

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

Semiannual Report to Congress

October 1, 2018–March 31, 2019



A MESSAGE FROM THE INSPECTOR GENERAL

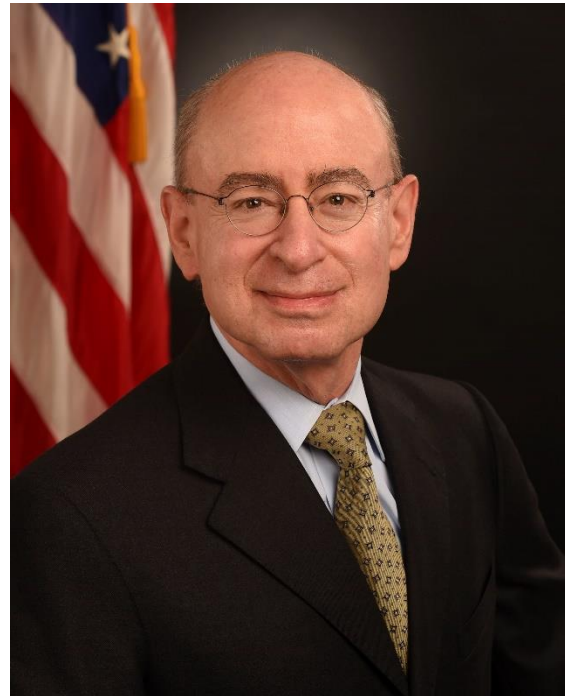
I am pleased to present the enclosed *Semiannual Report to Congress* summarizing significant work of the Office of Inspector General (OIG), Department of Health and Human Services (HHS or the Department), for the reporting period October 1, 2018, to March 31, 2019. This is my final *Semiannual Report* submission as Inspector General of HHS.

For the past decade and a half, I have had the great privilege to serve alongside the most dedicated professionals in Federal service, who every day fight fraud, waste, and abuse in HHS's \$1.2 trillion portfolio of programs; promote the health and safety of beneficiaries; and leverage data and technology to provide modern oversight in a rapidly changing program environment. The public servants at OIG have been instrumental in delivering positive results and pioneering innovative methods of oversight that will continue serving the public interest for years to come.

Since fiscal year 2004, OIG has reported over \$53 billion in expected investigative recoveries. OIG has undertaken substantial enforcement actions, including 50,877 exclusions of individuals and entities from participation in Federal healthcare programs; 11,149 criminal actions against individuals or entities that engaged in crimes against HHS programs; and 7,280 civil actions, which included false claims and unjust-enrichment lawsuits filed in Federal district court, civil monetary penalties settlements, and administrative recoveries related to provider self-disclosure matters.

OIG has continued to innovate to meet pressing oversight challenges. For example, beginning in 2007, OIG worked with its Government partners to create the Medicare Fraud Strike Force and later the Health Care Fraud Prevention and Enforcement Action Team, which have proven extraordinarily effective at analyzing data and investigative intelligence to identify fraud and prosecute cases quickly. Further, OIG auditors and evaluators have crafted groundbreaking methodologies for collecting and analyzing data to identify patients at risk of harm, including from opioid misuse, abuse and neglect in group home settings, and preventable harm in hospitals. Today, OIG has a new Affirmative Litigation Branch devoted solely to enforcing OIG's civil monetary penalties and exclusions authorities, and a new Cyber Information Technology Audit Division focused on growing cyber threats to Department programs.

OIG is at the forefront of the Nation's efforts to fight fraud in HHS programs and hold wrongdoers accountable. During this semiannual reporting period, OIG conducted a series of investigations nationwide to support two important law enforcement takedowns in April 2019. In Operation Brace Yourself, OIG and law enforcement partners dismantled one of the largest healthcare fraud schemes ever investigated,



involving allegations of almost \$1 billion paid for medically unnecessary orthopedic braces furnished through a telemarketing scam to seniors. OIG agents and investigators also partnered with the Department of Justice, Federal Bureau of Investigation, the Drug Enforcement Administration, Medicaid Fraud Control Units, the Centers for Disease Control and Prevention, State public health officials, and U.S. Attorney's Offices in five States to execute the largest-ever law enforcement operation involving prescription opioids.

During this reporting period, OIG continued to provide independent, objective oversight to identify key program vulnerabilities and recommend actions the Department can take to protect HHS beneficiaries from harm and ensure they receive high quality care. For example, OIG determined that more than 4 in 10 Medicare patients in long-term-care hospitals (LTCHs) experienced some type of harm from their care and more than half of these harm events were preventable with better care. OIG recommended that the Centers for Medicare & Medicaid Services and Agency for Healthcare Research and Quality collaborate to help LTCHs reduce the incidence of patient harm. The agencies agreed to create and disseminate a list of potential adverse events in LTCHs to improve patient safety. OIG has continued its comprehensive work examining the Office of Refugee Resettlement (ORR) program for unaccompanied children and has continued to encourage Department efforts to improve communication, transparency, and accountability for the identification, care, and placement of children separated from their parents. A notable OIG review during this reporting period found that the total number of unaccompanied children in ORR care who had been separated from a parent or guardian by immigration authorities is unknown.

OIG continues building its capabilities to harness emerging technologies in its oversight of Department programs. For example, OIG's multidisciplinary cybersecurity team helps the Department prevent and combat cyber threats by fostering enhancements in information technology controls, risk management, and resiliency. OIG work in this semiannual report identified opportunities for the National Institutes of Health to strengthen controls over sensitive data and also recommended that the Food and Drug Administration better address cybersecurity risks to medical devices. Moving forward, OIG will continue to modernize technology infrastructure, develop new data analytic tools, and explore emerging areas such as artificial intelligence and machine learning.

Since our establishment in 1976, OIG has worked collaboratively with our partners to oversee and protect the integrity of the Department's programs and the beneficiaries they serve. OIG appreciates the continued recognition, commitment, and support of Congress and the Department for our vital work. I am optimistic about the future of HHS-OIG and have full confidence in the organization to advance OIG's important mission and make a positive difference in the lives of our fellow Americans.

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OIG's Approach to Driving Positive Change

THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS or Department), 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), the U.S. Department of Justice (DOJ), and the Inspector General community. Through a nation-wide 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, the Office of Evaluation and Inspections, and the Office of Investigations—with assistance from the Office of Counsel to the Inspector General and Executive Management.

OIG Organization

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

The Office of Evaluation and Inspections (OEI). 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.

The Office of Investigations (OI). 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).

The Office of Counsel to the Inspector General (OCIG). 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 False Claims Act (FCA), 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 healthcare industry about the anti-kickback statute and other OIG enforcement authorities.

Mission Support and Infrastructure (MSI). 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 Plan

As delineated in OIG’s *Strategic Plan for 2014–2018*, OIG’s approach to protecting the integrity of HHS programs has four key goals: (1) to fight fraud, waste, and abuse; (2) to promote quality, safety, and value; (3) to secure HHS programs’ future; and (4) 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 own assessment of its effectiveness.

OIG Work Plan

OIG’s *Work Plan* sets forth various projects that OIG plans to undertake during the fiscal year (FY) and beyond. Projects listed in the Work Plan span HHS’s operating divisions, 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.

IG's Top Unimplemented Recommendations

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

IG's Semiannual Report to Congress

IG's [Semiannual Report\(s\) to Congress](#) (Semiannual Reports) describe IG'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 IG expected recoveries, criminal and civil actions, and other statistics as a result of our work for the semiannual reporting period of October 1, 2018, through March 31, 2019. We also highlight some of our work completed during this semiannual reporting period.

Top Management and Performance Challenges Facing HHS

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

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, 2018, through March 31, 2019.

During this semiannual reporting period, OIG issued 71 audits and 10 evaluations, resulting in 212 recommendations issued to HHS operating divisions. Additionally, OIG remains at the forefront of the Nation's efforts to fight fraud in HHS programs and hold wrongdoers accountable. Along with our partners DOJ, State Medicaid Fraud Control Units (MFCUs or Units), and other Federal, State, and local law enforcement agencies, we detect, investigate, and prosecute healthcare fraud through a coordinated and data-driven approach.

OIG oversight of HHS programs ensures integrity, effectiveness, and efficiency. During this reporting period, our audit work identified \$496 million in expected recoveries. We also identified \$247 million in questioned costs (costs questioned by OIG because of an alleged violation, costs not supported by adequate documentation, or the expenditure of funds where the intended purpose is unnecessary or unreasonable). Our audit work also identified \$777 million in potential savings for HHS. These are funds that could potentially be saved if HHS programs implemented all of OIG's audit recommendations.

OIG also remains at the forefront of the Nation's efforts to fight fraud in HHS programs and hold wrongdoers accountable. OIG investigative work led to \$2.3 billion in expected investigative recoveries and 421 criminal actions during this reporting period. OIG also excluded 1,293 individuals and entities from Federal healthcare programs and took civil actions, such as assessing monetary penalties against 331 individuals or entities.

Audit and evaluation recommendations are crucial to encourage positive change in HHS programs. OIG made 212 new audit and evaluation recommendations during this reporting period. Meanwhile, HHS operating divisions implemented 186 prior recommendations leading to positive impact for HHS programs and beneficiaries.

At-a-Glance Highlights October 1, 2018–March 31, 2019

\$496.42 Million Expected Audit Recoveries

\$246.93 Million Questioned Costs

\$776.58 Million Potential Savings

\$2.30 Billion Expected Investigative Recoveries

421 Criminal Actions

1,293 Exclusions

331 Civil Actions

212 New Audit and Evaluation Recommendations

186 Recommendations Implemented by HHS Operating Divisions

OIG continued to focus on the most significant and high-risk issues in healthcare. Our mission is to protect the health and welfare of beneficiaries and to protect the integrity of HHS programs and grants. Work during this semiannual reporting period focused on the opioid crisis, children cared for in Office of Refugee Resettlement facilities, quality of care, and cybersecurity. Below we highlight our work from the semiannual reporting period October 1, 2018, through March 31, 2019, organized by subject area. Appendices A–F provide a comprehensive list of OIG work during this reporting period and provide data to meet the reporting requirements in the Inspector General Act of 1978 (IG Act).

Preventing and Treating Opioid Misuse

OIG uses data analytics and other investigative tools to combat the opioid crisis and to detect fraud and abuse. We use our criminal, civil, and administrative enforcement authorities to prevent fraud. Significant results of OIG work related to the opioid crisis during this semiannual reporting period include the following:

A California physician assistant was found guilty of conducting a scheme to unlawfully distribute prescription drugs. The physician assistant intentionally prescribed drugs knowing that the prescriptions were outside the usual course of professional practice and without a legitimate medical purpose. A jury found the physician assistant guilty of 39 counts of unlawful distribution of controlled substances, and the person was sentenced to 10 years in prison.

OIG found that New York did not provide adequate stewardship of substance abuse prevention and treatment block grant funds. New York failed to trace funds to a level of expenditure adequate to establish that the funds were used for the program's intended purpose. We made recommendations to SAMHSA and the New York State agency to improve its oversight of substance abuse prevention and treatment block grant funds. (See report [A-02-17-02009](#).)

Protecting Children in the Department's Care

HHS, through the Administration for Children and Families (ACF) Office of Refugee Resettlement (ORR), is responsible for ensuring the shelter and care of thousands of unaccompanied alien children who enter the United States without legal status. Most of these children were transferred into ORR's custody after initially being taken into custody at the border by the Department of Homeland Security. ORR provides temporary shelter, care, and other related services to children before they are released to sponsors (most often, family members). Significant OIG work during this semiannual reporting period related to ORR includes the following:

OIG found that the total number of children separated from a parent or guardian by immigration authorities is unknown. OIG encourages continued efforts to improve communication, transparency, and accountability for the identification, care, and placement of separated children. Pursuant to a June 2018 Federal District Court order, HHS has thus far identified 2,737 children in its care at that time who were separated from their parents. However, thousands of children may have been separated during an influx that began in 2017, before the accounting required by the Court. OIG testified before the United States House Committee on Energy and Commerce Subcommittee on Oversight and Investigations on this work and the fact that the number of separated children in ORR care is unknown. (See report [OEI-BL-18-00511](#).)

OIG identified two significant vulnerabilities at the now-closed Tornillo influx UAC facility that warranted immediate attention. OIG found that the facility was not conducting required fingerprint background checks for staff, and that it did not employ a sufficient number of staff clinicians to provide adequate mental health care for UAC. (See report [A-12-19-20000](#).)

OIG found that one UAC facility did not properly document the care and release of 13 percent of all children released to sponsors in FY 2015. The facility concurred with our recommendations that it comply with ORR regulations pertaining to safety of children. (See report [A-06-17-07007](#).)

Ensuring Quality of Care and Protecting Patients From Harm

OIG has long prioritized oversight and enforcement work to protect Medicare and Medicaid patients from harm and to help ensure that patients receive high quality care. This work ranges from assessing the safeguards in place to ensure quality and safety, examining the incidence and preventability of patient harm, and investigating and holding accountable healthcare providers who commit fraud that results in patient harm. Significant OIG work during this reporting period includes the following:

OIG investigation resulted in conviction of a doctor who implanted unnecessary pacemakers. A physician was found guilty of healthcare fraud after an OIG investigation showed that he implanted medically unnecessary pacemakers into his patients to bill for these unnecessary procedures and follow-up care. At trial, several patients testified that the physician had pressured them into the procedures and gave them misleading information about their health conditions.

OIG recommended improvements to better ensure that nursing homes correct deficiencies. In a series of audits, OIG found that seven of nine State agencies did not always verify that nursing homes corrected deficiencies, as required. Nursing home deficiencies can include quality and safety concerns. We recommended that CMS improve its guidance to State agencies on verifying nursing homes' corrections and improve its related forms and systems. (See report [A-09-18-02000](#).)

OIG determined that more than 4 in 10 Medicare patients in long-term-care hospitals (LTCHs) experienced some type of harm from their care. Based on medical expert review, we estimated that 25 percent of Medicare patients in LTCHs experienced temporary harm events from their care and an additional 21 percent experience more serious adverse events. This rate of patient harm is higher than OIG found in other settings and may be due, in part, to longer stays and high patient acuity in LTCHs. Medical reviewers determined that more than half of these harm events were preventable with better care. OIG made recommendations to CMS and the Agency for Healthcare Research and Quality (AHRQ) to help LTCHs reduce patient harm. (See report [OEI-06-14-00530](#).)

Ensuring Program Integrity and Effective Administration of the Medicare Program

Reducing improper payments and ensuring that Medicare funds are spent efficiently, effectively, and economically is crucial. In FY 2017, Medicare spent nearly \$700 billion, representing more than 15 percent of all Federal spending, and provided health coverage to 58.4 million beneficiaries. The 2018 Annual Report of the Board of Trustees estimates that the Trust Fund for Medicare Part A will be depleted by 2026. It also projects that spending for Medicare Part B will grow at an annual rate of about 8.2 percent over the next 5 years, outpacing the U.S. economy, which is projected to grow at a 4.7 percent annual rate during that time. Significant results from OIG work to identify improper payments or foster more prudent payment policies during this reporting period include the following:

A drug wholesale company entered into a False Claims Act settlement agreement and agreed to pay \$625 million to resolve a liability associated with a pre-filled syringe program. The company improperly repackaged oncology-supportive injectable drugs into pre-filled syringes and improperly distributed the syringes to physicians treating cancer patients.

A clinic owner and physician were convicted of charges resulting from their involvement in a scheme to defraud Medicare. They falsely certified information about patients' medical condition and their need for home health services. They then used the false paperwork to bill to, and receive payment from, Medicare for home health services that were not medically necessary or not provided. They were sentenced to a combined 55 years in prison and were ordered to pay up to \$26.7 million in restitution, jointly and severally.

OIG recommended steps to reduce improper Medicare payments to skilled nursing facilities (SNFs). An OIG audit identified \$86 million in improper Medicare payments to SNFs for beneficiaries not meeting the "3-day rule" (i.e., the requirement that a beneficiary must be an inpatient in a hospital for at least 3 days to be eligible for coverage of SNF care following their hospital discharge). OIG recommended improvements to a claims processing edit, education for hospitals and SNFs, and new notifications from hospitals to beneficiaries and to SNFs regarding whether the beneficiary's hospital stay qualifies him or her for SNF care coverage. (See report [A-05-16-00043](#).)

OIG identified duplicate payments for transportation services and payments for unallowable non-emergency transportation services. Medicare requirements for consolidated billing prohibit Part B payments to ambulance suppliers for transportation services that were also included in Medicare Part A payments to SNFs. However, OIG found that Medicare's edits were not designed to prevent or detect inappropriate payments to ambulance suppliers for transportation services for beneficiaries during SNF stays. We estimated that Medicare overpaid \$19.9 million and beneficiaries incurred an estimated \$5.2 million in coinsurance and deductible liabilities related to these incorrect payments. In related work, OIG found that a particular ambulance supplier incorrectly billed Medicare for 89 out of 100 sampled claims for non-emergency transport services. For these 89 claims, the beneficiaries' conditions did not meet medical necessity requirements, the services did not meet documentation requirements, or both. (See reports [A-01-17-00506](#) and [A-02-16-01021](#).)

