

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

Semiannual Report to Congress

October 1, 2020–March 31, 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), Office of Inspector General (OIG), for the 6-month period ending on March 31, 2021.

As COVID-19 relief and recovery efforts continue, oversight is imperative so that Americans can know whether these programs are working as intended and where improvements should be made. OIG has 67 ongoing or completed reviews of COVID-19 related programs. Completed work during this period detailed how the pandemic challenged the country's health system. This work included a review of infection control and complaint surveys at nursing homes during the early months of the pandemic, a second "pulse survey" of hospitals' challenges in responding to COVID-19, and a survey of opioid treatment programs' challenges and actions taken to provide services during the pandemic. OIG partnered with the Pandemic Response Accountability Committee and other Offices of Inspector General on a report examining COVID-19 testing efforts across six Federal health care programs. The report offers insights that policymakers should consider regarding availability, accessibility, and cost-effectiveness of COVID-19 testing.



OIG is aggressively investigating pandemic-related fraud that harms individuals and jeopardizes public health efforts. We are using every tool in our arsenal to bring criminals to justice, recover ill-gotten gains, and alert the public to emerging fraud schemes. OIG is partnering on this effort with law enforcement and oversight agencies across Government, including through the recently announced COVID-19 Fraud Enforcement Task Force. In addition, OIG is engaged in extensive oversight of the \$463 billion in COVID relief and recovery funding provided to or flowing through HHS. During this reporting period, OIG initiated additional audits of billions of dollars of funding from the Provider Relief Fund, and an OIG investigation led to the first criminal charge in the Nation related to misappropriating money received through the Provider Relief Fund.

As the COVID-19 pandemic response and recovery evolves in the United States, OIG's oversight will evolve as well. Although there has been progress on many fronts, much remains to be done, studied, and remedied going forward. It will be critical to understand the efficacy of pandemic response efforts over time and the lessons learned for future pandemics and broader emergency preparedness. For example, patient health and safety in nursing facilities will be an area of particular importance. Moreover, the pandemic has more sharply focused health care providers and policymakers on broader changes to delivery of health care, such as expanding use of telehealth and shifting to value-based care. Transparency and program integrity will be core to ensuring that these changes produce the intended benefits for patients, providers, and programs.

Beyond COVID-19, OIG conducted substantial oversight of HHS's \$2.2 trillion in spending in fiscal year 2020. During this reporting period, for example, investigative work led to 221 criminal actions and \$1.37 billion in expected investigative recoveries. OIG audits identified \$566 million in expected recoveries and \$920 million in potential savings for HHS programs. OIG reports addressed Medicare and Medicaid

program integrity and improper payments, grant funding, the Indian Health Service, cybersecurity, and more. Our mission is both broad and deep, touching at the heart of some of the most pressing challenges facing the Nation. One such challenge is the care of unaccompanied children crossing the U.S. southern border. OIG has continued its work overseeing HHS's Unaccompanied Children Program, including reviews of the contracting for, and safety and security of, HHS facilities for unaccompanied children. Another pressing challenge is health disparities. OIG oversees many HHS programs that are intended to reach underserved populations and reduce health disparities. OIG will continue to apply an equity lens to our work to identify opportunities for HHS programs to advance equity in areas such as access to care, quality of care, and health outcomes.

Through the talents of 1,600 dedicated, mission-driven professionals, OIG provides objective, independent oversight to protect HHS programs and the health and well-being of the people they serve. OIG pursues excellence and innovation in oversight and enforcement, supporting our reviews and investigations with modern data analytics techniques and cutting-edge technologies. We marshal our resources to foster transparency, hold wrongdoers accountable, and deliver actionable recommendations and insights to policymakers in HHS, Congress, and the public. To enhance our impact, OIG is assessing how to modernize the transparency and usability of our data, including information provided to the public and other stakeholders, to promote compliance with program requirements and reduce fraud, waste, and abuse. Across our work, we strive to ensure that HHS programs operate as intended to deliver positive outcomes for beneficiaries and taxpayers alike.

OIG appreciates the ongoing support of Congress and HHS for our important work.

Table of Contents

OIG’s Approach to Driving Positive Change	4
Highlights of OIG Accomplishments	5
OIG Participation in Congressional Hearings	13
Selected Acronyms and Abbreviations	14
Medicare and Medicaid Reports and Reviews	15
Legal and Investigative Activities Related to Medicare and Medicaid	41
Public Health and Human Service Agency Reports and Reviews	58
Legal and Investigative Activities Related to Public Health and Human Service Agencies	68
Other HHS-Related Reviews and Investigative Activities	69
Appendix A: Questioned Costs and Funds To Be Put to Better Use	74
Appendix B: Peer-Review Results	79
Appendix C: Summary of Sanction Authorities	82
Appendix D: Reporting Requirements in the Inspector General Act of 1978	85
Appendix E: Reporting Requirements in the Inspector General Empowerment Act of 2016	88
Appendix F: Anti-Kickback Statute—Safe Harbors	98

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 three operating components—the Office of Audit Services (OAS), Office of Evaluation and Inspections (OEI), and Office of Investigations (OI)—with assistance from the 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 October 1, 2020, through March 31, 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 October 1, 2020, through March 31, 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 Highlights

Statistic	Semiannual Reporting Period (10/1/2020–3/31/2021)
Audit Reports Issued	75
Evaluations Issued	20
Expected Audit Recoveries	\$566.46 million
Potential Savings	\$919.97 million
New Audit and Evaluation Recommendations	228
Recommendations Implemented by HHS OpDivs	181
Expected Investigative Recoveries	\$1.37 billion
Criminal Actions	221
Civil Actions	272
Exclusions	1,036

Results for the Semiannual Reporting Period

During this semiannual reporting period (October 1, 2020, through March 31, 2021), we issued 75 audit reports and 20 evaluation reports. Our audit work identified \$566.46 million in expected recoveries (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 \$919.97 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 228 new audit and evaluation recommendations to encourage positive change in HHS programs. Meanwhile, HHS OpDivs implemented 181 prior recommendations to drive 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 \$1.37 billion in expected investigative recoveries and 221 criminal actions during this reporting period. OIG also took civil actions, such as assessing monetary penalties, against 272 individuals and entities, and excluded 1,036 individuals and entities from Federal health care programs.

OIG continues to focus on the most significant and high-risk issues in health care and human services. Our mission is to provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve. Below we highlight results from selected OIG oversight and enforcement activities from the semiannual reporting period of October 1, 2020, through March 31, 2021, organized by subject area. A comprehensive list of OIG work during the reporting period follows, and Appendices A–F provide data to meet the reporting requirements in the Inspector General Act of 1978.

Responding to the COVID-19 Pandemic

OIG is conducting and continues to plan innovative work 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 to: (1) protect people, (2) protect funds, (3) protect infrastructure, and (4) promote effectiveness of HHS programs.

OIG is using risk assessment and data analytics to identify, monitor, and target potential fraud, waste, and abuse affecting HHS programs and beneficiaries and to promote the effectiveness of HHS's COVID-19 response and recovery programs. 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. OIG created a COVID-19 web page that alerts the public about emerging fraud schemes related to COVID-19. Additional information about the OIG COVID-19 strategic plan and work related to COVID-19 is available on our website, [COVID-19 Portal](#).

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

[OIG analyzed onsite surveys of nursing homes during the COVID-19 pandemic and identified opportunities for improvement.](#) Nursing home residents are particularly vulnerable to infectious diseases such as COVID-19, and infection control has been a persistent problem for most nursing homes. In a review of infection control and complaint surveys conducted during March 23–May 30, 2020, OIG found that some efforts instituted by CMS have resulted in less comprehensive oversight of nursing homes and residents. OIG recommended that CMS assess the results of the infection control survey and revise the survey as appropriate. (See report [OEI-01-20-00430](#).)

OIG conducted a nationwide “pulse survey” of hospitals responding to the COVID-19 pandemic. Hospitals reported that COVID-19 has significantly strained health care delivery. In February 2021, hospitals reported that operating in “survival mode” for an extended period of time has created new and different problems than experienced earlier in the pandemic and exacerbated longstanding challenges in health care delivery, access, and health outcomes. (See report [OEI-09-21-00140](#).)

OIG engaged with nursing homes and emergency medical services (EMS) providers throughout the country to help providers report allegations of unsafe practices. OIG identified nursing homes as having a significant number of COVID-19-related deaths and provided these nursing homes and EMS providers in close proximity to these facilities with information on how to report allegations of unsafe practices resulting in COVID-19 exposure, overall quality of care concerns, patient abuse and neglect, and fraud and misconduct. OIG also maintains a web page to provide additional elder care and safety awareness resources and support information for seniors, their families, and caregivers. (See [Operation Care Web Page](#).)

OIG co-led the first report by the Pandemic Response Accountability Committee (PRAC) Health Subcommittee focused on COVID-19 testing data across six Federal programs. We partnered with six Federal OIGs to analyze COVID testing in selected programs in each of our Departments. In HHS, OIG found that Medicare Part B paid for nearly 8 million COVID-19 tests from February through August 2020, with 13 percent of beneficiaries receiving at least one test. The proportion of Part B beneficiaries tested largely matched the distributions across overall Medicare Part B enrollment when compared by age, gender, and race/ethnicity. Medicare Part B paid more than \$551 million for COVID-19 tests during that time, with an average of \$69 per test. (See report [Federal COVID-19 Testing Report: Data Insights from Six Federal Health Care Programs](#).)

OIG alerted the public about fraud schemes related to COVID-19. Scammers are using telemarketing calls, text messages, social media platforms, and door-to-door visits to perpetrate COVID-19-related scams. Fraudsters are offering COVID-19 tests, COVID-19 vaccine appointments, HHS grants, and Medicare prescription cards in exchange for personal details, including Medicare information. However, these services are unapproved and illegitimate. The personal information collected can be used to fraudulently bill Federal health care programs and commit medical identity theft. (See [Fraud Alert](#).)

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 and the Child Abuse Prevention and Treatment Act (CAPTA).

The Office of Refugee Resettlement (ORR) did not award and manage the Homestead influx care facility contracts in accordance with Federal statutes, regulations, and HHS policies and procedures. ORR did not award a \$341 million sole source contract to Comprehensive Health Service, LLC, in accordance with Federal regulations and did not effectively manage its HHS contracts for services provided at Homestead in accordance with Federal statutes, regulations, and HHS policies and procedures. (See report [A-12-20-20001](#).)

OIG found that ACF does little to oversee States' compliance with CAPTA's requirement for court representation, relying instead on States' self-certification. OIG has found that ACF is neither supporting States in implementing the CAPTA's requirement for court representatives for child victims of abuse and neglect, nor is ACF monitoring States' compliance with the requirement. As a result, ACF cannot ensure that all such victims have court representation to protect their best interests. (See report [OEI-09-18-00430](#).)

Preventing and Treating Opioid Misuse

OIG continues to prioritize oversight activities to protect beneficiaries from prescription drug abuse and to provide insight into the challenges the COVID-19 pandemic is having on opioid users.

OIG found that the COVID-19 pandemic may be putting Medicaid beneficiaries at greater risk of opioid misuse or overdose in 2020 and beyond. OIG found that across 6 Appalachian States in 2018, nearly 6,000 Medicaid beneficiaries received potentially harmful amounts of opioids; more than 450 of these beneficiaries were at serious risk of opioid misuse or overdose; and 19 prescribers stood out in their prescribing of opioids to beneficiaries at serious risk. (See report [OEI-05-19-00410](#).)

OIG found that during the first 8 months of 2020—and the onset of the COVID-19 pandemic—at least 5,000 Medicare Part D beneficiaries per month suffered opioid overdoses and almost a quarter of a million received high amounts of opioids. At the same time, the number of beneficiaries receiving drugs for medication-assisted treatment (MAT) increased slightly and the number receiving naloxone declined through April 2020 but increased in the following months. (See report [OEI-02-20-00400](#).)

OIG found that few patients received high amounts of opioids from Indian Health Service (IHS)-run pharmacies, and IHS reported positive outcomes from opioid-related initiatives. However, IHS has opportunities to improve the efficiency of its opioid monitoring systems and IHS staff reported challenges in using State-run prescription drug monitoring programs (PDMPs) and in tracking care outside of IHS. (See report [OEI-05-18-00470](#).)

OIG surveyed opioid treatment programs (OTPs) to quantify the impact that the COVID-19 pandemic has had on OTPs. OIG found that OTPs reported a variety of challenges they have encountered during the COVID-19 pandemic and actions they have taken to address those challenges while ensuring the continuity of needed services and protecting the health and safety of their patients and staff. The information provides Substance Abuse and Mental Health Services Administration and other decisionmakers with a national snapshot of OTPs' challenges and the actions they have taken to continue providing services during the pandemic. (See report [A-09-20-01001](#).)

Ensuring Medicare Program Integrity

A key component of OIG's mission is to promote integrity and efficiency in Medicare through a nationwide program of audits, evaluations, inspections, investigations, and enforcement actions.

OIG found that hospitals did not comply with Medicare requirements for reporting cardiac device credits, resulting in potential Medicare overpayments. OIG found that hospitals likely did not comply with Medicare requirements associated with reporting manufacturer credits for recalled or prematurely failed

cardiac medical devices. As a result, 911 hospitals received payments of \$76 million rather than the \$43 million they should have received, resulting in \$33 million in potential overpayments. It was determined that Medicare contractors made these overpayments because they do not have a post payment review process to ensure that hospitals reported manufacturer credits for cardiac medical devices. (See report [A-01-18-00502](#).)

OIG found that CMS and its contractors did not use Comprehensive Error Rate Testing (CERT) data to identify and focus on error-prone providers for review and corrective action. Using CERT data, OIG identified 100 error-prone providers from 2014 through 2017. Of the \$5.8 million reviewed by CERT for these providers, \$3.5 million was incorrect, which is an improper payment rate of 60.7 percent. We determined that during the same period, Medicare made \$19.1 billion in fee-for-service (FFS) payments to these 100 error-prone providers. (See report [A-05-17-00023](#).)

OIG found that inpatient hospital billing in the years leading up to the COVID-19 pandemic indicates that some stays billed at the highest severity level in the diagnosis-related group (DRG) could be susceptible to inappropriate billing. OIG found that the number of inpatient stays billed at the highest severity level in the DRG increased by almost 20 percent from FY 2014 through FY 2019, ultimately accounting for nearly half of all Medicare spending on inpatient hospital stays. (See report [OEI-02-18-00380](#).)

OIG found that Medicare made payments that were not in accordance with Federal requirements to physicians for selected facet-joint injection sessions, and Noridian Healthcare Solutions made improper Medicare payments of \$4 million to physicians in Jurisdiction E for spinal facet-joint injections. The Medicare administrative contractors (MACs) in 11 jurisdictions with a coverage limitation made improper payments of \$748,555 for selected facet-joint injection sessions. OIG also estimated that Noridian improperly paid physicians \$4.2 million for spinal facet-joint injections in Jurisdiction E, which covers California, Hawaii, Nevada, and the U.S. territories of American Samoa, Guam, and Northern Mariana Islands. (See reports [A-09-20-03003](#) and [A-09-20-03010](#).)

OIG found that most of the selected diagnosis codes that Blue Cross Blue Shield of Michigan (BCBSM) submitted to CMS for use in its risk adjustment program did not comply with Federal requirements. OIG found that the diagnosis codes that BCBSM submitted to CMS were not supported in the medical records and resulted in net overpayments of \$668,264. On the basis of our sample results, we estimated that BCBSM received at least \$14.5 million of net overpayments for these high-risk diagnosis codes in 2015 and 2016. (See report [A-02-18-01028](#).)

Protecting Beneficiaries

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

OIG found that CMS can better leverage staffing data to provide consumers with required information and to help State survey agencies protect nursing home residents. CMS has taken important steps to build a new source for data on nursing home staffing on the Care Compare website and to use these data to better inform consumers and improve nursing home oversight. However, OIG found that the staffing

information that CMS provides on Care Compare could be more useful to consumers if it included data on nurse staff turnover and tenure, as required by Federal law. (See report [OEI-04-18-00451](#).)

[The chief executive officer \(CEO\) of a Texas-based group of hospice and home health entities was sentenced to 15 years in prison for falsely enrolling patients in hospice programs.](#) On February 3, 2021, Henry McInnis was sentenced to 15 years in prison for falsely telling thousands of patients with long-term incurable diseases they had less than 6 months to live, to enroll the patients in hospice programs for which they were otherwise unqualified, thereby increasing revenue to the company. OIG partnered with investigators from the Texas Medicaid Fraud Control Unit and the Federal Bureau of Investigation (FBI) to investigate the case. Between 2009 and 2018, over \$150 million in false and fraudulent claims for hospice and other health care services were submitted by McInnis and his co-conspirators.

Fighting Fraud To Protect the Medicare and Medicaid Programs

OIG remains at the forefront of the Nation's efforts to fight fraud in HHS programs and hold wrongdoers accountable for their actions.

[An individual was sentenced to 70 months in prison and ordered to pay restitution for health care fraud and conspiring to unlawfully distribute controlled substances.](#) Dr. Eugene Gosalbally was sentenced to 70 months in prison plus 3 years of supervised release and ordered to pay \$344,562 in restitution to his victims, including Medicare. OIG partnered on this investigation with investigators from the FBI and the Drug Enforcement Administration (DEA). Dr. Gosalbally and his employees issued more prescriptions for controlled substances annually than any other prescriber or prescribing entity in New York State, including hospitals.

Ensuring Medicaid Program Integrity

Medicaid is the largest Federal health care program, with over 70 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. For FY 2019, CMS estimated Federal and State Medicaid expenditures of \$614 billion.

[OIG found that most States did not provide complete or accurate payment data in the Transformed Medicaid Statistical Information System \(T-MSIS\) on managed care payments to providers.](#) In addition, two States failed to provide any data for January 2020. Effective oversight of Medicaid requires a national system with complete and accurate data. CMS established the T-MSIS for this purpose. Payment data are a critical component of T-MSIS. These data include the amounts paid, billed, and allowed for every service provided to Medicaid enrollees, including those services provided through managed care. (See report [OEI-02-19-00180](#).)

[OIG conducted high-level risk assessment of Puerto Rico's Medicaid program and identified key program areas at high risk for improper Medicaid program payments.](#) Specifically, we identified program integrity, beneficiary eligibility, provider enrollment, overpayment reporting, and contracting as key areas at high risk for improper Medicaid program payments. We used the results of this assessment to set priorities for future audits in Puerto Rico's program. (See report [A-02-20-01011](#).)

OIG found that New York claimed Federal reimbursement for personal care services that did not comply with certain Federal and State requirements. Specifically, New York received reimbursement for personal care services for which there was no valid nursing or social assessment, no independent medical review, no valid physician's order or the order was not timely, no documentation of services provided, and no plan of care. Moreover, the health and safety of some Medicaid beneficiaries may have been put at risk because their personal care aides had not undergone a criminal history check or did not meet training requirements. (See report [A-02-19-01016](#).)

Ensuring the Financial Integrity of HHS Programs

To protect financial integrity, OIG continues to examine how HHS may improve controls to prevent and detect improper and unauthorized payments, strengthen oversight of external funding recipients' use of Federal funds, and implement a robust program integrity strategy to protect current and future HHS programs.

OIG found that CMS authorized hundreds of millions of dollars in advanced premium tax credits (APTCs) on behalf of enrollees who did not make their required premium payments. We estimated that \$950 million of \$42.5 billion in authorized APTCs during 2018 were unallowable because they were made on behalf of enrollees who did not make their required premium payments. (See report [A-02-19-02005](#).)

