

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

Semiannual Report to Congress

April 1, 2018–September 30, 2018



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 April 1, 2018, to September 30, 2018.

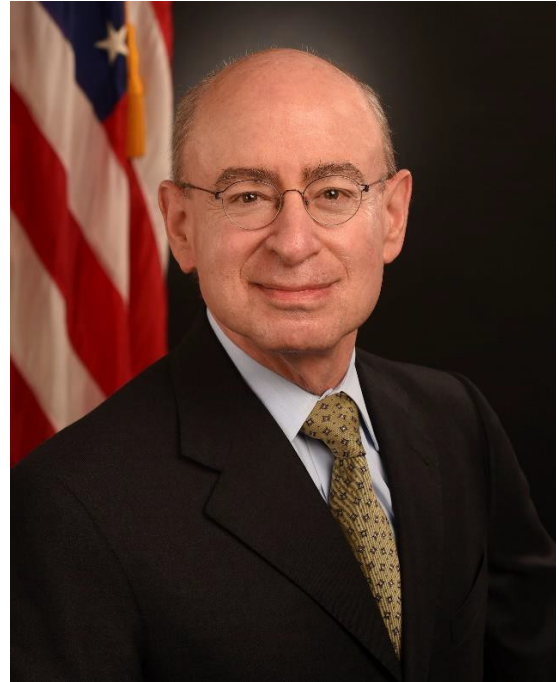
OIG continues to fulfill its crucial mission for the American people by providing objective, actionable information and recommendations to improve fiscal stewardship and quality of services provided by HHS programs and by holding those who harm HHS programs accountable. During this reporting period, we issued a seminal Hospice Portfolio report to spur improvements in the quality and integrity of care that hospices furnish to Medicare beneficiaries at the end of their lives. We also published a rollup report, based on reviews in five States that found troubling deficiencies in treatment planning and medication monitoring for children in foster care who were treated with psychotropic medications. We

intensified our oversight of the HHS Office of Refugee Resettlement's (ORR's) Unaccompanied Alien Children Program, with a focus on the care of children residing in ORR facilities and the reunification of separated children and their parents. Furthermore, OIG testified before Congress on strategies for combating Medicare and Medicaid fraud and overpayments and on ensuring quality of care and resident safety in nursing homes.

OIG's enforcement work continues to produce impressive results. During fiscal year 2018, OIG reported expected investigative recoveries of \$2.91 billion, criminal actions against 764 individuals or entities that engaged in crimes against HHS programs, exclusion of 2,712 individuals and entities, and civil actions against 813 individuals or entities. Key to these successes are our strong partnerships with the Department of Justice, Medicaid Fraud Control Units, and other Federal, State, and local agencies.

This reporting period saw continued progress in OIG's work combating the opioid epidemic. More than one-quarter of the 601 defendants in the June 2018 Health Care Fraud Takedown were charged with opioid-related conduct. Further, OIG published a toolkit setting out OIG's data-driven methodology for identifying beneficiaries at high risk of misuse of opioids. It is our hope that Federal, State, local, and private entities will use this toolkit to identify at-risk patients who may need case management or other followup. The Centers for Disease Control and Prevention recently posted the toolkit on its website.

OIG employs modern data, tools, and technology to support our multi-disciplinary workforce in providing efficient and effective oversight of HHS's over \$1 trillion in health and human services programs. We focus on achieving positive outcomes in established priority areas such as the opioid epidemic, Medicaid fraud, the safety of children, and home- and community-based services, as well as emerging areas such as cybersecurity and the shift to value-based care. We remain a nimble organization well prepared to address emergent oversight needs, including emergency preparedness and response.



Since our establishment in 1976, OIG has worked collaboratively with our partners to oversee and protect the integrity of the Department's programs. This work relies on the dedication, professionalism, and expertise of OIG employees. OIG appreciates the continued recognition, commitment, and support of Congress and the Department for our vital work.

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OIG's Approach to Driving Positive Change

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Office of Inspector General (OIG) provides independent and objective oversight that promotes economy, efficiency, and effectiveness in HHS programs and operations. OIG's program integrity and oversight activities are shaped by legislative and budgetary requirements and adhere to professional standards established by the Government Accountability Office (GAO), the 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 Mission Support and Infrastructure.

OIG Organization

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/or of HHS's 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.

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.

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).

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.

OIG's Top Unimplemented Recommendations

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

OIG's Semiannual Report to Congress

OIG's [Semiannual Report\(s\) to Congress](#) (Semiannual Reports) describe OIG's work on identifying significant problems, abuses, deficiencies, remedies, and investigative outcomes relating to the administration of HHS programs and operations that were disclosed during the reporting period. In the report below, we present OIG expected recoveries, criminal and civil actions, and other statistics as a result of our work for the entire FY 2018. We also highlight some of our work completed during this semiannual reporting period, April 1, 2018, through September 30, 2018.

Top Management and Performance Challenges Facing HHS

To focus HHS's attention on the most pressing issues, each year OIG identifies the [Top Management and Performance Challenges](#) facing HHS. These top challenges arise across HHS programs, and 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 SEMI-ANNUAL 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 reporting period. In the highlights section below, we present OIG expected recoveries, criminal and civil actions, and other statistics as a result of our work during FY 2018. Throughout FY 2018, OIG issued 163 audit reports and 45 evaluations, resulting in 578 new recommendations issued to HHS operating divisions. HHS operating divisions also implemented 420 recommendations during FY 2018.

We also highlight our most significant work completed during this semiannual reporting period, April 1, 2018, through September 30, 2018. During the semiannual reporting period, OIG issued 80 audits and 32 evaluations, resulting in 320 new recommendations issued to HHS operating divisions. Additionally, HHS operating divisions implemented 236 audit and evaluation recommendations during the semiannual reporting period.

Identifying Improper Payments and Opportunities for Savings in HHS Programs— Highlights of OIG Audit Accomplishments

OIG oversight of HHS programs ensures integrity, effectiveness, and efficiency. For FY 2018, OIG reported expected audit recoveries of \$521 million and issued reports with \$2 billion in questioned costs. For example, OIG identified unauthorized financial assistance payments to health plan issuers totaling \$939.3 million and \$180 million in unallowable Medicaid reimbursements for specialty mental health services. In FY 2018, OIG also issued reports with \$823 million in funds put to better use. This included, for example, a recommendation that CMS work with Medicare contractors to establish periodic reviews of claims for replacement positive airway pressure device supplies, which could have saved Medicare an estimated \$631 million over a 2-year period.

Fighting Fraud in HHS Programs—Highlights of Enforcement Accomplishments

OIG remains at the forefront of the Nation's efforts to fight fraud in HHS programs and hold wrongdoers accountable for their actions. Fraud increases not only HHS costs, but also risk and potential harm to beneficiaries. During FY 2018, OIG reported the following:

- Expected investigative recoveries of \$2.91 billion
- Criminal actions against 764 individuals or entities that engaged in crimes against HHS programs
- Exclusion of 2,712 individuals and entities from Federal healthcare programs
- Civil actions against 813 individuals or entities

To combat healthcare fraud, OIG partners with DOJ, State Medicaid Fraud Control Units (MFCUs or Units), and other Federal, State, and local law enforcement agencies. These partnerships include the Medicare Fraud Strike Force teams, which detect, investigate, and prosecute healthcare fraud through a coordinated and data-driven approach. For instance, OIG, along with our State and Federal law enforcement partners,

participated in an unprecedented nation-wide healthcare fraud takedown in June 2018. More than 600 defendants in 58 Federal districts were charged with participating in healthcare-related fraud schemes totaling \$2 billion.

Recent examples of significant enforcement accomplishments include the following:

- An owner of a Florida pharmacy was sentenced to 15 years in prison and ordered to pay \$54.5 million for a prescription drug fraud scheme. The owner operated multiple pharmacies, which he used to pay kickbacks and bribes in exchange for prescriptions, as well as submit false claims for prescription compounded medications to private insurance companies, Medicare, and Tricare.
- Two co-conspirators connected with clinics in Brooklyn, NY, were sentenced for their role in a \$48.5 million healthcare fraud scheme. The defendants paid cash kickbacks to patients to induce them to attend the clinics, and then submitted fraudulent claims to Medicare and Medicaid for services that were induced by prohibited kickback payments to patients or that were unlawfully rendered by unlicensed staff.

Preventing and Treating Opioid Misuse

Addressing the opioid abuse epidemic is a top priority for OIG. OIG has a longstanding and extensive history of investigative and oversight work focused on the national epidemic of prescription drug abuse, including opioid abuse. We investigate opioid fraud and diversion cases and use advanced data analytics and tools to detect suspected problems for further review. During this semiannual reporting period, OIG officials twice testified about our work curbing the opioid epidemic. First, we appeared before the Senate Committee on Finance, Health Care Subcommittee, to discuss efforts to prevent opioid overutilization and misuse in Medicare and Medicaid. Second, we appeared before the Senate Special Committee on Aging to discuss preventing and treating opioid misuse among older Americans. Other significant OIG work during this semiannual reporting period includes the following:

OIG released a [toolkit](#) to assist our public- and private-sector partners with combating the opioid crisis through data analysis.

