-19 infection prevention and control best practices that HHA providers can use to comply with CMS requirements and follow CMS guidance.

The Centers for Medicare & Medicaid Services Did Not Account for National Security Risks in Its Enterprise Risk Management Processes (A-18-20-06200), July 2021

CMS's ERM process did not consider national security risks for any of CMS's programs in accordance with Federal requirements. CMS lacked policies and procedures that required its programs to consider national security threats because it relied on HHS's ERM process. As a result, CMS was unable to ensure that it had implemented effective controls to protect against threats from foreign and domestic adversaries.

CMS concurred with our recommendation that it, as part of its ERM program, implement a process to assess all of its programs for national security risks in accordance with Office of Management and Budget (OMB) Circular No. A-123's requirement to include new or emerging risks in the risk profile.

CMS Needs To Issue Regulations Related to Phlebotomy Travel Allowances (A-06-20-04000), August 2021

In our two previous audits of MAC payments for phlebotomy travel allowances, we determined that the two MACs paid providers for phlebotomy travel allowances that did not comply with Medicare guidance. Specifically, in our 2 MAC audits, 93 of the 202 sampled paid claim lines we

reviewed complied with Medicare guidance, but 109 paid claim lines did not. (Some lines did not comply for more than one reason.) Errors identified in those audits were related to incorrect prorated mileage, incorrect payment rates, and inadequate documentation. On the basis of the sample results, we estimated that the two MACs paid providers a combined \$2.7 million in phlebotomy travel allowance payments that were not in accordance with Medicare guidance. In addition, we spoke with CMS in June 2020 and, at that time, it had not begun the notice and comment rulemaking process necessary to clarify provider guidance related to prorating mileage on claims for phlebotomy travel allowances or issue further guidance.

CMS concurred with our recommendations that it: (1) work with the MACs to educate providers about the documentation requirements for phlebotomy travel allowances and (2) instruct the MACs to identify and adjust any paid claims that incorrectly used the previous year's rate. Regarding our recommendation that CMS issue regulations related to phlebotomy travel allowances, CMS stated that such changes will need to go through notice and comment rulemaking.

Drug Spending and Reimbursement

Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2021 ([OEI-05-21-00170](#)), June 2021

We found that overall, the rate at which Part D plan formularies include the drugs commonly used by dual eligibles (i.e., individuals who are eligible for both Medicare and Medicaid) is high, with some variation. The 453 unique formularies used by the 5,128 Part D plans include 97 percent of the 195 drugs most commonly used by dual eligibles and covered by Part D. In addition, 74 percent of the commonly used drugs are included by all Part D plan formularies. On average, formularies applied utilization management tools to 29 percent of the unique drugs we reviewed in 2021.

Because some variation exists in formularies' inclusion of these drugs and in their application of utilization management tools to the drugs, some dual eligibles may need to use alternative methods to access the drugs they take. This report did not make recommendations.

Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2019 Average Sales Prices ([OEI-03-21-00130](#)), June 2021

Based on OIG's analysis of ASP and AMP data for 2019, CMS lowered Medicare Part B reimbursement for 18 drugs, saving Medicare and its beneficiaries \$6.2 million over 1 year. This finding highlights the success of OIG's mandated quarterly comparisons of average sales prices (ASPs) with average manufacturer prices (AMPs) and implementation of CMS's current price-substitution policy. (If OIG finds that the ASP for a drug exceeds the AMP by a certain

percentage—currently, 5 percent—the ASP-based payment amount is substituted with a lower calculated rate. This serves as a mechanism for monitoring market prices and limiting potentially excessive payment amounts.) This data snapshot does not contain any recommendations. However, OIG continues to support a previous recommendation that CMS expand the price-substitution criteria.

Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Fourth Quarter of 2020 (OEI-03-21-00070), May 2021, and Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the First Quarter of 2021 (OEI-03-21-00080), August 2021

OIG identified five drug codes in the fourth quarter of 2020 and six drug codes in the first quarter of 2021 that met CMS's criteria for price substitution. OIG compares ASPs to AMPs every quarter and identifies Part B-covered drug codes eligible for price substitutions. If OIG finds that the ASP for a drug exceeds the AMP by a certain percentage—currently, 5 percent—the ASP-based payment amount is substituted with a lower calculated rate. This 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.

Concerns Persist About Opioid Overdoses and Medicare Beneficiaries' Access to Treatment and Overdose-Reversal Drugs (OEI-02-20-00401), August 2021

More than 43,000 Medicare Part D beneficiaries suffered an opioid overdose in 2020. Overall, nearly one in four Part D beneficiaries received opioids during the year. The number of beneficiaries who received drugs for MAT through Part D increased but at a slower rate in 2020 than in prior years. And, unlike in other recent years, there was no growth in the number of beneficiaries receiving prescriptions through Part D for the opioid overdose-reversal drug naloxone. These slower growth rates add to ongoing concerns about access to MAT drugs and naloxone. Ensuring this access in 2021 and beyond is particularly important as we do not yet know the full extent to which the stressors of the COVID-19 pandemic may have increased the need for these drugs. It is also critical for CMS to closely monitor the number of beneficiaries receiving MAT drugs and naloxone and take action, if needed.

Audit of Medicare Part D Pharmacy Fees: Group Health Cooperative, Inc. (A-03-19-00002), July 2021

For CYs 2014 and 2015, Group Health Cooperative, Inc. (GHC), did not have adequate support for the point-of-sale fees that its pharmacy benefit manager (PBM) charged to pharmacies. For CYs 2014 and 2015, its PBM reported it received at least \$52,076 and \$36,346 respectively in point-of-sale fees. GHC refiled its direct and indirect remuneration (DIR) reports twice, and the refiled amounts were not supported by other documentation that its PBM provided. As a result, we could not validate whether the amounts GHC reported to CMS were accurate.

For CY 2016, GHC's PBM did not charge pharmacy fees, and, for CY 2017, we determined that GHC correctly reported the pharmacy fees collected by its PBM.

Kaiser Permanente, which acquired GHC in 2017, concurred with our recommendations that it: (1) validate the point-of-sale fee amounts for CYs 2014 and 2015 and refile the CY 2014 and 2015 DIR reports if appropriate, and (2) develop written policies and procedures to validate the amounts its PBM discloses before submitting the DIR reports to CMS.

Medicaid Program Reports and Reviews

Financial Management and Improper Payments

Minnesota Made Capitation Payments to Managed Care Organizations for Medicaid Beneficiaries With Concurrent Eligibility in Another State (A-05-19-00032), May 2021

Minnesota made an estimated \$1.1 million in August 2018 capitation payments on behalf of beneficiaries who were concurrently eligible and residing in another State. Of the 106 capitation payments in our stratified random sample, 71 were associated with beneficiaries who were residing and eligible for Medicaid benefits in Minnesota. However, for the remaining 35 capitation payments, totaling \$15,084 (\$9,167 Federal share), Minnesota made capitation payments on behalf of beneficiaries who should not have been eligible for Medicaid benefits in Minnesota because they were concurrently eligible and residing in another State. On the basis of our sample results, we estimated that Minnesota could have saved \$1.1 million (\$665,000 Federal share) for August 2018 capitation payments made to managed care organizations on behalf of beneficiaries with concurrent eligibility.

Minnesota accepted our recommendations that it: (1) develop new procedures or enhance current ones to identify beneficiaries with concurrent eligibility in another State, which could have saved Minnesota an estimated \$1.1 million (\$665,000 Federal share) in capitation payments for the month of August 2018; and (2) ensure that county caseworkers follow procedures to timely review and terminate eligibility for beneficiaries who were identified as concurrently eligible in another State.

New York Made Unallowable Payments Totaling More Than \$9 Million to the Same Managed Care Organization for Beneficiaries Assigned More Than One Medicaid Identification Number (A-02-20-01007), May 2021

New York improperly claimed Federal Medicaid reimbursement for Medicaid beneficiaries who were assigned more than one Medicaid identification (ID) number. The assignment of more than one Medicaid ID number and resulting improper payments occurred because: (1) New York's procedures for identifying whether an individual applying for Medicaid had already been assigned a Medicaid ID number were not always followed, (2) system queries were not adequate to ensure

that all individuals with existing Medicaid ID numbers were identified, and (3) local district and Marketplace staff did not use all available resources to ensure that qualified applicants were not issued more than one Medicaid ID number. We note that, in 2019 and 2020, New York took steps to improve its processes for identifying beneficiaries assigned more than one Medicaid ID number.

On the basis of our sample results, we estimated that New York claimed at least \$10.6 million in Federal Medicaid reimbursement for managed care payments made to the same MCO on behalf of beneficiaries assigned more than one Medicaid ID number. We reduced our recommended financial disallowance to reflect payments New York refunded after our fieldwork.

New York did not indicate concurrence or nonconcurrence with our recommendations, including that it refund \$9,325,338 to the Federal Government and identify and recover improper managed care payments made to the same MCO on behalf of beneficiaries with more than one Medicaid ID number prior to and after our audit period.

Nebraska Did Not Report and Refund the Correct Federal Share of Medicaid-Related Overpayments for 76 Percent of the State's Medicaid Fraud Control Unit Cases (A-07-18-02814), June 2021

Nebraska did not report and return the correct Federal share of MFCU-determined Medicaid overpayments identified during the period October 1, 2011, through September 30, 2018. Nebraska did not report \$4.6 million (\$2.6 million Federal share) of MFCU-determined Medicaid overpayments for this period. In addition, Nebraska did not report \$595,723 (\$311,352 Federal share) in a timely manner. Nebraska did not have adequate policies and procedures to ensure that it always reported MFCU-determined Medicaid overpayments in accordance with Federal requirements.

We recommended that Nebraska refund \$1.8 million (Federal share) of the unreported MFCU-determined Medicaid overpayments that related to paid claims and that it report and refund up to \$781,732 (Federal share) of the unreported MFCU-determined Medicaid overpayments that related to court-ordered awards if and when collected. We also recommend that Nebraska determine the value of overpayments identified after our audit period that have been collected but not reported, report them to CMS, and refund the Federal share of the collected overpayments. We made other recommendations for the improvement of relevant policies and procedures. Nebraska disagreed with the amount (\$2.6 million) in our draft report's first recommendation and added that it would work with CMS to determine and report the amount owed. We revised our recommendations for this final report by narrowing the focus and revising the amount of questioned costs in our first recommendation, by adding a new second recommendation, and by clarifying our first recommendation.

Kentucky Claimed Millions in Unallowable School-Based Medicaid Administrative Costs (A-04-17-00113), June 2021

Kentucky did not claim school-based Medicaid administrative costs in accordance with Federal requirements. It used an invalid random moment sampling (RMS) to allocate costs to Medicaid, and it included unallowable costs in its cost pools. In addition, Kentucky claimed these costs without promptly submitting cost allocation plan (CAP) amendments to Department of Health and Human Services, Division of Cost Allocation (DCA), for review and without obtaining DCA approval. As a result, the \$58.9 million (\$29.4 million FFP) that it claimed in school-based Medicaid administrative costs for FFYs 2009 through 2014 was unallowable.

Kentucky generally disagreed with our findings, and it did not specifically address our recommendations that it: (1) refund \$29.4 million to the Federal Government; (2) amend its CAP to address the statistical validity issues we identified; (3) enhance RMS procedures to ensure that its RMTS methodology complies with Federal requirements for statistical validity; (4) enhance RMS procedures to ensure that its Medicaid administrative cost claim complies with Federal requirements for allocable costs; (5) enhance policies and procedures to ensure that changes to its RMTS methodology are incorporated into a CAP amendment and promptly submitted to DCA for review; and (6) review school-based Medicaid administrative costs claimed after our audit period and refund any unallowable amounts.

Indiana Received Over \$22 Million in Excess Federal Funds Related to Unsupported Community Integration and Habilitation Waiver Services at 12 Selected Service Providers (A-05-19-00022), June 2021

Indiana did not ensure that all Community Integration and Habilitation Waiver (CIH Waiver) services were provided in accordance with Federal, State, and waiver requirements. We determined that services associated with 236 claims were provided in accordance with the requirements; however, services associated with 64 claims were not. Documentation provided by CIH Waiver service providers did not support that services associated with 39 claims were provided in accordance with the requirements. Overpayments associated with these 39 claims totaled \$10,675 (\$7,108 Federal share). In addition, some CIH Waiver service providers were unable to provide any documentation to support 25 claims totaling \$90,802 (\$60,448 Federal share). Therefore, overpayments associated with the 64 claims totaled \$101,477 (\$67,556 Federal share). On the basis of our sample results, we estimated that these providers were unable to support that they provided services totaling at least \$33.5 million (\$22.3 million Federal share) in accordance with the CIH Waiver requirements.

These issues occurred because Indiana's monitoring of CIH Waiver services was not adequate to ensure that services complied with Federal, State, and CIH Waiver requirements.

Indiana generally did not concur with our recommendations that it: (1) refund \$22.3 million to the Federal Government and (2) improve its monitoring of the CIH Waiver program to ensure that service providers comply with Federal, State, and CIH Waiver requirements.

New York's Claims for Federal Reimbursement for Payments to Health Home Providers on Behalf of Beneficiaries Diagnosed With Serious Mental Illness or Substance Use Disorder Generally Met Medicaid Requirements, but It Still Made \$6 Million in Improper Payments to Some Providers (A-02-19-01007), July 2021

Of the 150 payments in our random sample, New York properly claimed reimbursement for 141 payments but improperly claimed reimbursement for the remaining 9 payments. Specifically, New York's health home providers did not provide a comprehensive patient-centered care plan covering the sampled date of service for enrolled beneficiaries (five payments) and did not document health home services (four payments). The improper payments occurred because New York did not adequately monitor health home providers for compliance with certain Federal and State requirements for providing, documenting, and billing services.