OIG found that although CDC implemented corrective actions to improve oversight of the President's Emergency Plan for AIDS Relief (PEPFAR) recipients, some internal control weaknesses remained. OIG identified six trends in which recipients: (1) had either inadequate or no policies and procedures related to management of PEPFAR funds, (2) did not comply or may not have complied with HHS regulations regarding value added tax, (3) had transactions that were either not supported or unallowable, (4) did not accurately report PEPFAR expenditures on the financial reports or did not file reports on time, (5) did not have annual audits performed or submitted on time, and (6) could not reconcile PEPFAR expenditures to amounts reported on their financial reports. (See report [A-04-18-01010](#).)

OIG found that in selected states, 67 of 100 health centers did not use their Health Resources and Services Administration (HRSA) Access Increases in Mental Health and Substance Abuse Services (AIMS) grant funding in accordance with Federal requirements. OIG found that HRSA did not effectively monitor health centers' progress toward meeting service expansion requirements and did not ensure that health centers spent their AIMS grant funds in accordance with grant requirements. (See report [A-02-19-02001](#).)

Promoting High Quality and Safe Care in IHS

IHS is the principal Federal health care provider for American Indians and Alaska Natives. HHS must ensure adequate access to quality care and safety for IHS beneficiaries.

OIG found that an estimated 13 percent of patients in IHS hospitals experienced patient harm events, with higher rates of harm in smaller hospitals. Harm events were more prevalent among older adults and labor and delivery patients, and about half of events were preventable (i.e., they could have been avoided if patients had been given better care). (See report [OEI-06-17-00530](#).)

OIG found instances of IHS labor and delivery care not following national clinical guidelines or best practices. Through medical review of 48 IHS labor and delivery patients, OIG found that 27 of the patients in our sample received care at IHS hospitals that did not follow national clinical guidelines or best practices. Of these 27 patients, 6 patients received care that did not follow one or more national clinical guidelines and did not use the best practice of quantitative estimation of blood loss associated with a postpartum hemorrhage. Of the remaining 21 patients, 13 received care that did not meet one or more national clinical guidelines and 8 received care that did not use the best practice of quantitative estimation of blood loss. (See report [OEI-06-19-00190](#).)

OIG found that IHS facilities made progress incorporating patient protection policies, but challenges remain. In recent years, IHS had cases of health care providers abusing patients under facility care, including a pediatrician who was convicted of multiple counts of child sexual abuse. Although OIG found that IHS facilities made strides to incorporate the agency's updated policies to prevent and address child sexual abuse by health care providers, OIG recommended that IHS should work to resolve the challenges that its facilities report in carrying out the policies and their concerns that staff and patients may not feel safe reporting abuse. (See report [OEI-06-19-00331](#).)

Ensure Implementation of Geospatial-Related Requirements Across HHS

The Geospatial Data Act of 2018 (GDA) mandates that OIG conduct an audit of HHS's collection, production, acquisition, maintenance, distribution, use, and preservation of geospatial data.

OIG found that HHS made some progress to comply with GDA, but we identified certain covered agency responsibilities that HHS had yet to meet. OIG also found that HHS had not maintained a departmentwide inventory of all geospatial data assets, as required by GDA and had not designated a senior agency official in accordance with OMB guidance to Federal agencies. (See report [A-18-20-11500](#).)

Combating Cybersecurity Threats Within HHS

OIG continues to make strides at protecting the cybersecurity of HHS agencies and programs.

OIG identified cybersecurity vulnerabilities and possible compromise of HHS's systems and networks. Because of the current public health emergency and increased cyberactivity, we only posted the title of our cybersecurity audits. (See reports [A-18-19-06002](#), [A-18-20-06001](#), and [A-18-20-08012](#).)

OIG Participation in Congressional Hearings

OIG did not participate in any congressional hearings during the semiannual reporting period.

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

Cedars-Sinai Medical Center: Audit of Medicare Payments for Bariatric Surgeries (A-09-18-03010), October 2020

Cedars-Sinai Medical Center (Cedars-Sinai) did not fully comply with Medicare requirements and the Medicare contractor's local coverage determinations (LCDs) and local coverage article (LCA) when billing for bariatric surgeries. For 37 of the 62 claims we reviewed, Cedars-Sinai complied with Medicare requirements and the specifications in Noridian's LCDs and LCA for documenting previously unsuccessful medical treatment for obesity. However, Cedars-Sinai did not comply with the specifications in the LCDs for 12 claims, with payments totaling \$154,074, and did not comply with the specifications in the LCA for 13 claims, with payments totaling \$175,199.

Cedars-Sinai partially agreed with our recommendations that it: (1) refund to Medicare the portion of the \$154,074 in overpayments for bariatric surgery claims that did not comply with the specifications in the LCDs and that are within the 4-year reopening period; (2) exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule; (3) work with Noridian to take action deemed necessary regarding \$175,199 in payments for bariatric surgery claims with dates of service on or after the effective date of the LCA; (4) update its patient checklist to include all of Noridian's specifications for billing bariatric surgeries; and (5) obtain supporting medical record documentation from other providers before performing any future bariatric surgeries.

Medicare Improperly Paid Physicians for More Than Five Spinal Facet-Joint Injection Sessions During a Rolling 12-Month Period (A-09-20-03003), October 2020, and

Noridian Healthcare Solutions, LLC, Made Improper Medicare Payments of \$4 Million to Physicians in Jurisdiction E for Spinal Facet-Joint Injections (A-09-20-03010), February 2021

Medicare did not pay physicians for selected facet-joint injection sessions in accordance with Federal requirements, and Noridian Healthcare Solutions, LLC (Noridian), did not pay physicians in Jurisdiction E for spinal facet-joint injections in accordance with Medicare requirements. Specifically, the MACs in the 11 jurisdictions with a coverage limitation made improper payments of \$748,555. If the remaining MAC jurisdiction had kept the coverage limitation in place during our audit period, Medicare could have saved \$513,328.

CMS concurred with our recommendations that, for the 11 MAC jurisdictions with a coverage limitation for the number of facet-joint injection sessions during a rolling 12-month period, it: (1) direct the MACs that oversee the 11 jurisdictions to recover \$748,555 in improper payments made to physicians; (2) instruct the MACs to notify physicians so that they can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any returned overpayments as having been made; (3) develop oversight mechanisms for the MACs to implement to prevent or detect payments to physicians for more than 5 facet-joint injection sessions received by beneficiaries during a rolling 12-month period; and (4) direct the MACs that oversee the 11 jurisdictions to review claims for facet-joint injections after our audit period to identify instances in which Medicare inappropriately paid physicians and recover any improper payments identified. CMS concurred with our recommendation that, for the remaining MAC jurisdiction, which did not have a coverage limitation, it consider working with the MAC to determine whether it should re-implement this coverage limitation, which could have saved \$513,328 during our audit period.

Of Noridian's sampled 100 beneficiary days, 49 complied with the requirements; however, the remaining 51 beneficiary days did not comply with 1 or more of the requirements. As a result, Noridian improperly paid physicians \$12,546. On the basis of our sample results, we estimated that Noridian improperly paid physicians \$4.2 million for facet-joint injections for our audit period.

Noridian concurred with our recommendations that it: (1) recover \$12,546 in improper payments made to physicians; (2) based on the results of this audit, notify appropriate physicians (i.e., those for whom Noridian determines this audit constitutes credible information of potential overpayments) so that the physicians 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) provide annual training to physicians and their billing staff in Jurisdiction E specific to Medicare requirements for billing of facet-joint injections, which could have saved an estimated \$4.2 million for our audit period.

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 (A-07-19-00560), November 2020

CMS did not ensure that Outpatient Prospective Payment System (OPPS) payments for claims that included medical device credits were reduced in accordance with Federal regulations. These regulations require the use of the device offset amount—100 percent of the device offset amount for each without cost or full credit replacement device and 50 percent of the device offset amount for each partial credit replacement device—when calculating the reduced OPPS payment amount. By following the Medicare Claims Processing Manual (the Manual) instructions, MACs did not comply with these regulations when calculating the claims that we reviewed. As a result, Medicare made estimated overpayments of as much as \$35.4 million to hospitals for our audit period. This

error occurred because as part of Federal rulemaking in calendar year (CY) 2014, CMS announced its intention to update Federal regulations to reduce OPPS payments for replaced medical devices. This intended update was not finalized in the text of the Federal regulations. However, CMS revised the relevant language in its guidance—the Manual.

CMS did not concur with our recommendations that it: (1) work with the MACs to recover from hospitals Medicare OPPS overpayments, which total as much as an estimated \$35.4 million; (2) work with the MACs to recover Medicare OPPS overpayments from hospitals for any additional claims that included medical device credits and that were outside of our audit period; and (3) revise the OPPS regulations or the Manual instructions to resolve the conflict between these requirements for OPPS claims with medical device credits.

Despite Savings on Many Lab Tests in 2019, Total Medicare Spending Increased Slightly Because of Increased Utilization in Certain High-Priced Tests (OEI-09-20-00450), December 2020

In the second year of the new Medicare Part B clinical laboratory payment system that is required by the Protecting Access to Medicare Act of 2014, reduced payment rates on many lab tests resulted in savings for Medicare. However, total Medicare Part B spending on lab tests increased slightly because of increased utilization and spending on certain high-priced tests, such as genetic tests. Our data brief contains no recommendations.

The Centers for Medicare & Medicaid Services Could Improve Its Wage Index Adjustment for Hospitals in Areas With the Lowest Wages (A-01-20-00502), December 2020

When postpandemic conditions allow for new initiatives, CMS could consider focusing the bottom quartile wage index adjustment more precisely toward the hospitals that are the least able to raise wages without that adjustment. Those hospitals are the ones with low or negative profit margins rather than higher, positive profit margins. CMS could also consider studying the question of why some hospitals in a particular area were able to pay higher wages than other hospitals in the same area prior to the implementation of the bottom quartile wage index adjustment. More information might enable CMS to focus the adjustment even more precisely.

Trend Toward More Expensive Inpatient Hospital Stays in Medicare Emerged Before COVID-19 and Warrants Further Scrutiny (OEI-02-18-00380), January 2021

Hospitals play an essential role in our health care system; nearly one-fifth of all Medicare payments are for inpatient hospitalizations. Inpatient hospital billing in the years leading up to the pandemic indicates that some stays at the highest severity level could be susceptible to inappropriate billing. Our findings can help CMS gain a better understanding of how hospitals bill Medicare and improve its oversight of hospital billing. Our recommendation was for it to conduct targeted reviews of Medicare Severity Diagnosis Related Groups (MS-DRGs) and stays that are vulnerable to upcoding, as well as the hospitals that frequently bill them. CMS did not concur.

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS (A-02-18-01028), February 2021

Most of the selected diagnosis codes that BCBSM submitted to CMS for use in CMS's risk adjustment program did not comply with Federal requirements.

For 188 of the 248 enrollee-years, the diagnosis codes that BCBSM submitted to CMS were not supported in the medical records and resulted in net overpayments of \$668,264.

These errors occurred because the policies and procedures that BCBSM 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 BCBSM received at least \$14.5 million of net overpayments for these high-risk diagnosis codes in 2015 and 2016.

BCBSM concurred with our recommendations that it: (1) refund to the Federal Government the \$14.5 million of net overpayments; (2) 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 (3) examine its existing compliance procedures to identify areas where improvements can be made to ensure that diagnosis codes at high risk for being miscoded comply with Federal requirements, and take the necessary steps to enhance those procedures.

CMS Authorized Hundreds of Millions of Dollars in Advanced Premium Tax Credits on Behalf of Enrollees Who Did Not Make Their Required Premium Payments (A-02-19-02005), March 2021

For 13 of the 155 sampled policies, APTCs totaling \$43,455 authorized by CMS were unallowable because they were made on behalf of enrollees who did not make their required premium payments. Specifically, for seven sampled policies enrollees were improperly confirmed (i.e., treated as if they had made their first premium payments) or provided coverage by their qualified health plan (QHP) issuers when their policies should have been terminated for nonpayment of premiums. In addition, for nine sampled policies, CMS reported inaccurate enrollment data to the Internal Revenue Service (IRS), thereby preventing the IRS from recouping APTCs paid on behalf of enrollees who did not make their required premium payments. Three sampled policies contained both deficiencies.

On the basis of our sample results, we estimated that \$950 million of \$42.5 billion in authorized APTCs during 2018 for 659,143 of 5.3 million policies were unallowable because they were made on behalf of enrollees who did not make their required premium payments.

CMS did not concur with our recommendation that it work with the Department of the Treasury and QHP issuers to recover or take other remedial action for: (1) the \$43,455 in improper APTCs identified in our sample; and (2) the remaining improper APTCs, which we estimate to be

\$950 million, for policies for which the payments were not allowable. CMS concurred with our recommendation that it develop a process to collect additional information from QHP issuers.

Peninsula Regional Medical Center: Audit of Medicare Payments for Polysomnography Services (A-04-19-07087), March 2021, and

North Mississippi Medical Center: Audit of Medicare Payments for Polysomnography Services (A-04-19-07086), March 2021

Peninsula Regional Medical Center (Peninsula) submitted Medicare claims for some polysomnography services that did not comply with Medicare billing requirements. On the basis of our sample results, we estimated that Peninsula received overpayments of at least \$66,647 for polysomnography services provided during the audit period. The errors occurred because Peninsula'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.

North Mississippi Medical Center (North Mississippi) submitted Medicare claims for some polysomnography services that did not comply with Medicare billing requirements. On the basis of our sample results, we estimated that North Mississippi received overpayments of at least \$67,038 for polysomnography services provided during the audit period. North Mississippi stated that the errors occurred because of a misunderstanding of the Medicare policy. Although North Mississippi had some policies and procedures in place, they did not adequately explain how to process Medicare claims for polysomnography services and ensure that services billed to Medicare were coded correctly or that technicians attending a polysomnography service had the required credentials.

Peninsula concurred with our findings and recommendations that it: (1) refund to the Medicare program the estimated \$66,647 overpayment for claims that it incorrectly billed; (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.

North Mississippi concurred with our recommendations that it: (1) refund to the Medicare program the estimated \$67,038 overpayment for claims that it incorrectly billed; (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; (3) educate its staff on properly billing for polysomnography services; and (4) revise policies and procedures to ensure that claims are coded correctly and that sleep technicians have the required credentials before billing claims for polysomnography services to ensure full compliance with Medicare requirements.

An Ophthalmology Clinic in California: Audit of Medicare Payments for Eye Injections of Eylea and Lucentis (A-09-19-03022), March 2021

An ophthalmology clinic in California (the Clinic) generally complied with Medicare requirements when billing for intravitreal injections of Eylea and Lucentis, which accounted for 88 percent of the total payments 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). For 301 services and drugs, the Clinic did not comply with the requirements: 195 services were not separately payable, and 106 services and drugs were not reasonable and necessary.

Because the Clinic's medical director was unfamiliar with Medicare's billing requirements, the Clinic did not have policies and procedures to ensure that services and drugs billed to Medicare were correctly billed or reasonable and necessary. On the basis of our sample results, we estimated that at least \$398,625 of the \$4.3 million paid to the Clinic was unallowable for Medicare reimbursement.

The Clinic concurred in part with our recommendation that it refund to the Medicare contractor \$398,625 in estimated overpayments for intravitreal injections of Eylea and for other services provided on the same day as intravitreal injections of Eylea and Lucentis. The Clinic concurred with our recommendation that, based on the results of this audit, it exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule. We also made two procedural recommendations to ensure that the Clinic complies with Medicare requirements.

Quality of Care, Safety, and Access

Update on Oversight of Opioid Prescribing and Monitoring of Opioid Use: States Have Taken Action To Address the Opioid Epidemic (A-09-20-01000), October 2020

We identified actions that selected States took related to their oversight of opioid prescribing and their monitoring of opioid use. In July 2019, we issued a report summarizing and comparing information provided by eight selected States: Nebraska, Nevada, New Hampshire, Tennessee, Texas, Utah, Washington, and West Virginia. For this update to our original audit, we selected an additional three States in the Appalachian region, an area with high rates of opioid overdose deaths: Alabama, Kentucky, and Ohio. This report summarizes and compares information provided by all 11 States as of various dates between October 2018 and May 2020.

The selected States have created policies and procedures and passed laws and regulations related to opioids. The States are using opioid-related data to perform both data analytics and outreach to providers and patients. The States have implemented a number of opioid-related prevention, detection, and treatment programs. Finally, the States have taken many other actions to address the opioid epidemic. This report contains no recommendations.

Onsite Surveys of Nursing Homes During the COVID-19 National Emergency: March 23–May 30, 2020, (OEI-01-20-00430), December 2020

In response to the COVID-19 pandemic, CMS adjusted its oversight approach to suspend standard surveys, prioritize the most serious complaints, elevate attention on infection control, and develop a new survey tool to ensure that nursing homes implement actions to prevent the spread of COVID-19. However, these changes have resulted in less comprehensive oversight of nursing homes and residents. Our findings can help CMS enhance its approach to nursing home oversight. CMS did not explicitly concur with our first and third recommendations but stated that it has already taken steps to implement those recommendations. CMS did not concur with our second recommendation. We recommended that CMS:

- assess the results of infection control surveys and revise the survey as appropriate,
- work with States to help overcome challenges with PPE and staffing, and
- clarify expectations for States to complete backlogs of standard surveys and high-priority complaint surveys.

Federal COVID-19 Testing Report: Data Insights From Six Federal Health Care Programs ([Federal COVID-19 Testing Report: Data Insights From Six Federal Health Care Programs](#)), January 2021

COVID-19 testing trends in six Federal health care programs largely followed the same pattern as national testing from February 2020 through August 2020, the first 7 months of the pandemic. This report, conducted in partnership with the Council of the Inspectors General on Integrity and Efficiency's (CIGIE's) Pandemic Response Accountability Committee, provides policymakers with key insights on COVID-19 testing as the Federal Government continues to respond to the pandemic. These insights—presented at an aggregated level and individual program level—inform policymakers on the following: number of COVID-19 tests administered; populations that received COVID-19 tests, types of COVID-19 tests administered; costs of testing, places where COVID-19 tests were administered, and amount of time it took to return test results.

Program Integrity

Medicare Critical Care Services Provider Compliance Audit: Clinical Practices of the University of Pennsylvania (A-03-18-00003), October 2020

Clinical Practices of the University of Pennsylvania (Clinical Practices) complied with Medicare billing requirements for 136 of the 150 critical care services that we reviewed. However, Clinical Practices did not comply with Medicare billing requirements for the remaining 14 critical care services, and these errors resulted in Clinical Practices receiving \$1,399 in unallowable Medicare payments. These errors occurred because Clinical Practices incorrectly identified and billed critical care services for physician services that did not meet Medicare requirements.

On the basis of our sample results, we estimated that Clinical Practices received overpayments of at least \$151,588 for the audit period.

Clinical Practices did not indicate concurrence or nonconcurrence with our recommendations that it: (1) refund to the MAC a total of \$151,588 in estimated overpayments for critical care services; (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 identify any of those returned overpayments as having been made in accordance with this recommendation; and (3) strengthen policies and procedures to ensure that critical care services billed to Medicare are adequately documented and correctly billed.

Medicare Home Health Agency Provider Compliance Audit: Gem City Home Care, LLC
([A-05-18-00011](#)), October 2020;

Medicare Home Health Agency Provider Compliance Audit: Visiting Nurse Association of Central Jersey Home Care and Hospice, Inc. ([A-02-17-01025](#)), October 2020;

Medicare Home Health Agency Provider Compliance Audit: The Palace at Home
([A-04-17-07067](#)), November 2020;

Medicare Home Health Agency Provider Compliance Audit: Total Patient Care Home Health, LLC
([A-06-16-05005](#)), December 2020;

Medicare Home Health Agency Provider Compliance Audit: Tender Touch Health Care Services
([A-04-18-07077](#)), December 2020;

Medicare Home Health Agency Provider Compliance Audit: Southeastern Home Health Services ([A-03-17-00004](#)), January 2021; and

Medicare Home Health Agency Provider Compliance Audit: Brookdale Home Health, LLC
([A-04-18-06221](#)), February 2021

Gem City Home Care, LLC (Gem City), did not comply with Medicare billing requirements for 25 of the 100 home health claims that we reviewed. On the basis of our sample results, we estimated that Gem City received overpayments of at least \$2.67 million during this period.