OIG participated in the largest ever national healthcare fraud takedown of providers engaged in opioid-related fraud. Of over 600 individuals charged in conjunction with the June 2018 takedown, 162 defendants, including 76 doctors, were charged for their roles in prescribing and distributing opioids and other dangerous narcotics. In addition, between July 2017 and June 2018, OIG issued exclusion notices to 587 individuals based on their conduct related to opioid diversion and abuse.

OIG reported on the extent to which Medicare Part D beneficiaries receive extreme amounts of opioids or appear to be “doctor shopping” and also released a toolkit to assist our partners with combatting the opioid crisis through data analysis. OIG’s data analytics capabilities supported our criminal enforcement related to opioids. For instance, OIG analyzed Medicare Part D data to identify opioid prescribing patterns and, coinciding with the national takedown, released a data brief highlighting that about 15,000 beneficiaries appeared to be “doctor shopping.” Those beneficiaries received high amounts of opioids,

received their opioids from multiple prescribers and pharmacies, and did not have cancer or were not in hospice care. Further, OIG found that almost 300 prescribers engaged in questionable opioid prescribing by ordering opioids for the highest number of beneficiaries at serious risk of opioid misuse or overdose. In addition, OIG released an analysis toolkit in June 2018 to assist our public and private sector partners with analyzing their own prescription drug claims data to identify certain patients who are at risk of opioid misuse or overdose. (See reports at [OEI-02-18-00220](#) and at [OEI-02-17-00560](#).)

OIG's review of five states found that **one in three children in foster care** who were treated with psychotropic medication **did not receive required treatment planning or medication monitoring**. OIG recommended that ACF develop a comprehensive strategy to improve States' compliance in this area.

OIG identified the number of Medicaid beneficiaries in Ohio who are at serious risk of opioid misuse or overdose and prescribers who ordered opioids for more of these beneficiaries than their peers. OIG completed the first State-specific Medicaid review focused on curbing the opioid epidemic. We found that that more than 700 beneficiaries in Ohio are at serious risk of prescription opioid misuse or overdose and that nearly 50 prescribers stood out by ordering opioids for more of these beneficiaries than other prescribers. (See report at [OEI-05-18-00010](#).)

Protecting the Health and Safety of Children in HHS Programs

HHS programs provide critical health and human services to children in its care through programs such as the Unaccompanied Alien Children (UAC) program, foster care, and the Child Care and Development Fund (CCDF). OIG has found that some States and providers have not met certain requirements to ensuring the health and safety of children in their care. Significant OIG work during this semiannual reporting period includes the following:

OIG conducted site visits to 45 facilities as part of our ongoing initiative to identify vulnerabilities in the Office of Refugee Resettlement (ORR) facilities' efforts to protect UAC in their care. OIG began an expansive, multidisciplinary project during this reporting period focusing on the care and well-being of UAC residing in ORR facilities, including the subset of children who were separated and deemed ineligible for reunification. To date, we have conducted site visits of 45 ORR facilities across the country, and we are analyzing the data we collected. Results of our work will be available in the next reporting period.

Some ORR grantees may not have complied with health and safety requirements to ensure the safety of UAC in ORR's care. OIG found that Florence Crittenton Services of Orange County, Inc., did not meet safety standards in its release of some children to sponsors without conducting required background checks to ensure sponsors were vetted. Additionally, although Heartland Human Care Services, Inc., generally met applicable safety standards for the care and release of children in its custody, OIG found instances when it lacked appropriate supervision and monitoring of children in some classrooms and did not have documentation assuring that required records were provided upon children's release to sponsors. (See reports at [A-09-16-01005](#) and at [A-05-16-00038](#).)

Some States did not adequately ensure that children in foster care received required medication monitoring and case management services. OIG’s review of five States found that none fully complied with State requirements for treatment planning and medication monitoring for children in foster care receiving psychotropic medication. (See report at [OEI-07-15-00380](#).) In a separate review, OIG found that the State of Ohio did not always comply with requirements to maintain documentation that children residing in group homes received case management services and that case workers were qualified to provide services. (See report at [A-05-16-00022](#).)

State CCDF providers did not always take steps to ensure the health and safety of children in their care. Select New York City CCDF providers did not comply with applicable health and safety requirements for children, including having potentially hazardous physical conditions at provider locations and not complying with background check requirements for employees. (See report at [A-02-16-02003](#).) Additionally, while the States of Illinois, Georgia, Colorado, New Hampshire, and Nevada implemented most new CCDF criminal background check requirements, some remain unimplemented due to challenges such as unavailable finances and staff to process the checks. (See reports on Illinois at [A-05-17-00047](#), Georgia at [A-04-18-03578](#), Colorado at [A-07-17-06076](#), New Hampshire at [A-01-18-02500](#), and Nevada at [A-09-17-01003](#).)

Ensuring Quality and Integrity in Medicare’s Hospice Program

OIG is committed to ensuring that beneficiaries receive quality care and to safeguarding the hospice benefit from fraud, waste, and abuse. OIG has produced numerous evaluations and audits of the hospice program, including in-depth looks at specific levels of care and settings. OIG has also conducted criminal and civil investigations of hospice providers, leading to the conviction of individuals, monetary penalties, and civil False Claims Act settlements.

OIG is focused on **improving quality of care in Hospice settings**. During the last reporting period, OIG issued a range of recommendations to CMS to help patients better access quality care and strengthen program integrity.

OIG has identified significant vulnerabilities in the Medicare hospice program affecting quality of care and program integrity. OIG released a portfolio in July 2018 that highlights key vulnerabilities and makes 15 recommendations for protecting beneficiaries and improving the program. The portfolio synthesizes OIG’s body of work on the Medicare hospice benefit. Among its findings, OIG found that hospices do not always provide needed services to beneficiaries and sometimes provide poor quality care. Inappropriate billing and fraud by hospice providers cost Medicare hundreds of millions of dollars. In addition, OIG found that the current payment system creates incentives for hospices to minimize their services and seek beneficiaries who have uncomplicated needs. (See portfolio at [OEI-02-16-00570](#).)

A large hospice chain entered into a settlement agreement for providing services to patients who were not terminally ill. During this reporting period, a large hospice chain, Caris Healthcare LLC and Caris Healthcare, L.P. (collectively, “Caris”) entered into a settlement agreement to resolve allegations that, from April 1, 2010, through December 31, 2013, Caris submitted false claims and improperly retained payments

from Medicare for services provided to patients who were ineligible for hospice benefits because they were not terminally ill. Caris agreed to pay \$8.5 million to resolve its alleged liability.

Improving Financial Management and Reducing Improper Payments in Medicare

The 2018 Annual Report by Medicare’s Board of Trustees estimates that the Trust Fund for Medicare Part A (hospital insurance) will be depleted by 2026. It also projects that spending for Medicare Part B (medical insurance) will grow by almost 8.2 percent over the next 5 years, with the growth in spending outpacing that of the U.S. economy, which is projected to grow by 4.7 percent during that same time. To ensure continued beneficiary access to care, prudent financial management and reductions in improper payments are integral to the future of the Medicare program. Significant OIG work during this semiannual reporting period includes the following:

OIG estimates that Medicare paid inpatient rehabilitation facilities (IRFs) \$5.7 billion for care that did not meet Medicare’s necessary and reasonable care coverage requirements. OIG found that some hospitals did not comply with Medicare coverage and documentation requirements for inpatient rehabilitation facilities (IRFs). Based on a medical review of a sample of IRF claims, we estimate that in 2013 Medicare paid IRFs nation-wide \$5.7 billion for care to beneficiaries that did not meet requirements. (See report at [A-01-15-00500](#).)

OIG estimated Medicare overpayments of \$630 million for replacement positive airway pressure devices. OIG has a broad range of work identifying areas where Medicare requirements for services were not met. Within this reporting period, two areas of substantial savings include our work that found that most Medicare claims that durable medical equipment suppliers submitted for replacement positive airway pressure device supplies did not comply with Medicare requirements. Based on our analysis, we estimate that Medicare made overpayments of almost \$631.3 million. (See reports at [A-05-16-00058](#), at [A-01-15-00500](#), and at [A-04-17-04056](#).)

Protecting the Integrity 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. OIG officials twice testified on Medicaid issues during this reporting period. First, OIG testified to the Senate Committee on Homeland Security and Governmental Affairs on potential solutions to addressing Medicaid fraud and overpayments. Second, OIG testified to the House Committee on Oversight and Government Reform, Subcommittee on Government Operations and Subcommittee on Intergovernmental Affairs, regarding Medicaid improper payments. Below are some examples of significant OIG work during this semiannual reporting period.

OIG found that some MCOs identified and referred few cases of suspected fraud and abuse to the State. And when MCOs did take action against providers suspected of fraud or abuse, they did not typically inform the State. OIG recommended State improvement in these areas.