OIG highlighted vulnerabilities associated with Medicare's hospital wage index system and recommended reform. CMS collects wage data from hospitals annually through their Medicare cost reports and uses these data in several ways, including to reflect local labor prices by deriving local "wage indexes." CMS then uses these wage indexes to adjust inpatient payments to hospitals depending on their location. Inaccuracies in the wage data that hospitals submit can result in substantial overpayments to some hospitals and underpayments to other hospitals. Based on 41 OIG reviews of hospitals' wage data over the past 15 years, we identified significant vulnerabilities in the wage index system and recommended that CMS and HHS consider comprehensive reform to this system. (See report [A-01-17-00500](#).)

Ensuring Program Integrity and Effective Administration of the Medicaid Program

Protecting the integrity of Medicaid is a key focus in OIG's goal to fight fraud, waste, and abuse. We make recommendations to CMS and States to correct problems and mitigate program risks, and we work closely with State MFCUs to combat Medicaid fraud. Below are examples of significant OIG work during this semiannual reporting period.

OIG recommended that CMS recover \$1.6 billion due the Federal Government in Medicaid overpayments. CMS has not recovered all of the overpayments identified in OIG audit reports in accordance with Federal requirements. CMS concurred with our recommendations to recover the overpayments and to improve the timeliness of recovering overpayments in the future. (See report [A-05-17-00013](#).)

California made Medicaid payments on behalf of non-eligible beneficiaries. On the basis of our sample results, OIG estimated that California made Medicaid payments of \$959.3 million (\$536 million Federal share) on behalf of 802,742 ineligible beneficiaries and \$4.5 billion (\$2.6 billion Federal share) on behalf of 3.1 million potentially ineligible beneficiaries. We recommended that California redetermine, if necessary, the current Medicaid eligibility of the sampled beneficiaries and make procedural changes related to determining Medicaid eligibility. (See report [A-09-17-02002](#).)

OIG examined States' use of hospital tax programs to fund States' shares of Medicaid expenditures. An OIG audit of seven States' hospital tax programs showed that these tax programs raised more than \$38 billion in revenue to draw down almost \$55 billion in Federal Medicaid funds over 5 years. At the same time, the hospitals' tax payments to the States were largely offset by supplemental payments to hospitals. These State tax programs complied with Federal requirements because they fell under a legal provision (a "safe harbor") that enabled them to mitigate the tax impacts on hospitals more than would have been allowed outside that safe harbor. OIG recommended that CMS re-evaluate the impacts of the safe harbor and consider changing it. (See report [A-03-16-00202](#).)

Protecting HHS Data, Systems, and Beneficiaries From Cybersecurity Threats

The security of HHS IT systems and the personal information and data collected and maintained by HHS programs is critically important to the health and well-being of the American people. Furthermore, FDA is charged with regulating the safety, effectiveness, and security—including cybersecurity—of medical devices. OIG has developed a robust portfolio of oversight work focused on these issues, including the following:

OIG identified opportunities for NIH to strengthen controls over sensitive data. OIG found that NIH had not assessed risks to national security when permitting foreign principal investigators to access U.S. genomic data. We recommended, among other actions, that NIH develop a security framework, conduct a risk assessment, and implement additional security controls over genomic data. (See report [A-18-18-09350](#).)

OIG recommended that FDA better address cybersecurity risks to medical devices on the market. OIG found that FDA's policies and procedures were insufficient for addressing cybersecurity risks and events involving medical devices that it had already approved (known as "postmarket"). We recommended that FDA strengthen its policies and procedures so as to enhance its ability to manage and respond to postmarket medical device compromises resulting from cybersecurity vulnerabilities, exploitations, and threats. (See report [A-18-16-30530](#).)

OIG examined States' responses to breaches of Medicaid data. OIG found that most breaches of Medicaid data in 2016 disclosed information about a single individual and often resulted from misdirected mail or faxes; large breaches from hacking were rare. States follow a common framework for responding to breaches of Medicaid

data; however, States do not routinely notify CMS of breaches despite CMS guidance that they do so. (See report [OEI-09-16-00210](#).)

Protecting the Integrity of HHS Grants and Contracts

In FY 2018, HHS awarded \$109 billion in grants. OIG's oversight work reviews the appropriate and effective use of HHS grant and contract funds, effective grants and contracts management at the Department level, and program integrity and financial capability at the grantee or contractor level. Significant OIG work during this reporting period includes the following:

OIG identified continuing vulnerabilities in the HHS oversight of the Small Business Innovation Research (SBIR) program. OIG found that HHS has taken minimal steps to address known program integrity vulnerabilities. These vulnerabilities may allow ineligible awardees to receive SBIR funds and may result in duplicative funding. We recommended a number of actions to address these weaknesses. (See report [OEI-04-18-00230](#).)

OIG found that CDC reimbursed contractors for some World Trade Center Health Program administrative costs that did not comply with Federal requirements. We estimated that these improper reimbursements totaled \$8 million. We also determined that CDC did comply with Federal requirements for all eight of the selected fixed-price contract invoices that we reviewed. (See report [A-02-16-02012](#).)

OIG Participation in Congressional Hearings

<i>Date</i>	<i>Witness</i>	<i>Testimony/Committee</i>
02/07/2019	<u>Ann Maxwell, Assistant Inspector General for Evaluation and Inspections</u>	<u>"Examining the Failures of the Trump Administration's Inhumane Family Separation Policy,"</u> House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations

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
DHS	Department of Homeland Security
DOJ	Department of Justice
EHR	electronic health records
EMTALA	Emergency Medical Treatment and Labor Act
FCA	False Claims Act
FDA	Food and Drug Administration
FY	fiscal year
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HRSA	Health Resources and Service Administration
IHS	Indian Health Service
MAC	Medicare Administrative Contractor
MCO	managed care organization
MFCU	Medicaid Fraud Control Unit
NIH	National Institutes of Health
OAS	Office of Audit Services
OCIG	Office of Counsel to the Inspector General
OEI	Office of Evaluation and Inspections
OI	Office of Investigations
OIG	Office of Inspector General
ORR	Office of Refugee Resettlement
PCS	personal care services
SAMHSA	Substance Abuse and Mental Health Services Administration
SNF	skilled nursing facility
UAC	unaccompanied alien children

Centers for Medicare & Medicaid Services

Although the Centers for Medicare & Medicaid Services Has Made Progress, It Did Not Always Resolve Audit Recommendations in Accordance With Federal Requirements (A-07-18-03228), January 2019

Although CMS has made significant progress in the timely resolution of audit recommendations since our previous review (of Federal FYs 2006 and 2007), it did not always resolve audit recommendations in a timely manner during FYs 2015 and 2016. Specifically, CMS resolved 1,231 of the 1,371 recommendations that were outstanding during FYs 2015 and 2016. However, it did not resolve 405 of the 1,231 recommendations (32.9 percent) within the required 6-month resolution period. In addition, as of September 30, 2016, CMS had not resolved 140 audit recommendations that were past due for resolution. Some of the past-due recommendations had associated dollar amounts that totaled \$138.6 million; others were procedural in nature.

CMS had policies and procedures in place to ensure that audit recommendations were resolved in compliance with Federal requirements. Although CMS did not always issue management decisions and submit the related clearance documents within the required 6-month resolution period, CMS did make progress in this respect (compared with the findings of our previous review) by significantly increasing the percentage of audit recommendations that were resolved in a timely manner and by significantly reducing both the total number and associated dollar amounts of unresolved audit recommendations that were past due for resolution.

CMS concurred with our recommendations that it continue to follow its policies and procedures related to the audit resolution process, and enhance them where possible, and promptly resolve the 140 outstanding audit recommendations that were past due as of September 30, 2016.

Medicare Program Reports and Reviews

Financial Management and Improper Payments

CMS Did Not Always Ensure Hospitals Complied With Medicare Reimbursement Requirements for Graduate Medical Education (A-02-17-01017), November 2018

CMS generally ensured that hospitals in selected MAC jurisdictions claimed Medicare graduate medical education (GME) reimbursement in accordance with Federal requirements. However, in seven of our eight audits, we identified some instances in which teaching hospitals did not always comply with Federal requirements when claiming Medicare GME reimbursement for residents. Specifically, we found that hospitals in the six MAC jurisdictions we reviewed claimed GME reimbursement for residents who were claimed by more than one hospital for the same period and whose total full-time equivalent (FTE) count exceeded one, totaling almost \$4 million in excess Medicare GME reimbursement.

The overstated FTE counts and excess reimbursement occurred because CMS did not have adequate procedures to ensure that hospitals do not count residents as more than one FTE. For example, CMS did not review resident data submitted by hospitals to detect whether a resident had overlapping rotational

assignments (i.e., working at more than one hospital during the same period) or require the MACs to perform this work.

CMS agreed with our recommendation that it take steps to ensure that no resident is counted as more than one FTE.

Payments Made by Novitas Solutions, Inc., to Hospitals for Certain Advanced Radiation Therapy Services Did Not Fully Comply With Medicare Requirements (A-02-16-01006), November 2018, and

Payments Made by National Government Services, Inc., to Hospitals for Certain Advanced Radiation Therapy Services Did Not Fully Comply With Medicare Requirements (A-02-16-01007), December 2018

Intensity-modulated radiation therapy (IMRT) is an advanced type of radiation procedure used to treat difficult-to-reach tumors. Novitas Solutions, Inc. (Novitas), the MAC responsible for processing Medicare payments for outpatient services in Jurisdictions H and L, and National Government Services, Inc. (NGS), the MAC responsible for processing Medicare payments for outpatient services in Jurisdictions 6 and K, incorrectly paid hospitals for IMRT services provided to nearly all of the beneficiaries associated with our review.

Based on our sample results, we estimated that hospitals in Jurisdictions H and L received Medicare overpayments of at least \$7.2 million for unallowable IMRT services during our audit period. We estimated that hospitals in Jurisdictions 6 and K received Medicare overpayments of at least \$5.7 million for unallowable IMRT services during our audit period.

Novitas generally agreed with our recommendations that it (1) recover from hospitals the portion of the estimated \$7.2 million in identified overpayments for claims incorrectly billed that are within the reopening period, (2) notify the hospitals responsible for the remaining portion of the estimated \$7.2 million in potential overpayments so that those hospitals can investigate and return any identified overpayments, and (3) identify and recover any additional similar overpayments for IMRT services made after the audit period. Novitas agreed with two procedural recommendations to implement payment edits and to educate hospitals on properly billing for IMRT services.

NGS partially agreed with our recommendations that it (1) recover from hospitals the portion of the estimated \$5.7 million in identified overpayments for claims incorrectly billed that are within the reopening period and (2) notify the hospitals responsible for the remaining portion of the estimated \$5.7 million in potential overpayments so that those hospitals can investigate and return any identified overpayments. NGS disagreed with our recommendation that it identify and recover any additional similar overpayments for IMRT services made after the audit period and agreed with two procedural recommendations to implement payment edits and to educate hospitals on properly billing for IMRT services.

Medicare Improperly Paid Suppliers for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Provided to Beneficiaries During Inpatient Stays (A-09-17-03035), November 2018

For our audit period (January 1, 2015, through December 31, 2017), Medicare should not have paid suppliers for any of the \$34 million for durable medical equipment, prosthetics, orthotics, and supplies

(DMEPOS) that were provided during inpatient stays. In addition, beneficiaries were held responsible for unnecessary deductibles and coinsurance of \$8.7 million paid to the suppliers for the DMEPOS items.

Medicare overpaid the suppliers because the system edits that should have prevented or detected the overpayments were not adequate. If the system edits had been designed properly since 2008, Medicare could have saved \$223.1 million, and beneficiaries could have saved \$56.3 million in deductibles and coinsurance that may have been incorrectly collected from them or from someone on their behalf.

CMS concurred with our recommendations that it direct the Medicare contractors to (1) recover the \$34 million in identified improper payments to suppliers in accordance with CMS's policies and procedures, (2) recommend that the suppliers refund to beneficiaries up to \$8.7 million in deductible and coinsurance amounts that may have been incorrectly collected from them or from someone on their behalf, (3) identify and recover any improper payments to suppliers after our audit period, and (4) correct the system edits to fully prevent or detect overpayments to suppliers for DMEPOS items provided during inpatient stays. CMS did not concur with our recommendation that it seek legislative authority to require suppliers to refund to beneficiaries incorrectly collected Medicare Part B deductible and coinsurance amounts.

Midwood Ambulance & Oxygen Service, Inc., Billed for Nonemergency Ambulance Transport Services That Did Not Comply With Medicare Requirements (A-02-16-01021), December 2018

Midwood Ambulance & Oxygen Service, Inc. (Midwood), did not comply with Medicare requirements for billing nonemergency ambulance transport services for 89 of the 100 claims we reviewed. Specifically, Midwood incorrectly billed Medicare for beneficiaries whose conditions did not meet medical necessity requirements and billed for services that did not meet documentation requirements. These errors occurred because Midwood did not have adequate controls to prevent the incorrect billing of nonemergency ambulance transport claims. On the basis of our sample results, we estimated that Midwood received overpayments of at least \$19.2 million for the audit period. This amount includes claims with payment dates outside of the Medicare 4-year claim-reopening period.

Midwood partially agreed with our recommendation to strengthen its procedures for billing nonemergency ambulance transport services. Midwood disagreed with our recommendations that it (1) refund to the Medicare program the portion of the estimated \$19.2 million overpayment for claims incorrectly billed that are within the Medicare reopening period and (2) for the remaining portion of the estimated \$19.2 million in overpayments for claims that are outside of the Medicare reopening period, exercise reasonable diligence to identify and return additional overpayments. Midwood did not agree or disagree with our recommendation that it identify and return any additional similar improper payments made after our audit period.

First Coast Service Options, Inc., Paid Providers for Hyperbaric Oxygen Therapy Services That Did Not Comply With Medicare Requirements (A-04-16-06196), December 2018

Of the 120 sampled outpatient claims totaling \$415,513, First Coast Service Options, Inc. (First Coast), made payments for hyperbaric oxygen (HBO) therapy that did not comply with Medicare requirements for 110 claims (92 percent), resulting in overpayments for HBO therapy totaling \$351,970.

First Coast made payments for HBO therapy that did not always comply with Medicare requirements because it had limited policies and procedures in place to ensure that it made correct payments. Based on our sample results, we estimated that First Coast overpaid providers in Jurisdiction N \$39.7 million during the audit period for HBO therapy that did not comply with Medicare requirements.

First Coast concurred with our recommendations that it (1) recover the portion of the \$351,970 in Medicare overpayments, (2) notify the 70 providers responsible for the remaining 46,737 nonsampled claims with potential overpayments estimated at \$39.3 million so that those providers can investigate and return any identified overpayments, and (3) identify and recover any improper payments for HBO therapy services made after the audit period. First Coast partially concurred with our recommendation that it work with CMS to the extent possible in developing more effective automated HBO therapy prepayment edits in the claim processing system, which would result in millions of dollars in future cost savings.

Medicare Paid Twice for Ambulance Services Subject to Skilled Nursing Facility Consolidated Billing Requirements (A-01-17-00506), February 2019

Medicare made Part B payments to ambulance suppliers for transportation services that were also included in Medicare Part A payments to skilled nursing facilities (SNFs) as part of consolidated billing requirements. For 78 of the 100 beneficiary days we sampled with dates of service from July 1, 2014, to June 30, 2016, Medicare made Part B payments that were incorrect. Medicare overpaid the ambulance suppliers because the Common Working File (CWF) edits were not designed to prevent or detect Part B overpayments for all transportation subject to consolidated billing. In addition, ambulance suppliers did not have the necessary controls to prevent incorrect billing to Medicare Part B.

On the basis of our sample results, we estimated that Medicare made a total of \$19.9 million in Part B overpayments to ambulance suppliers for transportation services for beneficiaries in Part A SNF stays. In addition, we estimated that beneficiaries incurred an estimated \$5.2 million in coinsurance and deductible liabilities related to these incorrect payments.

CMS concurred with our recommendation that it redesign the CWF edits to prevent Part B overpayments to ambulance suppliers for transportation services provided to beneficiaries in Part A SNF stays. CMS also concurred with our six procedural recommendations.