Visiting Nurse Association of Central Jersey Home Care and Hospice, Inc. (VNA of Central Jersey), did not comply with Medicare billing requirements for 14 of the 100 home health claims that we reviewed. On the basis of our sample results, we estimated that VNA of Central Jersey received overpayments of at least \$2 million for the audit period.

The Palace at Home (The Palace) did not comply with Medicare billing requirements for 20 of the 100 home health claims that we audited. On the basis of our sample results, we estimated that The Palace received overpayments of at least \$731,304 for our audit period. All of the incorrectly billed claims are outside of the 4-year reopening period.

Total Patient Care Home Health, LLC (TPC), did not comply with Medicare billing requirements for 32 of the 100 home health claims that we reviewed. On the basis of our sample results, we estimated that TPC received overpayments of at least \$1.7 million for our audit period. As of the publication of this report, all 100 claims within our sample are outside of the Medicare 4-year claim-reopening period.

Tender Touch Health Care Services (Tender Touch) did not comply with Medicare billing requirements for 21 of the 100 home health claims that we reviewed. On the basis of our sample results, we estimated that Tender Touch received overpayments of at least \$478,780 for the audit period.

Southeastern Home Health Services (Southeastern) did not comply with Medicare billing requirements for 18 of the 100 home health claims that we reviewed. On the basis of our sample results, we estimated that Southeastern received overpayments of at least \$1.8 million for our audit period. All 100 claims within our sample are outside of the Medicare 4-year claim-reopening period.

Brookdale Home Health, LLC (Brookdale), did not comply with Medicare billing requirements for 46 of the 100 home health claims that we reviewed. On the basis of our sample results, we estimated that Brookdale received overpayments of approximately \$3.3 million for the audit period.

Gem City did not concur with our recommendations that it: (1) refund to the Medicare program the portion of the estimated \$2.67 million in overpayments for incorrectly billed claims that are within the 4-year reopening period; (2) for the remaining portion of the estimated \$2.67 million overpayment for claims that are outside of the reopening period, exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation; (3) exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period; and (4) strengthen its procedures to ensure that the homebound statuses of Medicare beneficiaries are verified and continually monitored, that the specific factors qualifying beneficiaries as homebound are documented, and that beneficiaries receive only reasonable and necessary skilled services.

VNA of Central Jersey disagreed with our recommendations that it: (1) refund to the Medicare program the portion of the estimated \$2 million overpayment for claims incorrectly billed that are within the reopening period; (2) exercise reasonable diligence to identify and return overpayments, in accordance with the 60-day rule, for claims that are outside the reopening period; (3) exercise

reasonable diligence to identify and return any additional similar overpayments outside of our audit period; and (4) strengthen its procedures for billing home health services.

We recommend that The Palace, 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 identify any of those returned overpayments as having been made in accordance with this recommendation. We also recommend that The Palace strengthen its procedures to ensure full compliance with requirements for billing home health services. The Palace stated that it plans to appeal our findings.

TPC disagreed with our recommendations that it: (1) exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule; (2) identify any of those returned overpayments as having been made in accordance with this recommendation; and (3) strengthen its procedures to ensure that the homebound statuses of Medicare beneficiaries are verified and continually monitored, that the specific factors qualifying beneficiaries as homebound are documented, and that beneficiaries receive only reasonable and necessary skilled services.

Tender Touch did not address our recommendations that it: (1) refund to the Medicare program the portion of the estimated \$478,780 overpayment for claims 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 identify any of those returned overpayments as having been made in accordance with this recommendation; and (3) strengthen its procedures.

Southeastern did not agree with our recommendations that it: (1) 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) strengthen its procedures to ensure that the homebound statuses of Medicare beneficiaries are verified and continually monitored, that the specific factors qualifying beneficiaries as homebound are documented, that beneficiaries receive only reasonable and necessary skilled services, and that the correct Health Insurance Prospective Payment System payment codes are billed.

Brookdale generally agreed with our recommendations that it: (1) refund to the Medicare program the portion of the estimated \$3.3 million overpayment for claims incorrectly billed that are within the reopening period; (2) 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) strengthen some of its procedures.

Medicare Hospital Provider Compliance Audit: St. Francis Hospital (A-05-18-00048),
October 2020;

Medicare Hospital Provider Compliance Audit: Edward W. Sparrow Hospital (A-05-18-00045),
November 2020;

Medicare Hospital Provider Compliance Audit: Providence Medical Center (A-07-18-05113),
December 2020; and

Medicare Hospital Provider Compliance Audit: Sunrise Hospital & Medical Center (A-04-19-08075),
March 2021

St. Francis Hospital complied with Medicare billing requirements for 86 of the 100 inpatient and outpatient claims we reviewed. On the basis of our sample results, we estimated that St. Francis Hospital received overpayments of at least \$1.6 million for the audit period.

Edward W. Sparrow Hospital complied with Medicare billing requirements for 91 of the 100 inpatient and outpatient claims we reviewed. However, Edward W. Sparrow Hospital did not fully comply with Medicare billing requirements for the remaining nine claims, resulting in overpayments of \$47,317 for the audit period. On the basis of our sample results, we estimated that Edward W. Sparrow Hospital received overpayments of at least \$550,917 for the audit period.

Providence Medical Center complied with Medicare billing requirements for 87 of the 100 inpatient and outpatient claims we reviewed. However, Providence Medical Center did not fully comply with Medicare billing requirements for the remaining 13 claims, resulting in overpayments of \$57,800 for calendar years 2016 and 2017. On the basis of our sample results, we estimated that Providence Medical Center received overpayments of at least \$325,241 for the audit period.

Sunrise Hospital & Medical Center complied with Medicare billing requirements for 46 of the 100 inpatient and outpatient claims we reviewed. However, Sunrise Hospital & Medical Center did not fully comply with Medicare billing requirements for the remaining 54 claims, resulting in net overpayments of \$999,950 for the audit period. On the basis of our sample results, we estimated that Sunrise Hospital & Medical Center received overpayments of at least \$23.6 million for the audit period. During the course of our audit, Sunrise Hospital & Medical Center submitted five of these claims for reprocessing, and we verified those claims as correctly reprocessed. Accordingly, we have reduced the recommended refund by \$8,914.

St. Francis Hospital generally disagreed with our recommendations that it: (1) refund to the Medicare contractor \$1.6 million in estimated overpayments for the audit period for incorrectly billed claims that are within the 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 identify any returned overpayments as having been made in accordance with this

recommendation; and (3) strengthen its controls to ensure full compliance with Medicare requirements; specifically ensure that all inpatient rehabilitation facility beneficiaries meet Medicare criteria for acute inpatient rehabilitation, that all inpatient beneficiaries meet Medicare requirements for inpatient hospital services, that procedure and diagnosis codes are supported in the medical records and staff are properly trained, and that medical records accurately document distinct procedural services and staff are properly trained.

Edward W. Sparrow Hospital partly concurred with our recommendations that it 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 strengthen its controls to ensure full compliance with Medicare requirements.

Providence Medical Center disagreed with our recommendations that it: (1) refund to the Medicare contractor the portion of the \$325,241 in estimated overpayments for the audit period for claims that it incorrectly billed that are within the reopening period and (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 identify any of those returned overpayments as having been made in accordance with this recommendation. Regarding our recommendation to strengthen controls to ensure full compliance with Medicare requirements, Providence Medical Center described corrective actions that it had taken or planned to take.

Sunrise Hospital & Medical Center generally disagreed with our recommendations that it: (1) refund to the Medicare contractor \$23.6 million in net estimated overpayments for the audit period for claims that it incorrectly billed that are within the 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 identify any of those returned overpayments as having been made in accordance with this recommendation; and (3) strengthen controls to ensure full compliance with Medicare requirements.

Medicare Hospice Provider Compliance Audit: Hospice Compassus, Inc., of Payson, Arizona (A-02-16-01023), November 2020;

Medicare Hospice Provider Compliance Audit: Hospice Compassus, Inc., of Tullahoma, Tennessee (A-02-16-01024), December 2020; and

Medicare Hospice Provider Compliance Audit: Tidewell Hospice, Inc. (A-02-18-01024), February 2021

Hospice Compassus, Inc., of Payson, Arizona (Payson), did not comply with Medicare requirements for 39 of the 100 claims in our sample. For these claims, Payson claimed Medicare reimbursement

for hospice services: (1) for which the associated beneficiary did not meet eligibility requirements, (2) that were not documented, and (3) at a reimbursement rate associated with a level of care higher than what the associated beneficiary required.

Hospice Compassus, Inc., of Tullahoma, Tennessee (Tullahoma), did not comply with Medicare requirements for 35 of the 100 claims in our sample. For these claims, Tullahoma claimed Medicare reimbursement for hospice services (1) for which the clinical record did not support the beneficiary's terminal prognosis, (2) that were not documented, and (3) for which the notice of election was not filed timely with the MAC.

Tidewell Hospice, Inc. (Tidewell), did not comply with Medicare requirements for 18 of the 100 claims in our sample. For these claims, Tidewell claimed Medicare reimbursement for hospice services for which the clinical record did not support the beneficiary's terminal illness prognosis or the level of care claimed and for services that were not eligible for Medicare reimbursement.

Payson generally disagreed with our recommendations that it: (1) exercise reasonable diligence to identify, report, and return overpayments in accordance with the 60-day rule; (2) based on the results of our audit, identify, report, and return any additional overpayments as having been made in accordance with our recommendations; and (3) strengthen its procedures to ensure that hospice services comply with Medicare requirements.

Tullahoma generally disagreed with our recommendations that it: (1) exercise reasonable diligence to identify, report, and return overpayments in accordance with the 60-day rule; (2) based on the results of our audit, identify, report, and return any additional overpayments as having been made in accordance with our recommendations; and (3) strengthen its procedures to ensure that hospice services comply with Medicare requirements.

Tidewell partly agreed and partly disagreed with our recommendations that it: (1) refund to the Federal Government the portion of the estimated \$8.3 million in Medicare overpayments that are within the 4-year claims reopening period; (2) exercise reasonable diligence to identify, report, and return overpayments, in accordance with the 60-day rule; and (3) strengthen its policies and procedures to ensure that hospice services comply with Medicare requirements.

CMS and Its Contractors Did Not Use Comprehensive Error Rate Testing Program Data To Identify and Focus on Error-Prone Providers (A-05-17-00023), January 2021

CMS and its contractors did not use CERT data to identify and focus on error-prone providers for review and corrective action. Using CERT data, we identified 100 error-prone providers from 2014 through 2017. Of the \$5.8 million reviewed by CERT, \$3.5 million was incorrect, which is an improper payment rate of 60.7 percent. We determined that during the same period, Medicare made \$19.1 billion in FFS payments to these 100 error-prone providers.

The term "error-prone provider" is an OIG-created term to refer to a list of providers identified as having higher rate of errors in the CERT sample data. When used to describe OIG analysis of CERT data from 2014 through 2017, the term refers to providers that had at least one error in each of the 4 CERT years analyzed, an error rate of higher than 25 percent in each of the 4 CERT years analyzed, and a total error amount of at least \$2,500. An error-prone provider is statistically more likely to submit an improper claim than the average provider.

CMS did not concur with our recommendations that it: (1) review the list of 100 error-prone providers identified in this audit and take specific action as appropriate, such as prior authorization, prepayment reviews, and postpayment reviews, and (2) use annual CERT data to identify individual providers that have an increased risk of receiving improper payments and apply additional program integrity tools to these providers.

Drug Pricing and Reimbursement

Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Second Quarter of 2020 (OIG-03-21-00050), November 2020, and

Comparison of Average Sales Prices and Average Manufacturer Prices: Results for the Third Quarter of 2020 (OIG-03-21-00060), February 2021

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

Opioid Use in Medicare Part D During the Onset of the COVID-19 Pandemic (OIG-02-20-00400), February 2021

During the first 8 months of 2020—and the onset of the COVID-19 pandemic—at least 5,000 Part D beneficiaries per month suffered opioid overdoses and almost a quarter of a million received high amounts of opioids. At the same time, the number of beneficiaries receiving drugs for MAT increased slightly and the number receiving naloxone declined through April but increased in the following months. As the COVID-19 pandemic continues to affect millions of Americans, vigilance remains important. It is essential that CMS—and HHS—monitor trends in prescriptions for drugs for MAT and naloxone and take appropriate action if the number of prescriptions begins to fall off.

Medicaid Program Reports and Reviews

Financial Management and Improper Payments

Colorado Improperly Claimed Millions in Enhanced Federal Medicaid Reimbursement for New Adult Group Beneficiaries Because of a Data Processing Error (A-07-17-02807), October 2020

Colorado claimed reimbursement for Medicaid services provided from January 1, 2014, through September 30, 2015, to some beneficiaries who were enrolled in the new adult group but who later became ineligible for Medicaid coverage. As a result, Colorado improperly claimed and received over \$1.9 million in Federal reimbursement for these beneficiaries past the termination dates of their Medicaid eligibility.

Colorado properly terminated 1,543 beneficiaries' eligibility in the Colorado Benefits Management System (CBMS), which determines Medicaid eligibility and interfaces with other automated systems, but erroneously kept them as eligible in the Medicaid Management Information System (MMIS). The beneficiaries' eligibility was not terminated in the MMIS because of a data processing error. Although the CBMS interfaced with the MMIS, for some beneficiaries a change in eligibility determination from eligible to ineligible that occurred in the CBMS did not transfer correctly to the MMIS.

Colorado disagreed with our recommendations that it: (1) refund to the Federal Government the over \$1.9 million in improperly claimed Medicaid reimbursement and (2) identify and refund to the Federal Government any payments made on behalf of ineligible beneficiaries for whom services after our audit period were claimed and reimbursed past the termination dates of their eligibility. Colorado did not comment on our recommendation that it establish adequate system controls that ensure that eligibility determinations transfer correctly from the CBMS to the MMIS to prevent payments from being made on behalf of ineligible beneficiaries.

Hospitals Did Not Comply With Medicare Requirements for Reporting Cardiac Device Credits (A-01-18-00502), November 2020

For 3,233 of the 6,558 Medicare claims that we reviewed, hospitals likely did not comply with Medicare requirements associated with reporting manufacturer credits for recalled or prematurely failed cardiac medical devices. As a result, 911 hospitals received payments of \$76 million rather than the \$43 million they should have received, resulting in \$33 million in potential overpayments. MACs made these overpayments because they do not have a postpayment review process that would ensure that hospitals reported manufacturer credits for cardiac medical devices.

CMS partly concurred with our recommendations that it: (1) instruct MACs to recover the portion of the \$33 million in identified Medicare overpayments that are within the reopening period; (2) notify hospitals associated with potential overpayments outside the reopening period so that they can

return any overpayments in accordance with the 60-day rule; (3) require hospitals to use condition codes 49 and 50 on claims; (4) instruct MACs to implement a postpayment review process; (5) obtain device credit listings from manufacturers and determine whether providers reported credits as required; (6) direct MACs to determine whether hospitals have engaged in a pattern of incorrect billing after our audit period and, if so, take appropriate action in accordance with CMS policies and procedures; and (7) consider eliminating the current Medicare requirements for reporting device credits by reducing the payments for cardiac device replacement procedures.

Ohio Did Not Correctly Determine Medicaid Eligibility for Some Newly Enrolled Beneficiaries (A-05-18-00027), November 2020, and

Louisiana Did Not Correctly Determine Medicaid Eligibility for Some Newly Enrolled Beneficiaries (A-06-18-02000), January 2021

For our sample of 150 beneficiaries, Ohio did not determine eligibility for 18 beneficiaries in accordance with Federal and State requirements and did not provide supporting documentation to verify that the remaining 66 potentially ineligible beneficiaries were newly eligible. (The total exceeds 150 because 3 beneficiaries were found to be ineligible for 1 determination period and found to be potentially ineligible for another period.)

For our sample of 120 Medicaid beneficiaries, Louisiana made Medicaid payments on behalf of 4 beneficiaries who did not meet requirements and 1 beneficiary who may not have met requirements. Based on our sample results, we estimated that Louisiana made Medicaid payments of \$20.1 million (100-percent Federal share) on behalf of 16,358 beneficiaries who did not meet requirements.

On the basis of our sample results, we estimated that Ohio made Medicaid payments of \$77.5 million (Federal share) on behalf of 51,219 ineligible beneficiaries and \$746.4 million (Federal share) on behalf of 241,998 potentially ineligible beneficiaries. Based on our sample results, we estimated that Louisiana made Medicaid payments of \$20.1 million (100-percent Federal share) on behalf of 16,358 beneficiaries who did not meet requirements.

Ohio did not indicate concurrence or nonconcurrence with our recommendations that it: (1) redetermine, if necessary, the current Medicaid eligibility of the sampled beneficiaries; (2) ensure that its eligibility determination system has the functionality to verify eligibility requirements and perform eligibility determinations in accordance with Federal and State requirements; (3) educate eligibility caseworkers about relevant Federal and State eligibility requirements; and (4) ensure that documentation supporting eligibility determinations is maintained in beneficiaries' records.

Louisiana agreed with our recommendations that it: (1) promptly provide notice and cancel the eligibility of beneficiaries identified with income over the allowable limit; (2) educate State analysts on established policies and procedures regarding requirements to promptly provide notice and

cancel eligibility, verify income, and provide retroactive eligibility; and (3) redetermine, if necessary, the current Medicaid eligibility status of the sampled beneficiaries for whom income or dependent verifications did not meet Federal and State requirements.

Ohio Made Capitation Payments to Managed Care Organizations for Medicaid Beneficiaries With Concurrent Eligibility in Another State ([A-05-19-00023](#)), November 2020, and

Illinois Made Capitation Payments to Managed Care Organizations for Medicaid Beneficiaries With Concurrent Eligibility in Another State ([A-05-19-00031](#)), February 2021

Ohio made an estimated \$5.9 million in August 2018 capitation payments on behalf of beneficiaries who were concurrently eligible and residing in another State. On the basis of our sample results, we estimated that Ohio could have saved \$5.9 million (\$4.2 million Federal share) for August 2018 capitation payments made to managed care organizations on behalf of beneficiaries with concurrent eligibility.

Illinois made an estimated \$3.8 million in August 2018 capitation payments on behalf of beneficiaries who were concurrently eligible and residing in another State. On the basis of our sample results, we estimated that Illinois could have saved \$3.8 million (\$2.1 million Federal share) for August 2018 capitation payments made to managed care organizations on behalf of beneficiaries with concurrent eligibility.

Ohio did not indicate concurrence or nonconcurrence with our recommendations that it: (1) develop or enhance current procedures to identify beneficiaries with concurrent eligibility in another State, which could have saved Ohio an estimated \$5.9 million (\$4.2 million Federal share) in capitation payments for August 2018, and (2) ensure that procedures are in place for county caseworkers to timely review and terminate eligibility for beneficiaries who were identified as concurrently eligible in another State.

Illinois concurred with our recommendations that it: (1) develop or enhance current procedures to identify beneficiaries with concurrent eligibility in another State, which could have saved Illinois an estimated \$3.8 million (\$2.1 million Federal share) in capitation payments for the month of August 2018, and (2) ensure that procedures are in place for caseworkers to timely review and terminate eligibility for beneficiaries who were identified as concurrently eligible in another State.