Health home providers' failure to develop comprehensive patient-centered care plans and provide health home services could have resulted in beneficiaries not getting the services that they needed and may have put their health and safety at risk. On the basis of our sample results, we estimated that New York improperly claimed at least \$6 million in Federal Medicaid reimbursement for payments made to health home providers for services provided to beneficiaries diagnosed with serious mental illness or substance use disorder.

New York did not indicate concurrence or nonconcurrence with our recommendations that it refund \$6 million to the Federal Government and that it should strengthen its monitoring of the health home program to ensure that health home providers comply with Federal and State requirements for: (1) providing services according to a comprehensive patient-centered care plan and (2) maintaining documentation to support services billed.

New York Improperly Claimed \$439 Million in Medicaid Funds for Its School-Based Health Services Based on Certified Public Expenditures (A-02-18-01019), July 2021

New York claimed unallowable Federal funds because it did not support that all random moments coded as health care were for Medicaid-eligible health services. New York also did not provide support that it did not double-claim for services when a student in one school district received services from another school district. In addition, New York improperly claimed excess costs for 1 year. Finally, New York did not follow Federal RMTS requirements and used an unsupported method to claim Medicaid costs.

New York and its contractor developed complex methods that were difficult or impossible to correctly implement and support with documentation. As a result, New York claimed estimated unallowable Federal funds totaling \$98 million. In addition, New York claimed \$32 million in Federal funds because it did not follow Federal RMTS requirements or document that CMS approved its allocation methodology, and \$309 million in Federal funds using ratios that were not supported.

New York generally disagreed with our findings and recommendations that it refund \$98 million in unallowable funds and support or refund the \$32 million and the \$309 million. We also made procedural recommendations to assist New York in preparing accurate, supportable claims.

Texas Made Unallowable Children's Health Insurance Program Payments for Beneficiaries Assigned More Than One Identification Number (A-06-20-10003), July 2021

Texas claimed Federal reimbursement for unallowable CHIP payments made to MCOs on behalf of beneficiaries who were assigned more than one identification number. For the 599 beneficiary matches, Texas improperly paid MCOs \$922,557 (\$856,456 Federal share) on behalf of 572 beneficiaries. Texas made the unallowable payments to MCOs under the different identification numbers for the same month. The remaining 27 beneficiary matches were different individuals.

Texas attributed the unallowable payments to eligibility worker and system errors. Specifically, eligibility workers did not ensure that beneficiaries were assigned only one identification number during the application process. Additionally, the State agency stated that it had already identified more than half of the beneficiaries included in our audit as having more than one identification number but that it encountered system compatibility issues that would not allow the data integrity workers to properly merge beneficiary records with both a CHIP and Medicaid history.

Texas generally concurred with our recommendations that it: (1) refund \$856,456 to the Federal Government, (2) identify and recover additional unallowable CHIP payments made before and after our audit period for the 572 beneficiary matches and repay the Federal share, (3) identify any other beneficiaries who are assigned more than one identification number and refund any unallowable CHIP payments associated with those beneficiaries, and (4) strengthen its procedures for determining whether applicants are enrolled in any medical or public assistance benefit programs throughout the State and ensure that no beneficiary is assigned more than one identification number.

Almost 15 Percent of Arkansas' Private Contractor Costs Were Either Unallowable or Claimed at Higher Federal Matching Rates Than Eligible, Resulting in Arkansas Inappropriately Claiming \$4.4 Million in Federal Medicaid Funds (A-06-18-09002), July 2021

Arkansas followed applicable Federal and State requirements related to procuring private Medicaid Management Information Systems (MMIS) contractor services and correctly claimed \$72.1 million (\$69.6 million Federal share) in private MMIS contractor costs. However, Arkansas incorrectly claimed the remaining \$12.4 million, or almost 15 percent of its costs. For those costs, Arkansas inappropriately received \$4.4 million in Federal funds.

Arkansas did not have policies and procedures in place to ensure that MMIS private contractor costs were tracked to the correct advanced planning documents (APDs). Due to the lack of policies

and procedures, Arkansas was not able to prevent or detect when it claimed costs that exceeded funding or time-period limits, contractor costs that were not approved, costs that were for programs other than Medicaid, and costs at incorrect matching rates.

Arkansas agreed with our recommendations that it: (1) refund the \$4.4 million Federal share to the Federal Government and (2) establish policies and procedures to track its private MMIS contractor costs to APDs and to ensure that it adheres to the funding and time-period limits established in those APDs.

Missouri Claimed Federal Reimbursement for \$3.4 Million in Payments to Health Home Providers That Did Not Meet Medicaid Requirements (A-07-20-04117), August 2021

Missouri claimed Federal Medicaid reimbursement for some payments made to health home providers that did not comply with Federal and State requirements. Missouri improperly claimed Federal Medicaid reimbursement for 14 of 150 payments. These 14 improper payments primarily involved deficiencies in documentation. Specifically, Missouri's health home providers did not always document core services, but all other requirements were met.

The improper payments occurred because Missouri did not adequately monitor providers for compliance with Federal and State requirements regarding the maintenance of medical records that documented the health home services that the providers furnished to beneficiaries.

On the basis of our sample results, we estimated that Missouri improperly claimed at least \$3.4 million in Federal Medicaid reimbursement for payments made to health home providers.

Missouri disagreed with our recommendation that it refund \$3.4 million to the Federal Government. Missouri concurred with our recommendation that it improve its monitoring of the health home program to ensure that health home providers comply with Federal and State requirements for maintaining documentation to support the services for which the providers billed and received payments.

Minnesota Medicaid Managed Care Entities Used a Majority of Medicaid Funds Received for Medical Expenses and Quality Improvement Activities (A-05-18-00018), September 2021

During CY 2017, Minnesota managed care entities used the majority of funds received for medical expenses and quality improvement activities. Specifically, of the eight Medicaid managed care entities that we reviewed, we calculated MLRs for their contracted Medicaid programs and found one entity that had an MLR less than 85 percent during CY 2017 for one of its contracts. We determined that the Minnesota Medicaid program could have saved \$82,427 (approximately \$41,213 Federal share) in CY 2017 if Minnesota: (1) required its Medicaid managed care entities to meet the minimum 85-percent MLR standard for each Medicaid managed care contract and (2) required remittances when Medicaid managed care entities did not meet the MLR standard.

Minnesota incorporated a remittance requirement for contracts beginning CY 2018 if managed care entities do not meet an MLR of at least 85 percent. This report contains no recommendations.

Kansas Made Capitation Payments to Managed Care Organizations After Beneficiaries' Deaths (A-07-20-05125), September 2021

During our audit period, Kansas made unallowable capitation payments to MCOs on behalf of deceased beneficiaries. Kansas made at least \$17.3 million in unallowable capitation payments to MCOs on behalf of beneficiaries whose dates of death preceded the service period covered by the monthly capitation payment, for which it claimed at least \$9.7 million in unallowable Federal reimbursement. On the basis of our sample results, we estimated that Kansas made unallowable capitation payments totaling at least \$14.6 million (at least \$8.2 million Federal share). In addition, Kansas had previously overreported capitation payments totaling over \$2 million (\$1.2 million Federal share) that were related to prior-period adjustments.

Kansas did not directly address our recommendations that it: (1) refund at least \$10.9 million to the Federal Government; (2) recover unallowable capitation payments totaling almost \$2.7 million that were made to MCOs on behalf of deceased beneficiaries; (3) identify and recover unallowable capitation payments made to MCOs on behalf of deceased beneficiaries who did not have a date of death recorded in Kansas's system, which we estimate to be at least \$14.6 million; and (4) identify and recover unallowable capitation payments made on behalf of deceased beneficiaries before and after our audit period and repay the Federal share of any amounts recovered. We made additional procedural recommendations for the strengthening of internal controls and policies and procedures regarding accurate and timely updates to Kansas's eligibility system and the accurate reporting of all Medicaid expenditures, to include prior-period adjustments.

Quality of Care, Safety, and Access

Potential Abuse or Neglect of Medicaid Beneficiaries

During this reporting period, OIG conducted a number of audits that were designed to assess potential abuse or neglect of Medicaid beneficiaries. Prior OIG reviews and investigations have identified Medicaid beneficiaries as being at risk for abuse or neglect. Complete recommendations and State responses can be found in the final reports.

Georgia Generally Ensured That Nursing Facilities Reported Allegations of Potential Abuse or Neglect of Medicaid Beneficiaries and Prioritized Allegations Timely (A-04-17-03084); April 2021

Georgia generally ensured that nursing facilities reported potential abuse or neglect of Medicaid beneficiaries transferred from nursing facilities to hospital emergency departments. Of 117 sampled claims with emergency department visits, 101 associated incidents were not reportable. Of the remaining 16 incidents, the nursing facilities reported 9 timely, reported 3 late, reported 2 that

we could not determine had been reported timely, and did not report 2 that they should have reported. In addition, Georgia generally complied with Federal and State requirements for assigning a priority level, investigating, and recording allegations of potential abuse or neglect. Finally, Georgia generally operated its complaint and incident report program effectively.

California Did Not Ensure That Nursing Facilities Always Reported Incidents of Potential Abuse or Neglect of Medicaid Beneficiaries and Did Not Always Prioritize Allegations Properly (A-09-19-02005), June 2021

California did not ensure that nursing facilities always reported incidents of potential abuse or neglect of Medicaid beneficiaries transferred from nursing facilities to hospital emergency departments. Of the 118 sampled incidents reviewed, 81 were not the result of potential abuse or neglect; therefore, nursing facilities were not required to report the incidents to the State. However, of the remaining 37 incidents, 8 incidents were the result of potential abuse or neglect and should have been reported to the State: 2 were reported in a timely manner, 4 were not reported in a timely manner, and 2 were not reported to the State by the nursing facilities. Although the State issued guidance to nursing facilities on the proper reporting of potential abuse or neglect, facilities did not always report incidents or report them in a timely manner. For the other 29 incidents, nursing facilities provided documentation that did not contain sufficient information to determine whether the incidents were the result of potential abuse or neglect; therefore, the State was unable to determine whether the requirements for reporting potential abuse or neglect were met.

Critical Incidents Involving Medicaid Beneficiaries With Developmental Disabilities

During this reporting period, OIG conducted a number of audits that were designed to assess critical incidents involving Medicaid beneficiaries with developmental disabilities. Prior OIG reviews and investigations have identified inadequate reporting of such incidents. Complete recommendations and State responses can be found in the final reports.

Louisiana Did Not Fully Comply With Federal and State Requirements for Reporting and Monitoring Critical Incidents Involving Medicaid Beneficiaries With Developmental Disabilities (A-06-17-02005), May 2021

Louisiana did not fully comply with Federal Medicaid waiver and State requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities residing in community-based settings. Specifically, Louisiana did not ensure that: (1) all hospital emergency room visits were reported as critical incidents and (2) all critical incidents were reported or followed up on, or both, within required timeframes. These issues occurred because Louisiana: (1) did not have a process, such as performing analytical procedures on Medicaid claims data, to determine whether there were unreported critical incidents; and (2) was unaware of the extent to which community-based providers were late in reporting and following up on critical incidents.

California Did Not Fully Comply With Federal and State Requirements for Reporting and Monitoring Critical Incidents Involving Medicaid Beneficiaries With Developmental Disabilities (A-09-19-02004), September 2021

California did not fully comply with Federal Medicaid waiver and State requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities who resided in Community Care Facilities. Specifically, California did not ensure that: (1) all critical incidents were reported and (2) all reported critical incidents were reported in a timely manner and followed up on completely to ensure beneficiaries' health and safety. In addition, California did not ensure that reported critical incidents involving the death of a beneficiary were properly reviewed.

California provided various reasons that providers and regional centers (contracted by the State to provide a wide range of services for individuals with developmental disabilities) did not properly report some critical incidents, as well as reasons that reported critical incidents were not always reported in a timely manner and followed up on completely. Because California did not fully comply with Federal and State requirements for reporting and monitoring critical incidents, it did not ensure compliance with safeguard assurances it provided to CMS in the Federal Medicaid waiver, which could impact the health and safety of Medicaid beneficiaries.

Program Integrity

Oklahoma's Oversight of Medicaid Outpatient Services for Opioid Use Disorder Was Generally Effective (A-06-20-08000), August 2021

Oklahoma's oversight of Medicaid opioid use disorder (OUD) drugs and outpatient services was generally effective. Specifically, Oklahoma ensured that facilities and staff met the requirements to provide services, that recipients were approved to receive services, and that payments were accurate. However, we identified a couple of areas that could be improved. Specifically, most of the people who received OUD drugs did not also receive outpatient counseling services because Oklahoma does not emphasize counseling in conjunction with OUD drugs. In addition, Medicaid beneficiaries are not included in behavioral health contract reviews conducted by the Oklahoma Department of Mental Health and Substance Abuse Services because it focuses on services that are paid with non-Medicaid funds.

Oklahoma concurred with our recommendations that it consider whether more of an emphasis on counseling could improve OUD outcomes and, if so, take steps to increase the appropriate use of counseling with OUD drugs in outpatient OUD treatment, and develop policies and procedures to ensure that Medicaid behavioral health services are reviewed on an ongoing basis.