OIG identified noncompliance in California’s Medicaid agency claims for specialty mental health services. When reviewing California’s Medicaid spending for specialty mental health services, OIG found that California did not always comply with Federal and State requirements when claiming Federal reimbursement for specialty mental health services expenditures. Based on our sample results, we estimated that California claimed at least \$180.6 million in unallowable Federal reimbursement. (See report at [A-09-15-02040](#).)

OIG raised concern about program integrity in Medicaid managed care. Managed care organizations (MCO) play an increasingly important role in fighting fraud and abuse in Medicaid, yet we found that weaknesses exist in their efforts to identify and address fraud and abuse. During this reporting period, OIG reported that although the number of cases varied widely, some MCOs identified and referred few cases of suspected fraud or abuse to the State. (See report at [OEI-02-15-00260](#).)

Protecting Health and Safety in Adult Day Care Facilities

HHS programs provide critical health and human services to adults receiving care at adult day care facilities and other providers. OIG’s work has found that some providers, such as adult day care facilities, have not met certain requirements to ensure the health and safety of adults in their care. In some cases, OIG has engaged in enforcement actions against these providers. Significant OIG work during this semiannual reporting period includes the following:

OIG found that **adult day care facilities in three States had numerous health and safety violations**. OIG recommended that States correct the identified violations, improve provider training programs, and take other steps to ensure future compliance.

OIG found that most adult day care facilities reviewed in four States did not comply with health and safety requirements. OIG identified 200 instances of noncompliance with health and safety administrative requirements in facilities providing adult day care in Minnesota, 105 in Illinois, and 564 in Mississippi. Instances of noncompliance occurred for reasons such as lack of sufficient training on State requirements and budget reductions. OIG recommended that these States correct the identified instances of noncompliance and improve oversight of staffing, training, and administration. (See reports on Minnesota at [A-05-17-00009](#), Illinois at [A-05-17-00028](#), and Mississippi at [A-04-17-00116](#).)

OIG engaged in enforcement actions against providers who were inflicting harm on patients or allegedly denying them access to safe and quality healthcare. In one case, a medical center entered into a \$90,000 settlement agreement with OIG to resolve allegations that it violated the Emergency Medical Treatment and Leave Act (EMTALA) by failing to provide an adequate medical screening examination and treatment for a patient and transferring him to another hospital, where his condition worsened and he later expired. In another case in Alabama, one doctor plead guilty to healthcare fraud and unlawful distribution of a controlled substance, and was sentenced to 5 years in prison and ordered to pay \$15 million in restitution. The doctor was convicted of running an insurance scam at his clinic in which he administered unnecessary medical tests and procedures and prescribed controlled substances without a legitimate medical purpose to patients.

Ensuring Quality and Integrity in Programs Serving American Indian/Alaska Native (AI/AN) Populations

OIG continues its oversight of programs serving AI/AN populations to ensure effective grants administration oversight and ensuring the quality and safety of services. For instance, OIG hosted a compliance and quality training for over 200 individuals representing Indian Health Service (IHS) facilities, Tribes, Tribal organizations, and other key stakeholders in May 2018. The purpose of the training was to increase knowledge about compliance and internal controls of Tribes and IHS officials and staff who carry out IHS programs. OIG also conducts audits of tribal grantees and healthcare providers focused on these issues. Two such audits issued during this reporting period are described below.

OIG identified **significant gaps in the quality of care** found at a tribal Federally qualified health center, such as an absence of clinical or administrative protocols. OIG has recommended that the health center put into place **measures to ensure and improve quality of care**.

OIG found that the Fort Peck Tribes did not properly administer some Low-Income Home Energy Assistance Program (LIHEAP) grant funds. Specifically, OIG found that the Fort Peck Tribes did not properly administer \$436,765 of Low-Income Home Energy Assistance Program (LIHEAP) grant funds in compliance with Federal laws, regulations, and guidance for FYs 2011 through 2015. The Fort Peck Tribes did not have policies and procedures or other internal controls in place to prevent these errors. (See report at [A-07-18-04106](#).)

OIG found that the Passamaquoddy Tribe's Pleasant Point Health Center did not always meet health and safety requirements. For instance, the Pleasant Point Health Center did not always have a physician who provided medical direction for the center, clear lines of authority and responsibility between medical and administrative decision making, and other medical and non-medical policies and procedures needed to comply with Federal and Tribal health and safety requirements. OIG has recommended measures to improve oversight by a medical director in addition to stronger administrative safeguards. (See report at [A-11-701500](#).)

OIG Participation in Congressional Hearings

| <i>Date</i> | <i>Witness</i> | <i>Testimony/Committee</i> |
|-------------|--|--|
| 09/06/2018 | Ruth Ann Dorrill, Regional Inspector General | <u>"Examining Federal Efforts to Ensure Quality of Care and Resident Safety in Nursing Homes,"</u> House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations |
| 07/17/2018 | Gloria L. Jarmon, Deputy Inspector General for Audit Services | <u>"Combating Fraud in Medicare: A Strategy for Success,"</u> House Committee on Ways and Means, Subcommittee on Oversight |
| 06/27/2018 | Brian P. Ritchie, Assistant Inspector General for Audit Services | <u>"Medicaid Fraud and Overpayments: Problems and Solutions,"</u> Senate Committee on Homeland Security and Governmental Affairs |
| 05/29/2018 | Maureen Dixon, Special Agent in Charge, Philadelphia Regional Office, Office of Investigations | <u>"Examining Efforts to Prevent Opioid Overutilization and Misuse in Medicare and Medicaid,"</u> Senate Committee on Finance, Health Care Subcommittee |
| 05/23/2018 | Gary Cantrell, Deputy Inspector General for Investigations | <u>"Preventing and Treating Opioid Misuse Among Older Americans,"</u> Senate Special Committee on Aging |
| 05/15/2018 | Ann Maxwell, Assistant Inspector General for Evaluation and Inspections | <u>"Examining Oversight Reports on the 340B Drug Pricing Program,"</u> Senate Committee on Health, Education, Labor, and Pensions |
| 04/12/2018 | Megan H. Tinker, Senior Advisor for Legal Review Office of Counsel to the Inspector General | <u>"Improper Payments in State Administered Programs: Medicaid,"</u> House Committee on Oversight and Government Reform, Subcommittee on Government Operations and Subcommittee on Intergovernmental Affairs |

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 |
| CCDF | Child Care and Development Fund |
| DHS | Department of Homeland Security |
| DOJ | Department of Justice |
| DME | durable medical equipment |
| EMTALA | Emergency Medical Treatment and Labor Act |
| FCA | False Claims Act |
| FDA | Food and Drug Administration |
| FY | fiscal year |
| GAO | Government Accountability Office |
| 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 |
| LIHEAP | Low-Income Home Energy Assistance Program |
| 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 |
| OMB | Office of Management and Budget |
| SAMHSA | Substance Abuse and Mental Health Services Administration |
| SNF | skilled nursing facility |

Centers for Medicare & Medicaid Services

Medicare Program Reports and Reviews

Financial Management and Improper Payments

CMS Paid Practitioners for Telehealth Services That Did Not Meet Medicare Requirements (A-05-16-00058), April 2018

Medicare paid a total of \$17.6 million in telehealth payments in 2015, compared with \$61,302 in 2001. Medicare telehealth payments include a professional fee, paid to the practitioner performing the service at a distant site, and an originating-site fee, paid to the facility where the beneficiary receives the service. We analyzed 2014 and 2015 (our audit period) telehealth claims and found that more than half of the professional telehealth claims paid by Medicare did not have matching originating-site facility fee claims. Therefore, we focused our review on telehealth claims billed through a distant site that did not have a corresponding originating-site fee.

CMS paid practitioners for some telehealth claims associated with services that did not meet Medicare requirements. For 31 of the 100 claims in our sample, telehealth services did not meet requirements. The deficiencies that we identified occurred because CMS did not ensure that: (1) there was oversight to disallow payments for errors for which telehealth claim edits could not be implemented; (2) all contractor claim edits were in place; and (3) practitioners were aware of Medicare telehealth requirements.

CMS concurred with our recommendations that it: (1) conduct periodic postpayment reviews to disallow payments for errors for which telehealth claim edits cannot be implemented; (2) work with Medicare contractors to implement all telehealth claim edits listed in the Medicare Claims Processing Manual; and (3) offer education and training sessions to practitioners on Medicare telehealth requirements and related resources.

Most Medicare Claims for Replacement Positive Airway Pressure Device Supplies Did Not Comply with Medicare Requirements (A-04-17-04056), June 2018

Most Medicare claims that durable medical equipment (DME) suppliers submitted for replacement positive airway pressure (PAP) device supplies did not comply with Medicare requirements. Of the 110 claims in our sample that Medicare paid in 2014 and 2015, 86 claims did not comply with Medicare requirements. Based on our sample results, we estimated that Medicare made overpayments of almost \$631.3 million for replacement PAP device supply claims that did not meet Medicare requirements.