CMS Improperly Paid Millions of Dollars for Skilled Nursing Facility Services When the Medicare 3-Day Inpatient Hospital Stay Requirement Was Not Met (A-05-16-00043), February 2019

To be eligible for coverage of posthospital extended care services, a Medicare beneficiary must be an inpatient in a hospital for not less than 3 consecutive calendar days (3-day rule) before being discharged from the hospital. CMS improperly paid 65 of the 99 SNF claims we sampled when the

3-day rule was not met. Improper payments associated with these 65 claims totaled \$481,034. On the basis of our sample results, we estimated that CMS improperly paid \$84 million for SNF services that did not meet the 3-day rule during 2013 through 2015. These problems will not be corrected until CMS requires a consistent documentation standard for SNFs that provides verifiable evidence of a qualifying hospital stay, which CMS can use to either certify allowable SNF reimbursements or detect and recover improper SNF reimbursements.

CMS agreed with our recommendations that it (1) ensure that the CWF qualifying inpatient hospital stay edit for SNF claims is enabled when SNF claims are processed for payment and (2) educate both hospitals and SNFs about verifying and documenting the 3-day inpatient hospital stay relative to supporting a Medicare claim for SNF reimbursement. CMS disagreed with our recommendations that it (1) require hospitals to provide beneficiaries a written notification of the number of inpatient days of care provided during the hospital stay and whether the hospital stay qualifies subsequent SNF care for Medicare reimbursement so that beneficiaries are aware of their potential financial responsibility before consenting to receive SNF services and (2) require SNFs to obtain a written notification from the hospital and retain it as a condition of payment for their claims.

Medicare Market Shares of Mail Order Diabetes Test Strips From April Through June 2018
([OEI-04-18-00440](#)), January 2019

We found that from April through June 2018, sampled suppliers provided 17 types of diabetes test strips (DTS) via Medicare's National Mail-Order Program. The top 2 strip types accounted for 53 percent of the Medicare mail-order market, and the top 10 strip types accounted for 98 percent of the market. The Medicare Improvements for Patients and Providers Act of 2008 prohibits CMS from awarding a contract to a DTS supplier in the National Mail-Order Program if the supplier's bid does not cover at least 50 percent, by volume, of all types of DTS provided to Medicare beneficiaries. The results from this report will help CMS to oversee future bids for suppliers to furnish DTS in the National Mail-Order Program.

Medicare Market Shares of Non-Mail Order Diabetes Test Strips From April Through June 2018
([OEI-04-18-00441](#)), March 2019

We found that from April through June 2018, sampled suppliers provided 34 types of diabetes test strips to Medicare beneficiaries via non-mail order. The top 3 strip types accounted for 53 percent of the Medicare mail-order market, and the top 10 strip types accounted for 93 percent of the market. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) prohibits CMS from awarding a Competitive Bidding Program contract to a supplier of diabetes test strips if the supplier's bid does not cover at least 50 percent, by volume, of the types of diabetes test strips provided to Medicare beneficiaries. This is known as the "50-percent rule." MIPPA requires OIG to determine the market shares of the types of diabetes test strips before each round of competitive bidding to assist CMS in ensuring that bidding suppliers meet the 50-percent rule. Initially, compliance with this rule was based on mail order claims only. The Bipartisan Budget Act of 2018 amended the 50-percent rule by requiring that, for bids on or after January 1, 2019, CMS must use data from the non-mail-order Medicare market as well as the mail-order one. The results from this report will help CMS to oversee future bids for suppliers to furnish diabetes test strips in the National Mail-Order Program.

Quality of Care, Safety, and Access

CMS Guidance to State Survey Agencies on Verifying Correction of Deficiencies Needs To Be Improved To Help Ensure the Health and Safety of Nursing Home Residents (A-09-18-02000), February 2019

State agencies must verify that nursing homes corrected identified deficiencies, such as the failure to provide necessary care and services, before certifying whether the nursing homes are in substantial compliance with Federal participation requirements for Medicare and Medicaid.

Of the nine selected State agencies in our previous reviews, seven did not always verify nursing homes' correction of deficiencies as required. Specifically, for 326 of the 700 sampled deficiencies, these State agencies did not obtain evidence of nursing homes' correction of deficiencies or maintain sufficient evidence that they had verified correction of deficiencies. If State agencies certify that nursing homes are in substantial compliance without properly verifying the correction of deficiencies and maintaining sufficient documentation to support the verification of deficiency correction, the health and safety of nursing home residents may be placed at risk.

In addition to summarizing the issues identified during our previous reviews, we determined that CMS's guidance to State agencies on verifying nursing homes' correction of deficiencies and maintaining documentation to support verification needed to be improved.

CMS concurred with our recommendations that it take specific actions to (1) improve its guidance to State agencies on verifying nursing homes' correction of deficiencies and maintaining documentation to support verification, (2) consider improving its forms related to the survey and certification process, and (3) work with State agencies to address technical issues with the system for maintaining supporting documentation.

Hospitals Reported Improved Preparedness for Emerging Infectious Diseases After the Ebola Outbreak (OEI-06-15-00230), October 2018

We found that most hospitals in the United States were not prepared for the domestic outbreak of Ebola virus disease (Ebola) in 2014, with 71 percent of hospital administrators reporting that their facilities were unprepared to receive patients with Ebola. By 2017, administrators from only 14 percent of hospitals reported their facilities were still unprepared for emerging infectious disease (EID) threats such as Ebola. Hospital actions to improve preparedness included updating emergency plans, training staff to care for patients with EIDs, purchasing additional supplies, and conducting EID-focused drills. Although hospital administrators believe their hospitals are ready to respond to a future EID threat, they cited challenges to maintaining that preparedness, given competing priorities for hospital resources and staff time. Administrators also cited the need to focus efforts on more common hazards, such as natural disasters, and difficulty in using government guidance to prepare for EIDs. We also found that administrators from one-third of hospitals did not know their hospital's role in a tiered hospital framework designed by the CDC to guide hospitals in receiving and treating cases of Ebola.

We recommend that to improve hospital preparedness and HHS assistance and oversight, the Office of the Assistant Secretary for Preparedness and Response (ASPR), CDC, and CMS continue to support hospital preparedness for potential EIDs by coordinating guidance and providing practical advice for all hospitals. We also recommended that CDC clarify and promote the details and ongoing status of its tiered

framework for hospitals, so that hospitals are clear regarding their responsibilities during an EID outbreak. Further, we recommended that CMS add EIDs to the definition of “all hazards” in the State Operations Manual to promote inclusion of EIDs in hospital emergency planning. ASPR, CDC, and CMS concurred with our recommendations.

Adverse Events in Long-Term-Care Hospitals: National Incidence Among Medicare Beneficiaries
([OEI-06-14-00530](#)), November 2018

We estimate that 21 percent of Medicare patients in long-term-care hospitals (LTCHs) experienced adverse events as a result of medical care; an additional 25 percent of patients experienced temporary harm events. This rate of patient harm is higher than OIG found in other settings and may be due, in part, to longer stays and high patient acuity. Nevertheless, these events endanger patient health and reviewers determined over half to be preventable. CMS and AHRQ concurred with all of our recommendations, which were:

- AHRQ and CMS should collaborate to create and disseminate a list of potential adverse events in LTCHs, and
- CMS should include information about potential events and patient harm in its quality outreach to LTCHs.

Payment Policy and Trends

Significant Vulnerabilities Exist in the Hospital Wage Index System for Medicare Payments ([A-01-17-00500](#)),
November 2018

CMS uses area wage indexes to adjust hospital payments annually to reflect local labor prices. The area wage indexes applied to urban hospitals in a State cannot be lower than the wage index for the rural hospitals in that State. This provision is called the “rural floor.” “Hold-harmless” provisions protect hospitals from having their wage indexes lowered because of the geographic reclassification of other hospitals.

We identified these significant vulnerabilities in the wage index system: (1) CMS lacks the authority to penalize hospitals that submit inaccurate or incomplete wage data, (2) MAC limited reviews do not always identify inaccurate wage data, (3) the rural floor decreases wage index accuracy, and (4) hold-harmless provisions decrease wage index accuracy.

CMS agreed with our recommendation that it work with the MACs to focus on hospitals whose wage data have high levels of influence on the wage index of their area. CMS disagreed with our recommendation that it rescind its hold-harmless policy. CMS stated that it will consider whether to recommend for inclusion in the President’s next budget our recommendations that (1) CMS and the Secretary of Health and Human Services revisit the possibility of comprehensive reform, (2) CMS seek legislative authority to penalize hospitals that submit inaccurate or incomplete wage data, (3) CMS seek legislation to repeal the law creating the rural floor, and (4) CMS seek legislation to repeal the hold-harmless provisions in Federal law.

Drug Pricing and Reimbursement

CMS's Enhanced Controls Did Not Always Prevent Terminated Drug Utilization in Medicare Part D (A-07-16-06068), November 2018

The steps CMS has taken to address terminated drug utilization in Medicare Part D were not entirely effective and, as a result, CMS continued to accept some prescription drug event (PDE) data for terminated drugs in CYs 2014 and 2015. Terminated drugs are discontinued drugs that have passed their shelf life or been withdrawn from the market. Although CMS has made improvements to prevent terminated drug utilization in Part D, it accepted PDE data totaling \$31.9 million in gross drug costs for 3,705 terminated drugs in CYs 2014 and 2015. CMS did not compare the information on termination dates in its quarterly Medicaid drug rebate files with the FDA file, did not investigate the discrepancies that existed between these two data sources, and did not update its system edits in a timely manner.

CMS agreed with our recommendation that it update its system edits with a new version of FDA's file on a more timely basis. CMS disagreed with our recommendation that it continue to strengthen its internal controls to ensure that all PDE data for terminated drugs are rejected by working with FDA to verify the accuracy of drug termination dates, to include comparing the information on termination dates in its two data sources, investigating discrepancies between the data sources, and verifying termination dates with the manufacturers. Although CMS remains committed to strengthening its controls to ensure that PDE data for terminated drugs are rejected, it regards FDA as the expert authority and source for national drug code listing information.

Medicaid Program Reports and Reviews

Financial Management and Improper Payments

Ohio Medicaid Managed Care Organizations Received Capitation Payments After Beneficiaries' Deaths (A-05-17-00008), October 2018

Ohio made capitation payments totaling \$90.5 million on behalf of deceased beneficiaries. We confirmed that all beneficiaries associated with the 100 capitation payments in our stratified random sample were deceased. Ohio properly recovered 37 of these capitation payments. However, Ohio did not recover the remaining 63 capitation payments totaling \$74,495 (\$51,431 Federal share). On the basis of our sample results, we estimated that Ohio did not recover unallowable payments to Medicaid Managed Care Organizations (MCOs) totaling at least \$51.3 million (\$38 million Federal share) during our audit period.

Ohio did not always identify and process Medicaid beneficiaries' death information. Although Ohio's eligibility systems regularly interfaced with Federal data exchanges that identify dates of death, county caseworkers did not always receive notification that beneficiaries had died.

Ohio did not indicate concurrence or nonconcurrence with our recommendations that it (1) refund \$38 million to the Federal Government; (2) identify and recover unallowable payments made to MCOs during our audit period on behalf of deceased beneficiaries, which we estimate to be at least \$51.3 million; (3) identify capitation payments made on behalf of deceased beneficiaries before and after our audit period and repay the Federal share of amounts recovered; and (4) ensure that the eligibility system Ohio

Benefits alerts county caseworkers of the beneficiaries' dates of death and that dates of death are recorded in a timely manner to prevent unallowable payments.

New York Claimed Federal Reimbursement for Some Assertive Community Treatment Services That Did Not Meet Medicaid Requirements (A-02-17-01008), October 2018

New York claimed Federal Medicaid reimbursement for some Assertive Community Treatment (ACT) services that did not comply with Medicaid requirements. Of the 100 claims in our random sample, 13 claims did not comply with Medicaid requirements.

Providers did not always ensure that ACT services were provided in accordance with a beneficiary's treatment plan and did not always verify that the required number of contacts needed to claim the ACT full payment rate was provided. Further, certain providers failed to maintain or provide documentation to support ACT services claims. Finally, although New York monitors ACT providers for compliance with Medicaid requirements, it did not ensure that its oversight was effective in preventing the errors identified in our review.

New York agreed with our recommendation that it ensure that ACT program guidance on claiming Medicaid reimbursement for services is reinforced with providers and continue to improve its monitoring of the ACT program but disagreed with our recommendation that it refund \$4.4 million to the Federal Government.

The Centers for Medicare & Medicaid Services Had Not Recovered More Than a Billion Dollars in Medicaid Overpayments Identified by OIG Audits (A-05-17-00013), December 2018

We reviewed CMS's efforts to collect overpayments identified in 313 audits issued in FYs 2010 through 2015 (the current period) that recommended recovering overpayment amounts totaling \$2.7 billion and 10 audits issued for FYs 2004 through 2009 (the prior period) that recommended recovering overpayment amounts totaling \$225.6 million.

CMS did not collect \$1.6 billion in overpayments identified in 77 current-period audits and \$188.6 million in overpayments identified in 7 prior-period audits. In addition, CMS did not ensure that States correctly reported Medicaid overpayments on the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program Form CMS-64 (CMS-64). Finally, we could not verify the accuracy of \$2.7 million that CMS told us was reported by States because before our review CMS disposed of documents supporting that overpayments were recovered.

CMS concurred with our recommendations that it (1) recover the remaining \$1.6 billion due the Federal Government from the current period and \$188.6 million due the Federal Government from the prior period; (2) improve the timeliness of recovering overpayments by setting guidelines about the time CMS has to work with States to obtain documentation and issue disallowance letters to States; and (3) verify that States report overpayments correctly, require States to resubmit corrected CMS-64s when they do not, and continue to educate States about their responsibility to report overpayments correctly.

California Made Medicaid Payments on Behalf of Non-Newly Eligible Beneficiaries Who Did Not Meet Federal and State Requirements (A-09-17-02002), December 2018

Historically, only certain groups of individuals who had incomes and assets below certain thresholds were eligible for Medicaid (traditional coverage groups). After the passage of the Patient Protection and Affordable Care Act (ACA), many beneficiaries remained eligible under these traditional coverage groups. We refer to these beneficiaries as “non-newly eligible beneficiaries.”

We reviewed a stratified random sample of 125 non-newly eligible beneficiaries for whom California made Medicaid payments for services provided from October 2014 through March 2015. On the basis of our sample results, we estimated that California made Medicaid payments of \$959.3 million (\$536 million Federal share) on behalf of 802,742 ineligible beneficiaries and \$4.5 billion (\$2.6 billion Federal share) on behalf of 3.1 million potentially ineligible beneficiaries.

California did not explicitly agree or disagree with our recommendations that it redetermine, if necessary, the current Medicaid eligibility of the sampled beneficiaries and ensure that (1) all eligibility requirements are verified properly and annual redeterminations are performed as required and (2) eligibility determinations are performed only for individuals who apply for Medicaid. California partly agreed with our recommendations that it maintain information in its case files to support eligibility determinations.

Wisconsin Did Not Report and Refund the Full Federal Share of Medicaid-Related Settlements and a Judgment (A-05-17-00041), December 2018

Wisconsin did not report and return \$27.6 million (Federal share) of Medicaid-related settlements and a judgment for the period October 2008 through September 2016. It (1) underreported \$18.7 million (Federal share) for six settlements and one judgment by computing the Federal share only on the net proceeds received after fees and interest were removed and (2) failed to report any of the \$9 million (Federal share) for two settlements.

Wisconsin did not properly report the settlements and a judgment because it lacked policies that addressed the reporting of recoveries from State actions taken because of harm to its Medicaid program and did not have procedures to help ensure that it reported recoveries on the Form CMS-64.

Wisconsin agreed with our recommendations that it (1) determine whether settlements and judgments received after September 30, 2016, were reported and refund the Federal share of any recoveries not reported in their entirety and (2) implement policies to ensure that all settlements and judgments are reported properly. Wisconsin disagreed with our recommendation that it refund \$27.6 million to the Federal Government.

Louisiana Did Not Comply With Federal and State Requirements Prohibiting Medicaid Payments for Inpatient Hospital Services Related to Provider-Preventable Conditions (A-06-16-02003), December 2018

Louisiana did not comply with Federal and State requirements prohibiting Medicaid payments for inpatient hospital services related to treating certain provider-preventable conditions (PPCs) because it did not have controls to identify claims with PPCs that would have required a reduction in claim payment. We identified inpatient hospital claims totaling \$55.4 million (\$34.9 million Federal share) that contained a diagnosis

code identified as a PPC and certain present-on-admission (POA) codes or the claims were missing POA codes.

Louisiana agreed with our recommendations that it (1) work with CMS to determine what portion of the \$34.9 million Federal share claimed was unallowable for Federal Medicaid reimbursement and refund to the Federal Government the unallowable amount; (2) review all claims before our audit period (with dates of admission from July 1, 2012, and paid through December 31, 2012) and all claims paid after our audit period (June 30, 2017) to determine whether payments should be reduced for any claims that contained PPCs, refunding to the Federal Government its share of any unallowable amounts; and (3) strengthen its internal controls to ensure hospitals submit services related to PPCs as noncovered days, postpayment reviews are conducted, and POA codes are submitted on claims.