Florida Received Unallowable Medicaid Reimbursement for School-Based Services ([A-04-18-07075](#)), November 2020

Florida did not always claim Federal Medicaid reimbursement for school-based services in accordance with Federal and State requirements. Of the 200 school-based services in our sample, 168 met Federal and State requirements. However, Florida incorrectly claimed reimbursement for the remaining 32 sampled services totaling \$644 because they did not meet 1 or more Federal

requirements as follows: individual education plans or plans of care without the required signature, not enough supporting documentation to substantiate services, and provider qualification requirements such as licenses and training courses missing.

These deficiencies occurred because Florida did not have formal policies and procedures to ensure that the claims school districts submitted were adequately documented. In addition, Florida did not adequately monitor for compliance with Federal and State requirements school-based services claims that the school districts submitted.

On the basis of our sample results, we estimated that Florida claimed at least \$1.4 million in unallowable costs during our audit period.

Florida did not concur with our recommendations that it: (1) refund \$1.4 million to the Federal Government, (2) work with CMS to review Medicaid claims for school-based services after our audit period and refund any overpayments, and (3) improve its policies and procedures to ensure that it is adequately monitoring school-based service claims to ensure compliance with Federal and State requirements.

Nebraska Claimed Almost All Medicaid Payments for Targeted Case Management Services in Accordance With Federal Requirements but Claimed Some Unallowable Duplicate Payments (A-07-19-03239), December 2020

Nebraska claimed almost all Federal Medicaid reimbursement for targeted case management services during FY 2016 through FY 2018 in accordance with Federal and State requirements. The 150 claims we sampled had no errors with respect to services provided, recipient eligibility, or provider qualifications.

However, 6 of the 150 sampled claims were not allowable because the claims had duplicate monthly payments. In these instances, a provider received two or more monthly payments on behalf of a single recipient in a single month, which resulted in a total payment amount that exceeded the approved monthly rate. Nebraska made 164 duplicate monthly payments during our audit period, which resulted in overpayments of \$22,484 (Federal share). Nebraska made these duplicate payments because its system edits did not always prevent it from paying total monthly amounts that exceeded the approved monthly rates to providers on behalf of these recipients.

Nebraska agreed with our recommendations that it refund \$22,484 (Federal share) in overpayments to the Federal Government and implement the necessary MMIS edits to prevent and detect duplicate payments.

New York Improved Its Monitoring of Its Personal Care Services Program But Still Made Improper Medicaid Payments of More Than \$54 Million (A-02-19-01016), December 2020

New York claimed Federal reimbursement for personal care services that did not comply with certain Federal and State requirements for 28 of the 100 sampled claims. Specifically, New York received reimbursement for personal care services for which there was: (1) no valid nursing or social assessment, (2) no independent medical review, (3) no valid physician's order or the order was not timely, (4) no documentation of services provided, and (5) no plan of care. Additionally, for some claims, the personal care aide who provided the associated services had not undergone a timely criminal history check or did not meet training requirements.

The unallowable claims occurred because New York's monitoring of the personal care services program was not adequate to ensure that services complied with Federal and State requirements. However, we noted that in 2017, New York made some improvements to its monitoring of the program.

On the basis of our sample results, we estimated that New York improperly claimed at least \$54.5 million in Federal Medicaid reimbursement for personal care services during our audit period. In addition, the health and safety of some Medicaid beneficiaries may have been put at risk because their personal care aides had not undergone a criminal history check or did not meet training requirements.

New York did not specifically indicate concurrence or nonconcurrence with our recommendations that it refund \$54.5 million to the Federal Government, continue to improve its monitoring of local districts, and reinforce Medicaid requirements related to personal care services.

California Claimed at Least \$2 Million in Unallowable Medicaid Reimbursement for a Selected Provider's Opioid Treatment Program Services (A-09-20-02001), January 2021

California did not claim Medicaid reimbursement for the selected provider's OTP services in accordance with Federal and State requirements. Of the 100 sample items, 1 sample item was allowable, but 99 sample items had services that were unallowable. On the basis of our sample results, we estimated that California claimed at least \$2.4 million in unallowable Federal Medicaid reimbursement for OTP services during our audit period.

These deficiencies occurred because California's oversight activities did not ensure that OTP services met Federal and State requirements. We also identified deficiencies in two areas in which California could improve the quality of care provided to beneficiaries receiving OTP services.

California agreed with our recommendations that it: (1) refund \$2.4 million to the Federal Government for unallowable OTP services furnished by the selected provider, (2) ensure that the selected provider complies with Federal and State requirements for providing and claiming

reimbursement for OTP services, (3) verify that the selected provider implements corrective action plans that were approved by California, (4) perform postpayment reviews to identify disallowances for OTP services that did not comply with State requirements, and (5) work with the selected provider to improve the quality of care provided to beneficiaries by correcting deficiencies.

Massachusetts Made at Least \$14 Million in Improper Medicaid Payments for the Nonemergency Medical Transportation Program (A-01-19-00004), January 2021

Massachusetts claimed Federal Medicaid reimbursement for 86 of 100 sampled lines of service submitted by transportation providers that did not comply with certain Federal and State requirements. The improper claims for unallowable services were made because the State's monitoring and oversight of the nonemergency medical transportation (NEMT) program did not ensure that NEMT services were for qualifying medical services and were adequately documented. In addition, for all 100 sample items, driver qualifications and vehicle inspection, registration, and maintenance policies or schedules were not adequately documented. On the basis of our sample results, we estimated that at least 758,847 Medicaid claims totaling \$14,142,730 (\$7,071,365 Federal share) did not comply with certain Federal and State regulations.

Massachusetts generally concurred with our recommendations, including that it: (1) refund \$7,071,365 to the Federal Government, (2) perform data matches to all claims billed on the day of an NEMT service to ensure that only NEMT claims are paid when there is a corresponding qualifying medical service, (3) work with its brokers to ensure that documentation contains all necessary elements to support the NEMT service, (4) evaluate opportunities to better monitor transportation services, and (5) work with its brokers to implement controls that ensure drivers and vehicles used to provide NEMT services can be directly and clearly traced to the correct driver qualifications and vehicle records.

Quality of Care, Safety, and Access

Aspects of Texas' Quality Incentive Payment Program Raise Questions About Its Ability To Promote Economy and Efficiency in the Medicaid Program (A-06-18-07001), December 2020

Certain aspects of Texas' Quality Incentive Payment Program (QIPP) raise questions about its ability to promote economy and efficiency in Medicaid. Specifically: (1) nursing facilities received less than half of the earned incentive payments, (2) nursing facilities participating in QIPP generally rated below average in overall quality, (3) nursing facilities that declined in performance continued to receive quality improvement incentive payments, and (4) two local government entities participating in QIPP funded \$1.3 million (\$737,944 Federal share) of the non-Federal share of QIPP payments through intergovernmental transfers (IGTs) financed by means of debt instruments.

QIPP provides some incentives for nursing facilities to improve the quality of resident care. However, the results of our audit suggest that further analysis of the program is warranted.

We recommended that CMS: (1) work with Texas to determine whether the source of IGTs and the practice of using debt instruments to fund the non-Federal share of QIPP payments meets program objectives and promotes economy and efficiency in Medicaid and (2) reevaluate Texas' QIPP to ensure that it operates in a manner that meets program objectives while promoting economy and efficiency in Medicaid. Texas did not concur with our first recommendation but did concur with our second recommendation.

Risk Assessment Puerto Rico Medicaid Program (A-02-20-01011), December 2020

To fulfill OIG's responsibilities under P.L. No. 116-94, we conducted a high-level risk assessment of Puerto Rico Medicaid program controls and processes. Our approach included interviewing program officials from the various units that administer the Puerto Rico Medicaid program and reviewing documents that they provided.

We identified program integrity, beneficiary eligibility, provider enrollment, overpayment reporting, and contracting as key areas at high risk for improper Medicaid program payments. In addition, we determined that the risk of improper Medicaid program payments in Puerto Rico could be increased because there have been no recent reviews of Puerto Rico Medicaid program payments performed by CMS, and because Puerto Rico's MMIS has not been fully implemented. Finally, we identified one area (program management) at moderate risk for improper Medicaid program payments due to limitations in staff hiring and training.

Based on the results of our high-level risk assessment, we determined that to protect Federal funds by identifying inaccurate program payments, audits of Puerto Rico's Medicaid program are warranted. We have used the results of this assessment to set priorities for performing these audits. We plan to initiate two audits in FY 2021 related to potentially improper payments. Specifically, we will determine whether Puerto Rico improperly claimed Medicaid reimbursement for payments on behalf of deceased beneficiaries and beneficiaries assigned multiple Medicaid identification numbers.

Iowa Should Improve Its Oversight of Selected Nursing Homes' Compliance With Federal Requirements for Life Safety and Emergency Preparedness (A-07-19-03238), February 2021

Iowa did not ensure that selected nursing homes in the State that participated in the Medicare or Medicaid programs complied with CMS requirements for life safety and emergency preparedness. During our onsite inspections, we identified deficiencies in areas related to life safety and emergency preparedness at all 20 nursing homes we reviewed. We found 122 instances of noncompliance with life safety requirements and 133 instances of noncompliance with emergency preparedness requirements. As a result, residents at the 20 nursing homes were at increased risk of injury or death during a fire or other emergency.

The identified areas of noncompliance occurred because Iowa did not have a standardized life safety training program for all staff (not currently required by CMS). In addition, Iowa did not adequately follow up on deficiencies previously cited or require nursing homes or inspection contractors to: (1) tag systems that are critical to the health and safety of nursing home residents when these systems may not work as required and (2) notify the State.

Iowa agreed with our recommendations that it: (1) follow up with the 20 nursing homes to ensure that corrective actions have been taken regarding the deficiencies identified in this report, (2) work with CMS to develop standardized life safety training for nursing home staff, and (3) conduct more frequent surveys and followup at nursing homes with a history of multiple high-risk deficiencies. Iowa disagreed with our recommendation that it require nursing homes to tag deficient critical systems.

New York Did Not Fully Comply With Federal and State Requirements for Reporting and Monitoring Critical Incidents Involving Medicaid Beneficiaries With Developmental Disabilities (A-02-17-01026), February 2021

New York did not ensure that providers fully complied with Federal waiver and State requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities residing in community-based settings. Of the 30 incidents of potential abuse and neglect in our sample, 23 incidents were properly reported and investigated; however, 7 incidents were not. Because incidents of potential abuse and neglect were not properly reported or investigated, beneficiaries were put at an increased risk of harm.

Of the 48 reported and substantiated incidents of abuse and neglect in our judgmental sample, we found that the associated providers complied with the critical incident reporting and monitoring requirements.

New York agreed with our recommendations that it: (1) reinforce guidance to the provider community on various specific requirements related to the reporting and investigating of critical incidents; (2) issue guidance and/or provide training to the provider community on the importance of identifying the root cause of an incident, and identifying trends in incidents; and (3) review the three internal occurrence investigations identified in our report for compliance with investigative requirements, and make any necessary changes to the incident classifications in accordance with Part 624.

CMS Use of Data on Nursing Home Staffing: Progress and Opportunities To Do More (OEI-04-18-00451), March 2021

CMS has taken important steps to build and use a new data source for information on nursing home staffing, but CMS has opportunities to better leverage this information. Our findings can help CMS identify ways to better inform consumers and improve oversight of staffing in nursing

homes. CMS concurred with all four of our recommendations. Our recommendations were for CMS to:

- provide data to consumers on nurse staff turnover and tenure, as required by Federal law;
- ensure the accuracy of non-nurse staffing data used on Care Compare;
- consider residents' level of need when identifying nursing homes for weekend inspections; and
- take additional steps to strengthen oversight of nursing home staffing.

Data on Medicaid Managed Care Payments to Providers Are Incomplete and Inaccurate, (OEI-02-19-00180), March 2021

Effective oversight of Medicaid requires a national system with complete and accurate data. CMS established the T-MSIS for this purpose. Payment data are a critical component of T-MSIS. These data include the amounts paid, billed, and allowed for every service provided to Medicaid enrollees, including those services provided through managed care. CMS did not concur with any of our recommendations, which were to:

- review States' managed care payment data in T-MSIS and ensure that States have corrective action plans to improve data completeness and quality, as appropriate;
- make public its reviews of States' managed care data; and
- clarify and expand its initiative on payment data.

Florida Did Not Ensure That Nursing Facilities Always Reported Allegations of Potential Abuse or Neglect of Medicaid Beneficiaries and Did Not Always Assess, Prioritize, or Investigate Reported Incidents (A-04-17-08058), March 2021

Florida did not ensure that nursing facilities always reported potential abuse or neglect of Medicaid beneficiaries transferred from nursing facilities to hospital emergency departments. Additionally, we could not determine whether Florida complied with Federal requirements for assigning a priority level, initiating onsite surveys, and recording allegations of potential abuse or neglect. Lastly, Florida's incident report program may not have been effective in accomplishing the program's goal and objectives. Certain internal control deficiencies and practices could limit the effectiveness of Florida's complaint and incident program. Specifically, Florida: lacked written policies and procedures for processing incident reports, had inadequate intake staffing, had inadequate incident report processing, lacked written policies and procedures for managing late incident report filings, and lacked written policies and procedures for managing APS abuse and neglect investigation notifications.

Florida generally concurred with our recommendations that it: (1) work with CMS to provide clear guidance to nursing facilities regarding what constitutes a reportable incident, (2) establish procedures to require assessment start and end dates and priority level assignments, and (3)

establish and implement written policies and procedures for incident report processing. We made further recommendations to improve the effectiveness of the complaint and incident report process.

Drug Pricing and Reimbursement

Massachusetts Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs (A-06-18-04001), October 2020

Massachusetts did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Massachusetts did not invoice manufacturers for rebates associated with \$11.4 million (Federal share) in physician-administered drugs. Of this amount, \$10.5 million was for single-source drugs, and \$883,000 was for top-20 multiple-source drugs. Of the \$11.4 million, \$9.7 million was related to claims identified as hospital outpatient. Massachusetts did not invoice for rebates for any physician-administered drug claims identified as hospital outpatient claims. In addition, some claims identified as physician claims were not invoiced for rebates. Because Massachusetts' internal controls did not always ensure that it invoiced manufacturers to secure rebates, Massachusetts improperly claimed Federal reimbursement for these single-source drugs and top-20 multiple-source drugs.

Further, Massachusetts did not submit the utilization data necessary to secure rebates for all other physician-administered drugs. Providers submitted claims totaling \$4.2 million (Federal share) that did not have National Drug Codes (NDCs) or had invalid NDCs. Furthermore, under the Medicaid drug rebate program, claims totaling \$782,917 (Federal share), which contained NDCs, could have been eligible for rebates.

Massachusetts partly agreed with our recommendations that it: (1) refund to the Federal Government \$10.5 million (Federal share) for claims for single-source physician-administered drugs that were ineligible for Federal reimbursement; (2) refund to the Federal Government \$882,892 (Federal share) for claims for top-20 multiple-source physician-administered drugs that were ineligible for Federal reimbursement; and (3) work with CMS to determine the proper resolution of the other claims in question, \$4.9 million Federal share. We also made procedural recommendations.

Minnesota Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations (A-05-17-00018), October 2020

Minnesota did not fully comply with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to managed care organization (MCO) enrollees. Minnesota did not bill for and collect manufacturers' rebates that we calculated to be \$6.1 million (Federal share). Specifically, it did not bill for and collect manufacturers' rebates that we calculated to be (1) \$5.9 million (Federal share) for pharmacy drugs and for single-source and top-20 multiple-source

physician-administered drugs that were eligible for rebates and (2) \$173,780 (Federal share) for physician-administered drugs that may have been eligible for rebates. Minnesota did not always bill for and collect manufacturers' rebates because Minnesota and its contractor did not identify all of the rebate-eligible drugs in the utilization data submitted by the MCOs.

Minnesota agreed with our recommendations that it: (1) bill for and collect manufacturers' rebates for pharmacy drugs and for single-source and top-20 multiple-source physician-administered drugs that we calculated to be \$5.9 million (Federal share) and refund the Federal Government and (2) work with CMS to determine whether the non-top-20 multiple-source physician-administered drugs were eligible for rebates that we calculated to be \$173,780 (Federal share) and, if so, upon receipt of the rebates, refund the Federal share. We also made a recommendation related to pharmacy and physician-administered drugs that were not billed for rebates after our audit period and a procedural recommendation to ensure that all rebate-eligible drugs are properly identified and billed for rebate.

Opioids in Medicaid: Concerns About Opioid Use Among Beneficiaries in Six Appalachian States in 2018 (OEI-05-19-00410), December 2020

We found that across 6 Appalachian States in 2018, nearly 6,000 Medicaid beneficiaries received potentially harmful amounts of opioids; more than 450 of these beneficiaries were at serious risk of opioid misuse or overdose; and 19 prescribers stood out in their prescribing of opioids to beneficiaries at serious risk. The COVID-19 pandemic may be putting beneficiaries at greater risk of opioid misuse or overdose in 2020 and beyond. OIG is committed to fighting the opioid crisis and protecting beneficiaries from prescription drug abuse and misuse. As part of this commitment, OIG is working with our law enforcement partners to bring resources and expertise to these six States through the Appalachian Regional Prescription Opioid Strike Force.

States Could Do More To Oversee Spending and Contain Medicaid Costs for Specialty Drugs, (OEI-03-17-00430), December 2020

Overall, State Medicaid programs—FFS programs and Medicaid MCOs—used over 100 distinct criteria to categorize thousands of drugs as specialty drugs. Further, States reported limited oversight of their Medicaid MCOs' management of specialty drug categorization and spending. These findings indicate that as more expensive specialty drugs enter the market, CMS and States may not be using all available tools to contain rising expenditures for specialty drugs in their Medicaid programs. CMS concurred with our first and third recommendations and did not concur with our second recommendation. Our recommendations were for it to:

- work with States to expand alternative reimbursement models to address the rising costs for drugs often categorized as specialty drugs;
- provide States with acquisition cost data for a wider range of specialty drugs; and

- collaborate with States to conduct greater oversight of Medicaid MCOs' management of specialty drugs; this oversight could include a review of contract language that allows States to obtain requested information on specialty drug categorizations, specialty drug reimbursement methodologies, and cost management strategies from the MCOs.

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 213 criminal and 261 civil actions against individuals or entities who engaged in offenses related to health care. We also reported over \$799.4 million in investigative receivables due to HHS and more than \$568.2 million in non-HHS investigative receivables, including civil and administrative settlements or civil judgments related to Medicare, Medicaid, and other Federal, State, and private health care programs.

Criminal and Civil Enforcement Activities Related to Medicare and Medicaid

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

Ambulance Transportation Company

The following case example involves an ambulance transportation company:

New York—On December 16, 2020, Aleksandr Radinovskiy was sentenced to 24 months in prison, followed by 24 months of probation, and ordered to pay \$10,650,670 in restitution. Radinovskiy pleaded guilty to one count of conspiracy to offer and pay health care kickbacks, and one count of conspiracy to defraud the lawful functions of the IRS. Radinovskiy and his father, Igor Radinovskiy, participated in a conspiracy in which they paid more than \$8.6 million in kickbacks to co-conspirator companies not enrolled in the Medicaid program for the referral of beneficiaries recruited by those co-conspirators, so that Sabe Ambulette Services (Sabe) could falsely bill Medicaid as if Sabe had transported those beneficiaries to various clinics in Brooklyn and Queens. The defendants then falsely reported to the IRS that the illegal kickback payments were legitimate business expenses, which caused relevant tax forms to falsely under-report business income and claim deductions.

Physical Therapy

The following case example involves physical therapy:

Georgia—On December 15, 2020, physical therapy provider McLeod-Hughes and Associates, LLC, and its owner Barry McLeod-Hughes, agreed to pay \$506,811 to resolve allegations that it violated the False Claims Act by submitting bills to the Medicare and TRICARE programs for physical therapy services provided by unlicensed, uncredentialed or otherwise unapproved individuals. Additionally, McLeod-Hughes has voluntarily agreed to be excluded as a provider from Medicare and other Federal health care programs. Federal health care programs, such as Medicare and TRICARE, allow services to be provided and billed only by certain licensed and approved providers and only under certain circumstances.