These overpayments occurred because CMS oversight of replacement PAP device supplies was not sufficient to ensure that suppliers complied with Medicare requirements or to prevent payment of

claims that did not meet those requirements. Without periodic reviews of claims for replacement supplies, Medicare contractors were unable to identify suppliers that consistently billed claims that did not meet Medicare requirements or to take remedial action.

CMS concurred with our recommendations that it: (1) recover the portion of the overpayments of \$13,414 associated with the sample claims that are within the 4-year reopening period; (2) work with Medicare contractors to establish periodic reviews of claims for replacement PAP device supplies and take remedial action for suppliers that the contractors find consistently bill claims that do not meet Medicare requirements, which could have saved Medicare an estimated \$631.3 million over a 2-year period; and (3) instruct the Medicare contractors to exercise reasonable diligence to investigate and return any identified overpayments, in accordance with the 60-day rule, and to identify and track any returned overpayments.

CMS Did Not Detect Some Inappropriate Claims for Durable Medical Equipment in Nursing Facilities (OEI-06-16-00380), June 2018

We found that CMS allowed \$18.4 million in Medicare payments for inappropriate claims for DME provided during skilled nursing facility (SNF) stays not covered by Medicare, and may also have allowed additional inappropriate claims for DME provided in Medicaid-only nursing facilities. CMS requires facilities to provide DME as a standard part of nursing care, and does not permit separate Medicare payment for DME except when Medicaid-only nursing facilities serve as beneficiary homes. CMS uses two payment edits designed to identify and reject inappropriate claims, but neither edit rejected the claims because SNFs and DME suppliers did not submit full and accurate information required for processing. CMS concurred with our recommendations to:

- strengthen oversight of place-of-service codes by developing a process to determine whether DME claims with “home” as the place of service fit the circumstances permitting separate payment;
- assess the costs and benefits of strengthening oversight of no-payment bills by developing a process to identify noncovered stays when SNFs do not submit no-payment bills; and
- assess the costs and benefits of collecting and maintaining information regarding the level of care provided by Medicaid-only nursing facilities.

The MEDIC Produced Some Positive Results but More Could be Done to Enhance its Effectiveness (OEI-03-17-00310), July 2018

While the Medicare Drug Integrity Contractor’s (MEDIC) reported recoveries resulted in a positive return on investment (\$3 in recoveries for every \$1 invested in 2017), CMS has no measures that specifically assess the MEDIC’s effectiveness. CMS directed the MEDIC to devote more resources to proactive data analysis and administrative actions in 2014 and 2015, which led to a sharp increase in proactive data analysis, but a decrease in the MEDIC resources available to follow up on the results of these analyses. As a result, there have been fewer MEDIC investigations and referrals to law enforcement agencies, including OIG. Through its increased proactive analyses, the MEDIC was able to identify thousands of high-risk leads involving drugs, including opioids, to plan sponsors from 2014 through 2017. The impact of these activities, however, cannot be measured, as

plan sponsors are not required to report to CMS the actions taken in response to these leads. In addition, MEDIC staff described numerous barriers that limit the MEDIC's overall impact.

CMS concurred with the following recommendations to:

- require plan sponsors to report fraud and abuse incidents and the corrective actions taken to address them to a centralized system;
- provide the MEDIC with centralized access to all Part C encounter data;
- clarify the MEDIC's authority to require records from pharmacies; pharmacy benefit managers; and other entities under contract with Part C and Part D plan sponsors; and
- establish measures to assess the MEDIC's effectiveness.

CMS did not concur with the recommendation to require that Part C and Part D providers and pharmacies enroll in Medicare. Additionally, CMS did not concur or non-concur with the remaining recommendation to provide the MEDIC with the authority to require medical records from providers who prescribe Part D prescription drugs but are not under contract with plan sponsors.

Setting Medicare Payment Rates for Clinical Diagnostic Laboratory Tests: Strategies to Ensure Data Quality (OEI-09-17-00050), July 2018

The Protecting Access to Medicare Act of 2014 (PAMA) requires CMS to set Medicare Part B payment rates for clinical diagnostic laboratory tests (lab tests) using private sector payment rates. Under PAMA, labs report private payer rates for lab tests to CMS every 3 years. To provide oversight, PAMA mandated that OIG monitor Medicare payments for lab tests and CMS's implementation of the new payment system. CMS issued new payment rates for lab tests that took effect on January 1, 2018. Payment rates decreased for 75 percent of lab tests, which are generally in line with savings estimated in previous OIG reports. During the initial implementation of the new payment system, labs experienced some one-time challenges complying with the new data-reporting requirement. However, CMS's limited data quality assurance efforts present an ongoing risk and we identified strategies to help CMS ensure that future payment rates are based on complete and accurate data. Our report contains no recommendations.

Medicare Improperly Paid Providers for Nonemergency Ambulance Transports to Destinations Not Covered by Medicare (A-09-17-03018), July 2018

Medicare made improper payments of \$8.7 million to providers for nonemergency ambulance transports to destinations not covered by Medicare. The majority of the improperly billed claim lines (59 percent) were for transports to diagnostic or therapeutic sites, other than a physician's office or a hospital, that did not originate from SNFs. As of the publication of this report, the total improper payment amount of \$8.7 million included claim lines outside of the 4-year claim-reopening period.

CMS concurred with our recommendations that it: (1) direct the Medicare contractors to recover the portion of the \$8.7 million in improper payments made to providers for claim lines that are

within the claim-reopening period; (2) for the remaining portion of the \$8.7 million, which is outside of the Medicare reopening and recovery periods, instruct the Medicare contractors to notify providers of potential improper payments so that those providers can exercise reasonable diligence to investigate and return any identified similar improper payments, and identify and track any returned improper payments; (3) direct the Medicare contractors to review claim lines for nonemergency ambulance transports to destinations not covered by Medicare after our audit period and recover any improper payments identified; and (4) require the Medicare contractors to implement nation-wide prepayment edits to ensure that payments to providers for nonemergency ambulance transports comply with Federal requirements.

Medicare Improperly Paid Providers for Items and Services Ordered by Chiropractors (A-09-17-03002), July 2018

Medicare payments for selected items and services ordered by chiropractors did not comply with Federal requirements. Specifically, for calendar years (CY) 2013 through 2016, Medicare improperly paid providers \$6.7 million. Medicare overpaid providers because CMS's claim-processing edits were not fully effective in preventing overpayments. CMS did not begin using these edits to deny claims until January 2014. Of the improper payments for our audit period, 89 percent were for items and services provided before CMS's implementation of the edits.

CMS concurred with our recommendations that it: (1) direct the Medicare contractors to recover the portion of the \$6.7 million in overpayments to providers for claims that are within the reopening period; and (2) instruct the Medicare contractors to notify providers of potential overpayments so that those providers can exercise reasonable diligence to investigate and return any identified similar overpayments and identify and track any returned overpayments. CMS did not concur with our recommendation that it revise the claim-processing edits to ensure that all claims for items and services ordered by chiropractors are denied.

Medicare Made Improper and Potentially Improper Payments for Emergency Ambulance Transports to Destinations Other Than Hospitals or Skilled Nursing Facilities (A-09-17-03017), August 2018

Medicare payments to providers for emergency ambulance transports did not comply or potentially did not comply with Federal requirements. Specifically, for CYs 2014 through 2016, Medicare made improper and potentially improper payments totaling \$1.9 million: (1) improper payments of \$975,154 for transports to destinations that were not covered by Medicare for either emergency or nonemergency ambulance transports; and (2) potentially improper payments of \$928,092 for transports that may not have met Medicare coverage requirements or might have been paid by Medicare as nonemergency ambulance transports.

CMS concurred with our recommendations that it direct the Medicare contractors to: (1) recover improper payments for emergency ambulance transports within the 4-year claim-reopening period; and (2) review claim lines that are within that period for emergency ambulance transports any improper payments identified. CMS also concurred with our recommendations related to: (1) returning any identified improper payments outside of the reopening period; (2) reviewing and

recovering any improper payments for emergency ambulance transports to destinations not covered by Medicare after our audit period; and (3) addressing two procedural recommendations.

Medicare Improperly Paid Hospitals Millions of Dollars for Intensity-Modulated Radiation Therapy Planning Services (A-09-16-02033), August 2018

Payments for outpatient intensity-modulated radiation therapy (IMRT) planning services did not comply with Medicare billing requirements. Based on our sample results, we estimated that Medicare overpaid hospitals nation-wide as much as \$21.5 million for complex simulations billed during our audit period (CYs 2013 through 2015). In addition, we identified \$4.2 million in potential overpayments for other IMRT planning services that were not included in our sample. In total, Medicare overpaid hospitals as much as \$25.8 million during our audit period. For IMRT planning services billed in the 2 years after our audit period (for CYs 2016 and 2017), we identified an additional \$3.7 million in potential overpayments for complex simulations and \$1.7 million for other IMRT planning services. In total, Medicare overpaid hospitals as much as \$5.4 million after our audit period.