States Follow a Common Framework in Responding to Breaches of Medicaid Data (OEI-09-16-00210), October 2018

We found that most of the 1,260 breaches that State Medicaid agencies and their contractors identified in 2016 disclosed information about a single individual, and often resulted from misdirected letters or faxes; large breaches from hacking were rare. States follow a common framework for responding to breaches of Medicaid data. However, although CMS has issued guidance that advises States to notify CMS of breaches, most States do not routinely do so. CMS concurred with our recommendation to reissue guidance to States about reporting Medicaid breaches to CMS.

Virginia Received Millions in Unallowable Bonus Payments (A-04-17-08060), January 2019

Some of the Children's Health Insurance Program Reauthorization Act of 2009 bonus payments that Virginia received for FYs 2011 through 2013 were not allowable in accordance with Federal requirements. Most of the data used in Virginia's bonus payment calculations were in accordance with Federal requirements. However, Virginia overstated its current enrollments in its bonus requests to CMS for FYs 2011 through 2013 because it improperly inflated its current enrollment by a fixed percentage estimate to account for potential retroactive enrollment, instead of using actual enrollment and the adjustment process to account for actual retroactive enrollment. CMS guidance instructed Virginia to calculate current enrollment based on actual enrollment.

As a result of the overstated current enrollment numbers, CMS overpaid Virginia approximately \$13.8 million in bonus payments.

Virginia disagreed with our recommendation that it refund approximately \$13.8 million to the Federal Government.

New Jersey Did Not Provide Adequate Oversight of Its Medicaid Delivery System Reform Incentive Payment Program (A-02-17-01007), March 2019

We could not determine whether New Jersey appropriately claimed Medicaid reimbursement for pay-for-performance incentive payments to five selected hospitals. Specifically, we could not determine whether the hospitals met performance goals calculated from Medicaid claim data. In addition, the hospitals did not report patients' health records information consistent with performance measure criteria. As a result,

we could not determine what portion of pay-for-performance incentive payments, totaling approximately \$51 million (\$25 million Federal share), that New Jersey made to the five selected hospitals based on determinations from New Jersey's Delivery System Reform Incentive Payment (DSRIP) program contractor was appropriate.

This occurred because New Jersey did not ensure that the DSRIP program contractor maintained Medicaid claim data to support the achievement of performance goals and did not provide adequate guidance to the hospitals regarding how they should report patients' health records information.

New Jersey disagreed with our findings and did not indicate concurrence or nonconcurrence with our recommendations that it work with its DSRIP manager and program contractor and the five selected hospitals to determine whether the approximately \$51 million (\$25 million Federal share) in pay-for-performance incentive payments to the hospitals was appropriate. New Jersey should also work with its DSRIP manager and program contractor and the 44 hospitals not selected for review to determine whether the approximately \$132 million (\$66 million Federal share) in remaining pay-for-performance incentive payments was appropriate. We also recommended that New Jersey improve its oversight of the DSRIP program to ensure compliance with Medicaid requirements.

Quality of Care, Safety, and Access

Wisconsin Did Not Comply With Federal Waiver and State Requirements at All 20 Adult Day Care Centers Reviewed (A-05-17-00030), October 2018

Wisconsin did not comply with Federal waiver and State requirements in overseeing centers that serve vulnerable adults who receive services through the Family Care program. All 20 of the centers we reviewed did not comply with State certification requirements. In total, we found 208 instances of noncompliance with health and safety and administrative requirements.

Wisconsin said that instances of noncompliance occurred partly because of low staffing levels that did not allow State surveyors to make recertification visits every 2 years. Additionally, Wisconsin officials confirmed that the certification checklist was outdated and lacked clarity on certain requirements, and certification requirements were not in the Wisconsin Administrative Rules. Wisconsin also said that there was minimal attendance by center personnel at State- or trade association-sponsored voluntary training programs. Finally, center personnel indicated the need for improved State agency communication and more guidance related to the specific center certification requirements.

Wisconsin concurred with our recommendations that it update the certification checklist and promulgate rules as required by Wisconsin Statutes, identify and address reasons for low attendance by center personnel at training programs, and increase State agency guidance related to center requirements. Wisconsin partially concurred with our recommendations that it ensure that the 208 instances of noncompliance with health and safety and administrative requirements identified in this report are corrected and consider revising staffing standards and caseload thresholds for State surveyors.

Program Integrity

Vulnerabilities Exist in State Agencies' Use of Random Moment Sampling To Allocate Costs for Medicaid School-Based Administrative and Health Services Expenditures (A-07-18-04107), December 2018

Inadequate oversight at both CMS and the State Medicaid agency (State agency) level created vulnerabilities in State agencies' use of random moment time studies (RMTS) as a basis to allocate and claim Federal Medicaid reimbursement for costs associated with school-based administrative activities and health services.

Of the 10 State agencies, 5 claimed unallowable school district administrative claiming (SDAC) and school-based health services (SBHS) costs, 3 claimed SDAC costs without having properly submitted cost allocation plans that described their RMTS methodologies, and all 10 did not correctly develop the RMTS methodologies used to allocate costs. Furthermore, some of the annual cost settlements performed by three State agencies did not take all interim payments into account. In addition, three State agencies could not provide medical record documentation to support the responses provided by RMTS participants; therefore, we could not determine whether services for which the State agencies had claimed SBHS costs had actually been performed. Finally, we could not determine which portions of an additional \$325.1 million of SDAC and SBHS costs were allowable in two States whose RMTS methodologies used sample universes that were or may have been inaccurate.

CMS concurred with our recommendations that it distribute formal guidance for the use of RMTS to allocate SBHS costs or consider no longer permitting States to use RMTS methodologies to allocate and claim SBHS costs and with our procedural recommendations for instructions to all State agencies regarding their SDAC and SBHS programs and their RMTS methodologies.

Payment Policy and Trends

Although Hospital Tax Programs in Seven States Complied With Hold-Harmless Requirements, the Tax Burden on Hospitals Was Significantly Mitigated (A-03-16-00202), November 2018

The healthcare-related hospital tax programs in the seven States we reviewed (California, Illinois, Indiana, Michigan, Missouri, Ohio, and Pennsylvania) complied with hold-harmless requirements. The States collected \$38.4 billion in tax revenue from their hospitals during State FYs 2011 through 2015. The \$38.4 billion was used as the State share of Medicaid payments and resulted in a drawdown of \$54.6 billion in Federal matching funds for a total of \$93 billion. From the \$93 billion, \$60.2 billion was used for supplemental payments for non-disproportionate share hospitals (non-DSHs) to mitigate most of the hospital tax payments, and \$32.7 billion was used mostly for additional hospital services.

In the States reviewed, we found that non-DSH supplemental payments exceeded 75 percent of hospital tax payments in each year for all States, except for 2 years in Pennsylvania and 1 year for Ohio. However, because the tax rate was less than the 6 percent safe-harbor threshold, the tax programs could return more than 75 percent of the tax payments to more than 75 percent of the taxpayers without violating the hold-harmless requirement (75/75 requirement). Had the tax rates exceeded 6 percent, CMS could have deemed those hospital tax programs as impermissible, which would disqualify the use of the tax revenue for drawing down Federal matching funds.

CMS concurred with our recommendation that it re-evaluate the effects of the healthcare-related tax safe-harbor threshold and the associated 75/75 requirement to determine whether modifications are needed, such as the reduction or elimination of the safe harbor threshold or adjusting the 75/75 requirement.

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 Medicare and Medicaid, 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; 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.

Specific case types include fraud schemes related to:

- controlled and noncontrolled prescription drugs,
- home health agencies and personal care services,
- ambulance transportation,
- durable medical equipment, and
- diagnostic radiology and laboratory testing.

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

In addition to investigating Medicare and Medicaid fraud, OIG investigates fraud, waste, and abuse—including the potential misuse of grants and contracts funds—in other HHS programs, including ACF, IHS, HRSA, ACL, CDC, NIH, SAMHSA, and other HHS agencies. Under certain circumstances, OIG investigates noncustodial parents who fail to pay court-ordered child support. OIG also investigates allegations of employee misconduct, whistleblower reprisals, and wrongdoing by HHS agency officials.

One of the most common types of fraud perpetrated against Medicare, Medicaid, and other Federal healthcare programs involves filing false claims for reimbursement. False claims may be pursued under Federal and State criminal statutes and, when appropriate, under the FCA. 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 healthcare 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 394 criminal and 327 civil actions against individuals or entities that engaged in offenses related to healthcare. We also reported more than \$2.05 billion in investigative receivables due to HHS and more than \$246.6 million in non-HHS investigative receivables, including civil and administrative settlements or civil judgments related to Medicare, Medicaid, and other Federal, State, and private healthcare programs.

The following are recently completed actions and settlements organized by subject area.

Prescription Drugs

The following case example involves prescription drugs:

- California—Physician Assistant David Lague was found guilty of conducting a scheme to unlawfully distribute prescription drugs. During the trial, evidence showed that Lague intentionally prescribed drugs to five different patients, knowing that the prescriptions were outside the usual course of professional practice and without a legitimate medical purpose. On two occasions, a patient asked Lague to double his prescriptions for powerful opioids so that the patient could sell the drugs. Lague not only doubled the prescriptions, he also discussed with the patient how to do it in a way to avoid scrutiny by pharmacies or law enforcement. Lague admitted at trial that he wrote false medical records of those visits in order to cover up what he was doing. The evidence at trial also showed that Lague falsified records as to other patients as well, detailing exams that never took place and indicating that he had reviewed lab work that he never reviewed. An expert who reviewed four of Lague's patient files found that his handling of those patients was an extreme departure from the standard of care. A jury found Lague guilty of 39 counts of unlawful distribution of controlled substances, and he was sentenced to 10 years in prison.

Pharmacies

The following case example involves a pharmacy:

- Missouri—The United States entered into False Claims Act settlement agreements (Agreements) with Howard Stark Professional Pharmacy, Inc., Steven Baraban, Gary Gray, and Steven Schafer (collectively, Stark Pharmacy). The Agreements resolve allegations that from March 1, 2013, through December 31, 2015, Stark Pharmacy, which had two locations—one in Kansas and one in Missouri, (1) submitted claims to Medicaid for payment of compounded pain creams with formulas that were different from the formulas in the pain creams provided to Medicaid beneficiaries; (2) manipulated compounds without physician authorizations; (3) submitted claims for payment of prescriptions that were returned to the manufacturer or for prescriptions that were not actually provided to Medicaid beneficiaries; and (4) created documentation that falsely represented pain creams were compounded in Missouri and that falsely represented the base creams used in the compounds. OIG entered into a 3-year Integrity Agreement with Howard Stark Professional Pharmacy, Gary Gray, and Steven Schafer.

Quality of Care

The following case example involves quality of care:

- Kentucky—Dr. Anis Chalhoub defrauded Medicare, Medicaid, and other insurers by implanting medically unnecessary pacemakers in his patients and causing the unnecessary procedures and follow-up care to be billed to health insurance programs. Specifically, between 2007 and 2011, Dr. Chalhoub implanted approximately 234 pacemakers in patients at St. Joseph London hospital. The evidence at trial showed that dozens of those patients' pacemakers were medically unnecessary,

under well-established national guidelines and Medicare coverage rules. Several patients testified at trial that Dr. Chalhoub pressured them into getting the procedures and told them misleading information about their health conditions. For instance, several patients recalled Dr. Chalhoub telling them that they might die without a pacemaker. Sinus node dysfunction, the diagnosis Dr. Chalhoub gave the patients, is a non-fatal heart rate. A Holter monitor would indicate a heart rate that was slightly slow in the middle of the night, and Chalhoub would cite this as a reason to place a pacemaker. This would then be followed by years of additional testing and check-ups. Patients receiving a pacemaker were as young as 28 years old. Several patients had their pacemaker removed or turned off and testified that they felt better after having done so. Dr. Chalhoub was found guilty of healthcare fraud and sentenced to 3 years and 6 months in prison and ordered to pay \$257,515 in restitution.

Pharmaceutical Companies

The following case example involves a pharmaceutical company:

- New York—AmerisourceBergen Corporation (ABC) entered into a False Claims Act settlement agreement and agreed to pay \$625 million to resolve liability associated with a pre-filled syringe program operated by certain ABC subsidiaries between 2001 and January 2014. More specifically, the United States alleged that the ABC subsidiaries improperly repackaged oncology-supportive injectable drugs into pre-filled syringes and improperly distributed the syringes to physicians treating cancer patients. The government also alleged that, in connection with the pre-filled syringe program, ABC and its subsidiaries caused the submission of false claims to Federal healthcare programs. ABC agreed to enter into a 5-year Corporate Integrity Agreement (CIA) with OIG. The CIA covers a wide array of ABC business units and makes executives accountable for compliance across a broad spectrum of operations.

Home Health

The following case example involves home health:

- Michigan—Two Detroit-area home health agency owners were sentenced to a total of 16 years in prison for their roles in a scheme to defraud Medicare by billing for home health services that were never provided. Hafiz and Tasneem Tahir were ordered to pay restitution of \$9.6 million and \$4.4 million, respectively, jointly and severally with their co-conspirators. The defendants each pleaded guilty to conspiracy to commit healthcare fraud and wire fraud and conspiracy to pay and receive healthcare kickbacks. As part of their guilty pleas, they admitted that they paid illegal kickbacks in exchange for the referral of Medicare beneficiaries to home health agencies that they owned. The defendants further admitted that between 2009 and 2017, they submitted false claims to Medicare for home health services that were never provided. Hafiz and Tasneem Tahir were charged along with Hoda Sabbagh, Emma King, and Antonio Kho. King and Kho pleaded guilty and are pending sentencing. Sabbagh remains a fugitive.

Transportation

The following case examples involve transportation:

- Texas—Anthony Chukwudi Nwosah was convicted of charges resulting from his involvement in a scheme to defraud Medicare. Nwosah, the owner of Tonieann EMS and Rosenberg EMS, admitted to submitting false claims to Medicare for ambulance transport services that were not provided and not medically necessary. Nwosah admitted he submitted the ambulance claims for Medicare beneficiaries transported by vans, not ambulances, to routine psychotherapy appointments and for at least one other beneficiary who did not require ambulance transportation. Nwosah also admitted he instructed a licensed emergency medical technician (EMT) to create fake ambulance transport records which included fake vital signs, patient narratives and transport mileage. Additionally, he admitted that more than 2,000 fake ambulance transport records contained the name of another EMT who never worked for him. Nwosah pleaded guilty to conspiracy to commit healthcare fraud and was sentenced to 4 years in prison and ordered to pay \$1.09 million in restitution.
- Texas—Fort Bend County (Fort Bend) made a submission pursuant to OIG’s Self-Disclosure Protocol (Protocol), and OIG accepted Fort Bend into the Protocol. On January 9, 2019, Fort Bend entered into a settlement agreement with the OIG wherein Fort Bend agreed to pay \$4,526,740.26 to resolve the OIG’s allegations that Fort Bend knowingly presented to Medicare, TriCare, the Department of Veterans Affairs/Champus, and the Railroad Retirement Board claims for items or services that Fort Bend knew or should have known were not provided as claimed and were false or fraudulent. Specifically, the OIG contends that during the period from October 1, 2009, to January 31, 2016, Fort Bend submitted claims for ambulance transportation services provided to beneficiaries which were improper because Fort Bend failed to obtain the necessary beneficiary authorization for the ambulance transports.

Durable Medical Equipment

The following case example involves durable medical equipment:

- California—Covidien LP entered into a civil settlement with the United States relating to its Solitaire device, a mechanical thrombectomy device. Through the settlement, Covidien resolved False Claims Act liability for allegedly paying kickbacks to induce the use of the device. The Solitaire device is intended to restore blood flow and retrieve blood clots in certain stroke patients. The alleged kickbacks took the form of payments made in connection with a registry study that collected data about experiences using the Solitaire device to treat stroke patients. The United States alleged that Covidien paid hospitals and institutions that participated in the registry a fee each time they used a new Solitaire device and reported certain data about their practices in treating stroke patients.

Laboratories

The following case example involves laboratories:

- California—GenomeDx Biosciences Corp. (GenomeDx) entered into a settlement agreement to resolve allegations that it improperly billed Medicare for genetic testing services from September 1, 2015, through June 30, 2017. Specifically, the United States alleged that GenomeDx submitted claims for Decipher Prostate tests (its "flagship" service) that were not medically necessary. GenomeDx agreed to pay over \$1.9 million to resolve its alleged liability.