Nationwide, Almost All Medicaid Managed Care Plans Achieved Their Medical Loss Ratio Targets (OEI-03-20-00230), August 2021

Federal requirements for MLRs were established to ensure that Medicaid managed care plans spend most of their revenue on health care services and quality improvement, thereby limiting the amount that plans can spend on administration and keep as profit. An MLR is the percentage of revenue that a managed care plan spends on services related to the health of its enrollees. We found that 92 percent of Medicaid managed care plans (471 of 513) achieved MLRs that met or exceeded the Federal 85-percent standard for MLRs. Although Federal MLR regulations do not require States to set minimum MLRs, 34 States had established minimum MLRs for 434 Medicaid managed care plans. Ninety-one percent of plans met these State-set minimum MLRs. However, 39 plans failed to meet their State-set minimum MLRs for the period reviewed. Nineteen of these plans reported owing a total of \$198 million to States that had opted to require their plans to return money to the State when the plans did not meet minimum MLRs. This data brief demonstrates that States that choose to establish minimum MLRs with requirements to return monies may recoup millions of Medicaid dollars from plans that fail to meet the State-set minimum MLRs. The data brief does not contain any recommendations.

States Reported Multiple Challenges With Using Telehealth To Provide Behavioral Health Services to Medicaid Enrollees ([OEI-02-19-00400](#)), September 2021

We found that States reported multiple challenges with using telehealth to provide behavioral health services to Medicaid enrollees, including a lack of training for providers and enrollees, limited internet connectivity for providers and enrollees, difficulties with providers' protecting the privacy and security of enrollees' personal information, and the cost of telehealth infrastructure and interoperability issues for providers. Some States also reported other challenges, including a lack of licensing reciprocity and difficulties with providers obtaining informed consent from enrollees. This data brief provides a useful foundation for CMS and States by highlighting longstanding challenges with the use of telehealth that existed prior to the additional challenges caused by the pandemic. CMS concurred with our recommendation that it share information to help States address the challenges they face with using telehealth.

Opportunities Exist To Strengthen Evaluation and Oversight of Telehealth for Behavioral Health in Medicaid ([OEI-02-19-00401](#)), September 2021

We found that a few States reported being unable to identify which services are provided via telehealth, limiting their ability to evaluate and oversee telehealth. We also found that only a few States have evaluated the effects of telehealth on behavioral health services, and that despite concerns about fraud, waste, and abuse, many States do not conduct monitoring and oversight specific to telehealth. This data brief provides a useful foundation to inform CMS and State decisions about how to evaluate the impacts of telehealth on access, cost, and quality of behavioral health services and to strengthen oversight of program integrity. Our recommendations were for CMS to: (1) ensure that the three States that are unable to distinguish telehealth from in-person services implement indicators to identify which services are provided via telehealth; (2) conduct evaluations, and support State efforts to evaluate the effects of telehealth on access, cost, and quality of behavioral health services; and (3) conduct monitoring for fraud, waste, and abuse, and

support State efforts to oversee telehealth for behavioral health services. CMS concurred with our first recommendation but did not explicitly indicate whether it concurred with the other two recommendations.

About Seventy-Nine Percent of Opioid Treatment Program Services Provided to Medicaid Beneficiaries in Colorado Did Not Meet Federal and State Requirements (A-07-20-04118), September 2021

Colorado's oversight during the audit period did not ensure that opioid treatment program (OTP) services provided to Medicaid beneficiaries met Federal and State requirements. Colorado's oversight of the OTPs consisted primarily of biennial audits conducted by the State Opioid Treatment Authority, which were not sufficient in scope and depth of coverage to ensure that OTPs maintained a recordkeeping system that was adequate to document and monitor patient care, or to ensure that OTP services met Federal and State requirements. On the basis of our sample results, we estimated that over 1.1 million OTP services, or about 79 percent, did not meet Federal and State requirements during the audit period.

We recommended that Colorado strengthen its biennial audits of OTPs to ensure that services provided are in accordance with Federal and State requirements, provide technical assistance to OTPs to ensure that the providers maintain adequate recordkeeping systems, and educate OTPs on the deficiencies we identified to increase their awareness of compliance issues regarding Federal and State requirements. Colorado described corrective actions it had taken or planned to take to address our recommendations.

Drug Spending and Reimbursement

Medicaid Physician-Administered Drugs

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.

New Mexico Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations (A-06-16-00001), June 2021

New Mexico properly billed manufacturers for all pharmacy rebates and some rebates for physician-administered drugs. However, New Mexico did not bill for and collect from manufacturers rebates for 70,131 claim lines totaling at least \$1.5 million (\$1.1 million Federal share) for physician-administered drugs. In addition, New Mexico did not bill for rebates for 183,859 claim lines for other physician-administered drugs that may have been eligible for rebates. These errors occurred because New Mexico's internal controls did not always ensure that it billed

manufacturers to secure rebates and because New Mexico did not always collect the utilization data necessary to bill the manufacturers.

Colorado Did Not Invoice Rebates to Manufacturers for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations (A-07-17-06075), September 2021

Colorado did not comply with Federal Medicaid requirements because it did not collect National Drug Codes (NDCs) and invoice manufacturers for rebates for physician-administered drugs dispensed to MCO enrollees. Because the information we received from Colorado lacked NDC-level detail, we identified the physician-administered drugs that would have been eligible for a drug rebate and calculated that Colorado did not invoice for, and collect from manufacturers, an estimated \$2 million (\$1 million Federal share) in rebates that were associated with these physician-administered drugs.

Legal and Investigative Activities Related to Medicare and Medicaid

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

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

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

Frequently used exclusion and penalty authorities are described on our website at <http://oig.hhs.gov/fraud/enforcement/cmp/>.

During this semiannual reporting period, we reported 291 criminal and 408 civil actions against individuals or entities that engaged in offenses related to health care. We also reported over \$1.20 billion in investigative receivables due to HHS and more than \$406.0 million in non-HHS investigative receivables, including civil and administrative settlements or civil judgments related to Medicare, Medicaid, and other Federal, State, and private health care programs.

Criminal and Civil Enforcement Activities Related to Medicare and Medicaid

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

Ambulance Transportation Company

The following case example involves an ambulance transportation company:

Puerto Rico—On April 15, 2021, Ocean Medical Services, Inc. (“Ocean”) entered into a False Claims Act settlement agreement with the United States, acting through the U.S. Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services. Ocean, an ambulance service provider located in Coamo, Puerto Rico, will pay \$30,000 to resolve allegations that from March 12, 2020, through April 14, 2020, it billed Medicare for services that were actually provided by another ambulance service provider.

Nursing Home

The following case example involves a nursing home:

New York—On July 2, 2021, Select Medical Corporation and Encore GC Acquisition LLC agreed to pay \$8.4 million to resolve allegations that Select Medical Rehabilitation Services Inc. (SMRS) violated the False Claims Act by knowingly causing 12 skilled nursing facilities (SNFs) in New York and New Jersey to submit false claims to Medicare for rehabilitation therapy services that were not reasonable, necessary or skilled. Select Medical Corporation was the prior parent company of SMRS, while Encore GC Acquisition LLC is the successor-in-interest to SMRS. The alleged conduct occurred prior to Encore’s acquisition of SMRS. From 1997 through March 31, 2016, SMRS offered contract rehabilitation therapy services to SNFs across the country. The United States alleged that, at various times between January 1, 2010, and March 31, 2016, SMRS contracted with 12 SNFs in New York and New Jersey to provide rehabilitation therapy services. The United States alleged that SMRS’s corporate policies and practices encouraged and resulted in the provision of medically unnecessary,

unreasonable and unskilled therapy services being provided to patients at the 12 SNFs. The civil settlement includes the resolution of claims brought under the qui tam or whistleblower provisions of the False Claims Act by a former SMRS employee. Under those provisions, a private party can file an action on behalf of the United States and receive a portion of any recovery.

DME Companies

The following case examples involve durable medical equipment companies:

Missouri—On June 23, 2021, Nurse Practitioner Donna Gill, a resident of Palm Coast, Florida, was sentenced to 12 months and 1 day in prison, 2 years supervised release, and ordered to pay \$23,880,678 in restitution. Gill pleaded guilty on October 13, 2020, to: (a) defrauding a health care benefit program, (b) creating and using false and fraudulent documents, and (c) soliciting and receiving illegal kickbacks. Gill also pleaded guilty to one count of executing a health care fraud scheme. Between 2017 and 2019, Donna Gill received illegal kickbacks from telemedicine and other companies to sign orders and prescriptions for medically unnecessary durable medical equipment (DME), genetic testing and prescription medications for patients identified through mass marketing. Telemarketers in the United States and elsewhere solicited patients through media ads and cold calls and then contacted the patients to obtain their insurance information. Although the telemarketers were not health care professionals, they completed order forms and sometimes encouraged patients to exaggerate the extent of their pain or need for braces and pain creams. The orders were then sent to telemedicine doctors or nurse practitioners, who were typically paid \$30 to \$50 for each patient for whom they signed orders and prescriptions. Gill did not have a prior doctor-patient relationship with the patients for which she signed orders and prescriptions, did not evaluate or assess the patients' needs for the items, and in most cases had no contact with the patients, who lived in States distant from her. Gill received numerous complaints from patients, indicating that they had not requested and did not want or need the DME. Between 2017 and 2019, Gill was paid \$681,114 for signing orders and prescriptions for patients for whom she never determined a medical need for the ordered items and services. Federal health care benefit programs paid \$23,880,678 for the false and fraudulent orders and prescriptions signed by Gill, including false claims that were paid to DME companies in Missouri.

Florida—On July 26, 2021, Dr. Richard Davidson was sentenced to 74 months of incarceration, followed by 3 years of supervised release. Dr. Davidson had previously pleaded guilty to one count of conspiracy to commit health care fraud. Dr. Davidson was involved in the "Operation Brace Yourself" takedown that occurred in April 2019. Dr. Davidson owned and operated several DME companies, many of which were operating in nominee owner names, that submitted high volumes of claims to Medicare for DME orthotics. Dr. Davidson purchased pre-signed doctors' orders from purported "marketing"

companies who paid bribes and kickbacks to telemedicine companies/physicians in exchange for authorizing medically unnecessary equipment. The doctors' orders were purchased at a "price per brace" in violation of the Anti-Kickback Statute. In total, Dr. Davidson caused over \$20 million dollars in false claims to be submitted, of which approximately \$10,711,490 was paid.

Pharmacies

The following case example involves pharmacies:

Georgia—On May 11, 2021, AlixaRx, LLC, a national provider of pharmacy services to long-term care facilities, agreed to pay the United States \$2.75 million to resolve allegations that it violated Federal law by allowing opioids and other controlled substances to be dispensed without valid prescriptions between January 1, 2014, and December 13, 2021. The Government alleged that AlixaRx violated the Federal Controlled Substances Act ("CSA") in its dispensing pursuant to purported "emergency prescriptions." In nearly all circumstances, Schedule II controlled substances require a written prescription by a physician, and refills are not permitted by law. The CSA allows pharmacists to dispense Schedule II controlled substances, such as opioid pain medications, without a written prescription only in true emergency situations and, even then, only for the quantity of drugs necessary to treat the patient during the emergency period. Emergency prescriptions must promptly be reduced to writing and signed by an authorizing physician within 7 days of issuance. Failure to meet these requirements results in an illegal dispensing of controlled substances without a valid prescription. The Government's investigation revealed that AlixaRx routinely abused the emergency prescription provisions of the CSA by requesting and obtaining verbal "emergency" refills from prescribers, in the absence of any true emergency. Instead, the company used these purported emergency prescriptions to effectuate simple refills of the patients' medications. Moreover, AlixaRx routinely failed to obtain written prescriptions within 7 days after the verbal authorization. Rather than disclose these violations to the Drug Enforcement Administration (DEA) as required by law, AlixaRx engaged in a nationwide scheme to cover up its violations by obtaining backdated prescriptions from the prescribing physicians, in many cases over a year after the controlled substances had been dispensed. The Government also resolved claims that AlixaRx billed Medicare Part D for claims that had already been reimbursed through claims paid to long-term care facilities under Medicare Part A. Finally, the Government resolved allegations that AlixaRx submitted false claims to Medicare for invalid emergency prescriptions, as discussed above.

Prescription Drugs

The following case examples involve prescription drugs:

Washington, DC—On June 4, 2021, Ivan Lamont Robinson, a licensed nurse practitioner, was sentenced to 135 months in Federal prison and ordered to forfeit \$108,000. Robinson was previously found guilty by a Federal jury of 42 Federal charges that he distributed oxycodone outside the legitimate scope of professional practice and without a legitimate medical purpose, and two counts of money laundering. According to the testimony and evidence at trial, Robinson ran a pain management clinic and his practice received numerous complaints from pharmacists who suspected that he was operating a “pill mill” rather than a legitimate medical pain management practice. “Pill mill” is a shorthand terminology for a medical practice that sells prescriptions to customers, usually for cash. Through his position as a nurse practitioner, under District of Columbia law, Robinson had authority to prescribe oxycodone to patients. Robinson sold prescriptions to customers in exchange for \$370 in blank money orders. Customers came from outside the District of Columbia to purchase identical prescriptions for 60 tablets of 30 milligrams of oxycodone. During the trial, the Government presented testimony from a medical expert who stated that Robinson provided no real medical treatment, and there was no medical basis to prescribe oxycodone.