CMS concurred with our recommendations that it: (1) implement an edit to prevent improper payments for IMRT planning services that are billed before (e.g., up to 14 days before) the procedure code for the bundled payment for IMRT planning is billed, which could have saved as much as \$25.8 million during our audit period and as much as \$5.4 million in the next 2 years; and (2) work with the Medicare contractors to educate hospitals on properly billing Medicare for IMRT planning services.

Many Inpatient Rehabilitation Facility Stays Did Not Meet Medicare Coverage and Documentation Requirements (A-01-15-00500), September 2018

IRFs did not comply with all Medicare coverage and documentation requirements specified for reasonable and necessary care. For 175 of 220 stays that we sampled, which corresponded to 135 IRFs, medical record documentation did not support that IRF care was reasonable and necessary in accordance with Medicare's requirements. Based on our sample results, we estimated that Medicare paid IRFs nation-wide \$5.7 billion in 2013 for care to beneficiaries that was not reasonable and necessary.

CMS concurred with our recommendations that it: (1) educate IRF clinical and billing personnel on Medicare coverage and documentation requirements and work with providers to develop best practices to improve internal controls; (2) increase oversight activities for IRFs, such as postpayment medical review; (3) work with the Office of Medicare Hearings and Appeals to ensure that Medicare coverage and documentation requirements for IRF care are fairly represented at administrative law judge hearings; and (4) re-evaluate the IRF payment system.

Medicare Payments for Clinical Diagnostic Laboratory Tests in 2017: Year 4 of Baseline Data (OEI-09-18-00410), September 2018

Medicare paid \$7.1 billion under Part B for lab tests in 2017, a total that changed very little over 4 years. The top 25 tests by Medicare payments totaled \$4.5 billion and represented 64 percent of all Medicare payments for lab tests in 2016. More than half of payments for the top 25 tests went to 1 percent of labs.

Congress mandated that OIG monitor Medicare payments for lab tests and publicly release an annual analysis of the top 25 lab tests by Medicare payments. The new payment system for lab tests took effect on January 1, 2018, and resulted in significant changes to the Medicare payment rates for lab tests. This data brief, like those before it, will provide baseline statistics that OIG will use to measure the effects of changes to the payment system when data from 2018 become available. Our data brief contains no recommendations.

Quality of Care, Safety, and Access

Round 2 Competitive Bidding for Oxygen: Continued Access for Vast Majority of Beneficiaries (OEI-01-15-00041), May 2018

We found that Medicare payments for oxygen equipment and contents continued for the vast majority of beneficiaries in both Round 2 bidding areas and nonbidding areas, indicating that the Competitive Bidding Program likely did not disrupt their access. The percentage of beneficiaries for whom Medicare payments did not continue was slightly higher in Round 2 bidding areas than in nonbidding areas, which may or may not indicate disruptions in receiving needed oxygen equipment and contents for a very small proportion of beneficiaries.

This report is part of a series examining the effect of Round 2 Competitive Bidding on Medicare beneficiary access to DME. Other reports in the series examined beneficiary access to enteral nutrition supplies and continuous positive airway pressure devices and respiratory assist (CPAP/RAD) devices and related supplies.

Round 2 Competitive Bidding for Enteral Nutrition: Continued Access for Vast Majority of Beneficiaries (OEI-01-15-00042), May 2018

We found that Medicare payments for enteral nutrition supplies continued for the vast majority of beneficiaries in both Round 2 bidding areas and nonbidding areas, indicating that the Competitive Bidding Program likely did not disrupt their access. The percentage of beneficiaries for whom Medicare payments did not continue was slightly higher in Round 2 bidding areas than in nonbidding areas, which may or may not indicate disruptions in receiving needed enteral nutrition supplies for a very small proportion of beneficiaries.

This report is part of a series examining the effect of Round 2 Competitive Bidding on Medicare beneficiary access to DME. Other reports in the series examined beneficiary access to CPAP/RAD devices (continuous positive airway pressure devices and respiratory assist devices) and related supplies and to oxygen equipment and contents.

Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials (OEI-09-16-00410), September 2018

High overturn rates when beneficiaries and providers appeal denials, and CMS audit findings about inappropriate denials, raise concerns that some beneficiaries and providers may not be getting services and payment that Medicare Advantage Organizations (MAOs) are required to provide. These findings are particularly concerning because beneficiaries and providers almost never use the appeals process designed to ensure access to care and payment. CMS concurred with our three recommendations to:

- enhance its oversight of MAO contracts including those with extremely high overturn rates and/or low appeal rates and take corrective action as appropriate;
- address persistent problems related to inappropriate denials and insufficient denial letters in Medicare Advantage; and
- provide beneficiaries with clear, easily accessible information about serious violations by MAOs.

Opioid Use in Medicare Part D Remains Concerning (OEI-02-18-00220), June 2018

We found that nearly one in three beneficiaries received a prescription opioid through Medicare Part D in 2017, a slight decrease from 2016. Overall Part D spending for opioids also decreased, from \$4.0 billion in 2016 to \$3.4 billion for opioids in 2017. This decrease was due in part to declining prices. Almost 460,000 beneficiaries received high amounts of opioids in 2017, fewer than in 2016. Of these, about 71,000 beneficiaries were at serious risk of opioid misuse or overdose, also fewer than in 2016. These 71,000 beneficiaries received extreme amounts of opioids or appeared to be doctor shopping. Moreover, almost 300 prescribers had questionable prescribing patterns for beneficiaries who are at serious risk. Ensuring the appropriate use and prescribing of opioids is essential to protecting the health and safety of beneficiaries and the integrity of Part D. The severity of the opioid crisis makes it imperative that HHS, including CMS and OIG, continues to work together to develop new strategies to address this epidemic.

Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2018 (OEI-05-18-00240), June 2018

Overall, we found that the rate of Part D plan formularies' inclusion of the drugs commonly used by dual eligible (i.e., individuals who are eligible for both Medicare and Medicaid) is high, with some variation. Because some variation exists in formularies' inclusion of these drugs and in their application of utilization management tools to the drugs, some dual eligibles may need to use alternative methods to access the drugs they take. This report did not make recommendations.

Analysis Toolkit: Calculating Opioid Levels to Identify Patients at Risk of Misuse or Overdose (OEI-02-17-00560), June 2018

This toolkit provides detailed steps for using prescription drug claims data to analyze patients' opioid levels and identify certain patients who are at risk of opioid misuse or overdose. It is based on the methodology that OIG has developed in our extensive work on opioids. It is intended to assist our partners, such as Medicare Part D plan sponsors, private health plans, and State MFCUs, with analyzing their own prescription drug claims data to help combat the opioid crisis.

Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio (OEI-02-16-00570), July 2018

Hospice use has grown steadily over the past decade, with Medicare paying \$16.7 billion for this care for 1.4 million beneficiaries in 2016. However, OIG has identified vulnerabilities in the program. OIG found that hospices do not always provide needed services to beneficiaries and sometimes provide poor quality care. Also, beneficiaries and their families and caregivers do not receive crucial information to make informed decisions about care. Further, hospices' inappropriate billing costs Medicare hundreds of millions of dollars. Lastly, the current payment system creates incentives for hospices to minimize their services and seek beneficiaries who have uncomplicated needs. Our findings make clear that more must be done to protect Medicare beneficiaries and the integrity of the program.

CMS concurred with the following recommendations to:

- develop other claims-based information and include it on Hospice Compare (a website that allows public users to compare hospice agencies based on the quality of care they provide);
- work with its partners, such as hospitals and caregiver groups, to make available consumer-friendly information explaining the hospice benefit to beneficiaries and their families and caregivers;
- analyze claims data to identify hospices that engage in practices or have characteristics that raise concerns;
- take appropriate actions to follow up with hospices that engage in practices or have characteristics that raise concerns;
- increase oversight of general inpatient care claims and particularly focus on general inpatient care provided in SNFs, given the higher rate at which these stays were inappropriate; and
- implement a comprehensive prepayment review strategy to address lengthy general inpatient care stays so that beneficiaries do not have to endure unnecessarily long periods of time in which their pain and symptoms are not controlled.

CMS did not concur with the following recommendations to:

- analyze claims data to inform the survey process;
- analyze deficiency data to inform the survey;

- include on Hospice Compare deficiency data from surveys, including information about complaints filed and resulting deficiencies;
- develop and execute a strategy to work directly with hospices to ensure that they are providing drugs covered under the hospice benefit as necessary and that the cost of drugs covered under the benefit are not inappropriately shifted to Part D;
- assess the current payment system to determine what changes may be needed to tie payments to beneficiaries' care needs and quality of care to ensure that services rendered adequately serve beneficiaries' needs;
- adjust payments based on these analyses, if appropriate, to ensure that the payment system is aligned with beneficiary needs and quality of care; and
- modify the payments for hospice care in nursing facilities.

CMS neither concurred nor nonconcurred with the recommendation to seek statutory authority to establish additional, intermediate remedies for poor hospice performance. Additionally, we clarified and combined two recommendations to state that CMS should ensure that a physician is involved in the decisions to start and continue general inpatient care.