Clinics

The following case example involves a clinic:

- Virginia—1st Class Sleep Diagnostic Center and 1st Class Medical owner, Young Yi, and manager, Dannie Ahn, conspired to defraud Medicare, TRICARE, private insurance, and the IRS of more than \$10 million. According to evidence presented at trial and court documents, Yi formed the primary entities used to commit the crimes. The defendants directed their employees to solicit patients who had been referred to the clinics for legitimate sleep studies for supplemental but medically unnecessary studies. To conceal the scheme, Yi instructed employees not to send the results of the fraudulent studies to the patients' doctors, lied to patients by telling them they did not have to pay copays or coinsurance, and cross-billed using different entities to conceal the repetition from the insurance companies and to get out-of-network payments for in-network services. The defendants also used the original referring doctors' names and identifying information on health insurance claims without their permission. Yi and Ahn were sentenced to a combined 9 years and 11 months in prison and were ordered to pay \$10.6 million in restitution, jointly and severally.

Hospices

The following case example involves hospice:

- Pennsylvania—SouthernCare, Inc., (SouthernCare) entered into a False Claims Act settlement agreement to resolve allegations that between January 1, 2009, and December 31, 2014, SouthernCare submitted false claims to Medicare for certain patients at SouthernCare's Pennsylvania offices when the patients did not meet the applicable Medicare eligibility requirements or documentation for the hospice benefit was not satisfied. SouthernCare agreed to pay over \$5.8 million to resolve its alleged liability.

Kickbacks

The following case example involves kickbacks:

- Vermont—Greenway Health, LLC (Greenway), a Health Information Technology (Health IT) software company, entered into a False Claims Act (FCA) settlement agreement wherein they agreed to pay \$57.25 million and enter into a 5-year Corporate Integrity Agreement with OIG covering the company's Health IT software. This settlement agreement resolves Greenway's FCA

liability for the following alleged conduct: (1) falsely representing during the HHS Office of National Coordinator for Health Information Technology (ONC) certification process that its electronic health record software product known as “Prime Suite” complied with all applicable requirements under the ONC Health IT Certification Program, when, in fact, Greenway knew that Prime Suite would not satisfy all such requirements, which consequently caused healthcare providers, who used Prime Suite, to falsely attest to compliance with CMS requirements necessary to receive incentive payments for the use of certified software under CMS’s EHR Incentive Program (aka “Meaningful Use Program”); (2) knowingly causing Prime Suite users/healthcare providers to report inaccurate information regarding Meaningful Use objectives and measures in attestations to CMS and state Medicaid agencies for purposes of obtaining Meaningful Use Program incentive payments; and (3) providing improper remuneration to certain healthcare providers to continue using Prime Suite and/or to recommend Prime Suite to other users, in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b.

Hospitals

The following case example involves hospitals:

- Tennessee—A Health Management Associates, Inc. (HMA) subsidiary, Carlisle HMA, LLC (Carlisle), formerly doing business as Carlisle Regional Medical Center, pled guilty to conspiracy to commit healthcare fraud. Up until 2017, Carlisle operated an acute care hospital in Carlisle, Pennsylvania. In September 2018, HMA entered into a 3-year Non-Prosecution Agreement (NPA) with the Department of Justice’s criminal division in connection with a corporate-driven scheme to defraud Federal healthcare programs by unlawfully pressuring and inducing physicians serving HMA hospitals to increase the number of emergency department patient admissions without regard to whether the admissions were medically necessary. The scheme involved HMA hospitals billing and obtaining reimbursement for higher-paying inpatient hospital care, as opposed to observation or outpatient care, from Federal healthcare programs, increasing HMA’s revenue. Under the terms of the NPA, HMA will pay a \$35 million monetary penalty and a criminal fine of \$2.5 million. Under the terms of the NPA, HMA and Community Health Systems, Inc. (CHSI), HMA’s parent company, agreed to cooperate with the investigation, report allegations of evidence of violations of Federal healthcare offenses, and ensure that their compliance and ethics program satisfies the requirements of an amended and extended Corporate Integrity Agreement between CHSI and OIG. This is part of a global resolution, including eight False Claims Act cases filed against HMA, and included a civil resolution where HMA agreed to pay a total of over \$261 million to resolve these FCA matters.

Physicians

The following case example involves physicians:

- Pennsylvania—The United States entered into a False Claims Act settlement agreement (Agreement) with Coordinated Health Holding Company, LLC together with its direct and indirect subsidiaries, including but not limited to CHS Professional Practice, P.C. and CH Hospital of Allentown, LLC (collectively, “Coordinated Health”) and its owner, Emil Dilorio, M.D. (Dr. Dilorio).

The Agreement resolves allegations that (1) from January 1, 2007 through May 31, 2014, Coordinated Health submitted claims to Medicare, Medicaid, TRICARE and FEHBP for orthopedic surgical procedures that were improperly unbundled using Modifier 59; and (2) from April 1, 2009 through December 31, 2009, Dr. Dilorio submitted claims to Medicare, Medicaid, TRICARE and FEHBP for orthopedic surgical procedures that were improperly unbundled using Modifier 59. Coordinated Health agreed to pay \$12.5 million and entered into a 5-year Corporate Integrity Agreement.

Healthcare Fraud Prevention and Enforcement

In May 2009, the Secretary of HHS and the U.S. Attorney General announced the creation of the Health Care Fraud Prevention and Enforcement Action Team (HEAT), an interagency effort focused on combating healthcare fraud. HEAT includes senior officials from DOJ and HHS who are strengthening programs and investing in new resources and technologies to prevent and combat fraud, waste, and abuse.

HEAT Provider Compliance Training

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

Indian Health and Human Services Compliance Training

In addition to the May 2018 compliance and quality training held in Oklahoma for more than 200 individuals representing IHS, Tribes, and Tribal healthcare and human services organizations, OIG participated throughout this semiannual reporting period in various HHS-sponsored conferences, providing training on fraud prevention, internal controls, and compliance. OIG Indian health and human services compliance training resources can be accessed at <https://oig.hhs.gov/AIAN>.

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 healthcare fraud, waste, and abuse. These partnerships among OIG and HHS, DOJ, U.S. Attorneys' Offices, the Federal Bureau of Investigation (FBI), and State and local law enforcement have a common goal: to successfully analyze healthcare fraud data and investigative intelligence to quickly identify fraud and bring prosecutions. Strike Force teams operate in 11 areas: Miami and Tampa/Orlando, Florida; Dallas and Houston, Texas; Los Angeles, California; Detroit, Michigan; Brooklyn, New York; Baton Rouge and New Orleans, Louisiana; Chicago, Illinois; and Newark, New Jersey/Philadelphia, Pennsylvania; along with a Corporate Strike Force located in Washington, D.C.

During this semiannual reporting period, Strike Force efforts resulted in the filing of charges against 47 individuals or entities, 139 criminal actions, and more than \$146.6 million in investigative receivables.

In October 2018, the Department of Justice announced the creation of a new initiative to combat the nation's opioid epidemic. The Appalachian Regional Prescription Opioid (ARPO) Strike Force covers 10 Federal judicial districts in Alabama, Kentucky, Ohio, Tennessee, Virginia and West Virginia. The Office of Investigations is working closely with its law enforcement partners at DEA, FBI and the state Medicaid Fraud Control Units 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, healthcare fraud and quality of care, including patient overdoses and deaths.

The following case examples involve Strike Force cases:

- Texas—Ann Shepherd, owner and operator of Amex Medical Clinic (Amex), and Dr. John Ramirez were convicted of charges resulting from their involvement in a scheme to defraud Medicare. According to evidence presented at trial, from about December 2011 through about August 2015, Shepherd and Ramirez conspired to defraud Medicare out of payments for medical services. Shepherd sold medical orders and other documents signed by Ramirez to home health agencies in and around Houston. In these medical orders, Ramirez falsely certified information about the patient's medical condition and need for home health services. Co-conspirators at home health agencies then used the false paperwork to bill to, and receive payment from, Medicare for home health services that were not medically necessary or not provided. Shepherd also caused Amex to bill Medicare for purported physician services that were actually provided by an unlicensed practitioner, if at all. Shepherd and Ramirez were sentenced to a combined 55 years in prison and were ordered to pay up to \$26.7 million in restitution, jointly and severally.
- Florida—Pharmacy owner Antonio Perez Jr. engaged in an \$8.4 million Medicare fraud scheme in the Miami area. According to admissions made in connection with his guilty plea, Perez Jr. owned a pharmacy called A.R.A Medical Services Inc., which did business under the name Valles Pharmacy Discount (Valles). Between January 2011 and August 2017, Perez Jr. allegedly engaged in a conspiracy to defraud Part D of the Medicare program. Specifically, Perez Jr. agreed to pay illegal healthcare kickbacks to Medicare beneficiaries in exchange for a promise from the beneficiaries to fill their prescriptions at Valles, and to allow Valles to submit claims to Medicare for prescription drugs that were not provided to the beneficiaries. According to admissions made in connection with Perez Jr.'s plea, during the course of the scheme, Valles submitted over \$32 million in claims to Medicare for prescription drugs, of which approximately \$8.4 million was for medically unnecessary prescription drugs that Valles never purchased and were never provided to Medicare beneficiaries. Perez Jr. was sentenced to 7 years and 3 months in prison and ordered to pay \$8.4 million in restitution.

Other Criminal and Civil Enforcement Activities

Most Wanted Fugitives Listed on OIG's Website

The OIG Most Wanted Fugitives website continues to garner national and international attention and has greatly assisted in helping to capture fugitives charged with defrauding Federal healthcare programs and stealing millions of taxpayer dollars. The Most Wanted Fugitives website is continually updated and features a profile for each fugitive as well as an online tip form and a hotline number for individuals to report fugitive-related information to OIG, in English or Spanish, 24 hours a day, 365 days a year. The Most Wanted Fugitives list can be accessed at <https://oig.hhs.gov/fraud/fugitives/>. During this semiannual reporting period, one fugitive was captured, as described below:

One of OIG's Most Wanted Fugitives, David Kim, was captured during this reporting period. Kim was involved in a scheme to fraudulently bill Medicare approximately \$15.2 million for physical therapy services that were either not reimbursable or were not fully provided. Kim has been a fugitive since 2015 and was recently found to be residing in Ho Chi Minh City, Vietnam. He is currently in U.S. custody and will face charges stemming from his indictment.

In October 2015, Kim was indicted on charges of healthcare fraud, illegal remunerations, and aggravated identity theft. Kim was a licensed chiropractor and owner of New Hope Clinic (New Hope) in Los Angeles.

According to the indictment, Kim was recruited by co-conspirators to solicit Medicare beneficiaries to receive purported physical therapy services, which would then be fraudulently billed to Medicare. Kim recruited Medicare beneficiaries to his clinics, obtained their unique Medicare identification numbers and patient information, and supplied the information to his co-conspirators, Joseff Sales, a physical therapist, and Danniell Goyena, a physical therapy assistant.

Sales and Goyena hired physical therapists to evaluate clients and created physical therapy treatment plans. Ultimately, clients received services that were not reimbursable through Medicare, such as acupuncture or massage, and some clients never received any follow-up physical therapy services. Kim was aware that his partners submitted claims using clients' names and unique identification numbers to Medicare for reimbursement for physical therapy services, despite the clients having received other non-reimbursable services.

Between March 2012 and January 2014, Kim received \$379,785 in kickback payments from companies owned by Sales and Goyena for the patients who were referred by Kim and purportedly received physical therapy services at New Hope. Goyena and Sales both pleaded guilty to healthcare fraud and illegal remunerations and were each sentenced to 4 years and 3 months in prison and held jointly liable for \$7,896,007 in restitution.

HHS-OIG Hotline

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 "Report Fraud" link on the HHS-OIG website. During this semiannual reporting period, the OIG Hotline reported expected recoveries of \$28 million as a direct result of cases originating from hotline complaints.

OIG Hotline Activity (10/01/18–03/31/19)

Contacts to 1-800-HHS-TIPS phone line, including callers seeking information	59,956
Total tips evaluated	79,398
Tips referred for action	9,632
Closed; no basis provided for further action	5,027
Closed; no HHS violation	2,192

Sources of Tips Referred for Action

Phone	4,310
OIG website	4,135
Letters/faxes	998
Other	188

State Medicaid Fraud Control Units

OIG Oversight of State MFCUs

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 Unit operations. MFCUs operate in 49 States and the District of Columbia, and in this reporting period OIG certified two new MFCUs in the U.S. territories of Puerto Rico and the U.S. Virgin Islands. The Federal Government reimburses 90 percent of Units' total expenditures during their first 3 years of operation and 75 percent thereafter. MFCUs investigate and prosecute Medicaid provider fraud and patient abuse and neglect in healthcare facilities or board and care facilities.

Medicaid Fraud Control Units Fiscal Year 2018 Annual Report (OEI-09-19-00230), March 2019

This annual report highlights statistics on the accomplishments of the 50 MFCUs in operation during FY 2018. OIG found that the number of convictions in FY 2018 remained similar to those in recent years. Forty-five percent of the 1,109 MFCU fraud convictions involved personal care services attendants and agencies. Fraud cases accounted for 74 percent of the MFCU convictions, while 26 percent involved patient abuse or neglect. MFCUs were responsible for 810 civil settlements and judgments, 27 percent of

which involved pharmaceutical manufacturers. MFCUs reported \$859 million in criminal and civil recoveries.

In an appendix to the report, OIG summarizes beneficial practices identified by OIG in its onsite reports that may be useful to other MFCUs.

OIG Onsite Reviews of MFCUs

In addition to an annual recertification review of each MFCU, OIG conducts periodic onsite reviews of a sample of MFCUs. OIG evaluates MFCU operations based on 12 performance standards and assesses compliance with laws, regulations, and OIG policy guidance. OIG may also make observations of Unit operations and practices, including identifying beneficial practices useful to other Units. In addition, OIG provides training and technical assistance to Units while onsite and on an ongoing basis.

OIG Joint Casework with MFCUs

The following case is an example of OIG's many joint efforts with MFCUs:

- Tennessee—Dr. Robert Maughon used his staff and popularity in the community to engage in a scheme to defraud Medicare, Medicaid, and commercial insurance plans for over \$3.5 million. According to court documents, from July 2013 through October 2015, Maughon and his staff ran a mobile allergy clinic where they tested people at carnivals, car shows, employee benefit fairs, and other gatherings, for allergies. Maughon offered bonuses to the employees that worked his mobile allergy clinics—the more people tested, the higher the bonus. Maughon provided “free” allergy testing to anyone with insurance, then ordered allergy drops for them to use at home. The allergy drops were ordered for people that tested negative, for infants, and even for people who specifically instructed Maughon's employees that they did not want anything ordered. Maughon then fraudulently billed Medicare, Medicaid, and private insurance for non-FDA approved oral allergy treatment that was not covered by insurance. Maughon was sentenced to 5 years and 3 months in prison and ordered to pay over \$3.5 million in restitution.

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 healthcare 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 healthcare fraud and abuse sanctions. During this semiannual reporting period, OIG received 24 requests for advisory opinions and issued 7 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 healthcare programs and their beneficiaries. Sanctions include the exclusion of individuals and entities from Federal healthcare programs and the imposition of CMPs for submitting

false and fraudulent claims to a Federal healthcare program or for violating the anti-kickback statute, the physician self-referral law (commonly referred to as the “Stark Law”), or 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 1,377 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 healthcare programs and their beneficiaries.

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

Program Exclusions

During this semiannual reporting period, OIG excluded 1,293 individuals and entities from Medicare, Medicaid, and other Federal healthcare 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 exclusion. 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 examples of program exclusions:

- Maryland—Tormarco Harris, the owner of a pain management clinic, was excluded for a minimum of 50 years based on his conviction for conspiracy to distribute controlled substances, violation of the drug kingpin statute, and conspiracy to keep a common nuisance. Harris and his co-conspirators ran a pill mill, dispensing controlled substances without a legitimate medical purpose. From about January 2013 to about April 2017, Harris was responsible for issuing prescriptions signed by a co-conspirator for oxycodone, morphine, and Tramadol that were not medically necessary. Patients would pay Harris cash to receive these prescriptions. Harris was sentenced to 20 year in prison based on his conviction.
- Kansas—Thomas James Tholstrup, a certified nursing assistant, was excluded for a minimum of 20 years based on his conviction for attempted aggravated criminal sodomy and mistreatment of a dependent adult. While working in a skilled nursing home, Tholstrup sexually abused patients in the facility. Tholstrup was sentenced to 7 years and 7 months in prison.

Suspension and Debarments

Suspensions and debarments are administrative tools used by HHS and other Federal agencies to protect the Government from individuals and entities that have engaged in contract fraud, have misused grant funds, or are otherwise not presently responsible. Because these are Government-wide 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.