The alleged scheme resolved by the settlement concerned McLeod-Hughes's submission of claims to Medicare and TRICARE for physical therapy services purportedly provided by approved providers when, in fact, athletic trainers and other unlicensed, uncredentialed, or otherwise unapproved individuals furnished the physical therapy services.

Pharmaceutical Companies

The following case example involves pharmaceutical companies:

Massachusetts—On December 17, 2020, Cambridge-based pharmaceutical company, Biogen Inc. agreed to pay \$22 million to resolve allegations that it violated the False Claims

Act by illegally using two foundations, the Chronic Disease Fund (CDF) and the Assistance Fund (TAF), as conduits to pay the Medicare copayments for patients taking Biogen's multiple sclerosis drugs, Avonex and Tysabri. Advanced Care Scripts (ACS), a specialty pharmacy that performed services for Biogen, has also agreed to pay \$1.4 million to resolve allegations that it conspired with Biogen to enable Biogen to use CDF and TAF as conduits for Biogen to pay Medicare copayments for Avonex and Tysabri patients. In separate settlements in late 2019, CDF paid \$2 million and TAF paid \$4 million to resolve allegations concerning their respective roles in enabling certain pharmaceutical companies to pay kickbacks to Medicare patients.

As part of the settlements, the Government alleged that Biogen, acting with ACS's help, used CDF and TAF, each of which claimed status as nonprofit organizations for tax purposes, as conduits to pay the copayment obligations of thousands of Medicare patients taking Avonex and Tysabri. The Government specifically alleged that in 2011, Biogen identified Medicare-eligible Avonex patients in Biogen's free drug program, and arranged for ACS to transfer those patients from the Biogen free drug program to CDF, so that CDF could cover those patients' Medicare copayments and the patients' purchase of Avonex would generate Medicare revenue for Biogen. Biogen then paid CDF, and ACS promptly sent CDF batch files of copayment assistance applications for Medicare-eligible Avonex patients who had been receiving the free drug from Biogen. CDF subsequently approved most of those applications and covered the costs of those patients' Medicare copayments for Avonex.

Durable Medical Equipment Companies

The following case examples involve durable medical equipment (DME) companies:

New York—On December 21, 2020, Apria Healthcare Group, Inc., and its affiliate, Apria Healthcare LLC (Apria), entered into a settlement agreement under which it agreed to pay \$40.5 million to resolve allegations that Apria submitted false claims to Federal health programs, including Medicare and Medicaid, seeking reimbursement for the rental of costly non-invasive ventilators ("NIVs") to program beneficiaries who were not using the NIVs, making them not medically necessary, in addition to the improper waiver of patient co-insurance payments.

According to court documents, Apria decided in 2014 to prioritize the expansion of its NIV rental business because health care programs like Medicare paid as much as \$1,400 per month to cover NIVs, a type of complex respiratory equipment that can dynamically adjust the pressure level of air delivery. That expansion, however, came at the cost of Apria's compliance with the basic medical necessity requirement of Federal health programs. Specifically, while Apria knew that it was responsible for monitoring patients' utilization of their NIVs and to stop billing when NIVs were no longer being used, it did not have enough

respiratory therapy staff to conduct such monitoring. As a result, Apria routinely billed Medicare and other programs when it did not know whether NIVs were still being used by patients, which would have made their use medically necessary. Further, even when Apria had information indicating that patients were no longer using their NIVs, it often continued to bill the Federal health programs.

In connection with this settlement, Apria also entered into a CIA with HHS-OIG, which requires Apria to implement board oversight, a claims review process by an Independent Review Organization, and other compliance steps designed to foster adherence to Federal health care program requirements and thereby protect the programs.

New York—On November 23, 2020, Etienne Allonce, the former co-owner of Medical Solutions Management, Inc. (MSM), a DME supplier in Hicksville, New York, was sentenced to 36 months in prison for health care fraud and ordered to pay \$4,444,468 in restitution. Between April 2003 and March 2007, Allonce, along with his wife and MSM co-owner Michel Allonce, submitted approximately \$10 million in false claims to Medicare and Medicaid, seeking payment for medical supplies never ordered by MSM and never delivered to patients at nursing homes. Etienne Allonce fled the United States just hours before Federal agents arrested his wife in 2007. In September 2018, Allonce was expelled from Haiti where he had fled shortly before his indictment in the Eastern District of New York 11 years earlier. Prior to his return to the United States, Allonce was placed on HHS-OIG's Most Wanted List.

Pharmacies

The following case examples involve pharmacies:

New York—On October 23, 2020, Sajid Javed, an owner and operator of a number of pharmacies in the New York City area, was sentenced to 30 months in prison for using his pharmacies to submit more than \$7.1 million in fraudulent claims to Medicare and Medicaid. Javed was ordered to pay restitution in the amounts of \$6,040,451.32 to Medicare and \$1,150,562.16 to Medicaid. While owning and operating pharmacies located in Brooklyn and Queens, Javid conducted a multimillion-dollar scheme to defraud Medicare and Medicaid programs by seeking reimbursement for prescription drugs that were not distributed to customers. Specifically, from January 2013 through December 2014, Javed obtained more than \$7.1 million in reimbursements from Medicare and Medicaid for prescription drugs that his pharmacies never actually dispensed to customers. Javed defrauded Medicare and Medicaid into providing him with these reimbursements by obtaining prescriptions from other individuals who were willing to forego delivery of the medications in exchange for a share of the reimbursed proceeds, in the form of kickbacks. Javed offered to pay, and did actually pay, kickbacks in furtherance of this scheme.

Prescription Drugs

The following case example involves prescription drugs:

New York—On October 15, 2020, Dr. Eugene Gosy was sentenced to 70 months in prison and 3 years of supervised release, and ordered to pay \$344,562.65 in restitution to his victims, including Medicare. The sentence was the result of Dr. Gosy's guilty plea, entered on January 7, 2020, in which he pleaded guilty to one count of conspiracy to unlawfully distribute controlled substances and one count of health care fraud.

In carrying out the conspiracy, Dr. Gosy and his employees issued more prescriptions for controlled substances annually than any other prescriber or prescribing entity in New York State, including hospitals. Specifically, Dr. Gosy and his employees carried out their conspiracy by: (1) prescribing controlled substances without conducting a physical examination and/or after conducting only a limited and inadequate physical examination; (2) prescribing controlled substances in ways that were likely to cause, and did cause, dependence and addiction, and that contributed to existing addictions; (3) issuing prescriptions for controlled substances in dosages and/or in combinations dangerous to the health and safety of the patient; (4) issuing prescriptions for controlled substances despite indications that patients were abusing and misusing the prescribed controlled substances; (5) issuing prescriptions for controlled substances to patients despite knowing that such patients had overdosed or had otherwise been hospitalized for conditions relating to misuse of controlled substances; (6) continuing to prescribe controlled substances in the same manner, and failing to adapt practices to prevent additional deaths and overdoses, despite having notice that the treatment they were following had resulted in obvious drug-seeking behavior and addiction, numerous patient overdoses, and patient deaths; (7) signing death certificates in the absence of an autopsy or medical examination for deceased patients to whom Gosy and/or his employees had prescribed controlled substances despite aberrant behaviors; and (8) recommending a course of treatment, including the prescribing of controlled substances, which caused the death of at least six individuals, and contributed to the deaths of others.

Kickbacks

The following case example involves kickbacks:

Wisconsin—On January 11, 2021, AutoGenomics, Inc., entered into a settlement agreement under which it agreed to pay \$2,538,000 to resolve allegations that it violated the False Claims Act and anti-kickback statute by engaging in a scheme to bill Medicare for molecular genetic testing performed for nursing home patients that were induced by the payment of remuneration, or “kickbacks,” for the referral of those genetic tests.

AutoGenomics, located in Carlsbad, California, formerly owned and operated a laboratory doing business as PersonalizeDx Labs (collectively “AutoGenomics”). In April 2013 and March 2015, AutoGenomics entered into agreements with a California-based health care marketing company to utilize AutoGenomic’s laboratory services for tests ordered by the health care marketing company’s clients. Pursuant to these agreements, AutoGenomics paid the health care marketing company a specified monetary kickback for each test that was reimbursed by Medicare, but only if Medicare paid the claim. Under these agreements, the amount of the kickback was based on either a percentage or fixed amount of Medicare’s reimbursement for each test.

Electronic Health Records

The following case example involves electronic health records (EHRs):

Massachusetts—On January 28, 2021, athenahealth, Inc. (Athena), a developer of EHR services, agreed to pay \$18.25 million to resolve allegations that it violated the False Claims Act (by paying illegal kickbacks to generate sales of its EHR product, athenaClinicals). The United States alleged that Athena violated the False Claims Act and the anti-kickback statute through three marketing programs. First, Athena allegedly invited prospects and customers to all-expenses-paid sporting, entertainment, and recreational events. The most lavish of these events, such as “bucket list” trips to the Masters Tournament and the Kentucky Derby, included complimentary travel along with luxury accommodations, meals, and alcohol. Second, Athena allegedly paid illegal fees to its customers through its “Lead Generation” program designed to identify new prospective customers. Under this program, Athena paid up to \$3,000 per physician who signed up for Athena services, regardless of how much time (if any) the client spent speaking or meeting with the lead. Finally, it is alleged that Athena entered into deals with competing companies that had decided to discontinue their health IT products. Pursuant to those agreements, known as “Conversion Deals,” the other companies agreed to refer their clients to Athena, and Athena paid competitors based on the value and volume of practices that were successfully converted into Athena customers. As a result of these kickbacks, it is alleged that Athena improperly generated sales for itself while causing health care providers to submit false claims to the Federal Government related to incentive payments for adoption and “meaningful use” of Athena’s EHR technology.

Hospice

The following case example involves a hospice:

Texas—On February 3, 2021, Henry McInnis, the CEO of a Texas-based group of hospice and home health entities, was sentenced to 15 years in prison for falsely telling thousands

of patients with long-term incurable diseases that they had less than 6 months to live, in order to enroll the patients in hospice programs for which they were otherwise unqualified, thereby increasing revenue to the company. In November 2019, McInnis was convicted by a Federal jury in Brownsville, Texas, of one count each of conspiracy to commit health care fraud, conspiracy to commit money laundering, and obstruction of justice; as well as six counts of health care fraud. McInnis's co-conspirator, Rodney Mesquias, 50, the owner of the hospice and home health entities, was also convicted following the November 2019 trial. Mesquias was sentenced to 20 years in prison in December 2020. Two other co-conspirators have pleaded guilty and are awaiting sentencing.

From 2009 to 2018, McInnis, Mesquias and others orchestrated a scheme that involved the submission of over \$150 million in false and fraudulent claims for hospice and other health care services. McInnis served as the top corporate officer and administrator and oversaw the day-to-day operations of the Merida Group, a large health care company that operated dozens of locations throughout Texas. McInnis also oversaw and enforced a companywide practice of falsifying medical records to conceal the scheme. Multiple witnesses testified that McInnis ordered employees to alter medical records to make it appear that patients were terminally ill, while in reality some patients were employed or even participating in sporting events. As CEO, McInnis also adopted a policy that paid illegal kickbacks. They directed bribes to physicians under the guise of medical director fees to certify unqualified patients for hospice and home health. In some cases, they improperly offered payoffs to marketers in exchange for recruitment of patients who could be placed on extremely expensive hospice services.

Medicare Fraud Strike Force Activities

In 2007, Medicare Fraud Strike Force teams began an effort to combine resources of Federal, State, and local law enforcement entities to prevent and combat health care fraud, waste, and abuse. These partnerships among OIG and HHS, DOJ, U.S. Attorneys' Offices, FBI, and State and local law enforcement have a common goal: to analyze health care fraud data and investigative intelligence to quickly identify fraud and bring prosecutions. Strike Force teams operate in the following areas: Miami and Tampa/Orlando, Florida; Dallas and Houston, Texas; McAllen/Rio Grande, Texas; Los Angeles, California; Detroit, Michigan; Brooklyn, New York; The Gulf Coast (Baton Rouge and New Orleans, Louisiana; Southern Mississippi); Chicago, Illinois; and Newark, New Jersey/Philadelphia, Pennsylvania; along with National Rapid Response Strike Force located in Washington, DC. During this semiannual reporting period, Strike Force efforts resulted in the filing of charges against 72 individuals or entities, 54 criminal actions, and more than \$207.0 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 examples involve Strike Force cases:

Florida—On November 13, 2020, Tania Rodriguez was sentenced to 30 months in prison and 24 months of supervised release and Rafael Vidal was sentenced to 18 months in prison and 24 months of supervised release for their roles in submitting false and fraudulent claims to Medicare. Rodriguez, the owner and operator of American United Pharmacy, and co-defendant Vidal were ordered to pay \$1,450,000 in restitution.

Rodriguez and Vidal participated in a conspiracy to use their company, American United Pharmacy Corp. of Miami, to offer and pay kickbacks for the referral of Medicare beneficiaries to their pharmacy, and to submit false and fraudulent claims to Medicare for prescription drugs that were not provided to Medicare beneficiaries. As a result, Medicare paid American United Pharmacy approximately \$1,450,000 that it was not entitled to receive.

Florida—On October 30, 2020, Sebastian Ahmed was sentenced to 210 months in prison and ordered to pay \$4,231,288 in restitution following his conviction, after a 6-week jury trial, of conspiracy to commit health care fraud and wire fraud, 5 counts of health care fraud, conspiracy to commit money laundering, and 11 counts of money laundering. As part of the scheme, the conspirators exploited vulnerable drug addicts; falsified paperwork; and entered into various kickback arrangements, all to receive millions of dollars of falsely and fraudulently obtained funds for their own personal use and benefit.

Ahmed was the CEO, president and CFO of the two substance abuse treatment centers: Jacob's Well and Medí MD; as well as a medical health clinic, Arnica Health, all of which he operated under the umbrella of Serenity Treatment Center, Serenity Living, and "Serenity Ranch Recovery" in Davie, Florida. Ahmed operated the three clinics from in or around June 2016 through May 2019. The Government emphasized at trial that defendant (1) engaged in illegal billing to private insurance plans through Jacob's Well prior to the clinic being certified by the Department of Children and Families (DCF) in February 9, 2017; (2) provided unlawful inducements to the approximately 500 patients consisting of free airline travel, housing, vapes, manicures, cash, and failure to collect patient responsibilities for copayments and deductibles; and (3) billed for medically unnecessary therapeutic services consisting of therapy and urine analyses, the former having not been provided but billed by defendant's substance abuse clinics. The patients were also permitted to reside in co-ed housing in which destructive sexual relationships, not conducive to real addiction treatment, formed—sometimes between the staff and patients, according to the testimony and evidence. From June 2016 through May 2019, the Government attributed approximately \$38 million in

fraudulent billing submitted by Ahmed’s clinics, which resulted in the reimbursement of over

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>.

Fugitives List

The OIG Fugitives website has greatly assisted in helping to capture fugitives charged with defrauding Federal health care programs and stealing millions of taxpayer dollars. The Fugitives website is continually updated and features a profile for each fugitive, a Most Wanted List, 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 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 \$19,292,750 as a direct result of cases originating from hotline complaints.

OIG Hotline Activity (10/1/20–3/31/21)

Contacts to 1-800-HHS-TIPS phone line, including callers seeking information	55,541
Total tips evaluated	18,262
Tips referred for action	9,732
Closed; no basis provided for further action	3,699

Closed; no HHS violation ¹	790
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Sources of tips referred for action

Phone	3,553
OIG website	4,676
Letters or faxes	556
Other	947

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.

¹ Some of the closed complaints in this reporting period may have been evaluated or referred for action in a previous reporting period.

Medicaid Fraud Control Units Fiscal Year 2020 Annual Report (OEI-09-21-00120), March 2021

This annual report provides statistics that highlight the accomplishments of the 53 MFCUs during FY 2020. MFCUs reported that the COVID-19 pandemic created significant challenges for MFCU staff, operations, and court proceedings. However, MFCUs reported taking steps to mitigate the effects of the pandemic and, despite challenges, continued to carry out their Medicaid program integrity functions in FY 2020. MFCUs reported 1,017 convictions in FY 2020. Fraud cases accounted for 76 percent of the MFCU convictions, while 24 percent involved patient abuse or neglect. Approximately 47 percent of the 774 MFCU fraud convictions involved personal care services attendants and agencies. MFCUs were responsible for 786 civil settlements and judgments, 33 percent of which involved pharmaceutical manufacturers. MFCUs reported \$1 billion in criminal and civil recoveries. In an appendix to the report, OIG summarizes beneficial practices identified by OIG in its reviews or inspections that may be useful to other MFCUs.

IG Reviews and Inspections of MFCUs

In addition to an annual recertification review of each MFCU, OIG conducts reviews and inspections 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:

Illinois Medicaid Fraud Control Unit: 2019 Onsite Inspection (OEI-06-19-00510), March 2021

IG Joint Casework With MFCUs

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

Missouri—On February 5, 2021, Denis Mikhlin was sentenced in Federal court to 108 months in prison and was ordered to pay \$181,665 in restitution. In August 2020, the 41-year-old resident of St. Louis County, Missouri, pleaded guilty to four felony counts of conspiracy, obtaining oxycodone and other opioid drugs by fraud and deceit, receiving illegal kickbacks in return for sending urine specimens to Central Diagnostic Laboratory for medically unnecessary testing, and causing the Medicare and Medicaid programs to pay \$4,704,568 for medically unnecessary services. Mikhlin conspired with Dr. Jerry Leech and others to issue and distribute illegal prescriptions for opioids and other controlled substances to patients. Mikhlin and his co-conspirators knew the patients did not have a legitimate medical need for drugs and instead were abusing the drugs or selling them. Additionally, Mikhlin recruited individuals and paid them for the use of their names on the fraudulent prescriptions. Once the prescriptions were filled, some of the drugs were returned to Mikhlin and the rest were kept by the individuals or sold to others. To conceal this illegal activity, Mikhlin and others created patient files, falsely indicating the patients had been examined by the prescribing doctors and were regularly monitored and tested. OIG investigated this case with the

FBI, Missouri Medicaid Fraud Control Unit, Missouri Attorney's General Office, and the Department of Defense.

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 19 requests for advisory opinions and issued 5 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 1,086 administrative sanctions in the form of program exclusions or administrative actions for alleged fraud or abuse or other activities that posed a risk to Federal health care programs and their beneficiaries.

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

Program Exclusions

During this semiannual reporting period, OIG excluded 1,036 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:

Texas—Anthony Mamboleo Nyakeo (Nyakeo), a certified nurse aide (CNA), was excluded under Section 1128(a)(4) for a minimum period of 75 years based on his conviction of two counts of aggravated sexual assault of an elderly or disabled person. While employed as a CNA of a licensed nursing home facility, Nyakeo sexually assaulted one of his patients. The victim suffered from dementia, was disabled, nonverbal, incontinent, and unable to feed herself, move on her own, or vocalize. The victim suffered significant injuries from the assault that required medical intervention and surgical repair. The Court sentenced Nyakeo to life imprisonment and ordered him to register as a sex offender.