Questionable Billing for Compounded Topical Drugs in Medicare Part D (OEI-02-16-00440), August 2018

We found that Medicare Part D spending for compounded topical drugs was 24 times higher in 2016 than it was in 2010 and that nearly 550 pharmacies had questionable Part D billing for compounded topical drugs in 2016. This explosive growth and identification of pharmacies raises concerns about fraud and abuse. CMS concurred with our recommendations to:

- clarify Part D policies for coverage of compounded topical drugs and use of utilization management tools;
- conduct additional analysis on compounded topical drugs;
- conduct training for Part D sponsors on fraud schemes and safety concerns related to compounded topical drugs; and
- follow up on pharmacies with questionable Part D billing and the prescribers associated with these pharmacies.

Program Integrity

2017 Performance Data for the Senior Medicare Patrol Projects (OEI-02-18-00130), May 2018

The Senior Medicare Patrol (SMP) projects receive grants from ACL to recruit and train retired professionals and other senior citizens to prevent, recognize, and report healthcare fraud, errors, and abuse. In 2017, the 53 SMP projects had a total of 6,130 active team members who conducted a total of 26,429 group outreach and education events, reaching an estimated 1.9 million people. In addition, the projects had 226,261 individual interactions with, or on behalf of, a Medicare beneficiary. The projects reported \$2,010,475 in expected Medicare recoveries, which came primarily from one project that prompted law enforcement to open an investigation that resulted in a

settlement with a hospice company. The SMP projects also reported \$211,749 in cost avoidance and \$44,468 in savings to beneficiaries and others.

Payment Policy and Trends

Open Payments Data: Review of Accuracy, Precision, and Consistency in Reporting ([OEI-03-15-00220](#)), August 2018

The Open Payments program promotes transparency by making available to the public the financial relationships that physicians and teaching hospitals have with applicable manufacturers and group purchasing organizations. Of 11.9 million records published on the Open Payments website for 2015, less than 1 percent were missing required data elements. Although the Open Payments data elements reported to CMS were complete overall, we did identify records that contained inaccurate, imprecise, or inconsistent information. The Open Payments program can benefit the public only if the data reported are complete and accurate. As such, potential issues with these data may undermine the public benefit of this program. CMS concurred with the following recommendations to:

- ensure that records contain all required data;
- strengthen validation rules and revise data-element definitions so that actual drug and device names must be reported;
- revise the definition of the device-name data element so that the information reported is required to be more specific; and
- ensure that manufacturers and group purchasing organizations report valid national drug codes for drugs.

Drug Pricing and Reimbursement

CMS's Policies and Procedures Were Generally Effective in Ensuring That Prescription Drug Coverage Capitation Payments Were Not Made After the Beneficiaries' Dates of Death ([A-07-16-05088](#)), April 2018

CMS had policies and procedures in place that were generally effective in ensuring that capitation payments to Medicare Advantage organizations' prescription drug plans and stand-alone prescription drug plans (collectively referred to as "sponsors") for Medicare Part D coverage were not made on behalf of deceased beneficiaries after the individuals' dates of death. These policies and procedures generally ensured that CMS did not make improper capitation payments on behalf of deceased beneficiaries when its data systems indicated at the time of a monthly capitation payment that the beneficiaries in question had died.

CMS did not, however, identify and recoup all improper capitation payments. As of March 7, 2017, CMS had not recouped \$1.1 million associated with 65,398 separate capitation payments. For our audit period, these improper payments represented .0004 percent of the total capitation payments

made to sponsors and .097 percent of the total adjustments that CMS made after receiving information on beneficiaries' dates of death.

CMS concurred with our recommendations that it: 1) use the information in this report to recoup the \$1.1 million in capitation payments to sponsors for Medicare Part D coverage on behalf of deceased beneficiaries; and 2) continue to implement system enhancements to identify, adjust, and recoup improper capitation payments in the future.

Increases in Reimbursement for Brand-Name Drugs in Part D (OEI-03-15-00080), June 2018

We found that Part D reimbursement for brand-name drugs increased at a pace greater than the rate of inflation while utilization for these drugs decreased. Specifically, total reimbursement for all brand-name drugs in Part D increased 77 percent from 2011 to 2015, while utilization decreased 17 percent across the 5 years. Continued increases in reimbursement for brand-name drugs may have long-term effects on Medicare and its beneficiaries, especially those beneficiaries who need access to expensive maintenance drugs. This data brief did not include recommendations.

Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2016 Average Sales Prices (OEI-03-18-00120), August 2018

Based on 2016 data, CMS lowered Part B reimbursement for 16 drugs, saving Medicare and its beneficiaries \$13.1 million over 1 year. This finding highlights the success of OIG's mandated quarterly comparisons of average sales prices with average manufacturer prices and implementation of CMS's current price-substitution policy. OIG continues to recommend that CMS expand the price-substitution criteria. CMS did not concur with this recommendation and believes that more experience with the price-substitution policy is needed before it can be expanded.

Medicaid Program Reports and Reviews

Financial Management and Improper Payments

Texas Did Not Make Increased Primary Care Provider Payments and Claim Reimbursement in Accordance With Federal Requirements (A-06-15-00045), April 2018

Texas did not always make increased Medicaid payments to providers and claim reimbursement in accordance with Federal requirements. Of the \$721 million in Federal funds that it received, Texas inappropriately received \$20.7 million because it: (1) incorrectly claimed the 100-percent matching rate for payments that were only eligible for the regular matching rate; and (2) made payments that were unallowable.

Additionally, we are setting aside \$1.1 million in Federal funds Texas received for payments that exceeded the providers' actual billed charges. Providers did not complete the billed charges field

for some payment data with meaningful amounts, so we could not determine the correct payment amounts for the data.

Texas concurred with our recommendation that it work with CMS to determine the portion of the \$1.1 million it received for payments that exceeded providers' billed charges that should be refunded to the Federal Government. Texas did not indicate concurrence or nonconcurrence with our recommendation that it refund \$20.7 million to the Federal Government.

Most of New York's Claims for Federal Reimbursement for Monthly Personal Emergency Response Service Charges Did Not Comply with Medicaid Requirements (A-02-15-01019), April 2018

New York provides Personal Emergency Response Services (PERS) to eligible Medicaid beneficiaries through contracts negotiated between local social services districts (local districts) and PERS providers. Payment for PERS includes a monthly service charge for monitoring agency services.

For 87 of the 100 claims in our sample, New York claimed Federal reimbursement for PERS monthly service charge claims that did not comply with Medicaid requirements. Based on our sample results, we estimated that New York improperly claimed at least \$5.5 million in Federal Medicaid reimbursement. New York's ineffective oversight of the PERS program leaves the program vulnerable to misuse of Federal funds and could potentially place beneficiaries at risk of harm.

New York did not indicate concurrence or nonconcurrence with our recommendations that it refund \$5.5 million to the Federal Government and strengthen its monitoring activities of local districts for compliance with Medicaid requirements. New York described actions it was taking or planned to take in response to each of our recommendations.

New York Claimed Federal Reimbursement for Consumer-Directed Personal Assistance Services That Did Not Meet Medicaid Requirements (A-02-16-01026), June 2018

New York's consumer-directed personal assistance program (CDPAP) includes personal care, home health, and nursing services. New York claimed Federal Medicaid reimbursement totaling more than \$579 million for CDPAP services provided from January 2012 through June 2016.

For 27 of 120 sampled claims, New York claimed Federal reimbursement for CDPAP services claims that did not meet Medicaid requirements. New York also claimed reimbursement for services provided after a 6-month authorization period had lapsed. This occurred because New York did not effectively monitor the CDPAP for compliance with certain CDPAP requirements.

Based on our sample results, we estimated that New York improperly claimed at least \$74.8 million in Federal Medicaid reimbursement during our audit period. New York's lack of effective monitoring of the CDPAP leaves the program vulnerable to misuse of Federal funds and could potentially place beneficiaries at risk of harm.

New York did not indicate concurrence or nonconcurrence with our recommendations that it refund \$74.8 million to the Federal Government, reinforce guidance related to CDPAP documentation and billing requirements, and improve its monitoring of the CDPAP to ensure compliance with requirements. New York described the actions it was taking or planned to take in response to each of our recommendations.

Virginia Did Not Claim Some Medicaid Administrative Costs for Its Medallion 3.0 Waiver Program in Accordance With Federal Requirements (A-03-17-00200), June 2018

Of the \$220 million (Federal share) in administrative costs claimed for Virginia's waiver program in State FYs 2016 and 2017, Virginia correctly claimed \$211.2 million (Federal share). However, we found that Virginia claimed \$7.7 million (Federal share) in unallowable waiver program administrative costs not identified in its Cost Allocation Plan (CAP). In addition, Virginia incorrectly claimed \$1.2 million (Federal share) in administrative costs that were misclassified as waiver program administrative costs. The misclassified expenditures did not directly benefit the waiver program but directly benefited a separate public welfare program, Virginia's Children's Health Insurance Program (CHIP).