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

The following case examples involve debarment:

- Ohio—Robert Roche served as Executive Director of the American Indian Education Center, a not-for-profit agency which was awarded Federal grant funds from the Substance Abuse and Mental Health Services Administration, an operating division of HHS. The grant application identified an individual who was supposed to have served as the Project Coordinator. Instead of this individual, Roche named himself as the Project Coordinator and paid himself the salary for the position. This was a conflict of interest, as the Project Coordinator was supposed to have reported to the Executive Director. Because of Roche's false statements on the grant application, he embezzled Federal grant funds that were intended to support tribal mental health and wellness for children, youth and families. He was sentenced to serve 4 months in prison and ordered to pay \$77,097 in restitution. Roche was debarred for a 3-year period based on an OIG referral to the Department.
- South Dakota—Wehnona Stabler was the Chief Executive Officer of the Indian Health Service's (IHS) Pine Ridge Hospital. IHS is an operating division of HHS. Stabler failed to report, as required, a gift of \$5,000 on her Office of Government Ethics (OGE) Form-450, Confidential Financial Disclosure Report. Stabler was convicted of making a false statement on the aforementioned report and was subsequently sentenced to 1 year of unsupervised probation. Stabler was debarred for 3 years on the basis of an OIG referral to the Department.

Civil Monetary Penalties Law (CMPL)

The CMPL authorizes OIG to impose administrative penalties, assessments, and exclusions against a person who, among other things, submits, or causes to be submitted, claims to a Federal healthcare 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 \$38.3 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 cases under the CMPL:

- Michigan—In 2015, Millennium Health, LLC f/k/a Millennium Laboratories, Inc. (Millennium) entered into a False Claims Act settlement to resolve, in part, allegations that Millennium provided free point of care urine drug testing cups (POCT cups) to physicians—expressly conditioned on the physicians’ agreement to return the urine specimens to Millennium for additional testing provided by and billed to Federal healthcare programs by Millennium, in violation of the Anti-Kickback Statute and the Prohibition on Certain Physician Referrals. Since September 2017, more than \$2 million has been recovered from OIG-initiated affirmative litigation actions against physicians, physician practices, and other providers based on their alleged unlawful receipt of free POCT cups from Millennium during the relevant timeframe. A recent example of this is OIG’s settlement with Recovery Pathways, LLC (Recovery), a drug and alcohol rehabilitation center, which resolved its alleged liability for soliciting and receiving remuneration in the form of POCT cups from Millennium. Recovery agreed to pay \$64,555 to resolve its alleged liability under the CMPL.
- Oklahoma—Comanche County Hospital Authority d/b/a Comanche County Memorial Hospital (CCHA), agreed to pay \$566,806 to resolve its potential liability under the CMPL related to allegations that CCHA submitted claims to Medicare for emergency ambulance transportation to destinations such as skilled nursing facilities and patient residences that should have been billed at the lower non-emergency rate. Additionally, during the course of OIG’s investigation, CCHA discovered and disclosed that it submitted claims to Medicare for emergency ambulance transportation that were not medically reasonable or necessary. CCHA also disclosed that it submitted claims to Medicare for transports where the documentation for the transport was not consistent with the patient’s condition, and therefore did not support the documented medical necessity for the transport. This settlement resulted from OCIG’s collaboration with OIG’s Consolidated Data Analysis Center. OCIG has settled eight affirmative CMPL cases based on this conduct since September 2016.

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 examples relate to the EMTALA statute:

- Iowa—Effective April 30, 2018, Covenant Medical Center (Covenant) entered into a \$90,000 settlement agreement with OIG to resolve allegations that it violated EMTALA when it failed to provide an adequate medical screening examination and stabilizing treatment for a patient and then inappropriately transferred him to another hospital. The patient, a 54-year-old man, arrived by ambulance to Covenant’s Emergency Department (ED) complaining of shortness of breath, chest pain, and diaphoresis. The ED physician screened the patient and consulted the on-call cardiologist. The patient’s condition worsened, and he was intubated. On advice of the on-call cardiologist, the ED physician

began transcutaneous pacing. The ED physician did not request the on-call cardiologist present to the ED nor did the on-call cardiologist present to the ED to examine and treat the patient. The ED physician requested transfer to a nearby hospital for placement of a transvenous pacemaker. The patient was transferred to the receiving hospital nearly three hours after he presented to Covenant's ED. The receiving hospital placed a transvenous pacemaker on the patient, but he expired shortly after. OIG alleged that Covenant's on-call cardiologist was capable of providing a transvenous pacemaker.

- North Carolina—Washington County Hospital (WCH) agreed to pay \$52,414 to resolve its potential liability under EMTALA. OIG alleged that WCH violated EMTALA when it failed to provide an appropriate medical screening examination and stabilizing treatment for a patient. Specifically, OIG alleged that an ambulance was called to provide assistance to a patient, who was suffering from a worsening of shortness of breath that she had been experiencing for two weeks. The emergency medical technicians (EMTs) arrived at the patient's house, found that she was experiencing uncontrolled hypertension and increased shortness of breath with dyspnea on exertion, and drove her to WCH's ED, two minutes away from the patient's house. En route, the EMTs notified WCH's ED that they were bringing the patient, but when the ambulance was on WCH's property, WCH's ED informed the ambulance that WCH was on diversion and could not see the patient. However, WCH was not on diversion and, while WCH knew the ambulance was on their property, WCH directed the ambulance to take the patient to another hospital about 22 miles away.

Self-Disclosure Programs

Healthcare 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 FCA or other Federal criminal laws prohibiting fraud, conflict of interest, bribery, or gratuity. This self-disclosure process is available only to those with a Federal Acquisition Regulation-based contract with HHS. The OIG Grant Self-Disclosure program is available 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 \$33 million in HHS receivables.

The following examples pertain to provider self-disclosure settlements:

- Tennessee—After self-disclosing conduct to OIG, BenchMark Rehabilitation Partners, LLC, BenchMark Growth Partners, LLC, BenchMark Premier Partners, LLC, BenchMark East

Partners, LLC, BenchMark Development Partners, LLC, and BenchMark West Partners, LLC (collectively, BenchMark), agreed to pay more than \$3.1 million to resolve its alleged liability under the CMPL. Specifically, OIG alleged that BenchMark submitted claims to Medicare and TRICARE for time-based outpatient rehabilitation therapy services provided to Medicare and TRICARE beneficiaries when BenchMark’s therapists did not provide constant attendance or direct one-on-one contact because the therapy services were provided concurrently with another Medicare or TRICARE beneficiary.

- Texas—After self-disclosing conduct to OIG, HVHC LLC, Visionworks of America, Inc., Visionary Properties, Inc., Visionworks, Inc., Empire Vision Center, Inc. (collectively, Visionworks), agreed to pay more than \$3.6 million to resolve its alleged liability under the CMPL. Specifically, OIG alleged that Visionworks paid excess remuneration to certain optometrists in the form of space and equipment leases that were below fair market value and/or by failing to collect one or more rental amounts under space and equipment leases, in violation of the Anti-Kickback Statute.

Corporate Integrity Agreements

Many healthcare 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 healthcare 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:

- Massachusetts—In May 2017, eClinicalWorks, LLC (ECW), one of the nation’s largest vendors of electronic health records (EHR) software, agreed to pay \$155 million and entered into a CIA to resolve ECW’s alleged False Claims Act liability when ECW concealed from its customers that its software did not comply with the requirements for “meaningful use” certification. Among other obligations, the CIA requires ECW to retain an Independent Software Quality Oversight Organization, which evaluates ECW’s software quality control systems, to provide notice to its customers of any safety related issues, and to maintain on its customer portal a comprehensive list of such issues and any steps users should take to mitigate potential patient safety risks. Pursuant to its authority under the CIA, the OIG issued a \$132,500 stipulated penalty on July 5, 2018, for ECW’s failure to timely report patient safety issues to OIG as reportable events.

Public Health Agencies

Public Health Agencies Reports and Reviews

Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention Has Controls and Strategies To Mitigate Hurricane Preparedness and Response Risk (A-04-18-02014), November 2018

Within the 4 risk areas related to CDC's hurricane preparedness and response activities, we identified 22 sub-risk areas and rated 19 as low risk and 3 as moderate risk. Even though we rated three sub-risk areas as moderate, CDC had developed various controls and strategies that are designed to mitigate the risks we identified for preparing for and responding to hurricanes and other natural disasters.

This report contains no recommendations.

CDC Reimbursed Contractors for Some Unallowable World Trade Center Health Program Administrative Costs (A-02-16-02012), February 2019

CDC reimbursed contractors for some World Trade Center Health Program (WTCHP) administrative costs that did not comply with Federal requirements. CDC improperly reimbursed contractors for 43 of the 234 invoice line items that we sampled, totaling more than \$1 million. On the basis of our sample results, we estimated that CDC improperly reimbursed contractors for WTCHP administrative costs totaling \$8 million that did not comply with Federal requirements. In addition, CDC paid contractors for claims management services at different rates. Our review quantified the impact of this payment differential and determined that CDC could have saved \$360,000 if contractors were reimbursed at the lowest negotiated rate. Finally, we determined that CDC complied with Federal requirements for all eight of the non-statistically selected fixed-price contract invoices.

CDC agreed with our recommendation to recover the \$1 million associated with the 43 unallowable sampled items and generally agreed with our recommendations to improve its monitoring of WTCHP contractors' invoices and review contractor costs for claims management services for reasonableness, which could result in cost savings totaling \$360,000. CDC generally disagreed with our recommendation to work with WTCHP contractors to identify and recover the remaining unallowable payments made during the audit period, which are estimated to be \$7 million, because it disagreed with some of our findings.

President's Emergency Plan for AIDS Relief

The President's Emergency Plan for AIDS Relief (PEPFAR) was authorized to receive \$48 billion in funding for the 5-year period beginning October 1, 2008, to assist foreign countries in combating HIV/AIDS, tuberculosis, and malaria. CDC awards PEPFAR funds to and works with ministries of health and other partners in 60 countries to combat HIV/AIDS globally. Additional funds were authorized to be appropriated through 2018.

During the semiannual reporting period, OIG issued one report related to PEPFAR funding:

The Centers for Disease Control and Prevention's Namibia Office Implemented Our Prior Audit Recommendations (A-04-18-01008), October 2018

Congress authorized the President's Emergency Plan for AIDS Relief (PEPFAR) to receive \$48 billion in funding for the 5-year period beginning October 1, 2008, to assist foreign countries in combating HIV/AIDS, tuberculosis, and malaria. Congress authorized additional funds to be appropriated through 2018.

We have conducted a series of audits of organizations receiving PEPFAR funds from CDC. We selected CDC's Namibia office (CDC-Namibia) for review because a prior OIG audit determined that CDC-Namibia did not always properly monitor recipients' use of PEPFAR funds.

CDC-Namibia implemented corrective actions for all three of the recommendations from our prior audit report. Accordingly, this report contains no recommendations.

Food and Drug Administration

The Food and Drug Administration's Policies and Procedures Should Better Address Postmarket Cybersecurity Risk to Medical Devices (A-18-16-30530), October 2018

FDA's policies and procedures were insufficient for handling postmarket medical device cybersecurity events; FDA had not adequately tested its ability to respond to emergencies resulting from cybersecurity events in medical devices; and, in 2 of 19 district offices, FDA had not established written standard operating procedures to address recalls of medical devices vulnerable to cyber threats. These weaknesses existed because, at the time of our fieldwork, FDA had not sufficiently assessed medical device cybersecurity, an emerging risk to public health and to FDA's mission.

FDA agreed with our recommendations that it (1) continually assess the cybersecurity risks to medical devices and update, as appropriate, its plans and strategies; (2) establish written procedures and practices for securely sharing sensitive information about cybersecurity events with key stakeholders who have a "need to know"; (3) enter into a formal agreement with Federal agency partners, including the Department of Homeland Security's Industrial Control Systems Cyber Emergency Response Team, establishing roles and responsibilities as well as the support those agencies will provide to further FDA's mission related to medical device cybersecurity; and (4) ensure the establishment and maintenance of procedures for handling recalls of medical devices vulnerable to cybersecurity threats.

National Institutes of Health

The National Institutes of Health Generally Complied With Federal Requirements for the Preparation and Receipt of Select Agent Shipments (A-03-15-00354), December 2018

Generally, NIH has designed and put in place controls to ensure that select agent shipments are prepared and received in accordance with Federal regulations and related supporting laboratory guidance and instruction. However, two NIH registered entities' security plans did not include certain procedures for

notifying the Federal Select Agent Program (FSAP) if (1) a select agent shipment is not received within 48 hours after the expected delivery time, (2) a select agent shipment receives damage to the extent that a select agent release may have occurred, or (3) an authorization for a select agent transfer expires or becomes void before the shipment is completed. In addition, NIH's third registered entity had not updated its policies and procedures to ensure compliance with new requirements for shipping select agents that have undergone inactivation.

NIH concurred with our recommendations to update two registered entities' security plans to include procedures for notifying FSAP when required and that it work with its third registered entity to implement a policy to ensure compliance with new requirements for shipping inactive select agents.

Office of the Assistant Secretary for Financial Resources

Recommendation Followup: Vulnerabilities Continue To Exist in the HHS Small Business Innovation Research Program (OEI-04-18-00230), March 2019

Created by the Small Business Innovation Development Act of 1982, the Small Business Innovation Research (SBIR) program is a competitive awards program that provides Federal funding to small businesses that pursue research for potential commercialization that meets the priorities of the Federal Government. Within HHS, four operating divisions participate in the SBIR program: NIH; CDC; FDA; and ACL.

In 2014, we reported vulnerabilities with HHS's SBIR program and made four recommendations to improve HHS's oversight. Since that report, HHS had not formally notified OIG of any actions to implement the two outstanding recommendations—with which HHS had concurred—regarding awardee eligibility and duplicative funding. For this recommendation followup report, we assessed HHS's progress in implementing those two outstanding recommendations. We found that HHS has not implemented OIG's recommendations to ensure the eligibility of awardees for the SBIR program and to prevent duplicative funding. As a result, HHS's SBIR program continues to have weaknesses in these two areas.

Substance Abuse and Mental Health Services Administration

New York Did Not Provide Adequate Stewardship of Substance Abuse Prevention and Treatment Block Grant Funds (A-02-17-02009), March 2019

New York failed to trace funds to a level of expenditure adequate to establish that the funds were used for the Substance Abuse Prevention and Treatment Block Grant (SABG) program's intended purpose. By not implementing procedures for reporting actual expenditures and tracing payments, New York may have retained unexpended funds and hindered its ability to ensure that substance abuse prevention and treatment programs received necessary funds. New York is responsible for implementing effective accounting procedures; however, a lack of guidance from SAMHSA contributed to its inadequate stewardship of the SABG funds.

In addition, New York does not have procedures in place to determine whether providers are accurately reporting Medicaid revenues. Specifically, one opioid treatment provider received excess SABG funding from New York totaling more than \$1.8 million because the provider underreported Medicaid revenue on

its fiscal report. This occurred because State agency staff who reconciled providers' fiscal reports did not have access to necessary data.

SAMHSA did not concur with our recommendation that it provide formal guidance to New York on accounting for and reporting SABG expenditures and unexpended funds but agreed to recover \$1.8 million from New York. New York generally agreed with our recommendations that it (1) review the revenues reported on the fiscal reports of providers not reviewed in this audit and recover any excess unexpended funds and (2) develop and implement procedures to ensure that the necessary staff have access to Medicaid revenue data and reconcile the data with the revenue reported on the providers' fiscal reports.

The Substance Abuse and Mental Health Services Administration Followed Grant Regulations and Program-Specific Requirements When Awarding State Targeted Response to the Opioid Crisis Grants (A-03-17-03302), March 2019

SAMHSA followed HHS grant regulations and program-specific requirements when awarding State Targeted Response to the Opioid Crisis grants authorized under the 21st Century Cures Act. Specifically, SAMHSA performed an adequate review of all 57 grant applications and adequately followed up with applicants to address their concerns. As part of the pre-award process, SAMHSA created teams of expert staff members to review the applications and evaluate the information.

We also determined that SAMHSA's funding formula elements (unmet need for opioid use disorder and drug poisoning deaths) were based on the 21st Century Cures Act. According to SAMHSA, these funding elements provided the most comparable and uniform data on a national scale to assess the prevalence of the opioid crisis. Lastly, we found that the 2018 State Opioid Response grant legislation provides an additional 15-percent set-aside for the 10 States with the highest mortality rates related to drug poisoning deaths.

This report contains no recommendations.

Legal Actions and Investigations Related to Public Health Agencies

Health Education Assistance Loan Program

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

HEAL Exclusions

During this semiannual reporting period, 32 individuals and related entities were excluded because of a PSC referral of their cases to OIG. Individuals who have been excluded because of default may enter into settlement agreements whereby the exclusions are stayed while they pay specified amounts each month to satisfy their debts. If they default on these settlement agreements, they may be excluded until the entire debt is repaid, and they may not appeal the exclusions. Of that amount, six were as a result of a default on a settlement agreement.