New York—On July 8, 2021, following a jury trial, Gordon Freedman was sentenced in Federal court to 121 months in prison for participating in a scheme to receive bribes and kickbacks in the form of fees for sham educational programs (“Speaker Programs”) from pharmaceutical company Insys Therapeutics in exchange for prescribing millions of dollars’ worth of Subsys, a potent fentanyl-based spray manufactured by Insys, among other offenses. In March 2013, a Regional Sales Manager for Insys sent an email to Freedman informing him that he would receive more Speaker Programs in the coming months because Insys wanted prescriptions of Subsys to increase and urging Freedman to put more patients on Subsys. Freedman responded, in part, “Got it,” and significantly increased his Subsys prescriptions in the following months, during which he received approximately \$33,600 in Speaker Program fees. Freedman was also sentenced to 210 months in prison, to run concurrently with the other sentence, for distributing oxycodone and fentanyl to a patient for no legitimate medical purpose. During the period in which Freedman was receiving kickbacks from Insys, he was also distributing powerfully addictive prescription drugs to a particular patient (“Patient-1”) with no legitimate medical purpose. From 2013 through 2017, Freedman prescribed enormous quantities of oxycodone and fentanyl to Patient-1. For example, in 2013 alone, Freedman prescribed for Patient-1 approximately 85,427 oxycodone pills—an average of approximately 234 oxycodone pills per day—containing a total of approximately 2,422,435 mg of oxycodone. In April 2017, Freedman gave Patient-1 prescriptions for approximately 150 doses of a drug containing fentanyl, and for approximately 950 oxycodone pills containing approximately 30 mg of oxycodone per pill. On or about May 4, 2017, Patient-1 died of a fentanyl overdose after ingesting a quantity of the drug prescribed by Freedman on or about April 13, 2017. In addition to the prison sentence, Freedman was sentenced to 3 years of supervised release, ordered to forfeit \$308,600, and ordered to pay a total fine of \$75,000 across the two cases.

Kickbacks

The following case example involves kickbacks:

Tennessee—On July 30, 2021, Alere, Inc. (Alere) and its wholly owned subsidiary Arriva Medical, LLC (Arriva) agreed to pay \$160 million to resolve allegations that they violated the False Claims Act. Arriva was a Florida-based mail-order supplier of diabetic testing supplies, including blood glucose testing meters (glucometers), testing strips, and lancets. In November 2011, Arriva was purchased by Alere, a medical device company, and Arriva continued to operate as a wholly owned subsidiary of Alere. In September 2017, Abbott Laboratories acquired Alere and Arriva, and in December 2017 announced that it was shutting down Arriva’s business. The settlement resolves allegations that: (1) from April 1, 2010, through December 31, 2016, Arriva and Alere violated the Anti-Kickback Statute by paying kickbacks to Medicare beneficiaries in the form of free glucometers and the routine waiver of beneficiary copayments, and then submitted or caused the submission of false claims for diabetic testing supplies on behalf of those beneficiaries; (2) from March 1, 2009, until December 31, 2016, Arriva and Alere submitted or caused to be submitted false Arriva claims to Medicare for new glucometers for beneficiaries who the Arriva Defendants knew had received a glucometer paid for by Medicare within the past 5 years, even though the new glucometers were, for that reason, not covered by Medicare; and (3) from April 15, 2011, to April 25, 2016, Arriva submitted or caused to be submitted 227 false claims to Medicare for 211 beneficiaries who had been deceased for more than 14 days as of Arriva’s reported dates of service for the claims.

Electronic Health Records

The following case example involves electronic health records:

Florida—On April 30, 2021, CareCloud Health, Inc. (CareCloud), a Miami-based developer of electronic health record (EHR) software products and related services, agreed to pay \$3,806,966.70 to resolve allegations that it paid unlawful kickbacks to generate sales of its EHR products. The United States alleged that CareCloud violated the False Claims Act and the Anti-Kickback Statute through its marketing referral program called the “Champions Program.” In particular, it is alleged that between January 1, 2012, and March 31, 2017, CareCloud provided its existing clients with cash-equivalent credits, cash bonuses, and percentage-success payments to recommend CareCloud’s EHR products to prospective clients. Existing clients who participated in the Champions Program (“participants”) signed written agreements that prohibited them from providing negative information about CareCloud’s EHR products to prospective CareCloud clients. Prospective CareCloud clients were not told about this referral-kickback arrangement or about the contract that prohibited participants from sharing negative company information with them.

Home Health

The following case example involves hospitals:

Texas—On May 26, 2021, in the Southern District of Texas, Taiwo Dipeolu signed a settlement agreement with CMS and the United States Attorney’s Office for the Southern District of Texas under which Taiwo Dipeolu relinquished all rights to \$3,974,873.63 that was being held in escrow by CMS after Uphill Home Health was sold to Santa Margarita Healthcare Services in October 2018. During the ownership transition from November 2018 to December 2018, Uphill Home Health submitted approximately \$3,857,023.67 in Request for Anticipated Payment (RAP) claims for home health services that were not provided to Medicare beneficiaries.

Laboratories

The following case example involves laboratories:

Florida—On May 7, 2021, the University of Miami (UM) agreed to pay \$22 million to resolve allegations that it violated the False Claims Act, and to enter into a 5-year Corporate Integrity Agreement with OIG. The settlement resolves allegations that UM: (1) ordered medically unnecessary laboratory tests and submitted false claims to Federal health care programs through its transplant laboratory; (2) caused Jackson Memorial Hospital (JMH) an affiliate, to submit inflated claims for pre-transplant testing in violation of the Related Party Rule, 42 C.F.R. 413.17; and (3) failed to satisfy the notification requirements of 42 C.F.R. 413.65 and thus billed for hospital outpatient department rates rather than physician clinic rates. The United States reached a separate \$1.1 million settlement agreement with JMH relating to its role in this conduct.

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 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 127 individuals or entities, 55 criminal actions, and more than \$173.1 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 DEA, FBI, and the MFCUs to provide investigative support. Cases involve physicians and pharmacies that are responsible for medically unnecessary opioid prescriptions and dangerous drug combinations that are being paid for by Medicare and Medicaid. In many instances, there are other allegations of wrongdoing relating to kickbacks, health care fraud, and quality of care, including patient overdoses and deaths.

The following case example involves Strike Force case:

Texas—On May 4, 2021, Brenda Rodriguez, The owner and operator of a purported medical clinic, QC Medical Clinic, was sentenced to 25 years in prison and ordered to pay \$250,000 in restitution for participating in an \$11 million Medicare fraud scheme in which fraudulent medical documents were sold to home health agencies in and around Houston. According to the evidence presented at trial, from October 2012 through August 2015, Rodriguez and others conspired to defraud Medicare by selling Plans of Care, and other medical documents signed by a doctor, through QC Medical Clinic (“QC Medical”) to various home health services, resulting in approximately \$11 million in false and fraudulent claims for home health services billed to Medicare. The evidence at trial showed that home health agencies billed Medicare for home health services that were not medically necessary and, in many instances, not provided.

Compliance Trainings

Health Care Provider Compliance Training

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

Most Wanted Fugitives List

The OIG Most Wanted Fugitives website continues to garner national and international attention and has greatly assisted in helping to capture fugitives charged with defrauding Federal health care programs and stealing millions of taxpayer dollars. The Most Wanted Fugitives website is continually updated and features a profile for each fugitive as well as an online tip form and a hotline number for individuals to report fugitive-related information to OIG, in English or Spanish, 24 hours a day, 365 days a year. The Most Wanted Fugitives list is available at <https://oig.hhs.gov/fraud/fugitives/>. During this semiannual reporting period, no fugitives were captured.

HHS-OIG Hotline

As part of OIG’s Office of Investigations, the hotline is the public-facing division for OIG’s intake and evaluation of fraud tips. The mission of the HHS-OIG Hotline is to support OIG’s oversight responsibilities in safeguarding the integrity of all programs and personnel under HHS’s purview and protecting them from fraud, waste, and abuse. The hotline achieves its mission through its staff’s dedication to timely intake and analysis of information received from various sources, such as the “Submit a Complaint” link on the HHS-OIG website. During this semiannual reporting period, the OIG Hotline reported expected recoveries of \$43,941,367 as a direct result of cases originating from hotline complaints.

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

Contacts to 1-800-HHS-TIPS phone line, including callers seeking information	54,995
Total tips evaluated	18,674
Tips referred for action	10,624
Closed; no basis provided for further action	1,887
Closed; no HHS violation ¹	995

Sources of tips referred for action

Phone	3,555
OIG website	5,414
Letters or faxes	567
Other	1,088

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 patient abuse and neglect in health care facilities and board and care facilities.

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:

Mississippi Medicaid Fraud Control Unit: 2020 Inspection (OEI-12-20-00200), August 2021;
Louisiana Medicaid Fraud Control Unit: 2020 Inspection (OEI-12-20-00650), August 2021;
South Carolina Medicaid Fraud Control Unit: 2020 Inspection (OEI-02-20-00610), September 2021; and *New Mexico Medicaid Fraud Control Unit: 2020 Review (OEI-06-20-00550), September 2021.*

OIG Joint Casework With MFCUs

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

Texas—On April 23, 2021, four executives of Continuum Healthcare and its various health centers were ordered to Federal prison for a massive scam perpetrated in the Houston area. Bobby Rouse, 81, and Steven Houseworth, 47, both of Houston; Jeffery Parsons, 62, of Crockett, Texas; and David Edson, 72, of Palm Harbor, Florida; all pleaded guilty to their respective roles in the scam. Rouse, Houseworth, Edson, and Parsons were part of the executive team for Continuum Healthcare LLC, which owned Westbury Community Hospital in Houston as well as community mental health centers in the Houston area known by their locations as Hornwood, Baytown, and Missouri City. Each location operated a PHP. The PHP was supposed to be a treatment program for individuals with mental illness, intended to closely resemble a highly structured, short-term hospital inpatient program. However, although it was a distinct and organized intensive treatment program, it offered less than 24-hour daily care.

The four men were responsible for the day-to-day operation of Continuum/Westbury and were involved in the implementation of the various kickback programs. Numerous people were referred for treatment in exchange for payment. However, the vast majority did not qualify for PHP services, because they were not experiencing an acute psychotic episode or were actually suffering from mental retardation, dementia, or Alzheimer's. In total, Continuum billed Medicare approximately \$189 million in total for fraudulent PHP services and Medicaid paid approximately \$66 million on those claims.

As a result, Rouse was sentenced to 120 months in prison and ordered to pay \$21,359,798 in restitution. Edson was sentenced to 48 months in prison and ordered to pay \$21,359,798 in restitution. Parsons was sentenced to 30 months in prison and ordered to pay \$19,533,806 in restitution, and Houseworth was sentenced to 30 months in prison and ordered to pay \$1,500,000 in restitution.

HHS-OIG, FBI, Texas Attorney General's Medicaid Fraud Control Unit, and Internal Revenue Service (IRS)-Criminal Investigation participated in the joint investigation.

Advisory Opinions and Other Industry Guidance

Advisory opinions, which are developed in consultation with DOJ, are issued to requesting parties regarding the interpretation and applicability of certain statutes relating to Federal health care programs. The Health Insurance Portability and Accountability Act of 1996 (HIPAA), § 205, allows OIG to provide case-specific formal guidance on the application of the anti-kickback statute and safe harbor provisions and other OIG health care fraud and abuse sanctions. During this semiannual reporting period, OIG received over 20 requests for advisory opinions and issued 13 advisory opinions.

Sanction Authorities and Other Administrative Actions

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

During this semiannual reporting period, OIG imposed 737 administrative sanctions in the form of program exclusions or administrative actions for alleged fraud or abuse or other activities that posed a risk to Federal health care programs and their beneficiaries.

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

Program Exclusions

During this semiannual reporting period, OIG excluded 654 individuals and entities from Medicare, Medicaid, and other Federal health care programs. Most of the exclusions resulted from convictions for crimes relating to Medicare or Medicaid, patient abuse or neglect, financial

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

The following are case examples of program exclusions:

Pennsylvania—On May 20, 2021, a private business owner in Pennsylvania was excluded for the minimum period of 95 years based on his conviction of Wire Fraud, Mail Fraud and Theft of Government Property: Aiding and Abetting. From about 1999 to about October 2014, this individual participated in a scheme that promised to return expired drugs from his business’s health care client facilities (hospitals, pharmacies, long-term care facilities) in exchange for a fee for service. The business owner would then launder the proceeds of the fraud by keeping the profits that his entity received for the return of the expired drugs. Over 13,000 clients were impacted by this fraudulent activity. The court ordered the business owner to forfeit approximately \$114,832,400 and also sentenced him to serve 5 years of incarceration.

Wyoming—On July 20, 2021, a medical doctor in Wyoming was excluded for a minimum period of 45 years based on his convictions for conspiracy to dispense and distribute oxycodone, alprazolam, hydromorphone and carisoprodol resulting in death, dispensing of oxycodone, possession with intent to distribute oxycodone and aid and abet, unlawful use of a communications facility and engaging in monetary transactions derived from specified unlawful activity. From about January 2011 to about November 2016, the medical doctor prescribed addictive opioids for payment in small rural communities located in and around Arizona, Wyoming, and Wind River Indian Reservation, specifically targeting vulnerable addicts for addictive opioids prescriptions. The medical doctor’s conduct resulted in the death of an individual, and the court sentenced him to 300 months of incarceration. In addition, the Arizona Board of Medicine suspended his license to practice as a medical doctor.

Virginia—On August 19, 2021, Indivior Solutions, Inc., a Virginia pharmaceutical manufacturer, was excluded for a minimum period of 80 years based on its conviction of knowingly and willfully making materially false statements relating to health care matters. From about December 2012 to December 2015, this entity marketed Suboxone film to physicians and health care programs using false and misleading claims that Suboxone film was less subject to diversion and abuse than other buprenorphine products and that Suboxone film was less susceptible to accidental pediatric exposure than Suboxone tablets. In addition, to increase sales, employees and agents of the entity persuaded MassHealth that Suboxone film had a safety benefit compared to other drugs. This entity also failed to correct inaccurate and misleading statements that it made to MassHealth about

unintended pediatric exposure. The entity caused an estimated loss of approximately \$244,165,000 based on its conduct.