Virginia did not concur with our recommendation that it refund to the Federal Government \$7.7 million for administrative costs that were not identified in the CAP and concurred with our recommendation that it reclassify \$1.2 million (Federal share) in administrative costs that directly benefited Virginia's CHIP program and not the waiver program.

Weaknesses Exist in Medicaid Managed Care Organizations' Efforts to Identify and Address Fraud and Abuse (OEI-02-15-00260), July 2018

We found that MCOs play an increasingly important role in fighting fraud and abuse in Medicaid, yet weaknesses exist in their efforts to identify and address fraud and abuse. Although the number of cases varied widely, some MCOs identified and referred few cases of suspected fraud or abuse to the State in 2015. In addition, MCOs took actions against providers suspected of fraud or abuse but did not typically inform the State, including when MCOs terminated provider contracts for reasons associated with fraud or abuse. Finally, MCOs did not always identify and recover overpayments, including those associated with fraud or abuse. At the same time, selected States employ a number of strategies to address MCOs' weaknesses and improve MCO efforts.

CMS concurred with the following recommendations to:

- improve MCO identification and referral of cases of suspected fraud or abuse;
- increase MCO reporting of corrective actions taken against providers suspected of fraud or abuse to the State;
- clarify the information MCOs are required to report regarding providers who are terminated or otherwise leave the MCO network;
- identify and share best practices about payment retention policies and incentives to increase recoveries;
- improve coordination between MCOs and other State program integrity entities;

- ensure that MCOs provide complete, accurate, and timely encounter data; and
- monitor encounter data and impose penalties on States for submitting inaccurate or incomplete encounter data.

CMS did not concur with our recommendation to standardize reporting of referrals across all MCOs in the State.

California Claimed Millions of Dollars in Unallowable Federal Medicaid Reimbursement for Specialty Mental Health Services (A-09-15-02040), August 2018

California did not always comply with Federal and State requirements when claiming Federal reimbursement for specialty mental health services (SMHS) expenditures. Based on our sample results, we estimated that California claimed at least \$180.6 million in unallowable Federal reimbursement.

California claimed unallowable Federal reimbursement because its oversight was not effective in ensuring that its SMHS claims complied with Federal and State requirements. Although California issued guidance and provided training and technical support to its county-run managed care mental health plans (health plans), the plans continued to report to California unallowable expenditures as allowable expenditures. In addition, although California's triennial reviews were effective in identifying unallowable expenditures, California did not ensure that adequate corrective action was taken. We found repeat deficiencies at some health plans.

California agreed with our recommendation that it strengthen its oversight of the health plans to ensure that SMHS claims comply with Federal and State requirements. California disagreed with our recommendation that it refund to the Federal Government \$180.6 million for unallowable Federal reimbursement claimed for SMHS expenditures.

California Created a Medicaid Program Vulnerability by Reporting Placeholders That Did Not Represent Actual Expenditures Supported by Documentation (A-09-15-02027), August 2018

California reported SMHS placeholders totaling \$47.5 million for FY 2013 that did not represent actual expenditures supported by documentation. California did not have policies and procedures to ensure that supporting documentation for the placeholders was: (1) available at the time the Form CMS-64 (the CMS-64) was filed; and (2) retained. California's reporting of placeholders created a program vulnerability: California could have withdrawn funds related to the unsupported placeholders that CMS had not acted to defer before the 60-day deadline as required by Federal regulations or to disallow. According to its placeholder record, California reported for FY 2013 additional placeholders totaling \$1.2 billion for other types of Medicaid expenditures.

California agreed with our recommendations that it:

- report adjustments on the CMS-64 to reduce SMHS placeholder amounts by the \$47.5 million that did not represent actual expenditures supported by documentation;

- work with CMS to resolve the \$1.2 billion of additional Medicaid placeholders reported for FY 2013 and any placeholders reported for prior and later FYs and determine whether adjustments should be made;
- develop and implement policies and procedures to ensure that supporting documentation for reported placeholders is available at the time the CMS-64 is filed and that the supporting documentation is retained; and
- report on the CMS-64 only actual expenditures that are supported by documentation.

Alaska Received Millions in Unallowable Bonus Payments (A-04-17-08059), August 2018

Under the Children’s Health Insurance Program Reauthorization Act of 2009, Congress appropriated \$3.2 billion for qualifying States to receive bonus payments to offset the costs of increased enrollment of children in Medicaid. Some of the bonus payments that Alaska received for the audit period were not allowable in accordance with Federal requirements. While most of the data used in Alaska’s bonus payment calculations were in accordance with Federal requirements, Alaska overstated its FYs 2009 through 2013 current enrollment in its bonus requests to CMS because it included individuals who did not qualify because of their basis-of-eligibility category. As a result of the overstated current enrollment numbers, CMS overpaid Alaska almost \$8.9 million in bonus payments.

Alaska did not concur with our recommendation that it refund almost \$8.9 million to the Federal Government.

Quality of Care, Safety, and Access

Opioids in Ohio Medicaid: Review of Extreme Use and Overprescribing (OEI-05-18-00010), July 2018

We found that more than 700 beneficiaries are at serious risk of prescription opioid misuse or overdose and that nearly 50 prescribers stood out by ordering opioids for more of these beneficiaries than other prescribers. Our results underscore the tenacity of the opioid crisis and the importance of Ohio’s ongoing commitment to addressing it. We encourage Ohio to continue its ongoing efforts to explore new strategies to address its opioid crisis and look for ways to improve its existing strategies.

Minnesota Did Not Comply with Federal Waiver and State Requirements for All 20 Adult Day Care Centers Reviewed (A-05-17-00009), May 2018

Illinois Did Not Comply with Federal Waiver and State Requirements at 18 of 20 Adult Day Service Centers Reviewed (A-05-17-00028), July 2018

Mississippi Did Not Comply with Federal Waiver and State Requirements at All 20 Adult Day Care Facilities Reviewed (A-04-17-00116), August 2018

Minnesota, Illinois, and Mississippi did not comply with Federal waiver and State requirements in overseeing providers that serve vulnerable adults receiving adult day care services. In Minnesota,

we found 200 instances of noncompliance with health and safety and administrative requirements at all 20 of the centers we reviewed. In Illinois, we found 105 instances of noncompliance at 18 of the 20 centers we reviewed. In Mississippi, we found 564 instances of noncompliance at all 20 of the centers we reviewed.

Minnesota said that the instances of noncompliance occurred because low staffing levels did not allow State licensors to make relicensing visits every 2 years. Additionally, Minnesota and the centers indicated that there was a need to develop templates for administrative records that the State requires.

Illinois said that most instances of noncompliance occurred because center personnel did not have sufficient training on State requirements. Although Illinois offers initial training to new centers, more State-led training is needed for established centers.

According to Mississippi, budget reductions and low auditor staffing levels limited its oversight and monitoring of provider facilities, staffing, and training, and the lack of State licensing requirements contributed to provider noncompliance.

Minnesota, Illinois, and Mississippi concurred with our recommendations that they: (1) ensure that the instances of noncompliance with health and safety and administrative requirements are corrected; and (2) improve their oversight of staffing, training, and administration.

Drug Pricing and Reimbursement

CMS Did Not Always Provide Accurate Medicaid Unit Rebate Offset Amounts to State Medicaid Agencies (A-07-17-06074), May 2018

CMS did not always provide accurate Medicaid unit rebate offset amounts (UROAs) to States from 2010 through 2014 in accordance with Federal guidance. (Under the Medicaid drug rebate program, drug manufacturers enter into rebate agreements with the Federal Government and pay rebates to States. Amounts collected by the States that are attributable to increased rebates mandated by recent legislation—UROAs—are applied against the amounts that the Federal Government pays to the States.)

CMS did not update the quarterly UROA information that it sent to the States to include changes to the UROAs when covered drugs' best prices changed but the unit rebate amounts stayed the same. The States would have used these incorrect UROA amounts to calculate rebates, which would have resulted in incorrect rebate amounts being claimed.

CMS concurred with our recommendation that it conduct periodic matches that would compare the UROA information sent to States to the Medicaid drug rebate system to ensure that CMS is sending accurate rebate information.

Legal and Investigative Activities Related to the Medicare and Medicaid Programs

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

Specific case types include fraud schemes related to:

- controlled and noncontrolled prescription drugs,
- home health agencies and personal care services,
- ambulance transportation,
- DME, 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 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 in other HHS programs, including ACF, IHS, Health Resources and Services Administration (HRSA), and ACL. OIG investigates potential misuse of grants and contract funds awarded by CDC, NIH, the Substance Abuse and Mental Health Services Administration (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 305 criminal and 449 civil actions against individuals or entities that engaged in offenses related to healthcare. We also reported over \$1.4 billion in investigative receivables due to HHS and more than \$284.5 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 recently completed actions and settlements are organized by subject area.