After being excluded for nonpayment of their HEAL debts, 2,779 individuals chose to enter into settlement agreements or completely repay their debts. That figure includes 34 individuals who entered into such settlement agreements or completely repaid their debts during this semiannual reporting period. More than \$221 million is being repaid through settlement agreements or through complete repayment. Of that amount, more than \$2.9 million is attributable to this semiannual reporting period.

The following are examples of settlement agreements. These practitioners entered into settlement agreements to repay the amounts indicated:

- California—Karen Yvonne Kirby, Medical Doctor—\$380,484
- New York—Altagracia Rafaela Bueno, Dentist—\$146,500

Human Services Agencies Reviews and Enforcement Activities

Administration for Children and Families

The Tornillo Influx Care Facility: Concerns About Staff Background Checks and Number of Clinicians on Staff (A-12-19-20000), November 2018

The memorandum was issued in response to two significant vulnerabilities identified by OIG during a site visit to the influx care facility in Tornillo, Texas (Tornillo), a grantee of the Unaccompanied Alien Children (UAC) Program operated by ORR. Specifically, OIG found that Tornillo is not conducting required FBI fingerprint background checks for staff working at Tornillo, instead using checks conducted by a private contractor that has access to less comprehensive data. Secondly, OIG found that Tornillo does not employ a sufficient number of staff clinicians to provide adequate mental healthcare for UAC. Both issues warrant immediate attention because they pose substantial risks to children receiving care at this facility.

OIG requested that ACF provide a written response as soon as possible, but no later than 30 days of the date of the memorandum, apprising OIG of the actions taken to ensure (1) employees at Tornillo are receiving FBI fingerprint background checks as required and (2) children's safety and well-being with respect to the insufficient clinician-to-child staffing ratios at Tornillo.

BCFS Health and Human Services Did Not Always Comply With Federal and State Requirements Related to the Health and Safety of Unaccompanied Alien Children (A-06-17-07007), December 2018

On the basis of our UAC case file sample review results, we estimated that BCFS Health and Human Services (BCFS HHS) did not properly document the care and release of 13.7 percent of all children

released to sponsors in FY 2015. Without adequate documentation in the UAC case files, ORR could not be assured that for 501 children, BCFS HHS had followed ORR policies regarding sponsor background checks or prompt care or that the Department of Homeland Security (DHS) was notified about the child's release to a sponsor. Finally, we determined that BCFS HHS was unable to support the number of reunifications it reported to ORR for FY 2015.

BCFS HHS concurred with our recommendations that it comply with ORR regulations pertaining to (1) video monitoring in common areas, (2) sponsor and other household members background checks, (3) admission/intake assessments and medical exams, and (4) discharge notifications to DHS and other stakeholders. BCFS HHS also concurred with our recommendations that it comply with State regulations pertaining to (1) minimum bedroom space, (2) health and safety standards for shelters and foster care homes, and (3) employee background investigations. Finally, BCFS HHS concurred with our recommendations that it ensure that information reported to ORR is accurate and that it operate its UAC program in accordance with Federal and State regulations.

The Administration for Children and Families Has Controls and Strategies To Mitigate Hurricane Preparedness and Response Risk (A-04-18-02013), December 2018

Within the 4 risk areas related to ACF's hurricane preparedness and response activities, we identified 15 sub-risk areas and rated 14 as low risk and 1 as moderate risk. Even though we rated one sub-risk area as moderate, ACF had developed various controls and strategies that are designed to mitigate the risks that we identified for preparing for and responding to hurricanes and other natural disasters.

This report contains no recommendations.

Lincoln Hall Boys' Haven, an Administration for Children and Families Grantee, Did Not Always Comply With Applicable Federal and State Policies and Requirements (A-02-16-02007), February 2019

Lincoln Hall Boys' Haven (Lincoln Hall) did not meet or properly document that it met certain safety requirements for the care and release of children in its custody. Further, it could not identify actual expenditures incurred and charged to the UAC program and did not monitor its subrecipients' and contractors' performance. In addition, Lincoln Hall could not identify the actual expenditures incurred that comprised the \$29.8 million charged to the UAC program (the entire amount that Lincoln Hall received in FYs 2014 and 2015) and did not ensure that its subrecipients and contractors met the terms and conditions of their agreements.

As a result, Lincoln Hall may have placed the health and safety of children at risk and charged unallowable expenditures to the UAC program and the services provided by its subrecipients and contractors could have been inadequate.

Lincoln Hall did not indicate concurrence or nonconcurrence with our recommendations that it (1) adhere to policies that meet applicable safety requirements for the care and release of children in its custody and maintain supporting documentation, (2) provide documentation to support the \$29.8 million of program costs or refund the Federal Government, and (3) develop policies and procedures that adhere to requirements for monitoring subrecipients and contractors. Lincoln Hall also did not indicate concurrence or nonconcurrence with five procedural recommendations.

Separated Children Placed in Office of Refugee Resettlement Care (OEI-BL-18-00511), January 2019

OIG found that the total number of children separated from a parent or guardian by immigration authorities is unknown. Pursuant to a June 2018 Federal District Court order, HHS has thus far identified 2,737 children in its care at that time who were separated from their parents. However, thousands of children may have been separated during an influx that began in 2017, before the accounting required by the Court. Further, from July 1 through November 7, ORR received at least 118 newly separated children. However, the Department of Homeland Security provided ORR with limited information about the reasons for these separations, which may impede ORR's ability to determine appropriate placements. OIG encourages continued efforts to improve communication, transparency, and accountability for the identification, care, and placement of separated children.

Health Resources and Services Administration

The Health Resources and Services Administration Has Controls and Strategies To Mitigate Hurricane Preparedness and Response Risk (A-04-18-02015), December 2018

Within the 4 risk areas related to HRSA's hurricane preparedness and response activities, we identified 13 sub-risk areas and rated 12 as low risk and 1 as moderate risk. Even though we rated one sub-risk area as moderate, HRSA had developed various strategies and controls that are designed to mitigate the risks we identified for preparing for and responding to hurricanes and other natural disasters.

This report contains no recommendations.

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 nation-wide resulted in 4 criminal actions and court-ordered restitution and settlements of \$334,784.

The following case examples involve child support enforcement:

- South Dakota—In September 2014, Daniel Vincent was ordered to pay child support payments of \$416.33. Vincent only sporadically made payments to the custodial parent of his child, and last made a payment in 2014. Vincent pleaded guilty to failure to pay child support and cyberstalking, was sentenced to 5 years and 11 months in prison and was ordered to pay \$20,246.50 in restitution.
- Pennsylvania—In November 2012, Darryl Thomas Averett Mitchell was ordered to pay child support payments of \$358 per week. Mitchell only sporadically made payments to the custodial parent of his child, and last made a payment in 2012. Mitchell pleaded guilty to

Social Security fraud, passport fraud, willful failure to pay child support, and student loan fraud, was sentenced to 2 years and 1 month in prison and ordered to pay \$196,278 in restitution.

Engaging the Public in Capturing Deadbeat Parents

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

Other HHS-Related Reviews and Investigations

Grants and Contracts

HHS is the largest grant-making organization and one of the largest contracting agencies in the Federal Government. In FY 2018, HHS awarded more than \$500 billion in grants and over \$20 billion in contracts across all program areas. OIG's direct annual discretionary appropriation funding is used to conduct program integrity and enforcement activities for 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.

Reviews

Grant Fraud Investigations

The following case example involves misuse of grant funds:

- Texas—The University of Texas Health Science Center at Houston (UTHSCH) entered into a False Claims Act (FCA) settlement agreement, wherein UTHSCH agreed to pay \$2.3 million to resolve allegations of grant fraud. UTHSCH was a recipient of National Institutes of Health (NIH) Federal research funding. The United States contends that, from September 1, 2012, to December 31, 2017, UTHSCH misappropriated funds in the amount of more than \$1.1 million from the grant. UTHSCH then misrepresented to the United States the "unobligated balance of Federal funds" remaining under the grant in that amount in its written Federal Financial Report (SF-425), which closed out the grant. The United States further alleged that this misappropriation of Federal funds deprived the NIH of grant funds to which it would have otherwise been entitled.

Small Business Innovation Research Program

The National Defense Authorization Act for Fiscal Year 2012, § 5143, requires OIG to report annually on the number of cases referred to OIG to fraud, waste, or abuse in the Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) program. OIG must also report on the actions taken in each case; justification for not taking action on a case; and an accounting of funds used to address waste, fraud, and abuse in this program. In our December 2018 report delivered to the three congressional oversight committees, we reported that OIG spent approximately \$392,837 in salaries on oversight related to the SBIR/STTR program. In FY 2018, four new SBIR/STTR cases were referred to OIG.

Recovery Act Retaliation Complaint Investigations

The Recovery Act, § 1553, prohibits non-Federal employers that have received Recovery Act funding from retaliating against employees who disclose evidence of mismanagement of Recovery Act funds or any violation of law related to Recovery Act funds. OIGs are required to include in their Semiannual Report the retaliation complaint investigations that they decided

not to conduct or continue during the reporting period. During this semiannual reporting period, OIG did not close, decline, or give extensions on any investigations of whistleblower retaliation.

Contract Audits

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

OIG Reviews of Non-Federal Audits

OIG reviews audits conducted by non-Federal auditors of entities receiving Federal awards. In this semiannual period, OIG’s National External Audit Review Center reviewed 312 reports covering \$429.3 billion in audited costs. Federal dollars covered by these audits totaled \$92.6 billion, of which about \$58.6 billion were HHS funds.

Uniform guidance at 2CFR200 Subpart F, establishes audit requirements for certain State and local governments, colleges and universities, and nonprofit organizations receiving HHS awards. Under the uniform guidance, covered entities must conduct annual organization-wide single audits. 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 follow-up. 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.

The following table categorizes OIG’s reports on non-Federal audits reviewed during this reporting period:

Non-Federal Audits, October 1, 2018, Through March 31, 2019

Not requiring changes or having minor changes	310
Requiring major changes	2
Having significant technical inadequacies	0
Total Number of Non-Federal Audits	312

Other Reporting Requirements and Reviews

Legislative and Regulatory Reviews

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

- Our [Semiannual Report\(s\) to Congress](#) describes findings and recommendations from recently completed reviews, many of which focus on existing laws and regulations.
- Our [Solutions to Reduce Fraud, Waste, and Abuse in HHS Programs: Top Unimplemented Recommendations](#) describes priority findings and recommendations from past periods that remain to be implemented.
- Our [Work Plan](#) provides citations to laws and regulations that are the subject of ongoing or future reviews.

We also review proposed legislation and regulations related to HHS programs and operations. HHS routinely involves OIG and HHS operating divisions and other staff divisions in the review and development of HHS regulations through a well-established HHS process. Our audits, evaluations, and investigations are sometimes cited in regulatory preambles as influencing HHS regulations. In addition, we provide independent, objective technical assistance on a bipartisan, bicameral basis to congressional committees and Members who request it.

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

The following tables summarize OIG’s monetary recommendations and HHS responses to them. This information is provided in accordance with the IG 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 IG Act, the term “questioned cost” means a cost that is questioned by the 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.

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	174	\$2,034,829,000	\$505,724,000
Issued during the reporting period	27	\$246,926,000	\$7,020,000
Total Section 1	201	\$2,281,755,000	\$512,744,000
Section 2			
Reports for which management decisions were made during the reporting period ^{2, 3}			
Disallowed costs	147	*\$496,427,000	\$9,000
Costs not disallowed	6	\$17,467,000	\$243,000
Total Section 2	153	\$513,894,000	\$252,000
*Audit receivables (expected recoveries)			
Section 3			
Reports for which no management decisions had been made by the end of the reporting period (Section 1 minus Section 2)	48	\$1,767,861,000	\$512,492,000
Section 4			
Reports for which no management decisions were made within 6 months of issuance ⁴	26	\$1,542,660,000	\$505,472,000

Audit Reports With Funds Recommended To Be Put to Better Use

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

Table 2—Audit Reports With Funds Put to Better Use

Description	Number of Reports	Dollar Value
Section 1		
Reports for which no management decisions had been made by the beginning of the reporting period ¹	5	\$15,826,030,000
Reports issued during the reporting period	4	\$263,385,000
Total Section 1	9	\$16,089,415,000
Section 2		
Reports for which management decisions were made during the reporting period		
Value of recommendations agreed to by management		
Based on proposed management action	3	\$776,585,000
Based on proposed legislative action		\$0
Value of recommendations not agreed to by management	0	\$0
Total Section 2	3	\$776,585,000
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>)	6	\$15,312,830,000

End Notes

Table 1 End Notes

¹ The opening balance was adjusted upward by \$69.8 million because of a reevaluation of previously issued recommendations.

² Revisions to previously reported management decisions:

- A-05-11-00016 *National Government Services, Inc., Did Not Always Refer Medicare Cost Reports and Reconcile Outlier Payments*. CMS conducted a subsequent review and approved rescinding an outlier reconciliation. As result, CMS reduced the previously sustained amount by \$26,293,543.
- A-01-07-00003 *Review of Medicaid Outpatient Drug Expenditures in Connecticut for the Period October 1, 2003, Through September 30, 2005*. Due to additional documentation provided by the State, CMS reduced the sustained amount by \$7,395,316.

- A-05-12-00080 *Medicare Compliance Review of University of Cincinnati Medical Center for Calendar Years 2010 and 2011*. The provider appealed the recommendation and is awaiting adjudication. As a result, OIG and CMS agreed to re-calculate the overpayments estimates based on already known settlement results. Therefore, the sustained amount was reduced by \$6,149,995 to reflect the adjustment.
- A-07-10-02774 *Noridian Healthcare Solutions, LLC, Did Not Always Refer Medicare Costs Reports and Reconcile Outlier Payments*. CMS was able to recoup \$2,029,787 that were within the 3-year reopening limit. The remaining \$4,890,187 was not recoverable.
- **Not detailed are reductions to previously disallowed management decisions totaling \$2.7 million.**

³ Included are management decisions to disallow \$37.4 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 26 audits were not completed within 6 months of issuance of the reports; however, agency management has informed us that the agency is working to resolve the outstanding recommendations before the end of the next semiannual reporting period.

Audits Not Completed Within 6 Months of Issuance

Audit CIN	Audit Title
A-02-15-02013	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
A-02-15-01010	New Jersey Claimed Hundreds of Millions in Unallowable or Unsupported Medicaid School-Based Reimbursement, November 2017, \$300,452,930
A-02-14-02017	New York Misallocated Costs to Establishment Grants for a Health Insurance Marketplace, November 2016, \$149,654,512
A-01-14-02503	Maryland Misallocated Millions to Establishment Grants for a Health Insurance Marketplace, March 2015, \$28,400,000
A-04-14-07050	Kentucky Misallocated Millions to Establishment Grants for a Health Insurance Marketplace, February 2017, \$25,530,429
A-02-15-02008	New York Did Not Comply With Federal Grant Requirements for Allocating and Claiming Marketplace Contract Costs, December 2017, \$20,415,344
A-07-15-04226	Not All of Missouri's Child Care Subsidy Program Payments Complied With Federal and State Requirements, November 2017, \$19,076,167
A-07-17-00529	Wisconsin Physician Services Insurance Corporation Understated Medicare's Share of the Medicare Segment Excess Pension Assets, May 2018, \$17,732,694
A-01-15-02500	Vermont Did Not Properly Allocate Millions to Establishment Grants for a Health Insurance Marketplace, September 2016, \$11,243,006
A-02-14-02024	Newark Preschool Council, Inc., Did Not Always Comply With Head Start Requirements, February 2017, \$9,950,556

A-09-17-03018	Medicare Improperly Paid Providers for Nonemergency Ambulance Transports to Destinations Not Covered by Medicare, July 2018, \$8,633,940
A-07-17-02808	The Colorado Health Insurance Marketplace’s Financial Management System Did Not Always Comply With Federal Requirements, July 2018, \$2,567,604
A-07-11-06013	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
A-05-14-00045	The Minnesota Marketplace Misallocated Federal Funds and Claimed Unallowable Costs, November 2016, \$1,279,677
A-07-16-04230	The Three Affiliated Tribes Improperly Administered Low-Income Home Energy Assistance Program Funds for FYs 2010 through 2014, July 2017, \$1,221,425
A-09-17-03017	Medicare Made Improper and Potentially Improper Payments for Emergency Ambulance Transports to Destinations Other Than Hospitals or Skilled Nursing Facilities, August 2018, \$975,154
A-09-14-01007	Nevada Misallocated Costs for Establishing a Health Insurance Marketplace to Its Establishment Grants, February 2016, \$893,464
A-05-16-00038	Heartland Human Care Services, Inc., Generally Met Safety Standards, but Claimed Unallowable Rental Costs, September 2018, \$768,460
A-06-16-07007	BCFS Health and Human Services Did Not Always Comply with Federal Requirements Related to Less-Than-Arm’s Length Leases, February 2018, \$658,248
A-07-16-04233	The Turtle Mountain Band of Chippewa Indians Improperly Administered Some Low-Income Home Energy Assistance Program Funds for Fiscal Years 2010 Through 2013, September 2017, \$587,248
A-04-16-04044	The Ministry of Health and Social Welfare National AIDS Control Program Did Not Always Manage and Expend PEPFAR Funds in Accordance With Award Requirements, August 2017, \$495,379
A-07-18-04106	The Fort Peck Assiniboine and Sioux Tribes Improperly Administered Some Low-Income Home Energy Assistance Program Funds for Fiscal Years 2011 Through 2015, August 2018, \$436,765
A-04-13-01024	The University Of North Carolina At Chapel Hill Did Not Always Claim Selected Costs Charged Directly to Department of Health and Human Services Awards in Accordance With Federal Requirements, June 2014, \$352,843
A-12-17-00002	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
A-04-15-04039	Mildmay Uganda Did Not Always Manage the President’s Emergency Plan for AIDS Relief Funds in Accordance With Award Requirements, March 2017, \$170,386
A-06-11-00058	Crowley’s Ridge Development Council, Inc., Claimed Unallowable Costs Under a Recovery Act Grant, August 2012, \$115,420
TOTAL CINS: 26	
TOTAL AMOUNT: \$1,542,660,477	

Table 2 End Notes

¹The opening balance had no prior period adjustments of previously issued recommendations.