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.

Civil Monetary Penalties Law

The Civil Monetary Penalties Law (CMPL) authorizes OIG to impose administrative penalties, assessments, and exclusions against a person who, among other things, submits, or causes to be submitted, claims to a Federal health care program that the person knows, or should know, are false or fraudulent. The exclusions statute also authorizes OIG to exclude a person who violates the CMPL. During this semiannual reporting period, OIG concluded cases involving more than \$44.2 million in CMPs and assessments.

Affirmative Litigation

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

The following case examples involve affirmative litigation under the CMPL:

Minnesota—Ritesh Patel (Patel) entered into a settlement agreement with OIG in which he agreed to be excluded under 42 U.S.C. 1320a-7a and 42 U.S.C. 1320a-7(b)(7) for 10 years. OIG alleged that Patel knowingly presented or caused to be presented specified claims under an HHS grant that he knew or should have known were false or fraudulent and made or caused to be made false statements of material fact in documents that are required to be submitted to directly or indirectly receive funding provided by HHS. Specifically, OIG

alleged that: (1) Patel misrepresented to a federally qualified health center (FQHC) that he had a Doctor of Medicine (M.D.) degree from the Saint James School of Medicine and a Doctor of Philosophy (Ph.D.) degree in Economics and a Master of Business Administration (M.B.A.) degree from the University of Florida, causing the FQHC to submit a prior approval request that contained these same misrepresentations to the Health Resources and Services Administration (HRSA) to obtain Patel's approval as the FQHC's Chief Executive Officer; and (2) Patel misrepresented to HRSA in funding applications that he had an M.D., Ph.D., and M.B.A.

Florida—Bay Pharmacokinetic Associates LLC, Daniel Deana, M.D., Cynthia Greathouse, M.D., and David Weinrach, M.D. (collectively, "Bay Pharmacokinetic"), entered into a \$1,082,182.50 settlement agreement with OIG. The settlement agreement resolves allegations that Bay Pharmacokinetic submitted claims for comprehensive clinical pathology consultations under CPT code 80502 that were for services provided: (1) by Bay Pharmacokinetic Associates pharmacists in a hospital setting that did not meet the requirements to be billed incident to a physician's professional services; and (2) to hospital inpatients on consecutive days of the patient's stay where no consultation request had been made, no written narrative report by a consultant pathologist was produced, and no exercise of medical judgment by a consultant pathologist was required.

Massachusetts—Cataldo Ambulance Service, Inc. (Cataldo) entered into a \$704,706.62 settlement agreement with OIG to resolve allegations that Cataldo presented claims to Medicare Part B for ambulance transportation to and from SNFs where such transportation was already covered by the SNF consolidated billing payment under Medicare Part A.

Patient Dumping

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

The following case example involves EMTALA:

South Carolina—Three Rivers Behavioral Health (Three Rivers) entered into a \$25,000 (maximum penalty) settlement agreement with OIG to resolve allegations that Three Rivers violated EMTALA when it failed to accept the appropriate transfer of a patient with an unstable emergency medical condition. Specifically, the patient presented to the Emergency Department of a small community hospital complaining of headaches, hearing voices, and thoughts of suicide by shooting herself or jumping off a bridge. Because it did not have the capabilities to stabilize the patient's emergency medical condition, the hospital faxed the patient's medical record to Three Rivers with a request for a "bed for this

[patient].” Soon thereafter, Three Rivers called the transferring hospital and claimed that Three Rivers “had no appropriate beds available for this patient at this time.” In fact, Three Rivers had 26 available beds in its adult and crisis stabilization units. OIG determined that the fax and telephone conversation clearly constituted a request for transfer and that Three Rivers refused to accept the appropriate transfer of the patient when it had both the capabilities and the capacity to stabilize the patient’s emergency medical condition.

Self-Disclosure Programs

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

Application processes for two additional self-disclosure programs were recently added to the OIG website for HHS contractors and grantees. The OIG contractor self-disclosure program provides contractors the opportunity to self-disclose when they have potentially violated the False Claims Act or other Federal criminal laws prohibiting fraud, conflict of interest, bribery, or gratuity. This self-disclosure process is only available to those with a Federal Acquisition Regulations (FAR)-based contract with HHS. The OIG Grant Self-Disclosure Program is available for application by HHS grantees or HHS grant subrecipients and provides the opportunity for voluntary disclosure to OIG of potential fraud. OIG evaluates the reported results of each internal investigation under the provider self-disclosure protocol to determine the appropriate course of action. The self-disclosure guidelines are available on the OIG website at <https://oig.hhs.gov/compliance/self-disclosure-info/index.asp>. During this semiannual reporting period, provider self-disclosure cases resulted in more than \$41.2 million in HHS receivables.

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

Colorado—After it self-disclosed conduct to OIG, HealthONE Radiation Therapy at Red Rocks, LLC (HealthONE) (Colorado), paid \$3,569,645.76 for allegedly violating the Civil Monetary Penalties Law. OIG alleged that HealthONE submitted claims for certain radiation and oncology services that used incorrect CPT codes, used incorrect dates of service, had incomplete documentation, were not rendered, were unbundled, lacked documentation to support necessity of the services, and had no order supporting the service. The improper claims involved 25 different CPT codes, and encompassed radiation therapy planning and simulation services, also known as “physics and dosimetry,” as well as evaluation and management services provided to patients undergoing radiation therapy.

Texas—After they self-disclosed conduct to OIG, Ascension Texas and Ascension Seton d/b/a Dell Seton Medical Center at The University of Texas (DSMC), Ascension Seton

Medical Center Austin (ASMCA), and Ascension Seton Williamson (ASW), paid \$20,983,887.75 for allegedly violating the Civil Monetary Penalties Law, including provisions applicable to physician self-referrals and kickbacks. OIG alleged that: (1) DSMC and ASW paid remuneration to an orthopedic surgery group in the form of above fair market value (FMV) payments for on-call coverage; (2) DSMC paid remuneration to an Austin physician practice in the form of above FMV payments for on-call coverage; (3) ASMCA paid remuneration to the Austin physician practice in the form of above FMV payments for transplant on-call coverage and administrative services; (4) ASW paid remuneration to the Austin physician practice in the form of above FMV payments to lease the practice's employed registered nurses and surgical technologists that participates in surgeries performed by the Austin physician practice's physicians at ASW; (5) ASMCA paid remuneration to the Austin physician practice in the form of above FMV payments for administrative services relating to its thoracic surgery program; (6) ASMC paid remuneration to the Austin physician practice in the form of free physician assistants employed by ASMCA for which the Austin physician practice should have compensated ASMCA; and (7) ASMCA paid remuneration to the Austin physician practice in the form of free office space in a medical office building and related staff, service, and supply support for one half day per week to perform clinical services.

Corporate Integrity Agreements

Many health care providers elect to settle their cases before litigation. As part of the settlements, providers often agree to enter into CIAs with OIG to avoid exclusions from Medicare, Medicaid, and other Federal health care programs. Under a CIA, a provider commits to establishing a compliance program and taking other specified steps to ensure future compliance with Medicare and Medicaid rules. The compliance programs are designed, in part, to prevent future fraud. OIG monitors providers' compliance with these agreements and may impose penalties on parties that fail to comply with the requirements of their CIAs.

The following case examples involve CIA enforcement:

Virginia—After it disclosed conduct to OIG pursuant to its CIA, Medical Transport, LLC (MTL) entered into a \$86,856.35 settlement agreement with OIG. OIG alleged that MTL submitted claims for non-emergency ambulance services that did not meet the Medicare requirements relating to physician certification statements.

California—After it disclosed conduct to OIG pursuant to its CIA, Longwood Management Corp., and a facility it manages, Intercommunity Healthcare and Rehabilitation Center (Intercommunity), entered into a \$121,783.31 settlement agreement with OIG. OIG alleged that Intercommunity employed an individual that it knew or should have known was excluded from participation in the California Medicaid program (Medi-Cal) and that no Medi-Cal payments could be made for items or services the individual furnished.

Public Health and Human Service Agency Reports and Reviews

Centers for Disease Control and Prevention

Although CDC Implemented Our Prior Audit Recommendations, Its Corrective Actions Did Not Effectively Address Findings Related to 3 of Our 13 Recommendations (A-04-19-01014), August 2021

CDC implemented the 13 recommendations from our prior audit of FY 2013 expenditures; however, CDC's corrective actions for the following recommendations were not effective in addressing our previous findings. Those recommendations were: (1) conduct quality assurance reviews of Notices of Funding Opportunity and funded grant applicant information to monitor compliance with HHS and CDC policies when awarding U.S. President's Emergency Plan for AIDS Relief (PEPFAR) funds, (2) perform adequate cost analyses and business management evaluations of funded applicants, and (3) include necessary and accurate requirements in the Notices of Award (NOAs).

For our current audit, CDC: (1) did not comply with one or more HHS or CDC policies when awarding PEPFAR funds, (2) did not perform cost analyses before issuing some of the grant awards, and (3) issued several NOAs with missing or incorrect reporting requirements.

CDC officials concurred with our recommendations that CDC: (1) develop and implement a written policy requiring periodic internal review of PEPFAR award files for compliance with HHS and CDC policies; (2) fully implement its Cost Analysis Standard Operating Procedure (SOP) by establishing a formal date of effectiveness, updating the SOP periodically, and enforcing its use through regular compliance testing as part of the internal reviews of PEPFAR award files; (3) and establish a policy requiring periodic reviews of, and updates to, the NOA link to ensure functionality, accuracy, and relevance of the content.

Food and Drug Administration

Risk Assessment of the Food and Drug Administration's Travel Card Program (A-04-19-06235), May 2021

FDA generally designed and implemented controls and strategies to mitigate the potential risks of illegal, improper, or erroneous purchases in its travel card program. Within the 6 risk areas related to the FDA travel card program, we identified 46 sub-risk areas and assessed 38 as low risk and 8 as moderate risk. Overall, we assessed the FDA travel card program as low risk. This report contains no recommendations.

High-expenditure Medicare drugs often qualified for Orphan Drug Act incentives designed to encourage the development of treatments for rare diseases (OEI-BL-20-00080), September 2021

The majority of high-expenditure Medicare drugs often received Orphan Drug Act (ODA) financial incentives, with some generating significant Medicare expenditures and billions of dollars in annual revenue while treating only rare diseases or conditions and others being primarily used to treat relatively common conditions. This report provides several insights that raise important questions for further consideration: How do the trends and patterns observed in our findings align with the overall goals of the ODA? Are current eligibility requirements and incentives the most effective way to ensure the continued development of affordable drugs to treat patients suffering from rare diseases and conditions? How has the increasing number of orphan drugs in recent years affected other Federal programs outside of FDA (e.g., Medicare or the 340B Drug Discount Program)?

OIG encourages the policymaking, oversight, and research communities to seek answers to these compelling questions, while ensuring that the program continues to encourage the development of orphan drugs.

Indian Health Service

Indian Health Service Use of Critical Care Response Teams Has Helped To Meet Facility Needs During the COVID-19 Pandemic (OEI-06-20-00700), September 2021

The COVID-19 pandemic has disproportionately affected racial and ethnic minority groups in the United States, including American Indians and Alaska Natives. To strengthen the Indian Health Service (IHS) and Tribal health care facilities' response to the pandemic, IHS developed and deployed Critical Care Response Teams (CCRTs) to support facilities in caring for critically ill COVID-19 patients. While onsite, the CCRTs assessed facility needs and provided hands-on training to strengthen staff skills and capacity to handle patient surges. We found the CCRT program to be a positive step in IHS's efforts to address the immediate needs of facilities. This model also holds promise for addressing some of the longstanding challenges that facilities face related to quality of care and staffing. We made three recommendations to IHS to further leverage the successes of the CCRT model in support of IHS's broader care improvement efforts to solicit feedback from CCRTs regarding their observations of potential need for broader IHS-wide improvements; compile the CCRTs' recommendations to individual facilities and share them across all IHS and Tribal facilities; and assess whether IHS could use the CCRT model to provide support and training to facilities needing assistance with non-COVID-19-related care.

National Institutes of Health

Selected NIH Institutes Met Requirements for Documenting Peer Review but Could Do More To Track and Explain Funding Decisions (OEI-01-19-00140), June 2021

Although NIH met basic requirements for documenting first-level peer review, it has limited insight into the extent and nature of its institutes and centers' (ICs') decisions to fund less favorably ranked grant applications. This can raise questions about the transparency, impartiality, and fairness of NIH's grantmaking process. NIH concurred with both of our recommendations, which were for it to centrally track and monitor data on ICs' funding grant applications out of rank order, and update its policy and guidance to reflect the latest HHS grants policy on justifying funding out of rank order.

The National Heart, Lung, and Blood Institute Did Not Fully Comply With Federal Requirements for Other Transactions (A-04-20-04078), April 2021

During our audit period, the NIH National Heart, Lung, and Blood Institute (NHLBI) did not fully comply with Federal requirements for awarding and administering "other transactions" (OTs), which are special award instruments that are generally not subject to Federal laws and regulations that apply to traditional award instruments. For the 12 OTs in our sample, NHLBI did not adequately document: (1) its justifications for using OTs rather than traditional award instruments, (2) that awarded amounts were fair and reasonable and incurred costs were allowable, or (3) that it complied with Federal requirements for obligating annual appropriations.

NHLBI did not adequately document its compliance with applicable Federal requirements because its internal controls for awarding and administering OTs were ineffective. As a result, NHLBI could not ensure the proper stewardship of Federal funds used to award OTs, including the \$71.9 million we reviewed.