Massachusetts—Insys Pharma, Inc. (Insys Pharma) is a pharmaceutical company that developed and owns a liquid formulation of fentanyl called Subsys. HHS-OIG excluded Insys Pharma for a minimum period of 5 years due to its conviction of five counts of Mail Fraud in the United States District Court for the District of Massachusetts. Beginning in August 2012 and continuing until June 2015, Insys paid bribes and kickbacks to certain practitioners as part of a scheme to defraud patients and insurers, including Medicare. Insys disguised the bribes and kickbacks as honoraria purportedly given for the practitioners' participation in the Insys Speaker Program (ISP). Participants in the ISP were rewarded with lucrative speaking opportunities based on the volume of Subsys prescriptions that they wrote and were removed from the program if they failed to prescribe a sufficient volume of Subsys. ISP events were often social gatherings at high-priced restaurants that involved no education or presentation about the drug. Often the events had no attendees at all, and Insys sales representatives were instructed by management to falsify the names of ISP attendees on sign-in sheets. The Court sentenced Insys to pay a criminal monetary penalty of \$2 million and to surrender \$28 million in forfeiture.

The following subjects were also excluded for convictions related to the Insys Pharma scheme:

Massachusetts—John N. Kapoor (Kapoor) was excluded for a minimum period of 58 years based on his conviction of Racketeering Conspiracy by the United States District Court for the District of Massachusetts. Kapoor was the founder, owner, and sole investor of the parent company of Insys Pharma, Insys Therapeutics, Inc. (Insys). Kapoor also held executive management positions at Insys, including executive chairman of the board of directors and chief executive officer. From approximately May 2012 to December 2015, Kapoor directed, approved, and participated in the scheme to bribe and pay kickbacks to targeted medical practitioners and increase Subsys sales through fraud. Kapoor directed his co-conspirators to closely monitor ISP participating practitioners for "return on investment" by comparing the amount of speaker honoraria paid to each individual speaker versus the net revenue generated by the speaker. Kapoor also pressured Insys employees to mislead insurers to obtain payment authorization for illegal Subsys

prescriptions. The Court sentenced Kapoor to 66 months of incarceration and ordered him to pay \$59,755,362.45 in restitution.

Massachusetts—Michael L. Babich (Babich), who held executive management positions including vice president and CEO of Insys, was excluded for a minimum period of 50 years due to his conviction for conspiracy and wire fraud. From approximately May 2012 to December 2015, Babich conspired with other high-level officials at Insys to increase profits in connection with the sale of Subsys by providing kickbacks and bribes to medical practitioners. By paying and concealing the kickbacks and bribes, Babich fraudulently caused insurers, including Medicare and Medicaid, to pay for prescriptions and dosage increases that the insurers otherwise would not have agreed to pay. The Court sentenced Babich to 30 months of incarceration and ordered him to pay \$59,755,362.45 in restitution.

Massachusetts—Alec Burlakoff (Burlakoff) held executive management positions including regional sales manager for the Southeast Region and Vice President of Sales for Insys Therapeutics, Inc. (Insys). OIG excluded Burlakoff for a minimum period of 50 years due to his conviction of racketeering conspiracy. From approximately May 2012 to December 2015, Burlakoff played a key role in implementing the scheme whereby Insys would pay bribes and kickbacks to increase sales of Subsys. Burlakoff closely monitored the amount of Subsys being prescribed by each practitioner, and intentionally chose to bribe practitioners known to abusively prescribe opioid medication. Burlakoff also pressured his sales staff to advocate for higher doses of Subsys. The Court sentenced Burlakoff to 26 months of imprisonment and ordered him to pay \$59,755,362.45 in restitution.

Suspensions and Debarments

Suspensions and debarments are administrative tools used by HHS and other Federal agencies to protect the Government from individuals and entities who 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 who have potentially engaged in grant or contract fraud or misconduct to the HHS Suspension and Debarment Official, who is responsible for determining whether to impose a suspension or debarment. OIG continues to develop a robust Suspension and Debarment program and uses this tool to protect Government programs against fraud, waste, poor performance, and noncompliance with contract provisions or applicable law.

The following case example involves debarment:

Nebraska—Tillie Aldrich, a general member of the Tribal Council of the Omaha Tribe of Nebraska, directly and indirectly misrepresented the level of her involvement in the preparation of the claims submitted to IHS for unpaid contract support. Aldrich made a proposal to the Tribal Council for authorization of unreasonable bonus or incentive payments in which the proposal also include unreasonable bonus or incentive payment amounts to be paid to members of the Tribal Council and others to induce the Tribal Council to approve the proposal. Aldrich also caused checks to be prepared and issued in-house from the Carl T. Curtis Health Education Center account without going through the normal review and issuance procedure the Omaha Tribe had established with Bland and Associates. As a result, Aldrich pleaded guilty and received 5 years of probation and was ordered to pay \$13,404.44 in restitution.

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 \$32 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:

Texas—William Rosellini, Nexeon Medsystems, Inc., Pulsus Medical, LLC, and Nexeon Medsystems Puerto Rico Operating Company, Inc. (collectively, “Nexeon”), entered into a settlement agreement with OIG in which they agreed to pay \$50,000 and be excluded from participation in all Federal health care programs for 5 years under 42 U.S.C. 1320a-7a and 42 U.S.C. 1320a-7(b)(7). The settlement agreement resolves allegations that Nexeon drew down funds from the HHS Payment Management System from NIH Small Business Innovation Research (SBIR) awards that were: (1) sent to an overseas affiliate without NIH approval, in violation of NIH SBIR requirements; (2) based on quotes and other potential costs that were never incurred; (3) commingled among various affiliates and used for unallowable costs unrelated to the NIH SBIR awards; and (4) not supported by adequate documentation to ensure that the funds were used for allowable costs in accordance with the terms and conditions of the awards. Simultaneous to the execution of the settlement

agreement, Nexeon entered into a Voluntary Debarment Agreement with the HHS Suspension and Debarment Official in which they agreed to accept 5-year debarments from participation in covered transactions.

Texas—Miguel Angel Molinas, M.D., and Miguel Angel Molinas, M.D., P.A (collectively, “Molinas”), entered into a settlement agreement with OIG in which they paid \$185,410.68 to resolve allegations that Molinas billed Medicare for specified Current Procedural Terminology (CPT) codes while Dr. Molinas neither performed nor supervised the services himself.

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:

North Carolina—Frye Regional Medical Center (FRMC) entered into a \$100,000 settlement agreement with OIG. The settlement resolved allegations based on the following facts: on January 10, 2016, B.R. came to FRMC’s emergency department complaining of chest pain, nausea, vomiting, and diarrhea. FRMC failed to perform an adequate screening exam, and B.R. waited 3 hours and 44 minutes in the waiting room while his symptoms worsened, with no treatment. B.R. left FRMC and went to another hospital. The second hospital diagnosed him with triple vessel disease, performed an emergency heart catheterization, and sent him back to FRMC for an urgent triple coronary bypass surgery. FRMC paid \$100,000, the maximum penalty, to resolve these allegations.

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 program 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 \$59.3 million in HHS receivables.

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

Massachusetts—After it self-disclosed conduct to OIG, Steward Holy Family Hospital, Inc. (Steward) paid \$6,952,847 for allegedly violating the CMPL. OIG alleged that Steward failed to maintain physician certifications, recertifications, and treatment plans for inpatient psychiatry services in violation of Medicare billing requirements. Steward retained a third-party contractor who was responsible for managing Steward’s inpatient psychiatric unit including maintaining proper medical records for the patients in the unit.

Virginia—After it self-disclosed conduct to OIG, Virginia Hospital Center Arlington Health System d/b/a Virginia Hospital Center (VHC), Virginia, paid \$6,050,628 for allegedly violating the CMPL, specifically, provisions of the CMPL applicable to physician self-referrals and kickbacks. OIG alleged that VHC paid remuneration to two medical groups in the form of office space, office staff, and services rendered under call coverage arrangements.

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 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 entities that fail to comply with the requirements of their CIAs.

The following case example involves CIA enforcement:

Tennessee—Effective January 20, 2021, OIG excluded Grace and Theophilus Egbujor (collectively, “the Egbujors”), for a period of 5 years based on a material breach of their CIA. On August 4, 2020, OIG issued a Notice of Material Breach and Intent to Exclude letter to the Egbujors after their failure to abide by a Departmental Appeals Board decision affirming the Administrative Law Judge’s order that they pay \$1,322,500 in stipulated penalties assessed under their CIA. The stipulated penalties were assessed as a result of their failure to repay overpayments identified by the independent review organization in

the second and third CIA annual reports. The Egbujors failed to respond to OIG’s Notice of Material Breach and Intent to Exclude and did not appeal the subsequent OIG Notice of Exclusion. The exclusions went into effect on January 20, 2021.

Public Health and Human Service Agency Reports and Reviews

Public Health Agency Reports and Reviews

Hospitals Reported That the COVID-19 Pandemic Has Significantly Strained Health Care Delivery: Results of a National Pulse Survey February 22–26, 2021 (OEI-09-21-00410), March 2021

In February 2021, hospitals reported that operating in “survival mode” for an extended period of time has created new and different problems than experienced earlier in the pandemic and exacerbated longstanding challenges in health care delivery, access, and health outcomes. Hospital administrators described difficulty balancing the complex and resource-intensive care needed for COVID-19 patients with efforts to resume routine hospital care. They reported that staffing shortages have affected patient care, and that exhaustion and trauma have taken a toll on staff’s mental health. Administrators detailed challenges associated with vaccine distribution efforts and concerns about vaccine hesitancy among staff and members of their communities. Additionally, many hospitals reported experiencing financial instability because of increased expenses associated with responding to a pandemic and lower revenues from decreased use of other hospital services. Hospitals indicated that many of the challenges were more severe for rural hospitals. Hospitals reported a range of strategies to address their challenges, and identified areas in which further government support could help as they continue responding to the pandemic. Beyond the immediate needs in responding to COVID-19, the pulse survey reveals longer-term opportunities for improvement to address challenges that existed before, and were exacerbated by, the pandemic.

Centers for Disease Control and Prevention

Although CDC Implemented Corrective Actions To Improve Oversight of the President’s Emergency Plan for AIDS Relief Recipients, Some Internal Control Weaknesses Remained (A-04-18-01010), December 2020

Our analysis of 21 prior audit reports on PEPFAR recipients identified the following trends in which recipients: (1) had either inadequate or no policies and procedures related to management of PEPFAR funds (19 of 21 reports), (2) did not comply or may not have complied with HHS regulations regarding value-added tax (18 of 21 reports), (3) had transactions that were either not

supported (16 of 21 reports) or unallowable (15 of 21 reports), (4) did not accurately report PEPFAR expenditures on the financial reports or did not file reports on time (11 of 21 reports), (5) did not have annual audits performed or submitted on time (9 of 21 reports), and (6) could not reconcile PEPFAR expenditures to amounts reported on their financial reports (7 of 21 reports).

In response to the six trends identified in our prior audits, CDC took action to improve its oversight of PEPFAR recipients. Finally, CDC had two internal control weaknesses in its post-award oversight that it did not adequately address in its in-country office Standard Operating Procedures (SOPs).

CDC officials concurred with our recommendations that CDC implement requirements for CDC in-country offices to have SOPs for Cooperative Agreement (CoAg) management and periodically review and update CDC in-country office SOPs for CoAg management.

Independent Attestation Review: Centers for Disease Control and Prevention Fiscal Year 2020 Detailed Accounting Report, Performance Summary Report for National Drug Control Activities, Budget Formulation Compliance Report, and Accompanying Required Assertions (A-03-21-00355), January 2021

Based on our review, we are not aware of any material modifications that should be made to CDC's Detailed Accounting Report and Performance Summary Report for FY 2020 and CDC's Budget Formulation Compliance Report for FY 2022 for them to be in accordance with the Office of National Drug Control Policy (ONDCP) Compliance Reviews Circular.

Indian Health Service

Few Patients Received High Amounts of Opioids from IHS-Run Pharmacies (OEI-05-18-00470), December 2020

Data show that few patients received high amounts of opioids from IHS-run pharmacies, and that IHS reported positive outcomes from opioid-related initiatives. However, IHS has opportunities to improve the efficiency of its opioid monitoring systems and IHS staff reported challenges in using State-run PDMPs and in tracking care outside of IHS. Our findings recognize IHS's efforts to address the opioid crisis. Our recommendations aim to enhance the efficiency of IHS's monitoring and reducing the challenges that staff reported in using State-run PDMPs effectively. IHS concurred with our recommendations, which included:

- Assess the costs and benefits of updating its EHR system with tools to support more automated monitoring.
- Request support from States and Federal partners to address challenges with State-run PDMPs.

Incidence of Adverse Events in Indian Health Service Hospitals (OEI-06-17-00530), December 2020

An estimated 13 percent of patients in IHS hospitals experienced adverse events and temporary harm events during stays in FY 2017, with higher rates of harm in smaller hospitals. Adverse events and temporary harm events indicate that a patient's care resulted in an undesirable clinical outcome not caused by underlying disease. Within our sample, harm events were more prevalent among older adults and labor and delivery patients, and about half of events were preventable. IHS concurred with all three of our recommendations, which are:

- Establish patient harm monitoring and reduction as a key priority of the Office of Quality.
- Effectively track and monitor patient harm events using an improved incident reporting system.
- Implement quality improvement plans to improve patient safety across IHS, including plans that focus specifically on smaller hospitals and patient groups at higher risk of harm.

Indian Health Service Facilities Made Progress Incorporating Patient Protection Policies, but Challenges Remain (OEI-06-19-00331), December 2020

In recent years, IHS had cases of health care providers abusing patients under facility care, including a pediatrician who was convicted of multiple counts of child sexual abuse. In early 2019, IHS updated its policies to prevent and address child sexual abuse by providers. In December 2019, OIG issued its first report in a two-part series examining IHS patient protection policies. The first report found that IHS had strengthened its patient protection policies, but there were gaps in coverage and IHS facilities were still early in implementation. This is the second report in that series, which found that most facilities had fully incorporated the agencywide requirements into their local policies but faced challenges in carrying out the policies and reported remaining barriers that may deter staff and patients from reporting patient abuse. IHS concurred with our recommendations, which are:

- Provide additional guidance and training to facilities on patient protection policies, including the role of law enforcement and the reporting process related to patient abuse.
- Improve the process and timeliness for conducting staff background investigations and notifying facilities when staff are approved.
- Examine and revise, as needed, the reporting structure in the policies and the incident reporting system to ensure that staff and patients can report abuse anonymously.
- Establish and enforce a deadline by which all facilities must fully incorporate the new requirements into their policies and procedures, and actively monitor facility adherence.

Instances of IHS Labor and Delivery Care Not Following National Clinical Guidelines or Best Practices (OEI-06-19-00190), December 2020

About half of the labor and delivery patients (27 of 48) included in our review of maternal care provided in IHS hospitals received care that did not follow national clinical guidelines (13 patients),

did not use best practices for blood loss estimation (8 patients), or included both concerns (6 patients) during their stays at IHS hospitals. IHS is taking steps to further improve the care provided to labor and delivery patients, and we believe this report provides the agency with information that will assist in this effort. IHS concurred with all three of our recommendations, which are:

- Assess IHS’s labor and delivery practices and consider practice improvements based on the findings of this assessment.
- Take steps to ensure that IHS providers employ best practices in diagnosing and treating postpartum hemorrhage.
- Encourage and support greater adoption of the Alliance for Innovation on Maternal Health’s “bundles” of maternal-safety best practices.

Independent Attestation Review: Indian Health Service Fiscal Year 2020 Detailed Accounting Report, Performance Summary Report for National Drug Control Activities, Budget Formulation Compliance Report, and Accompanying Required Assertions (A-03-21-00351), January 2021

Based on our review, we are not aware of any material modifications that should be made to IHS’s Detailed Accounting Report and Performance Summary Report for FY 2020 and IHS’s Budget Formulation Compliance Report for FY 2022 for them to be in accordance with the ONDCP Compliance Reviews Circular.

Although the Bemidji Area Office Had Adequate Procedures To Disburse Indian Health Service Funds, It Needs To Strengthen Its Procedures for Monitoring the Use of the Funds (A-05-18-00019), February 2021

IHS’s Bemidji Area Office (BAO) generally had adequate procedures to disburse IHS funds to programs. However, BAO’s procedures for monitoring the use of funds did not include: (1) routine reconciliations of amounts reported in the Uniform Financial Management System (UFMS) with amounts recorded in supporting documents, (2) monitoring and evaluating IHS Direct programs’ use of no-year Health Service funds carried forward by appropriation year and budget activity programs, and (3) evaluating IHS Direct programs’ use of current no-year Health Service funds.

IHS concurred with our recommendations that BAO establish procedures to: (1) reconcile IHS funds recorded in the UFMS on a regular schedule with amounts reported in supporting documents, such as worksheets and funding agreements; (2) monitor and evaluate IHS Direct programs’ use of no-year Health Services funds carried forward by appropriation year and budget activity program; and (3) evaluate IHS Direct programs’ use of current no-year Health Services funds.

National Institutes of Health

The National Institutes of Health Administered Superfund Appropriations During Fiscal Year 2019 in Accordance With Federal Requirements (A-04-20-04077), December 2020

During FY 2019, NIH administered Superfund appropriations in accordance with applicable Federal requirements. Specifically, NIH obligated and disbursed Superfund appropriations in accordance with Federal requirements and in similar proportions to prior years. In addition, the Institute's monitoring of Superfund grants generally ensured that grantees met requirements for financial, performance, and audit reporting. This report contains no recommendations.

Independent Attestation Review: National Institutes of Health Fiscal Year 2020 Detailed Accounting Report, Performance Summary Report for National Drug Control Activities, Budget Formulation Compliance Report, and Accompanying Required Assertions (A-03-21-00352), January 2021

Based on our review, we are not aware of any material modifications that should be made to NIH's Detailed Accounting Reports and Performance Summary Report for FY 2020 and NIH's Budget Formulation Compliance Reports for FY 2022 for them to be in accordance with the ONDCP Circular.

Human Services Agency Reports and Reviews

Administration for Children and Families

Office of Refugee Resettlement Ensured That Selected Care Providers Were Prepared To Respond to the COVID-19 Pandemic (A-04-20-02031), November 2020

The Office of Refugee Resettlement (ORR) ensured that the 11 facilities we selected for review followed ORR requirements in preparing for and responding to communicable diseases and were prepared to respond to the COVID-19 pandemic. Specifically, ORR provided detailed COVID-19-response guidance, encouraged telehealth visits, and updated the Unaccompanied Alien Children (UAC) Portal.

The 11 selected facilities that we reviewed were generally prepared to respond to an emergency event, such as the COVID-19 pandemic, in accordance with Federal guidance. Specifically, they had policies and procedures, the capability to quarantine COVID-19 cases in their facilities, and adequate personal protective equipment.

ORR officials stated that, since 2006, ORR has had a policy in place that required its facilities to prepare for and respond to a communicable disease outbreak; therefore, the facilities were generally able to quickly pivot to respond to the COVID-19 pandemic. This report contains no recommendations.

The Office of Refugee Resettlement Did Not Award and Manage the Homestead Influx Care Facility Contracts in Accordance With Federal Requirements (A-12-20-20001), December 2020

ORR did not award a \$341 million sole source contract to Comprehensive Health Service, LLC (CHS), in accordance with Federal regulations and did not effectively manage its HHS contracts for services provided at Homestead in accordance with Federal statutes, regulations, and HHS policies and procedures. Because ORR did not follow Federal regulations or effectively manage its contracts for services provided at Homestead, it: (1) did not receive the benefit of a full and open competition, such as potentially receiving higher quality services or services at a lower cost when it awarded a sole-source letter contract to CHS; (2) paid approximately \$67 million to operate Homestead fully staffed and equipped for nearly 3 months after the last child left Homestead; (3) increased the risk of approving invoices that were incorrect or for services not performed; and (4) made approximately \$2.6 million in overpayments to CHS.

ACF, commenting on behalf of ORR, generally agreed with our recommendations that it: (1) develop plans for upcoming service needs by using all available data and indicators to ensure that it adheres to Federal requirements and (2) recoup the \$2,581,157 overpayment of fixed fees from CHS. We also made several other recommendations related to establishing policies and procedures to better protect Federal funds and manage its contracts in accordance with Federal statutes, regulations, and HHS policies and procedures.