² Because of administrative delays, some of which were beyond management control, 2 of the 6 audits open at end of the period were not resolved within 6 months of issuance of reports. OIG is working with management to reach resolution on these recommendations before the end of the next semiannual reporting period.

Audits Open at End of the Period

Audit CIN	Audit Title
A-05-12-00020	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
A-03-13-03002	HHS Did Not Identify and Report Antideficiency Act Violations, May 2017, \$49,445,025
TOTAL CINS: 2	
TOTAL AMOUNT: \$15,049,445,025	

Appendix B: Peer-Review Results

Peer-Review Results

The Inspector General Act of 1978, as amended, requires OIGs to report the results of peer reviews of their operations conducted by other OIGs, the date of the last peer review, outstanding recommendations from peer reviews, and peer reviews conducted by an OIG of other OIGs in the semiannual period. Peer reviews are conducted by member organizations of the Council of the Inspectors General on Integrity and Efficiency (CIGIE). Recently CIGIE has approved a new peer-review process for Inspection and Evaluation units within OIGs across the Federal Government, including at HHS-OIG, the implementation of which will begin in 2018.

Office of Audit Services

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

OAS	Date	Reviewing Office	Office Reviewed
	March 2018	U. S. Postal Service OIG	HHS-OIG, OAS

The system of quality control for the audit organization of HHS-OIG in effect for the year ending September 30, 2017, 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
	December 2015	HHS-OIG, OAS	U.S. Department of Agriculture (USDA) OIG

The system of quality control for the audit organization of USDA-OIG in effect for the year ending March 31, 2015, has been suitably designed and complied with to provide USDA-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. USDA-OIG received a peer-review rating of pass.

Office of Investigations

During this semiannual reporting period, one peer review involving OI was completed. Listed below is information concerning that peer review, as well as OI’s peer-review activity during a prior reporting period.

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

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

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

The system of internal safeguards and management procedures for the investigative function of the U.S. Postal Service OIG in effect for the year ending July 31, 2017, was in full compliance with the quality standards established by CIGIE and the Attorney General’s guidelines.

Office of Evaluation and Inspections

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

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

The DoD-OIG Inspection and Evaluation components’ policies and procedures generally met CIGIE’s *Quality Standards for Inspection and Evaluation* (Blue Book) standards. In addition, the 10 reports reviewed generally met the applicable Blue Book standards. Onsite visits for these reviews were conducted from October 2 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 healthcare 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 healthcare 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 healthcare fraud (other than Medicare or Medicaid); suspension or revocation of a license to provide healthcare 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 healthcare 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 healthcare 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 healthcare programs for engaging in certain activities. For example, a person who submits, or causes to be submitted, to a Federal healthcare 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 3 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 healthcare 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 healthcare 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 3 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 3 times the amount of funds at issue: (1) for each instance of knowingly making a false statement in a document required to be submitted in order 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 3 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 emergency room 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 \$52,414 against small hospitals (fewer than 100 beds) and up to \$104,826 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 \$104,826 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 healthcare 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 healthcare programs (Social Security Act, § 1128B(b) (42 U.S.C. § 1320a-7b(b)).

Individuals and entities that 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 FCA, 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 \$10,957 and \$21,916 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 FCA 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 FCA defines "knowing" to include not only the traditional definition but also instances in which the person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information. Under the FCA, no specific intent to defraud is required. Further, the FCA 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 FCA was again amended 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 FCA 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	Submitted to the Secretary under separate cover
(a)(7)	Summary of significant reports	Throughout this report
(a)(8)	Statistical Table 1—Reports With Questioned Costs	Appendix A
(a)(9)	Statistical Table 2—Funds Recommended To Be Put to Better Use	Appendix A
(a)(10)	Summary of previous audit reports without management decisions, in which no establishment comment was returned within 60 days, and in which there are any outstanding unimplemented recommendations	Appendix A
(a)(11)	Description and explanation of revised management decisions	Appendix A

Section	Requirement	Location
(a)(12)	Management decisions with which the Inspector General disagrees	None for this reporting period
(a)(13)	Information required by the Federal Information Security Management Act.	Reported annually in the spring Semiannual Report, "Other HHS-Related Reviews and Investigations" 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 F
(a)(18)	Metrics description for statistical tables	Appendix F
(a)(19)	Investigations on senior Government employees	Appendix F
(a)(20)	Description of whistleblower retaliation instances	Appendix F
(a)(21)	Description of attempts to interfere with OIG independence	Appendix F
(a)(22)	Description of closed and nondisclosed reports and investigations regarding senior Government employees	Appendix F

Other Reporting Requirements

Section	Requirement	Location
845	Significant contract audits required to be reported pursuant to the National Defense Authorization Act for FY 2008 (P.L. No. 110-181), § 845.	"Other HHS-Related Reviews and Investigations" section
205	Pursuant to HIPAA (P.L. No. 104-191), § 205, the Inspector General is required to solicit proposals annually via a Federal Register 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.	Reported annually in the fall Semiannual Report, Appendix G
1553	Pursuant to the American Recovery and Reinvestment Act of 2009, P.L. No. 111-5, § 1553, OIG reports to Congress the retaliation complaint investigations it decided not to conduct or continue during the period.	"Other HHS-Related Reviews and Investigations" section

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

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

Each Inspector General shall, not later than April 30 and October 31 of each year, prepare semiannual reports summarizing the activities of the Office during the immediately preceding six-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, inspection, and evaluation reports issued from FY 2011 through FY 2019, OIG had 93 reports with overdue final management decisions.¹

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

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

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

For this semiannual reporting period, OIG had no reports with comments exceeding 60 days.

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

OIG is actively tracking 1,058 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:

¹ 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 four additional audit reports with overdue management decisions from FY 1990 through FY 2010.

FY (2011–2019)	Number of Reports with Unimplemented Recommendations	Number of Unimplemented Recommendations	Dollar Value of Aggregate Potential Cost Savings
2011	14	25	\$434,404,003
2012	26	32	\$397,437,195
2013	38	71	\$261,261,308
2014	34	62	\$15,169,118,140
2015	37	69	\$357,006,677
2016	42	106	\$193,518,252
2017	52	182	\$1,119,345,258
2018	83	306	\$2,485,099,567
2019 (partial year)	57	205	\$509,970,995
Totals	383	1,058	\$20,927,161,395

OIG annually produces a [Solutions to Reduce Fraud, Waste, and Abuse in HHS Programs: Top Unimplemented 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 Department of Justice for criminal prosecution during the reporting period;

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

(D) the total number of indictments and criminal informations 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	0
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Total number of persons referred ² to Federal prosecuting authorities for criminal prosecution during the reporting period ³	1,186
Total number of persons referred to State and local prosecuting authorities for criminal prosecutions during the reporting period	115
Total number of Federal indictments and criminal informations during the reporting period that resulted from any prior referral to prosecuting authorities	321
Total number of State and local indictments and criminal informations during the reporting period that resulted from any prior referral to prosecuting authorities	41

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

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

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

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

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

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

² A referral includes OIG presentations to DOJ and/or State/local prosecutorial authorities.

³ OIG counts "persons" as both individuals and entities.

(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 two senior Government employees for misconduct, and OIG determined the allegations to be substantiated, but no prosecution resulted. Descriptions of the investigations are below.

Description of Investigation	Status	Disposition	DOJ Referral	DOJ Referral Date	DOJ Declination	DOJ Declination Date
A senior Government employee recently retired and failed to comply with the requirement for OGE-278 filers to file the Stock Act form on notification of post-government employment or compensation negotiation of agreement and recusal statement.	Closed	Case Closed	Yes	9/28/18	Yes	9/28/18
It was alleged that a senior policy analyst accessed or attempted access to	Closed	Case Closed	No	N/A	N/A	N/A

websites known to offer sexually explicit and/or sexually suggestive images, video, and other adult content. Subject retired.						
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(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. While 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, 2018, through March 31, 2019, 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, 2018, to March 31, 2019

Category/Description	Number of Reports
IT security reviews (involve IT systems, e.g., penetration test audits)	1
Homeland security issues (involve particularly sensitive topics, e.g., bioterrorism, emergency preparedness, and classified or potentially classified information)	
Recipient Capability Audits (primarily in Head Start/Early Head Start programs)	
Reimbursable audits performed for other Federal agencies (primarily contract audits)	
Confidential or proprietary information (e.g., Medicare Part B drug claims/imaging services, Medicare investment income)	
Medicare Adverse Event Reviews (required by law not to disclose)	
Medicare Prescription Drug Event Reviews	
Other	
HHS technical assistance reports ⁴	
Finance-related attestation reviews	1
Total	2

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

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

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

⁴ 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.

A personnel security specialist made a complaint regarding contract fraud. The complaint was against a senior Government employee for improperly handling a contract and allowing unauthorized employees access to it.	Closed	No evidence to support allegations	No	N/A	N/A	N/A
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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 the 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—not only to foster beneficial or innocuous arrangements but also to protect Federal healthcare programs and their beneficiaries from abusive practices.

Public Proposals for New and Modified Safe Harbors

In response to the 2017 annual solicitation, OIG received the following proposals related to safe harbors:

Proposal	OIG Response
New safe harbors to facilitate coordinated care and promote alternative payment models so physicians can pursue integration options that are not hospital driven.	On August 27, 2018, OIG issued an RFI seeking input from the public on how to address any regulatory provisions that may act as barriers to coordinated care or value-based care as well as other related topics, which encompasses the subjects presented in this proposal. See 83 Fed. Reg. 43607. Comments are due by October 26, 2018, and will be considered at that time. OIG is reviewing the comments received. In the meantime, questions about the application of the anti-kickback statute to specific arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.
New or modified safe harbors for incentive payment arrangements between hospitals and other providers operating under current, proposed, and new CMS alternative payment models.	On August 27, 2018, OIG issued an RFI seeking input from the public on how to address any regulatory provisions that may act as barriers to coordinated care or value-based care as well as other related topics, which encompasses the subjects presented in this proposal. See 83 Fed. Reg. 43607. OIG is reviewing the comments received. In the meantime, questions about the application of the anti-kickback statute to specific arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.
Modify the existing Cooperative Hospital Services Organization (CHSO) safe harbor (42 C.F.R. § 1001.952(q)) to clarify that the safe harbor protects only CHSO arrangements that involve the provision	OIG is considering modifying this safe harbor to address the concerns described in this proposal.

<p>of items or services that are components of the direct or indirect overhead costs associated with the inpatient or outpatient hospital services of nonprofit patron-hospitals.</p>	
<p>New safe harbors to protect value-based purchasing and payment arrangements that bundle products and related services, to protect value-based care including value-based risk-sharing network arrangements, and to protect value-based price adjustments with clinical or cost-related outcome-based assurances.</p>	<p>On August 27, 2018, OIG issued an RFI seeking input from the public on how to address any regulatory provisions that may act as barriers to coordinated care or value-based care as well as other related topics, which encompasses the subjects presented in this proposal. <i>See</i> 83 Fed. Reg. 43607. OIG is reviewing the comments received. In the meantime, questions about the application of the anti-kickback statute to specific arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.</p>
<p>A new safe harbor to protect arrangements that support patient adherence to a prescribed treatment or medication regimen.</p>	<p>On August 27, 2018, OIG issued an RFI seeking input from the public on how to address any regulatory provisions that may act as barriers to coordinated care or value-based care as well as other related topics, which encompasses the subjects presented in this proposal. <i>See</i> 83 Fed. Reg. 43607. OIG is reviewing the comments received. In the meantime, questions about the application of the anti-kickback statute to specific arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.</p>
<p>New safe harbors that permit sharing and donating items and services related to cybersecurity, with an emphasis on training and education services, software, and technology.</p>	<p>On August 27, 2018, OIG issued an RFI seeking input from the public on how to address any regulatory provisions that may act as barriers to coordinated care or value-based care as well as other related topics, which encompasses the subjects presented in this proposal. <i>See</i> 83 Fed. Reg. 43607. OIG is reviewing the comments received. In the meantime, questions about the application of the anti-kickback statute to specific arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.</p>
<p>Modify the current managed care safe harbor (42 C.F.R. § 1001.952(t)) to add Medicare Part D Sponsors to the list of eligible MCOs and to modify the definition of items and services to include care coordination, case management, chronic care and disease management, support for transitioning patients between different care settings, and discharge planning.</p>	<p>On August 27, 2018, OIG issued an RFI seeking input from the public on how to address any regulatory provisions that may act as barriers to coordinated care or value-based care as well as other related topics, which encompasses the subjects presented in this proposal. <i>See</i> 83 Fed. Reg. 43607. OIG is reviewing the comments received. In the meantime, questions about the application of the anti-kickback statute to specific arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.</p>
<p>New or modified safe harbors to protect donations to independent charitable foundations and to enable financial</p>	<p>OIG is not adopting this suggestion. Financial assistance programs could vary greatly and should be addressed on a</p>

<p>assistance from both charitable entities and directly from drug manufacturers.</p>	<p>case-by-case basis, such as under the advisory opinion process.</p>
<p>A new safe harbor to protect the infrequent and nominal incentives given by a health plan to a network provider's office or staff, such as a token of nominal amount or lunch for the office, as recognition for efforts associated with the delivery of preventative care.</p>	<p>OIG is not adopting the suggestion to protect a health plan's gifts to network providers because it does not satisfy the criteria for modifying or establishing safe harbor provisions, such as fostering access to healthcare services or improving the quality of healthcare services. However, to the extent efforts associated with encouraging the delivery of preventive care might be enhanced through safe harbors for coordinated care, on August 27, 2018, OIG issued an RFI seeking input from the public on how to address any regulatory provisions that may act as barriers to coordinated care or value-based care as well as other related topics. See 83 Fed. Reg. 43607. OIG is reviewing the comments received. In the meantime, questions about the application of the anti-kickback statute to specific arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.</p>
<p>New safe harbors to extend anti-kickback statute waivers for Medicare Shared Savings Program (MSSP) accountable care organizations to additional activities and care initiatives, and to protect all accountable care organizations and other organizations implementing alternative payments models, and to protect clinically and financially integrated programs.</p>	<p>OIG does not have authority to change the scope of activities permitted under the MSSP. Regarding a safe harbor to protect activities and initiatives outside of the MSSP, on August 27, 2018, OIG issued an RFI seeking input from the public on how to address any regulatory provisions that may act as barriers to coordinated care or value-based care as well as other related topics, which encompasses the subjects presented in this proposal. See 83 Fed. Reg. 43607. OIG is reviewing the comments received. In the meantime, questions about the application of the anti-kickback statute to specific arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.</p>
<p>Make permanent the regulatory safe harbor for donation and financial support of electronic health record software (42 C.F.R. § 1001.952(y)) and expand the scope of covered technologies under the safe harbor.</p>	<p>On August 27, 2018, OIG issued an RFI seeking input from the public on how to address any regulatory provisions that may act as barriers to coordinated care or value-based care as well as other related topics, which encompasses the subjects presented in this proposal. See 83 Fed. Reg. 43607. OIG is reviewing the comments received. In the meantime, questions about the application of the anti-kickback statute to specific arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.</p>