NIH concurred with our recommendations that NHLBI strengthen its internal controls for OTs by updating its policies and procedures to properly document its justifications for using OTs instead of traditional award instruments and to determine fairness and reasonableness of award amounts, allowability of costs, and compliance with Federal funding requirements.

The National Human Genome Research Institute Should Strengthen Procedures in Its Pre-Award Process To Assess Risk for Certain Foreign and Higher Risk Applicants (A-05-20-00026), August 2021

The National Human Genome Research Institute (NHGRI) generally had adequate policies and procedures in place for assessing risk in its grant pre-award process when awarding grant funds. However, we determined that NHGRI had inadequate policies and procedures as they relate to assessing the risk to NHGRI grant programs presented by foreign applicants and mitigating potential risk associated with applicants demonstrating higher risk factors. As a result, some risks associated with foreign applicants and applicants demonstrating higher risk factors may not have been identified and mitigated before grant funds were awarded.

NIH generally agreed with our recommendations that it direct NHGRI to: (1) improve its policies and procedures to ensure that Grants Specialists monitor whether required audit reports are submitted for foreign applicants; (2) clarify existing procedures to specify when Grants Specialists should take additional steps, including the imposition of specific award conditions, to mitigate risk for new grantees; and (3) update policies and procedures for Grants Specialists to require that they review available IRS Form 990s regarding grant applicants' risk factors before awarding grant funds.

Human Services Agency Reports and Reviews

New York Did Not Have Adequate Oversight of Its Reported Temporary Assistance for Needy Families Program Expenditures (A-02-17-02005), May 2021

New York's oversight did not ensure that its reported TANF and maintenance-of-effort (MOE) expenditures met Federal requirements. Specifically, although New York timely submitted required expenditure reports to ACF, except for certain State tax credits, it did not ensure the accuracy of the other expenditures reported to ACF. Rather, New York relied on its local districts and TANF-funded State programs to compile and maintain supporting documentation for its reported expenditures and did not review the documentation.

As a result, New York could not ensure that its reported TANF program expenditures for FY 2016, totaling \$4.8 billion in TANF and MOE expenditures, met Federal requirements and were used in accordance with the intended purposes of its TANF grant. Inaccurate reporting of TANF program expenditures could negatively impact ACF's program decision making related to how States use their TANF and MOE funds.

New York agreed with our recommendations that it: (1) work with its local districts and TANF-funded State programs to develop financial management procedures that would enable it to determine if TANF and MOE expenditures are accurately reported to ACF, including the \$4.8 billion in TANF and MOE expenditures reported for FY 2016; and (2) improve its oversight of the TANF program by providing additional guidance and training to ensure that its local districts accurately report expenditures and maintain adequate documentation to support TANF and MOE expenditures reported.

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 (A-02-18-02011), May 2021

Gateway did not account for HHS grant funds in accordance with Federal requirements. Specifically, Gateway claimed \$932,607 of unallowable costs and did not comply with Federal regulations on construction and renovations. These deficiencies occurred because Gateway did not have all necessary procedures in place and did not adhere to Federal procurement

requirements, and ACF's monitoring did not ensure that Gateway complied with Federal requirements related to construction and renovations. Further, some expenditures were not properly allocated. Finally, ACF relied on Gateway's documentation and did not thoroughly review it for consistency and accuracy. Gateway partially concurred with our recommendation that it refund \$932,607 and ensure compliance with Federal requirements and the accuracy of information submitted to ACF. Gateway did not indicate concurrence or nonconcurrence with our recommendations that ACF ensure that Gateway complies with Federal requirements and verifies submitted information to support Gateway's grant award applications, including requesting independent analyses of cost comparisons for Head Start facility construction and major renovations.

Colorado's Monitoring Did Not Ensure Child Care Provider Compliance With State Criminal Background Check Requirements at 18 of 30 Providers Reviewed (A-07-19-06084), April 2021

Colorado's monitoring process did not ensure provider compliance with State requirements related to criminal background checks for 18 of the 30 child care providers we reviewed. We found that 107 of 679 individuals requiring a background check did not obtain 1 or more of the required criminal background checks. Although Colorado reviewed required background checks during its annual inspections of child care providers, the providers did not always inform the State and properly obtain background checks when hiring individuals or when new individuals began to reside in family homes. Furthermore, Colorado did not retain criminal background check records for child care center individuals who required background checks and instead relied on the child care centers to retain these documents. Moreover, Colorado did not require child care providers and associated individuals to receive training on background check requirements. By not ensuring that all individuals who supervised or had routine unsupervised contact with children had passed all criminal background checks, Colorado potentially jeopardized the safety of children at these child care providers. Colorado concurred with our recommendations that it: (1) conduct all required criminal background checks for the 107 individuals in our sample who did not have the required checks at the time of our audit (if still employed), (2) ensure that child care providers and associated individuals requiring a background check receive training on background check requirements, and (3) ensure that all required background checks are completed and retain these records until the background check expires.

Toolkit: Insights From OIG's Work on the Office of Refugee Resettlement's Efforts To Care for Unaccompanied Children (OEI-09-21-00220), May 2021

This toolkit compiles insights from OIG's oversight of the Unaccompanied Children Program. The insights provided are largely drawn from the findings, recommendations, and conclusions in OIG's body of work conducted since 2008, including reports that were issued following site visits at 45 facilities during the 2018 surge of children entering the Unaccompanied Children Program.

Safety of Children in Foster Care

Missouri's Efforts To Protect Children Missing From Foster Care (OEI-07-19-00372), September 2021

The Missouri foster care agency (Missouri) missed opportunities to identify and mitigate children's risk for going missing from foster care. Additionally, there is no evidence that once children became missing, it complied with State and Federal requirements and effectively used all resources available to assist in locating the children. Further, Missouri appeared to do little, once the children were located, to ensure that the children would not go missing again and that they received supportive services to address trauma they experienced while missing from care.

These findings raise concerns about Missouri's ability to protect vulnerable children from the risks associated with being missing from foster care. Additionally, these findings suggest that other States may benefit from engaging with the ACF about potential deficiencies in their States. Such deficiencies may include problems with fulfilling requirements when children go missing from and return to foster care, as well as challenges in identifying and attempting to reduce risk factors for children's going missing. We made recommendations to Missouri and to ACF. Missouri did not explicitly concur or nonconcur with our three recommendations to its agency, but it did note actions it has taken in response to our recommendations and agreed to take additional responsive actions. ACF concurred with our two recommendations to its agency.

We recommended that Missouri develop policies to help identify: (a) children who have a heightened risk of going missing from care and (b) interventions that could reduce their risk; implement a monitoring mechanism to ensure that case managers comply with requirements and document their compliance when children are identified as missing and when they are located or return to care; and implement improvements to the case management system to enable accurate identification of children who are missing from foster care.

We recommended that ACF develop a forum for States to share experiences and best practices related to the following: reducing children's risk for going missing from foster care, locating missing children, and addressing their needs after they return to care; and supporting Missouri as it works to reduce children's risk for going missing from foster care and to improve compliance with Federal and State requirements related to children who go missing.

Substance Abuse and Mental Health Services Administration

SAMHSA Lacks Adequate Data To Monitor Access to Medication-Assisted Treatment Through the Buprenorphine Waiver Program (OEI-BL-20-00260), June 2021

The data reported to SAMHSA indicated that providers waived at the highest level treated an average of 116 MAT patients each—far below the limit of 275 patients. Also, less than a quarter of the providers required to submit data actually did so. Although SAMHSA collects these data to monitor provider compliance, the agency has exercised its discretion and not taken enforcement

actions to improve reporting. OIG believes that the data collected from these providers has benefits beyond compliance and enforcement. SAMHSA concurred with our recommendation to develop comprehensive methods and measures to assess access to MAT via office-based providers.

The Substance Abuse and Mental Health Services Administration Generally Had Controls and Strategies for Mitigating Disaster Preparedness and Response Risks (A-04-20-02026), May 2021

Within the four risk areas related to SAMHSA's disaster preparedness and response activities, we identified eight sub-risk areas and rated four as low risk and four as moderate risk.

Overall, we assessed SAMHSA's disaster preparedness and response activities as moderate risk. Generally, SAMHSA designed and implemented various controls and strategies to mitigate the potential moderate risks we identified. However, we did not perform procedures to determine the effectiveness of these mitigating controls and strategies.

Furthermore, we were unable to determine whether SAMHSA had any plans to mitigate the moderate risks associated with the sub-risk area of "Operating Structure and Reporting Lines." SAMHSA concurred with our recommendation that it mitigate its Governance risk by formally documenting its full organizational structure.

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

Health Education Assistance Loan Program Exclusions

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

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

Child Support Enforcement Activities

OIG Investigations

OIG investigates noncustodial parents who violate 18 U.S.C. § 228 by failing to pay court-ordered child support. OIG works with ACF's Office of Child Support Enforcement; DOJ; U.S. Attorneys' Offices; the U.S. Marshals Service; and Federal, State, and local partners to address egregious child support enforcement cases with appropriate law enforcement and prosecutorial action. During this semiannual reporting period, OIG investigations of child support enforcement cases nationwide resulted in one criminal action and court-ordered restitution and settlements of \$107,833.

The following case example involves child support enforcement:

New Hampshire—On April 1, 2021, Richard E. Goulet, Jr., was sentenced to 5 years of probation for failing to pay child support. According to court documents and statements made in court, in December 2007, a decree of divorce was issued in the Portsmouth Family Division Court ordering Goulet to pay support in a specified amount for his three children, all of whom are residents of New Hampshire. Since the date of the decree in 2007, the defendant failed to pay child support as ordered by the court. He owed over \$100,000 in unpaid support at the time of his arrest. Prior to sentencing, he paid over \$107,000 of past-owed child support to bring his obligations current. His sentence also includes a mandatory condition requiring him to keep his monthly support obligations current.

Engaging the Public in Capturing Deadbeat Parents

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

Other HHS-Related Reviews and Investigative Activities

General Departmental

Review of the Department of Health and Human Services' Compliance With the Federal Information Security Modernization Act of 2014 for Fiscal Year 2020 ([A-18-20-11200](#)), April 2021

Overall, through the evaluation of FISMA metrics, it was determined that the HHS information security program was "Not Effective." This determination was made based on: (1) the evaluation of HHS not meeting a "Managed and Measurable" maturity level for Identify, Protect, Detect, Respond, and Recover function areas; (2) the deficiencies within the Identify, Protect, and Respond function areas; and (3) the evaluation of a maturity level below "Consistently Implemented" for some FISMA metric questions both at HHS overall and at selected OpDivs. However, HHS continues to implement changes to strengthen the maturity of its enterprisewide cybersecurity program. Progress continues to be made to sustain cybersecurity maturity across all FISMA domains. Also notable were increased maturation of data protection and privacy and information systems continuous monitoring. Weaknesses continue to persist in Contingency Planning, which was the only domain assessed with a maturity level of "Defined" in FY 2019 and again in FY 2020. We identified opportunities where HHS can strengthen its overall information security program.

We recommend that HHS further strengthen its cybersecurity program and enhance information security controls at HHS. Recommendations specific to HHS OpDivs were provided to them separately. HHS generally concurred with our recommendations.

U.S. 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 2020 ([A-17-21-52000](#)), May 2021

Ernst & Young (EY), LLP, determined that HHS met many requirements but did not fully comply with the PIIA. Among the items required for compliance with PIIA that HHS complied with, EY determined that HHS: (1) published the AFR for FY 2020, (2) conducted risk assessments for 23 programs not susceptible to improper payments and determined the programs were not at risk for improper payments, and (3) published corrective action plans for 9 of the 13 programs identified as susceptible to significant improper payments or deemed by OMB to be susceptible to significant improper payments. EY also determined that HHS published and met annual reduction targets for the 2 programs for which it reported reduction targets in the FY 2019 AFR and reported an improper payment rate of less than 10 percent for 7 of the 13 programs identified as or deemed to be susceptible to significant improper payments.

EY concluded that HHS did not comply with several other PIIA requirements. EY found that HHS: (1) did not report an improper payment estimate for the TANF program, (2) reported improper payment rates in excess of 10 percent for Medicaid and CHIP, and (3) did not conduct recovery audits for the Medicare Advantage program. In addition, EY found that HHS did not record an improper payment estimate for the Advanced Premium Tax Credit and CDC and Office of Head Start disaster relief programs.

The Puerto Rico Department of Health's Implementation of Its Emergency Preparedness and Response Activities Before and After Hurricane Maria Was Not Effective (A-02-18-02002), July 2021

PRDOH did not effectively implement its emergency preparedness and response activities before and after Hurricane Maria. In addition, PRDOH did not have an effective process for contacting volunteer health professionals, did not describe in the Emergency Operation Plan (EOP) how it would utilize the emergency management assistance compact or other mutual aid agreements when responding to an emergency, and did not have procedures for health care coalitions to share information with each other.

These deficiencies occurred because PRDOH's planning efforts prior to Hurricane Maria did not prepare PRDOH to meet actual needs and PRDOH did not have procedures in place to ensure that activities were in accordance with its Hospital Preparedness Program-Public Health Emergency Preparedness Cooperative Agreement. As a result, PRDOH placed the health and safety of its residents at risk.

PRDOH did not indicate concurrence or nonconcurrence with our recommendations that it: (1) revise its EOP, (2) consider working with the HHS Office of the Assistant Secretary for Preparedness and Response to develop an effective method for contacting volunteers when there are communication challenges, and (3) consider coordinating with appropriate organizations to develop guidance on accurate cause-of-death certifications.