Virginia's Monitoring Did Not Ensure Child Care Provider Compliance With State Criminal Background Check Requirements at 8 of 30 Providers Reviewed (A-03-19-00253), February 2021

Virginia's monitoring process ensured provider compliance with State requirements related to criminal background checks at 22 of the 30 child care provider locations we reviewed but did not ensure provider compliance at the remaining 8 locations. In total, we found that 15 of the 377 household members and employees reviewed did not have a current and completed background check. By not ensuring that all child care staff members who supervised or had routine unsupervised contact with children had complete criminal background checks, Virginia potentially jeopardized the safety of children in its care.

Virginia concurred with our recommendations that it: (1) conduct all required criminal background checks for the 15 individuals in our sample who did not have the required checks at the time of our review; (2) revise State guidelines to specify that inspectors should use verified information, such as payroll data, from each child day center to determine which employees' criminal background checks must be reviewed; (3) revise State guidelines to increase the number of current employees that inspectors review at all child day centers to ensure provider compliance with criminal background check requirements; and (4) provide periodic training to providers to ensure they request required background checks.

ACF Cannot Ensure That All Child Victims of Abuse and Neglect Have Court Representation (OEI-12-16-00120), March 2021

Our findings demonstrate that ACF is neither supporting States in implementing CAPTA's requirement for court representatives for child victims of abuse and neglect, nor is ACF monitoring States' compliance with the requirement. As a result, ACF cannot ensure that all such victims have court representation to protect their best interests.

We recommend that ACF conduct oversight activities—seeking statutory authority as necessary—to identify, and proactively provide technical assistance to, States that may not appoint a court representative to every child victim. We also recommend that ACF proactively identify and address obstacles that States face in reporting complete and accurate data on court representatives. ACF did not explicitly concur or nonconcur with our recommendations. However, ACF asserted a lack of statutory authority to implement our recommendations and stated that our recommended approach is inconsistent with the structure of the CAPTA State grant program.

Health Resources and Services Administration

In Selected States, 67 of 100 Health Centers Did Not Use Their HRSA Access Increases in Mental Health and Substance Abuse Services Grant Funding in Accordance With Federal Requirements (A-02-19-02001), November 2020

Most health centers in the 30 States did not use their AIMS grant funding in accordance with Federal requirements and grant terms. In addition, HRSA did not effectively monitor health centers' progress toward meeting service expansion requirements and did not ensure that health centers spent their AIMS grant funds in accordance with grant requirements.

On the basis of our sample results, we estimated that 454 of 665 health centers did not use their AIMS grant funding in accordance with Federal requirements and grant terms. We also estimated that 125 health centers did not increase the total number of mental health and substance use disorder services patients, and that 99 health centers did not hire new staff or increase hours of existing staff within 120 days of their AIMS grant award. As a result, patients may not have received the services. In addition, we estimated that the health centers charged unallowable costs totaling nearly \$6 million and improperly allocated costs totaling \$10.9 million to their AIMS grants that could have been spent on AIMS-related purposes.

We made a series of recommendations to HRSA, including that it improve its monitoring of how health centers meet targets for future grant funding opportunities and charge expenditures to their HRSA grants. We also recommended that HRSA require the health centers to refund unallowable and improperly allocated costs to the Federal Government. HRSA generally concurred with our recommendations.

Drug Control Activities, Budget Formulation Compliance Report, and Accompanying Required Assertions (A-03-21-00354), January 2021

Our review identified that HRSA incorrectly asserted that its reported drug obligations were only actual obligations. This resulted in a deviation from the ONDCP Compliance Reviews Circular. Based on our review, except for this matter, we are not aware of any other material modifications that should be made to HRSA's Detailed Accounting Report and Performance Summary Report for FY 2020 and HRSA's Budget Formulation Compliance Report for FY 2022 for them to be in accordance with the ONDCP Compliance Reviews Circular.

Substance Abuse and Mental Health Services Administration

Opioid Treatment Programs Reported Challenges Encountered During the COVID-19 Pandemic and Actions Taken To Address Them (A-09-20-01001), November 2020

OTPs reported a variety of: (1) challenges they have encountered during the COVID-19 pandemic and (2) actions they have taken to address those challenges while ensuring the continuity of needed services and protecting the health and safety of their patients and staff.

The information in this report was gathered to support HHS's goal of reducing opioid morbidity and mortality and to help the Substance Abuse and Mental Health Services Administration (SAMHSA) by providing information on the impact that the COVID-19 pandemic has had on OTPs. This information was current when we conducted our interviews but may not represent all the challenges that OTPs have faced or the actions they have taken to address those challenges. We recognize that SAMHSA has taken actions to support OTPs as they work on the front lines to treat people diagnosed with opioid use disorders and to ensure the safety of the health care workforce. The information in this report provides SAMHSA and other decisionmakers (e.g., State and Tribal officials and other Federal agencies) with a national snapshot of OTPs' challenges and the actions they have taken to continue providing services during the pandemic.

SAMHSA described actions that it had taken after becoming aware of COVID-19's impact on operations for its behavioral health stakeholders, such as providing technical assistance and training during the pandemic.

New York Provided Projects for Assistance in Transition From Homelessness Grant Services to Ineligible Individuals and Did Not Contribute Any Required Non-Federal Funds (A-02-19-02006), December 2020

New York did not always comply with Projects for Assistance in Transition From Homelessness (PATH) program requirements. Specifically, 7 of the 50 consumers we sampled lived in permanent housing settings, and documentation in their case files did not indicate that they continued to need PATH services to prevent a recurrence of homelessness. In addition, New York did not meet its

funding obligation for non-Federal contributions to its PATH program and did not have written agreements with PATH providers, as required. Also, New York inaccurately reported the number of consumers enrolled in its PATH program and did not timely file its financial report to SAMHSA. Finally, New York had not performed the financial closeout of its PATH program and did not verify that funds were appropriately used by providers or that unused funds were returned to the Federal Government.

On the basis of our sample results, we estimated that 578 consumers (14 percent) were ineligible to receive PATH program services. Also, New York did not meet its funding obligation for non-Federal contributions, which resulted in the entire grant amount of \$4.2 million being unallowable.

New York disagreed with our recommendation that it refund the entire grant amount, totaling \$4.2 million, to the Federal Government. New York agreed with our procedural recommendations, including that New York ensure that PATH program services are only provided to eligible consumers.

Ohio Made Progress Toward Achieving Program Goals for Enhancing Its Prescription Drug Monitoring Program (A-05-18-00004), December 2020

We identified actions that Ohio has taken, using Federal funds for improving PDMPs, to achieve program goals of improving safe prescribing practices and preventing prescription drug abuse and misuse as of August 2019. Ohio also complied with Federal requirements for submitting its Federal Financial Report and Annual Performance Report and publicly reported the five CDC-directed indicators.

The Ohio Department of Health made improvements in its PDMP related to two required strategies of CDC's "Prescription Drug Overdose: Prevention for States" (PfS) program: (1) enhance and maximize a State PDMP and (2) implement community or insurer health system interventions aimed at preventing prescription drug overdose and abuse. It also made improvements in its PDMP related to the two optional PfS program strategies: (1) conduct policy evaluations to reduce prescription drug overdose morbidity and mortality and (2) develop and implement Rapid Response Projects.

Further, Ohio improved access and strengthened the State's PDMP using Substance Abuse and Mental Health Services Administration grant funding. Ohio's Board of Pharmacy (BoP) improved real-time access to PDMP data by integrating Ohio's PDMP with existing technologies such as EHRs to improve the ability of Ohio's PDMP to reduce the nature, scope, and extent of prescription drug abuse. BoP also strengthened Ohio's PDMP by providing resources to make the changes necessary to increase interoperability with other States' PDMPs.

Additionally, Ohio used the grant funds that we reviewed in accordance with Federal regulations. Therefore, we are making no recommendations.

Choctaw Nation of Oklahoma Made Progress Toward Meeting Program Goals During the First Year of Its Tribal Opioid Response Grant (A-07-20-04121), January 2021

The Choctaw Nation met some program goals for its Tribal Opioid Response (TOR) grant during the first grant year. Specifically, the Choctaw Nation met program goals in the areas of prevention and recovery. The Choctaw Nation also made progress toward meeting treatment program goals but encountered some challenges that prevented it from increasing the availability of MAT services for Tribal members within its health care system. The Choctaw Nation was unable to achieve one of its goals during the first grant year: to send a provider to a 12-month addiction and pain management fellowship to obtain credentialing as an Addiction Medicine Specialist. Although the Choctaw Nation was unable to establish MAT services by enrolling a provider in this addiction and pain management fellowship, the Tribe instead sent some of its current providers to become MAT waiver trained.

The Choctaw Nation generally complied with Federal cost principles when administering its TOR grant. However, during the first grant year the Choctaw Nation claimed a cost of \$2,405 to the TOR grant that was unallowable.

The Choctaw Nation did not directly agree or disagree with our recommendations, including that it refund unallowable costs of \$2,405 to the TOR grant. We also made procedural recommendations to the Choctaw Nation to train staff to identify contract costs that are allowable under Federal regulations and strengthen or establish policies and procedures regarding Tribal departmental responsibilities and staff access to contractual agreements.

Independent Attestation Review: Substance Abuse and Mental Health Services Administration Fiscal Year 2020 Detailed Accounting Report, Performance Summary Report for National Drug Control Activities, Budget Formulation Compliance Report, and Accompanying Required Assertions (A-03-21-00353), January 2021

Based on our review, we are not aware of any material modifications that should be made to SAMHSA's Detailed Accounting Report and Performance Summary Report for FY 2020 and SAMHSA's Budget Formulation Compliance Report for FY 2022 for them to be in accordance with the ONDCP Compliance Review Circular.

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, the 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 and PSC is not pursuing any settlement agreements 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 no criminal actions and court-ordered restitution and settlements.

Engaging the Public in Capturing Deadbeat Parents

Because of the success of OIG's Most Wanted Fugitives List, 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

HHS Made Some Progress Toward Compliance With the Geospatial Data Act (A-18-20-11500),
October 2020

HHS made some progress to comply with the GDA, but we identified certain covered agency responsibilities that HHS had yet to meet. Additionally, HHS had not maintained a departmentwide inventory of all geospatial data assets, as required by GDA section 759(b), and had not designated a senior agency official for geospatial information (SAOGI) in accordance with OMB guidance to Federal agencies.

These conditions occurred because of the lack of departmentwide oversight and coordination in HHS's implementation of geospatial-related responsibilities, requirements, policies, and activities. Additionally, the Department's senior agency officials were not aware of the GDA and HHS's responsibilities mandated by the GDA. These conditions contributed to HHS's noncompliance with the covered agency responsibilities established in the GDA.

As a result, HHS is susceptible to inefficient and ineffective management of geospatial assets, which increases the risk of inconsistent efforts or inability to minimize the costs to acquire, manage, share, and use geospatial data, expertise, technology, and services.

We recommended that HHS ensure that HHS and its components fully implement the covered agency's responsibilities found in GDA section 759(a), maintain an inventory of all geospatial data assets, and appoint an SAOGI. HHS did not concur or nonconcur with our recommendations. However, HHS indicated that it will take action to ensure compliance with the covered agency responsibilities established by the GDA.

Financial Statement Audit of the Department of Health and Human Services for Fiscal Year 2020 (A-17-20-00001), November 2020

Based on its audit, Ernst & Young found that the FY 2020 HHS consolidated balance sheets and the related consolidated statements of net cost and changes in net position and combined statements of budgetary resources were presented fairly, in all material respects, in conformity with U.S. generally accepted accounting principles. Ernst & Young was unable to obtain sufficient audit evidence for the amounts presented in the statements of social insurance as of January 1, 2020, 2019, 2018, 2017, and 2016, and the related statements of changes in social insurance amounts for the periods ended January 1, 2020, and 2019. As a result, Ernst & Young was not able to, and did

not, express an opinion on the financial condition of the HHS social insurance program and related changes in the social insurance program for the specified periods.

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

Report on the Financial Statement Audit of the Centers for Medicare & Medicaid Services for Fiscal Year 2020 (A-17-20-53000), November 2020

Based on its audit, Ernst & Young found that the FY 2020 CMS consolidated balance sheets and the related consolidated statements of net cost and changes in net position and combined statement of budgetary resources were presented fairly, in all material respects, in conformity with U.S. generally accepted accounting principles. Ernst & Young was unable to obtain sufficient audit evidence for the amounts presented in the statements of social insurance as of January 1, 2020, 2019, 2018, 2017, and 2016, and the related statements of changes in social insurance amounts for the periods ended January 1, 2020, and 2019. As a result, Ernst & Young was not able to, and did not, express an opinion on the financial condition of the CMS social insurance program and related changes in the social insurance program for the specified periods.

Ernst & Young also noted two matters involving internal controls with respect to the financial reporting: financial reporting processes and information systems controls. Also, during FY 2020, CMS was not in full compliance with the requirements of the Payment Integrity Information Act of 2019 or section 6411 of the Affordable Care Act.

U.S. Department of Health and Human Services Met the Requirements of the Digital Accountability and Transparency Act of 2014, With Areas That Require Improvement (A-17-20-54000), November 2020

Our performance audit determined that HHS complied with the reporting requirements of the Digital Accountability and Transparency Act of 2014 (DATA Act) as stipulated by OMB, the Council of the Inspectors General on Integrity and Efficiency, and Treasury. Although HHS met the reporting requirements, our performance audit determined that:

Although improvements with respect to the controls within HHS's IT infrastructure and financial systems have been made, we observed deficiencies related to access controls, configuration management, segregation of duties, and interface controls.

For the period of performance dates, we found discrepancies between File D2 and the supporting documents. HHS management indicated that a gap existed between the operating divisions' understanding of the standard interface file (SIF) creation process for these fields. Multiple date fields are collected through the SIF file process, and operating divisions misinterpreted the different definitions for these date fields including, specifically, the period of performance data element.

We recommend that HHS continue to focus its efforts on resolving issues related to its IT system controls, fully implementing interface controls by updating the governance for different environments to be compliant. We also recommend that HHS continue to progress toward producing high-quality data; remediating deficiencies in financial, procurement and grant-related systems; and better automating DATA Act data collection and submission processes. Finally, we recommend that HHS focus on refreshing operating divisions' understanding of Departmental guidance and identifying any potential need for operating division training to prevent and detect future accuracy issues.

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 \$559 billion in grants and over \$26 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 around the world. The size and scope of departmental awards make their operating effectiveness crucial to the success of programs designed to improve the health and well-being of the public.

Grant Fraud Investigations

The following case examples relate to misuse of grant funds:

Kansas—On November 23, 2021, KalScott Engineering, Inc. (KalScott) and its president, Thomas Sherwood, and Vice President Suman Saripalli, entered into a settlement agreement under which they agreed to pay \$672,352 to resolve allegations that the company submitted false claims to obtain grant funds from the SBIR and Small Business Technology Transfer (STTR) programs, which are competitive programs that encourage American small businesses to engage in research, on behalf of the Federal Government, that has the potential for commercialization. Grant recipients must designate a principal investigator and key personnel who will work on the grant-funded project. Small businesses may subcontract a portion of the work to other entities, but the small business itself must perform a majority of the grant-funded work. Between April 2012 and July 2015, KalScott received SBIR grants from NIH, the National Aeronautics and Space Administration (NASA), and the Air Force; as well as an STTR grant from the Navy. The United States contends that the company wrongfully obtained grant funds from NASA and the Navy because KalScott

designated Mr. Saripalli as a principal investigator when he was not eligible to serve in that role. In addition, it is alleged that KalScott did not perform a majority of work under the Air Force grant, and that KalScott used different key personnel than it listed in its proposal to obtain the NIH grant.

New York—On October 6, 2020, Geoffrey Girnun, a former associate professor and cancer researcher at Stony Brook University’s Department of Pathology of Medicine, was sentenced to 1 year and 1 day in prison for theft of Government funds related to a grant he received to research the effect of certain molecules on cancer. Girnun pleaded guilty in January 2020 and pursuant to his plea agreement, he agreed to forfeit \$225,000 and resign from his position at Stony Brook University. The court also ordered Girnun to pay \$225,000 in restitution to NIH and Stony Brook University.

In approximately 2013 and 2017, Girnun formed two sham companies, Atlas Metabolomics, LLC (Atlas) and Empyrean Biosciences, LLC (Empyrean) that purportedly provided research items and equipment for the defendant’s cancer-related research projects. From approximately December 2013 through September 2019, Girnun submitted fraudulent electronic invoices to Stony Brook University for payment to the sham companies for equipment, goods and services that were never received or provided. Stony Brook University then used NIH and the university’s grant and foundation funds to pay the sham companies over \$200,000. Girnun withdrew the fraudulently obtained grant funds from Atlas and Empyrean’s bank accounts and used the money for personal expenses, including payments toward the mortgage on his residence and tuition for his children.

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 388 reports covering \$930.2 billion in audited costs. Federal dollars covered by these audits totaled \$204.9 billion, of which about \$115.6 billion were HHS funds.

Uniform guidance at 2CFR200 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, October 1, 2020, Through March 31, 2021

Not requiring changes or having minor changes	365
Requiring major changes	22
Having significant technical inadequacies	1
Total Number of Non-Federal Audits	388

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	76	\$1,850,465,000	\$505,797,000
Issued during the reporting period	34	\$241,954,000	\$2,581,000
Total Section 1	110	\$2,092,419,000	\$508,378,000
Section 2			
Reports for which management decisions were made during the reporting period ^{2, 3}			
Disallowed costs	54	*\$566,464,000	\$0
Costs not disallowed	7	\$19,241,000	\$0
Total Section 2	61	\$585,705,000	\$0
* 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)	49	\$1,506,714,000	\$508,378,000
Section 4			
Reports for which no management decisions were made within 6 months of issuance ⁴	28	\$1,302,503,000	\$505,797,000

Table 1 End Notes

¹ The opening balance was adjusted upward by \$18.9 million because of a reevaluation of previously issued recommendations.

² Revisions to previously reported management decisions:

- A-07-13-02795, *Palmetto Government Benefits Administrator Did Not Always Refer Medicare Cost Reports and Reconcile Outlier Payments in Jurisdiction 1*. CMS reduced disallowed costs by \$12,821,146 as a result of a MAC settlement due to bankruptcy provisions.
- A-06-16-00018, *Arkansas Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs*. CMS’s subsequent review of support documentation provided by the State of Arkansas, determined that disallowed cost should be reduced by \$8,747,496.
- A-04-13-07043, *Medicare Compliance Review of Florida Hospital Orlando for the Period January 1, 2011, Through June 30, 2012*. Based on redetermination appeals for extrapolated overpayments totaling \$11,512,530, recoveries were reduced by \$7,403,950.
 - Not detailed are reductions to previously disallowed management decisions totaling \$8.9 million.

³ Included are management decisions to disallow \$10.8 million 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 28 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.

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, August 2018, \$939,287,686</i>
A-02-14-02017	<i>New York Misallocated Costs to Establishment Grants for a Health Insurance Marketplace, November 2016, \$149,654,512</i>
A-02-16-02007	<i>Lincoln Hall Boys’ Haven, an Administration for Children and Families Grantee, Did Not Always Comply With Applicable Federal and State Policies and Requirements, February 2019, \$29,807,160</i>
A-01-14-02503	<i>Maryland Misallocated Millions to Establishment Grants for a Health Insurance Marketplace, March 2015, \$28,400,000</i>
A-04-14-07050	<i>Kentucky Misallocated Millions to Establishment Grants for a Health Insurance Marketplace, February 2017, \$25,530,429</i>

A-07-18-04111	<i>Mississippi Needs To Improve Oversight of Its Child Care Payment Program, April 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, December 2017, \$20,415,344</i>
A-01-17-00506	<i>Medicare Paid Twice for Ambulance Services Subject to Skilled Nursing Facility Consolidated Billing Requirements, February 2019, \$19,938,117</i>
A-07-15-04226	<i>Not All of Missouri's Child Care Subsidy Program Payments Complied With Federal and State Requirements, November 2017, \$19,076,167</i>
A-06-17-07004	<i>Southwest Key Programs Failed To Protect Federal Funds Intended for the Care and Placement of Unaccompanied Alien Children, September 2020, \$13,130,848</i>
A-01-15-02500	<i>Vermont Did Not Properly Allocate Millions to Establishment Grants for a Health Insurance Marketplace, September 2016, \$11,243,006</i>
A-02-14-02024	<i>Newark Preschool Council, Inc., Did Not Always Comply With Head Start Requirements, February 2017, \$9,950,556</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, April 2019, \$2,623,785</i>
A-07-17-02808	<i>The Colorado Health Insurance Marketplace's Financial Management System Did Not Always Comply With Federal Requirements, July 2018, \$2,567,604</i>
A-04-16-00112	<i>North Carolina Made Capitation Payments to Managed Care Entities After Beneficiaries' Deaths, September 2020, \$1,948,657</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, June 2013, \$1,419,524</i>
A-05-14-00045	<i>The Minnesota Marketplace Misallocated Federal Funds and Claimed Unallowable Costs, November 2016, \$1,279,677</i>
A-01-19-02500	<i>Cape Cod Child Development Program Did Not Meet Its Head Start Non-Federal Share Obligations, April 2020, \$1,196,293</i>
A-01-18-02501	<i>Vermont's Office of Child Support Needs Better Oversight Over Its Administrative Costs Claimed, September 2019, \$1,058,309</i>
A-09-14-01007	<i>Nevada Misallocated Costs for Establishing a Health Insurance Marketplace to Its Establishment Grants, February 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, July 2018, \$341,616</i>
A-02-17-02003	<i>Sharon Baptist Head Start Claimed Unallowable Rent and Failed To Return Embezzled Funds, July 2020, \$207,264</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, September 2019, \$142,104</i>
A-09-18-03031	<i>CMS Could Have Saved \$192 Million by Targeting Home Health Claims for Review With Visits Slightly Above the Threshold That Triggers a Higher Medicare Payment, July 2020, \$41,613</i>
A-09-18-03018	<i>Medicare Improperly Paid Suppliers an Estimated \$92.5 Million for Inhalation Drugs, October 2019, \$36,825</i>
A-03-16-00250	<i>Youth For Tomorrow—New Life Center, Inc., an Administration for Children and Families Grantee,</i>

	<i>Did Not Comply With All Applicable Federal Policies and Requirements, September 2020, \$16,851</i>
A-04-18-02010	<i>Florida's Refugee Medical Assistance Payments Were Generally Allowable, January 2020, \$8,772</i>
A-05-18-00015	<i>The University of Minnesota Complied With Federal Requirements To Perform Risk Assessments and Monitor Subrecipients, November 2019, \$1,924</i>
TOTAL CINS: 28	
TOTAL AMOUNT: \$1,302,503,000	

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, deobligation of funds, and/or avoidance of unnecessary expenditures. Table 2 reports HHS program officials’ decisions to take action on these audit recommendations.

Description	Number of Reports	Dollar Value
Section 1		
Reports for which no management decisions had been made by the beginning of the reporting period	17	\$17,622,190,000
Reports issued during the reporting period	4	\$10,917,000
Total Section 1	21	\$17,633,107,000
Section 2		
Reports for which management decisions were made during the reporting period ¹		
Value of recommendations agreed to by management		
Based on proposed management action	8	\$919,971,000
Based on proposed legislative action	0	\$0
Value of recommendations not agreed to by management	1	\$103,514,000
Total Section 2	9	\$1,023,485,000
Section 3		
Reports for which no management decisions had been made by the end of the reporting period ² (<i>Sec. 1 minus Sec. 2</i>)	12	\$16,609,622,000

Table 2 End Notes

¹ Revisions to previously reported management decisions:

- A-01-15-00515, *Wisconsin Physicians Service Paid Providers for Hyperbaric Oxygen Therapy Services That Did Not Comply With Medicare Requirements*. CMS’s subsequent review of additional documentation realized savings totaling \$7,069,366, thus reducing the value agreed upon by \$35,259,970.

² Because of administrative delays, some of which were beyond management control, 9 of the 12 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.

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, April 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, July 2020: \$1,024,623,449</i>
A-03-16-03001	<i>The Centers for Medicare & Medicaid Services Did Not Identify and Report Potential Antideficiency Act Violations for 12 Contracts Used To Establish the Federal Marketplace Under the Affordable Care Act, February 2020, \$186,993,209</i>
A-06-17-08004	<i>Medicare Part D Is Still Paying Millions for Drugs Already Paid for Under the Part A Hospice Benefit, August 2019, \$160,800,000</i>
A-05-16-00060	<i>Hospitals Received Millions in Excessive Outlier Payments Because CMS Limits the Reconciliation Process, November 2019, \$125,000,000</i>
A-03-13-03002	<i>HHS Did Not Identify and Report Antideficiency Act Violations, May 2017, \$49,445,025</i>
A-04-18-04067	<i>Inadequate Edits and Oversight Caused Medicare To Overpay More Than \$267 Million for Hospital Inpatient Claims With Post-Acute-Care Transfers to Home Health Services, August 2020, \$40,610,333</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, September 2020, \$14,417,533</i>
A-09-18-03030	<i>Medicare Incorrectly Paid Providers for Emergency Ambulance Transports From Hospitals to Skilled Nursing Facilities, September 2019, \$968,718</i>
TOTAL CINS: 9	
TOTAL AMOUNT: \$16,602,858,000	

Appendix B: Peer-Review Results

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

Office of Audit Services

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

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*.

OAS	Date	Reviewing Office	Office Reviewed
	April 2019	HHS-OIG, OAS	Department of Transportation (DOT) OIG

The system of quality control for the audit organization of DOT-OIG in effect for the year ending September 30, 2018, has been suitably designed and complied with to provide DOT-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*. DOT-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 about 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 (USPS) OIG

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

Office of Evaluation and Inspections

During this semiannual reporting period, one peer review involving OEI was completed. Information concerning OEI’s peer-review activity during a prior reporting period is also listed 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* (Blue Book) standards. The seven covered standards are: Quality Control, Planning, Data Collections and Analysis, Evidence, Records Maintenance, Reporting, and Followup. In addition, each of the four reviewed VA-OIG reports complied with those standards and the VA-OIG’s internal policies and procedures. As a result of our findings, there are no recommendations associated with this external peer review. The report also noted a VA-OIG beneficial practice of using specialized staff to conduct independent referencing reviews of its reports to achieve greater consistency in its quality assurance processes.

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

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

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

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

Appendix C: 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 of the Social Security Act, 1128A (42 U.S.C. § 1320a 7a), imposes 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 \$15,270 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; violations of rules regarding the possession, use, and transfer of biological agents and toxins; 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 \$55,262 for each false statement, as well as activities relating to fraudulent marketing by MCOs, their employees, or their agents.

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 D: 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 (previously known as the Compendium of 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	Appendix A

Section	Requirement	Location
	within 60 days, and in which there are any outstanding unimplemented recommendations	
(a)(11)	Description and explanation of revised management decisions	Appendix A
(a)(12)	Management decisions with which the Inspector General disagrees	None for this reporting period
(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 B
(a)(17)	Investigative statistical tables	Appendix E
(a)(18)	Metrics description for statistical tables	Appendix E
(a)(19)	Investigations on senior Government employees	Appendix E
(a)(20)	Description of whistleblower retaliation instances	Appendix E
(a)(21)	Description of attempts to interfere with OIG independence	Appendix E
(a)(22)	Description of closed and nondisclosed reports and investigations regarding senior Government employees	Appendix E

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 F

Section	Requirement	Location
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 E: Reporting Requirements in the Inspector General Empowerment Act of 2016

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

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

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

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

For audit and evaluation reports issued from FY 2011 through FY 2021, OIG had a total of 115 reports with overdue final management decisions (FMDs) as of the end of this reporting period.² The breakdown of those 115 reports by HHS OpDiv is as follows:

OpDiv	Overdue FMDs
ACF	24
ASPR	1
CMS	50
FDA	1
IHS	13
NIH	6
OASH	1
OS	19

² OIG can track the status of management decisions for all reports back to FY 2011. OIG can track the status of management decisions for audit reports back to FY 1990. We have identified three additional audit reports (one CMS, one FDA, and one OS) with overdue management decisions from FYs 1990 through 2010.

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

(B) for which no establishment comment was returned within 60 days of providing the report to the establishment; 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 none 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 1,424 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	22	25	\$397,437,195
2013	27	40	\$234,261,321
2014	28	51	\$15,122,628,339
2015	27	44	\$332,579,636
2016	25	58	\$187,140,410
2017	39	101	\$1,116,136,306
2018	54	155	\$1,900,522,940
2019	80	264	\$789,241,080
2020	123	477	\$3,008,481,919
2021	58	191	\$240,344,137
Totals	495	1,424	\$23,736,908,798

OIG annually produces [Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs: OIG's Top Recommendations](#) (previously known as the Compendium of Unimplemented 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	1,253
Total number of persons referred to State and local prosecuting authorities for criminal prosecutions during the reporting period	125
Total number of Federal indictments and criminal information during the reporting period that resulted from any prior referral to prosecuting authorities	346
Total number of State and local indictments and criminal information during the reporting period that resulted from any prior referral to prosecuting authorities	47

(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

³ A referral includes OIG presentations to DOJ and/or State/local prosecutorial authorities.

⁴ OIG counts “persons” as both individuals and entities.

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 five 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 and gathers facts related to whistleblower complaints. Before 2015, OIG made no determinations as to whether retaliatory action had been taken. However, to better facilitate the report review process, OIG changed its process in 2015 to include findings in its reports as to whether it was more likely than not that whistleblower retaliation had occurred. Although OIG now includes these findings in its reports, it does not make recommendations as to what, if any, corrective action(s) should be taken.

During the time period from October 1, 2020, through March 31, 2021, OIG did not issue any reports that included findings of retaliation.

When determining the level of detail to provide for a description of any instance of whistleblower retaliation, OIG is always mindful of the risk that a detailed description of the allegation could inadvertently reveal the whistleblower's identity, thus having a chilling effect on future whistleblowers.

(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 notify Congress 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, October 1, 2020, Through March 31, 2021

Category/Description	Number of Reports
IT security reviews (involve IT systems, e.g., penetration test audits)	4
Homeland security issues (involve particularly sensitive topics, e.g., bioterrorism, emergency preparedness, and classified or potentially classified information)	None
Recipient Capability Audits (primarily in Head Start/Early Head Start programs)	None
Reimbursable audits performed for other Federal agencies (primarily contract audits)	None
Confidential or proprietary information (e.g., Medicare Part B drug claims/imaging services, Medicare investment income)	None
Medicare Adverse Event Reviews (required by law not to disclose)	None
Medicare Prescription Drug Event Reviews	None
Other	None
HHS technical assistance reports ⁵	None
Finance-related attestation reviews	1
Total	5

(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

⁵ OIG routinely provides technical assistance to HHS. Generally, that technical assistance is not part of a formal report and is not formally tracked. However, in some limited circumstances, OIG does provide technical assistance in a formal report, and only that category of technical assistance is reflected in this table.

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 employee(s) for misconduct, but OIG determined the allegations to be unsubstantiated. Descriptions of the investigations are below.

Description of Investigation	Status	Disposition	DOJ Referral	DOJ Referral Date	DOJ Declination	DOJ Declination Date
A complaint was received that alleged a senior Government employee made an unauthorized disclosure of confidential information related to the clinical trials of a COVID-19 treatment to a politico reporter.	Closed	Unsubstantiated	No	N/A	N/A	N/A
A complaint was received that a senior Government employee allegedly received financial benefits from a contractor in exchange for securing a 4-year, sole source contract with that same contractor.	Closed	Unsubstantiated	No	N/A	N/A	N/A

<p>A senior Government employee made both verbal and written false statements to an investigator. The senior Government employee's statements obstructed a critical investigation under the President's Emergency Plan for Aids Relief in five Central American countries. The senior Government employee also failed to report a grantee employee's allegations of grant fraud and other violations to the OIG or other qualified (investigative) agency.</p>	<p>Closed</p>	<p>Insufficient evidence</p>	<p>Yes</p>	<p>8/20/2020</p>	<p>Yes</p>	<p>12/7/2020</p>
<p>A complaint was received that a senior Government employee provided a subcontractor strategic advantage with information that was proprietary to itself and other information that was proprietary to another contractor. There was also an</p>	<p>Closed</p>	<p>Insufficient evidence.</p>	<p>No</p>	<p>N/A</p>	<p>N/A</p>	<p>N/A</p>

<p>allegation that the senior Government employee provided the subcontractor with access to agency systems, even though this subcontractor did not have access. Additionally, it was alleged that there was a personal relationship between the senior Government employee and one of the subcontractor’s employees.</p>						
<p>A complaint was received that alleged a senior Government employee owned several businesses and ran them during work hours. The senior Government employee was using government computers, phones, copy machines, and fax machines for their personal businesses. It was also alleged that the senior Government employee is collecting kickbacks from the Puerto</p>	<p>Closed</p>	<p>Insufficient evidence</p>	<p>No</p>	<p>N/A</p>	<p>N/A</p>	<p>N/A</p>

Rican government for work in Puerto Rico.						
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Appendix F: Anti-Kickback Statute—Safe Harbors

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

Public proposals for new and modified safe harbors

Annual Solicitation

In December 2019, OIG published its annual solicitation in the *Federal Register* (Annual Solicitation).⁶ In response to the Annual Solicitation, OIG received the following proposals related to safe harbors:

Proposal	OIG Response
Modification of the transportation safe harbor to: (i) permit marketing in defined circumstances; (ii) protect free or discounted local transportation services for health-related, nonmedical purposes; (iii) allow patients to schedule free or discounted transportation services and medical appointments online; and (iv) protect the provision of free or discounted local transportation services between or among	OIG recently issued a final rule that, among other things, revised the local transportation safe harbor and finalized a new patient engagement tools and supports safe harbor. This new safe harbor may also protect certain arrangements involving the provision of free or discounted local transportation services, provided all safe harbor conditions are met. See 81 Fed. Reg. 77684 (Dec. 2, 2020) (the “Regulatory Sprint Final Rule”). We believe these regulations and accompanying preamble in the Regulatory Sprint Final Rule are sufficiently responsive to these proposals.

⁶ OIG, Solicitation of New Safe Harbors and Special Fraud Alerts, 84 Fed. Reg. 72,289 (Dec. 31, 2019), available at <https://www.govinfo.gov/content/pkg/FR-2019-12-31/pdf/2019-27202.pdf>.

Proposal	OIG Response
<p>providers, where all such providers are furnishing home care to the same patient.</p>	<p>For example, in the Regulatory Sprint Final Rule, we expressly declined to extend the local transportation safe harbor to protect transportation services for health-related, nonmedical purposes. <i>Id.</i> at 77863. Similarly, we reiterated our longstanding concerns related to the marketing of transportation services. <i>Id.</i> at 77864; <i>see also</i> 81 Fed. Reg. 88368, 88386 (Dec. 7, 2016).</p> <p>For questions about the application of certain fraud and abuse authorities to particular factual arrangements, the advisory opinion process remains available.</p>
<p>A new safe harbor that would protect value-based contracting and outcomes-based contracting for the purchase of pharmaceutical products.</p>	<p>OIG is not adopting this suggestion. As we noted in the Regulatory Sprint Final Rule, we may consider this topic for future rulemaking.</p>
<p>A new safe harbor that would protect patient engagement and product support activities furnished by pharmaceutical manufacturers to patients.</p>	<p>In the Regulatory Sprint Final Rule, OIG finalized a new patient engagement and support safe harbor. 42 CFR § 1001.952(hh). This safe harbor does not protect the provision of patient engagement tools or supports furnished or funded by a pharmaceutical manufacturer, distributor, or wholesaler due to, among other reasons, concerns that such entities would 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.” 81 Fed. Reg. 77709, 77782. For the same reasons, we decline to adopt this suggestion.</p>
<p>A new safe harbor to protect data analytics arrangements between or among pharmaceutical manufacturers, pharmacy benefit managers, payors, and providers.</p>	<p>In the Regulatory Sprint Final Rule, OIG finalized a new care coordination arrangements safe harbor, 42 CFR § 1001.952(ee), that may protect the exchange of data analytic tools between or among eligible entities that are party to a value-based arrangement, provided all safe harbor conditions are met. 81 Fed. Reg. 77823. However, in the Regulatory Sprint Final Rule, we stated that, among other entities, pharmaceutical manufacturers and pharmacy benefit managers are ineligible to use this safe harbor. For the same reasons included in the Regulatory Sprint Final Rule, we decline to adopt a new safe harbor to protect arrangements involving these entities.</p>
<p>A new patient medication adherence safe harbor that would protect remuneration furnished to patients intended to support patient adherence to a medication treatment</p>	<p>As part of the Regulatory Sprint Final Rule, OIG finalized a new patient engagement tools and supports safe harbor that protects certain eligible entities’ provision of patient engagement tools or supports, of which, depending on the facts and circumstances, may include remuneration designed to</p>

Proposal	OIG Response
regimen prescribed by the patient's health care provider.	advance patients' medication adherence. We believe that regulation and our discussion related to that safe harbor in the Regulatory Sprint Final Rule is sufficiently responsive to this request.
A new safe harbor or modification to one or more existing safe harbors that would protect patient cost-sharing waivers in the following circumstances: (i) upon a good faith determination of financial need; (ii) by all providers and suppliers, so long as certain criteria are met (e.g., providers do not claim the cost-sharing waiver as bad debt); or (iii) applied to those amounts greater than a provider's good-faith estimate of a patient's cost-sharing liability.	OIG is not adopting these suggestions. As we recently articulated in the Regulatory Sprint Final Rule, beneficiary cost-sharing obligations are a programmatic requirement, and we do not believe it would be appropriate to broadly protect cost-sharing waivers that could obviate a programmatic requirement created by statute. 85 Fed. Reg. 77793.
With certain modifications, finalize the pharmacy benefit manager service fees safe harbor and the point-of-sale reductions in price for prescription pharmaceutical products safe harbor, as proposed by OIG in a February 2019 rulemaking.	Both safe harbors were finalized in a recent rulemaking entitled "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. 76666 (Nov. 30, 2020).

Regulatory Sprint to Coordinated Care

In addition to the Annual Solicitation, in the October 17, 2019, *Federal Register*, OIG issued a proposed rule in connection with HHS's Regulatory Sprint to Coordinated Care, which aimed to reduce regulatory barriers and accelerate the transformation of the health care system into one that better pays for value and promotes care coordination (OIG NPRM).⁷ The proposals set forth in the OIG NPRM were, in large part, finalized in the Regulatory Sprint Final Rule and, in certain instances, incorporates some of the ideas we received in responses to our Annual Solicitation. The Regulatory Sprint Final Rule adds new safe harbors to protect certain arrangements for value-based care, patient engagement tools and support, and

⁷ OIG, Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 84 Fed. Reg. 55,694 (Oct. 17, 2019), available at <https://www.govinfo.gov/content/pkg/FR-2019-10-17/pdf/2019-22027.pdf>.

cybersecurity technology and services; modifies several existing safe harbors; and implements a new exception under the CMPL provision prohibiting beneficiary inducements. The Regulatory Sprint Final Rule provides greater certainty for health care providers and others participating in value-based arrangements and providing coordinated care for patients. It is intended to ease compliance with OIG's authorities for health care providers and others across the industry, while including strong safeguards to help protect patients and Federal health care programs from fraud and abuse.