Grants and Contracts

HHS is the largest grant-making organization and one of the largest contracting agencies in the Federal Government. In FY 2019, HHS awarded more than \$531 billion in grants and over \$39 billion in contracts across all program areas. OIG's direct annual discretionary appropriation funding is used to conduct program integrity and enforcement activities with regard to the more than 100 public health and human services programs carried out by more than 80,000 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:

Ohio—On May 14, 2021, Song Guo Zheng, a rheumatology professor and researcher with strong ties to China, was sentenced to 37 months in prison for making false statements to Federal authorities as part of an immunology research fraud scheme. As part of his sentence, Zheng was also ordered to pay more than \$3.4 million in restitution to NIH and approximately \$413,000 to Ohio State University. Song Guo Zheng was arrested Friday, May 22, 2020, after he arrived in Anchorage, Alaska, aboard a charter flight and as he prepared to board another charter flight to flee to China. He was carrying three large bags, one small suitcase and a briefcase containing two laptops, three cell phones, several USB drives, several silver bars, expired Chinese passports for his family, deeds for property in China and other items. He was transported to the Southern District of Ohio and made his first Federal court appearance in Columbus last July. Zheng pleaded guilty last November and admitted he lied on applications in order to use approximately \$3.4 million in grants from NIH to develop China's expertise in the areas of rheumatology and immunology. According to court documents Zheng had been participating in a Chinese Talent Plan, a program established by the Chinese government to recruit individuals with knowledge or access to foreign technology intellectual property, since 2013. Since that time, Zheng used research conducted in the United States to benefit the People's Republic of China. Zheng failed to disclose conflicts of interest or his foreign commitments to his American employers or to NIH. According to court documents, Zheng was a professor of internal medicine who led a team conducting autoimmune research at Ohio State University and Pennsylvania State University. According to his plea, Zheng caused materially false and misleading statements to be made on NIH grant applications, seeking to hide his participation in Chinese Talent Plans and his affiliation and collaboration with a Chinese university controlled by the Chinese government.

Small Business Innovative Research Program

The National Defense Authorization Act for Fiscal Year 2012, § 5143, requires OIG to report annually on the number of cases referred to OIG to fraud, waste, or abuse in the Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) program. OIG must also report on the actions taken in each case; justification for not taking action on a case; and an accounting of funds used to address waste, fraud, and abuse in this program. From October 1, 2020, to September 30, 2021, OIG received one referral related to potential fraud, waste, or abuse with respect to HHS SBIR/STTR programs, and one case was opened. For FY 2021, there were approximately two civil actions with total money associated at \$1,307,353. The total case hours worked was 65.25 for a total cost of case time of \$11,992.30. At the end of FY 2021, OIG was working on two SBIR/STTR investigations.

Recovery Act Retaliation Complaint Investigations

The Recovery Act, § 1553, prohibits non-Federal employers that have received Recovery Act funding from retaliating against employees who disclose evidence of mismanagement of Recovery Act funds or any violation of law related to Recovery Act funds. OIGs are required to include in their Semiannual Report the retaliation complaint investigations that they decided not to conduct or continue during the reporting period. During this semiannual reporting period, OIG did not close, decline, or give extensions on Recovery Act Retaliation Complaint investigations of whistleblower retaliation.

Contract Audits

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

OIG Reviews of Non-Federal Audits

OIG reviews audits conducted by non-Federal auditors of entities receiving Federal awards. During this semiannual reporting period, OIG's National External Audit Review Center reviewed 342 reports covering \$2.1 trillion in audited costs. Federal dollars covered by these audits totaled \$816.2 billion, of which about \$436 billion were HHS funds.

Uniform guidance at 2 CFR 200 Subpart F establishes audit requirements for State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards. Under the uniform guidance, covered entities must conduct annual organization wide "single audits" of all Federal money they receive. These audits are conducted by non-Federal

auditors, such as public accounting firms and State auditors. OIG reviews the quality of these audits and assesses the adequacy of the entities' management of Federal funds.

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

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

Non-Federal Audits, April 1, 2021, Through September 30, 2021

Not requiring changes or having minor changes	314
Requiring major changes	25
Having significant technical inadequacies	3
Total Number of Non-Federal Audits	342

Other Reporting Requirements and Reviews

Legislative and Regulatory Reviews

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

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

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

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

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

Audit Reports With Questioned Costs

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

Table 1: Audit Reports With Questioned Costs

Description	Number of Reports	Dollar Value Questioned	Dollar Value Unsupported
Section 1			
Reports for which no management decisions had been made by the beginning of the reporting period ¹	59	\$1,546,493,000	\$508,377,000
Issued during the reporting period	46	\$934,215,000	\$341,274,000
Total Section 1	105	\$2,480,708,000	\$849,651,000
Section 2			
Reports for which management decisions were made during the reporting period ^{2, 3}			
Disallowed costs	34	*\$220,824,000	\$156,000
Costs not disallowed	14	\$174,781,000	\$751,000
Total Section 2	48	\$395,605,000	\$907,000
* Audit receivables (expected recoveries)			
Section 3			
Reports for which no management decisions had been made by the end of the reporting period (Section 1 minus Section 2)	57	\$2,085,103,000	\$848,744,000
Section 4			
Reports for which no management decisions were made within 6 months of issuance ⁴	22	\$1,290,832,000	\$507,471,000

Table 1 End Notes

¹ The opening balance was adjusted upward by \$39.8 million because of a reevaluation of previously issued recommendations.

² Revisions to previously reported management decisions:

- A-09-11-02020, *Review of Medicaid School-Based Administrative Costs Claimed by Arizona using RMTS Methodology*. In a settlement with the State, CMS agreed to accept the sum of \$7,266,850, reducing unallowable school-based administrative cost by \$4,450,000.
- A-05-14-00046, *National Government Services, Inc., Did Not Always Refer Medicare Cost Reports and Reconcile Outlier Payments in Jurisdiction 8*. CMS subsequent review of supporting documentation determined that overpayments totaled \$12,432,865, increasing disallowed cost by \$1,577,792.
- A-02-10-01009, *New Jersey Generally Reported Medicaid Overpayments in Accordance With Federal Regulations*. CMS reached a settlement agreement with the State and agreed not to contest the allowability of \$1,401,296.
- A-05-11-00019, *Cahaba Government Benefit Administrators, LLC, Did Not Always Refer Medicare Cost Reports and Reconcile Outlier Payments*. CMS's subsequent review of provider's documentation determined that disallowed cost should be reduced by \$1,098,376
- Not detailed are reductions to previously disallowed management decisions totaling \$1.97 million.

³ Included are management decisions to disallow \$48 thousand in questioned costs that were identified by non-Federal auditors in audits of State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards conducted in accordance with Office of Management and Budget Circular A-133. OIG is currently ensuring that work performed by these non-Federal auditors complies with Federal audit standards; accordingly, OIG tracks, resolves, and reports on recommendations in these audits.

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

Audits Not Completed Within 6 Months of Issuance

Audit CIN	Audit Title
A-02-15-02013	<i>CMS Did Not Always Accurately Authorize Financial Assistance Payments to Qualified Health Plan Issuers in Accordance With Federal Requirements During the 2014 Benefit Year, AUG 2018, \$939,287,686</i>
A-02-14-02017	<i>New York Misallocated Costs to Establishment Grants for A Health Insurance Marketplace, NOV 2016, \$149,654,512</i>
A-07-19-00560	<i>CMS Did Not Ensure That Medicare Hospital Payments for Claims That Included Medical Device Credits Were Reduced in Accordance With Federal Regulations, Resulting in as Much as \$35 Million in Overpayments, NOV 2020, \$35,398,147</i>
A-01-14-02503	<i>Maryland Misallocated Millions to Establishment Grants for a Health Insurance Marketplace, MAR 2015, \$28,400,000</i>
A-04-14-07050	<i>Kentucky Misallocated Millions to Establishment Grants for a Health Insurance Marketplace, FEB 2017, \$25,530,429</i>
A-07-18-04111	<i>Mississippi Needs To Improve Oversight of Its Child Care Payment Program, APR 2020, \$22,284,900</i>
A-02-15-02008	<i>New York Did Not Comply With Federal Grant Requirements for Allocating and Claiming Marketplace Contract Costs, DEC 2017, \$20,415,344</i>
A-07-15-04226	<i>Not All of Missouri's Child Care Subsidy Program Payments Complied With Federal and State Requirements, NOV 2017, \$19,076,167</i>
A-02-18-01028	<i>Medicare Advantage Compliance Audit Of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS, FEB 2021, \$14,534,375</i>
A-06-17-07004	<i>Southwest Key Programs Failed To Protect Federal Funds Intended for the Care and Placement of Unaccompanied Alien Children, SEP 2020, \$13,130,848</i>
A-01-15-02500	<i>Vermont Did Not Properly Allocate Millions To Establishment Grants for A Health Insurance Marketplace, SEP 2016, \$11,243,006</i>
A-02-16-02013	<i>The Children's Village Inc., An Administration for Children and Families Grantee, Did Not Always Comply With Applicable Federal and State Policies and Requirements, APR 2019, \$2,623,785</i>
A-12-20-20001	<i>The Office of Refugee Resettlement Did Not Award and Manage the Homestead Influx Care Facility Contracts in Accordance with Federal Requirements, DEC 2020, \$2,581,157</i>
A-07-17-02808	<i>The Colorado Health Insurance Marketplace's Financial Management System Did Not Always Comply With Federal Requirements, JUL 2018, \$2,567,604</i>
A-07-11-06013	<i>The University of Colorado Denver Did Not Always Claim Selected Costs Charged Directly to Department of Health and Human Services Awards in Accordance With Federal Regulations, JUN 2013, \$1,419,524</i>
A-05-14-00045	<i>The Minnesota Marketplace Misallocated Federal Funds and Claimed Unallowable Costs, NOV 2016, \$1,279,677</i>
A-09-14-01007	<i>Nevada Misallocated Costs for Establishing a Health Insurance Marketplace to Its Establishment Grants, FEB 2016, \$893,464</i>

A-12-17-00002	<i>The Office of the Secretary of Health and Human Services Did Not Comply With Federal Regulations for Chartered Aircraft and Other Government Travel Related to Former Secretary Price, JUL 2018, \$341,616</i>
A-05-18-00008	<i>The Next Door Foundation Claimed Unallowable Indirect Costs and Did Not Document the Funding Source of Program Expenditures in Accordance With Federal Requirements, SEP 2019, \$142,104</i>
A-03-16-00250	<i>Youth for Tomorrow–New Life Center, Inc., an Administration for Children and Families Grantee, Did Not Comply With All Applicable Federal Policies and Requirements, SEP 2020, \$16,851</i>
A-04-18-02010	<i>Florida's Refugee Medical Assistance Payments Were Generally Allowable, JAN 2020, \$8,772</i>
A-05-18-00015	<i>The University of Minnesota Complied With Federal Requirements To Perform Risk Assessments and Monitor Subrecipients, NOV 2019, \$1,924</i>
TOTAL CINS: 22	
TOTAL AMOUNT: \$1,290,832,000	

Audit Reports With Funds Recommended To Be Put to Better Use

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

Table 2: Audit Reports With Funds Put to Better Use

Description	Number of Reports	Dollar Value
Section 1		
Reports for which no management decisions had been made by the beginning of the reporting period	12	\$16,609,621,000
Reports issued during the reporting period	3	\$21,799,000
Total Section 1	15	\$16,631,420,000
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	5	\$318,909,000
Based on proposed legislative action	0	\$0
Value of recommendations not agreed to by management	1	\$40,610,000
Total Section 2	6	\$359,519,000
Section 3		

Reports for which no management decisions had been made by the end of the reporting period ¹ (Sec. 1 minus Sec. 2)	9	\$16,271,901,000
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Table 2 End Notes

¹ Because of administrative delays, some of which were beyond management control, 7 of the 9 audits open at end of the period were not resolved within 6 months of issuance of reports. OIG is working with management to reach resolution on these recommendations before the end of the next semiannual reporting period.

Audits Open at End of the Period

Audit CIN	Audit Title
A-05-12-00020	<i>Medicare And Beneficiaries Could Save Billions if CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates, APR 2014, \$15,000,000,000</i>
A-03-17-00010	<i>Hospitals Overbilled Medicare \$1 Billion by Incorrectly Assigning Severe Malnutrition Diagnosis Codes to Inpatient Hospital Claims, JUL 2020, \$1,024,623,449</i>
A-06-17-08004	<i>Medicare Part D Is Still Paying Millions for Drugs Already Paid for Under the Part A Hospice Benefit, AUG 2019, \$160,800,000</i>
A-03-13-03002	<i>HHS Did Not Identify and Report Antideficiency Act Violations, MAY 2017, \$49,445,025</i>
A-07-17-01176	<i>Incorrect Acute Stroke Diagnosis Codes Submitted by Traditional Medicare Providers Resulted in Millions of Dollars in Increased Payments to Medicare Advantage Organizations, SEP 2020, \$14,417,533</i>
A-09-18-03030	<i>Medicare Incorrectly Paid Providers for Emergency Ambulance Transports From Hospitals to Skilled Nursing Facilities, SEP 2019, \$968,718</i>
A-09-20-03003	<i>Medicare Improperly Paid Physicians for More Than Five Spinal Facet-Joint Injection Sessions During a Rolling 12-Month Period, OCT 2020, \$513,328</i>
TOTAL CINS: 7	
TOTAL AMOUNT: \$16,250,768,000	

Appendix B: Savings Decisions Supported by OIG Recommendations

The table below lists policy decisions reflected in legislation, regulations, or other directives from prior years that are supported by OIG recommendations and for which cost savings were estimated, usually by third parties, such as the Congressional Budget Office (CBO) or HHS actuaries. Of the \$23.9 billion in savings estimated for the decisions below, \$2.7 billion was attributed to FY 2021. This figure reflects the most recent available savings estimates issued by the third-party appraiser; actual savings may be higher or lower.

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

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

Centers for Medicare & Medicaid Services Programs		
OIG Recommendations	Policy Decisions	Estimated Savings
<p>Calculation of Average Manufacturer Price (AMP) under the Medicaid Drug Rebate Program Seek legislative change to exclude authorized generic drug transactions to secondary manufacturers from the AMP calculation of the brand name drug. The recommendation reflected findings in OIG report A-06-18-04002.</p>	<p>Section 1603 of the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 amended section 1927(k)(1)(C) of the Social Security Act (the Act) to exclude generic drug transactions to secondary manufacturers in the brand name drug's AMP calculations. CBO estimated savings of \$3.15 billion over 10 years.</p>	<p>\$270,000,000</p>

<p>Medicaid Rebate for Generic Drugs Generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 22 percent of the quarterly AMPs that OIG reviewed. If the provision for brand-name drugs were extended to generic drugs, the Medicaid program would receive additional rebates. This finding was noted in OIG reports A-06-07-00042 and A-06-15-00030.</p>	<p>Section 602 of the Bipartisan Budget Act of 2015 (P.L. No. 114-74) (see Tab 2) was enacted and included provisions extending the additional rebate to generic drugs. The additional rebate for generic drugs will apply to rebate periods beginning with the first quarter of 2017. CBO estimated savings of \$1.008 billion over 10 years.</p>	<p>\$127,000,000</p>
<p>Hospital Transfer Policy for Early Discharges to Hospice Care Change regulations or pursue a legislative change, if necessary, to establish a hospital transfer payment policy for early discharges to hospice care. The recommendation reflected findings in OIG report A-01-12-00507.</p>	<p>Section 53109 of the Bipartisan Budget Act of 2018 modified existing law to require that, beginning in FY 2019, discharges to hospice care would also qualify as a post-acute-care transfer and be subject to payment adjustments.</p>	<p>\$515,000,000</p>
<p>Reductions in Medicare Bad Debt Reimbursement Seek legislative authority to eliminate (or reduce) Medicare payments to hospitals for bad debt associated with beneficiaries' failure to pay their deductibles and coinsurance. The recommendations reflected findings in OIG report A-14-90-00339 and subsequent reviews.</p>	<p>Section 3201 of the Middle-Class Tax Extension and Job Creation Act of 2012 applied percentage reductions in bad debt reimbursement to all providers eligible to receive bad debt reimbursement. CMS estimated savings to Medicare of \$10.92 billion over 10 years with \$1.49 billion attributed to FY 2021. (77 Fed. Reg. 67450, 67523 (Nov. 9, 2012))</p>	<p>\$1,490,000,000</p>
<p>Payments for Prescription Drugs Provided to Incarcerated Beneficiaries Work with prescription drug plan sponsors to identify and resolve improper Medicare Part D</p>	<p>CMS issued a final rule about the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug programs. The eligibility requirements to enroll in Medicare Advantage and Part D are outlined in</p>	<p>\$191,000,000</p>

<p>payments made for prescription drugs provided to incarcerated beneficiaries. The recommendation reflected findings in OIG report A-07-12-06035.</p>	<p>Sections 1851(a)(3)(B) and 1860D-1(a)(3)(A) of the Act. To enroll in Medicare Advantage, a beneficiary must be entitled to Part A and enrolled in Part B. To enroll in Part D, a beneficiary must be entitled to Part A and/or enrolled in Part B. An incarcerated beneficiary is not precluded from meeting the eligibility requirements for Part A and Part B, but in general, no Medicare Payment is made for these individuals. CMS promulgated regulations to require Part D plans to disenroll incarcerated beneficiaries. CMS estimated savings of \$1.6 billion over 10 years with \$191 million attributed to FY 2021. (79 Fed. Reg. 29844, 29953 (May 23, 2014))</p>	
<p>Medicare Payments for Vacuum Erection Systems Seek legislative authority to include vacuum erection systems (VES) in the Competitive Bidding program and then implement a National Mail-Order Competitive Bidding Program for VES. The recommendation reflected findings in OIG report A-07-12-05024.</p>	<p>Section 203 of the Achieving a Better Life Experience Act of 2014 implements changes to treat VES prosthetic devices and related accessories as statutorily noncovered in the same manner that erectile dysfunction drugs are treated in Medicare Part D. CBO estimated savings of \$444 million over 10 years.</p>	<p>\$44,400,000</p>
<p>Excessive Medicaid Payments to New York State Ensure that expenditures related to developmental centers and other intermediate care facilities and any revised payment methodology be consistent with efficiency and economy. The recommendation reflected findings in OIG reports A-02-11-01029, A-02-13-01008, and other reviews.</p>	<p>Agreement between CMS and the State of New York, dated March 20, 2015, to repay \$1.95 billion over 12 years with \$100 million attributed to FY 2021.</p>	<p>\$100,000,000</p>

Appendix C: Peer Review Results

The Inspector General Act of 1978, as amended, requires OIGs to report the results of peer reviews of their operations conducted by other OIGs, the date of the last peer review, outstanding recommendations from peer reviews, and peer reviews conducted by an OIG of other OIGs in the semiannual 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, one peer review involving OAS was completed. Information concerning OAS’s peer review activity during a prior reporting period is also listed below.

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

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

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

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

Office of Investigations

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

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

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

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

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

Office of Evaluation and Inspections

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

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

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

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

The Veterans Affairs, Office of Inspector General, Office of Audits and Evaluations and Office of Healthcare Inspections (collectively VA-OIG) policies and procedures addressed the Quality Standards for Inspection and Evaluation of the Council of the Inspectors General on Integrity and Efficiency. The seven covered standards are: Quality Control, Planning, Data Collections and

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

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

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

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

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

Appendix D: Summary of Sanction Authorities

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

Program Exclusions

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

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

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

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

Civil Monetary Penalties Law

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

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

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

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

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

Patient Dumping

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

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

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

Anti-Kickback Statute and Civil False Claims Act Enforcement Authorities

The Anti-Kickback Statute

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

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

The False Claims Act

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

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

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

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

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

Other Reporting Requirements

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

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

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

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

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

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

For audit and evaluation reports issued from FY 2011 through FY 2021, OIG had a total of 84 reports with overdue final management decisions (FMDs) as of the end of this reporting period. The breakdown of those 84 reports by HHS OpDiv is as follows:

OpDiv	Overdue FMDs
ACF	22
ASPR	1
CMS	35
IHS	13
NIH	6
OASH	1
OS	6

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

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

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

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

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

OIG is actively tracking 1,369 unimplemented open recommendations made in reports issued since FY 2011. Given the volume of recommendations OIG makes each year, the table below reflects summary data by FY:

FY (2011–2021)	Number of Reports with Unimplemented Recommendations	Number of Unimplemented Recommendations	Dollar Value of Aggregate Potential Cost Savings
2011	12	18	\$408,135,515
2012	20	23	\$369,932,148
2013	27	40	\$234,261,321
2014	25	43	\$15,120,235,800
2015	24	39	\$313,122,644
2016	21	44	\$184,356,090
2017	30	80	\$1,090,560,442
2018	44	139	\$1,527,030,423
2019	69	220	\$734,747,701
2020	98	360	\$2,469,732,285
2021	126	363	\$1,012,913,539
Totals	496	1,369	\$23,465,027,908

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

these recommendations would most positively impact HHS programs in terms of cost savings and/or quality improvements and should therefore be prioritized for implementation.

(17) Statistical tables showing-

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

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

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

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

Total number of investigative reports issued during the reporting period, including Management Implication Reports and Investigative Advisories	None
Total number of persons referred ³ to Federal prosecuting authorities for criminal prosecution during the reporting period ⁴	1,393
Total number of persons referred to State and local prosecuting authorities for criminal prosecutions during the reporting period	144
Total number of Federal indictments and criminal information during the reporting period that resulted from any prior referral to prosecuting authorities	406
Total number of State and local indictments and criminal information during the reporting period that resulted from any prior referral to prosecuting authorities	82

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

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

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

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

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

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

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

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

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

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

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

For this section, OIG describes investigations during this reporting period, both criminal and administrative, involving senior Government employees for whom allegations of misconduct were substantiated. The descriptions below include a level of detail appropriate for each investigation, depending on whether the case details were available in public documents. During this reporting period, OIG investigated 5 senior Government employees for misconduct.

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

For departmental agencies, OIG conducts investigations related to whistleblower complaints. Before 2015, OIG made no determinations as to whether retaliatory action had been taken. OIG changed its process in 2015 to include findings in its reports as to whether, based on the facts and evidence presented, whistleblower retaliation had occurred. Where appropriate, OIG also issues recommendations as to whether corrective action(s) should be taken. Between April 1, 2021, and September 30, 2021, OIG issued one whistleblower retaliation report that contained a recommendation. However, OIG did not issue any reports during this reporting period that included findings of whistleblower retaliation.

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

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

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

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

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

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

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

Nonpublic Reports by Category, April 1, 2021, Through September 30, 2021

Category/Description	Number of Reports
IT security reviews (involve IT systems, e.g., penetration test audits)	2
Homeland security issues (involve particularly sensitive topics, e.g., bioterrorism, emergency preparedness, and classified or potentially classified information)	0
Recipient Capability Audits (primarily in Head Start/Early Head Start programs)	0
Confidential or proprietary information (e.g., Medicare Part B drug claims/imaging services, Medicare investment income)	0
Medicare Adverse Event Reviews (required by law not to disclose)	0
Medicare Prescription Drug Event Reviews	0
Other	0
HHS technical assistance reports ⁵	0
Finance-related attestation reviews	2
Total	4

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

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

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

Description of Investigation	Status	Disposition	DOJ Referral	DOJ Referral Date	DOJ Declination	DOJ Declination Date
<p>A senior Government employee allegedly made inappropriate gesturing comments to a female minor. The employee also allegedly made inappropriate requests and contact with two pharmacy students.</p>	<p>Closed</p>	<p>Insufficient evidence</p>	<p>Yes</p>	<p>6/16/2021</p>	<p>Yes</p>	<p>6/16/2021</p>
<p>Information regarding an insider threat was received regarding a senior Government employee. The information disclosed that the employee was showing a pattern of sponsoring and collaborating with individuals that have connections to institutes and organizations of concern. Possible criminal implications were noted.</p>	<p>Closed</p>	<p>Insufficient evidence</p>	<p>No</p>	<p>N/A</p>	<p>N/A</p>	<p>N/A</p>

An operational division provided information that a senior Government employee may be using HHS information systems to support personal, foreign work.	Closed	Unsubstantiated	No	N/A	N/A	N/A
An operational division provided information that a senior Government employee may be transferring agency data to personal cloud or storage devices without written official authorization.	Closed	Letter of reprimand by complainant agency	No	N/A	N/A	N/A
An operational division provided information that a senior Government employee may be using government technology and information systems to search for and view child-abuse material.	Closed	Unsubstantiated	No	N/A	N/A	N/A

Appendix G: Anti-Kickback Statute—Safe Harbors

Pursuant to HIPAA, § 205, the Inspector General is required to solicit proposals annually via a *Federal Register* notice for developing new and modifying existing safe harbors to the 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 providers and other industry stakeholders. Having done so, OIG must then determine, in consultation with DOJ, whether it can develop effective regulatory limitations and controls—not only to foster beneficial or innocuous arrangements—but also to protect the Federal health care programs and their beneficiaries from abusive practices.

Public proposals for new and modified safe harbors

Annual Solicitation

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

Proposal	OIG Response
A new safe harbor to protect the use of cash and cash-equivalent payments offered as part of contingency management in the treatment of substance use disorders.	In December 2020, as part of HHS’s broader Regulatory Sprint to Coordinated Care initiative, OIG issued a final rule (the “Regulatory Sprint Final Rule”), ² creating a new safe harbor for patient engagement tools and supports, which could protect certain in-kind incentives in connection with contingency management, if all safe harbor conditions were met. ³ Due to heightened fraud and abuse concerns with respect to incentives in the form of cash or cash equivalents, we elected

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

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

³ 42 CFR 1001.952(hh).

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

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

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

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

Proposal	OIG Response
<p>Modification of the space rental safe harbor to remove the fair market value requirement.</p>	<p>OIG is not adopting this suggestion. With respect to payments made by a lessee to a lessor for the use of premises, we believe that the fair market value requirement helps to ensure that such lease payments are for legitimate purposes and are not a payment to induce referrals or otherwise reward Federal health care program business generated between the parties.</p>
<p>Repeal or modification of the group purchasing organization (“GPO”) safe harbor to facilitate greater public transparency and address potential conflict of interests between GPOs, its members, and contracting vendors.</p>	<p>OIG is not adopting commenters’ suggestion to repeal or modify the GPO safe harbor, but we may consider this topic in future rulemaking. OIG also highlights that there is a statutory exception addressing GPOs at section 1128B(b)(3)(C) of the Social Security Act.</p>
<p>Repeal or modification of the pharmacy benefit manager service fees safe harbor and the point-of-sale reductions in price for prescription pharmaceutical products safe harbor, as finalized in a 2020 rulemaking.⁶</p>	<p>As required by an order issued by the U.S. District Court for the District of Columbia, the effective date of the 2020 final rule referenced by commenters has since been delayed until January 1, 2023. This rule is the subject of ongoing litigation and OIG cannot comment on it further.</p>

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