Prescription Drugs

The following case example involves prescription drugs:

- Alabama—Dr. Rasan Mohammad Tarabein was convicted of charges resulting from his pain management clinic. Tarabein operated the Eastern Shore Neurology and Pain Center in Daphne, Alabama, where he offered services relating to neurology and pain management, such as spinal injections. Tarabein admitted that, from around 2004 to May 2017, he ran an insurance scam in which he induced patients to visit his clinic so he could bill for medically unnecessary tests and procedures. The purpose of Tarabein’s admitted scheme was to maximize personal financial gain by fraudulently seeking payments from healthcare benefit programs including Medicare and Medicaid. Specifically, Tarabein admitted to violating traditional standards of medical care in a number of ways, including by administering unnecessary injections and attempting to inject patients in places where they were not experiencing pain; telling patients that they had to receive spinal procedures and diagnostic testing in order to receive prescriptions for controlled substances; prescribing controlled substances without a legitimate medical purpose; and failing to monitor his patients’ vital signs during and after procedures, putting them at risk for complications. Tarabein pleaded guilty to healthcare fraud and unlawful distribution of a controlled substance, and was sentenced to 5 years in prison and ordered to pay \$15 million in restitution.

Pharmaceutical Companies

The following case example involves a pharmaceutical company:

- New York—Pfizer Inc. (Pfizer) entered into a civil settlement to resolve its FCA liability associated with donations it made to a 501(c)(3) foundation, which operated funds that pay the copayments of certain patients, including Medicare patients. Specifically, Pfizer resolved allegations that, from 2012 through 2016, it used the foundation as a conduit to pay the copayments of Medicare patients taking Sutent, Inlyta, and Tikosyn, in violation of the Anti-Kickback Statute. Pfizer agreed to pay \$23.85 million and entered into a 5-year CIA with provisions relating to arrangements and interactions between Pfizer and any third-party patient assistance program to which Pfizer donates. The CIA also requires Pfizer to implement controls and monitoring designed to promote true independence from any patient assistance program to which it donates.

Home Health

The following case example involves home health:

- Virginia—Hope In-Home Care, LLC (Hope), a provider of Medicaid in-home healthcare services, entered into a settlement agreement to resolve allegations that it submitted false claims to the Virginia Medicaid Program. The agreement resolves allegations that, from January 1, 2011, to September 30, 2013, Hope submitted claims to Medicaid that were false or fraudulent for the following reasons: 1) Hope employed and submitted claims for uncertified personal care aides who were ineligible to provide services; 2) Hope falsified documents and statements in order to qualify ineligible beneficiaries for services; 3) Hope made false statements in prior authorization requests in order to obtain approval and reimbursement for non-reimbursable respite services; 4) Hope engaged in phantom billing by billing for services that were not performed; and 5) Hope hired family members of Medicaid beneficiaries as personal care aides and submitted ineligible claims for compensation for care provided by those family members. Hope agreed to pay \$3.3 million to resolve its FCA liability.

Durable Medical Equipment

The following case example involves DME:

- Tennessee—Six co-conspirators connected with Jaspan Medical Systems (Jaspan), a California based DME supplier, were convicted of charges resulting from their involvement in a scheme to defraud Medicare, Medicaid and Tricare. The defendants—Jaspan manager Bryan Mitchell Bailey and sales staff Sandra and Calvin Bailey, Cindy Mallard, and Brenda and Dennis Sensing—were sentenced to a combined 20 years and 9 months in prison, and ordered to pay \$2.1 million in restitution. The investigation found that the defendants marketed power wheelchairs to patients and represented them as paid fully by Medicare, and at no cost to the patients. An extensive network of illegally paid recruiters was used to find eligible patients. After finding the patients, the defendants falsified documents to make it appear that the patients qualified for the equipment. Bailey and his co-defendants also enlisted a local physician and nurse practitioner to order the equipment without the required physical examinations to determine if the equipment was medically necessary. Illegal kickbacks were paid to the medical providers to facilitate this scheme. Many patients testified that they never used the power wheelchairs, and that the power wheelchairs were too large to be used in their homes. Most of the patients could walk, drive vehicles, and care for themselves without the need for a power wheelchair.

Laboratories

The following case example involves a laboratory:

- Kentucky—Compliance Advantage, LLC (CAL) entered into a settlement agreement to resolve allegations that CAL fraudulently billed Medicare and Medicaid for specimen validity testing

(SVT) conducted on urine specimens and knowingly failed to return the overpayment amount after being notified that SVT was a non-covered service. Specifically, SVT is a control process used to analyze a urine specimen to ensure that it has not been diluted or adulterated. It was alleged, and CAL specifically admitted, that CAL submitted claims for SVT with dates of service from January 14, 2013, through November 2, 2016, using CPT Codes 81003, 32570, 83986, and 84311. In March 2016, CAL was notified that SVT is a non-covered service and that it had been wrongfully paid for claims for SVT services (including notice of the amount of the overpayments). However, despite knowing of the existence and amount of overpayments for SVT, and knowing of its statutory obligation to return such overpayments, CAL failed to return the overpayments to Medicare and Medicaid. CAL agreed to the entry of a judgment of \$2.8 million against it for violating the reverse false claims provision of the FCA.

Transportation

The following case example involves transportation:

- Florida—Liberty Ambulance Service, Inc. (Liberty) entered into an FCA settlement agreement to resolve allegations that it submitted false claims to Medicare for transportation services. Specifically, the settlement agreement resolves allegations that, from June 29, 2005, to January 5, 2016, Liberty billed for: (1) Non-Emergency Advanced Life Support (ALS) services when only the less expensive Non-Emergency Basic Life Support (BLS) services were medically reasonable and necessary; (2) emergency services for hospital-to-hospital transports and scheduled transports when only the less expensive Non-Emergency services were medically reasonable and necessary; (3) Non-Emergency BLS or ALS services for ambulance transports that were not medically necessary because transportation by other means was not contraindicated; and (4) emergency transports to residences when only the less expensive Non-Emergency services were medically reasonable and necessary. Liberty agreed to pay \$1.2 million and entered into a 5-year CIA.

Nursing Homes

The following case example involves a nursing home:

- Tennessee—Signature Healthcare, LLC (Signature), a company that operates approximately 115 SNFs, entered into an FCA settlement to resolve allegations associated with its submission of false claims to Medicare for unnecessary rehabilitation therapy. Specifically, the settlement agreement resolves allegations that, from January 1, 2011, through September 30, 2015, Signature billed the highest reimbursement level (Ultra High Resource Utilization Group) for patients for periods exceeding 30 days. Signature's corporate policies and practices allegedly encouraged the provision of unnecessary therapy untethered to the individual clinical needs of patients. Additionally, the settlement agreement resolves allegations that, from January 1, 2011, and June 1, 2013, Signature improperly submitted Pre-admission Evaluation Certifications that were photocopied or had forged physician signatures to illegally obtain reimbursement from Tennessee's Medicaid program. Signature agreed to pay \$30 million to resolve its potential liability and entered into a company-wide 5-year CIA. The CIA requires a Rehab Review and a

Therapy Systems Assessment.

Mental Health

The following case examples involves mental health:

- North Carolina—Shephard Lee Spruill II, president of Carolina Support Services, and his co-defendants engaged in a multistate healthcare fraud conspiracy. Others involved in the conspiracy were behavioral health provider Terry Lamont Speller, his biller, Donnie Lee Phillips, II, and another Medicaid provider named Reginald Saunders. According to court documents, from July 2013 through June 2014, Spruill, Speller, and Phillips billed Medicaid for various outpatient health services that were not performed. To perpetrate the scheme, Spruill supplied hundreds of patient names and identifiers to Speller, who in turn had Phillips bill the North Carolina Medicaid Program for millions of dollars in fictitious mental health services. Spruill, Speller, and Phillips split the fraud proceeds, with Spruill receiving his share in the form of fictitious, no-document loan repayments. Spruill appeared before a federal grand jury and lied about his involvement with Speller, falsely claiming that he had no business relationship with Speller. Speller, Phillips, and Saunders were previously sentenced to a combined 31 years and 11 months in prison. Spruill pleaded guilty to conspiracy to commit healthcare fraud and perjury and was sentenced to 8 years in prison and ordered to pay \$5.9 million in restitution, joint and several with his co-defendants.
- South Carolina—Early Autism Project, Inc. (EAP), South Carolina’s largest provider of behavioral therapy for children with autism, entered into an FCA settlement agreement resolving allegations that: (1) between January 1, 2009, and December 31, 2016, EAP submitted claims payable by the South Carolina Medicaid Waiver program for Early Intensive Behavioral Intervention therapy services by Consultants and Lead Therapists that either misrepresented the services provided or where services were not provided at all; and (2) between April 1, 2012, and July 9, 2016, EAP submitted claims to the Defense Health Agency for one-on-one Applied Behavioral Analysis therapy services that either misrepresented the services provided or where services were not provided at all. EAP agreed to pay \$8.8 million, and ChanceLight, Inc., for itself and on behalf of EAP, its wholly-owned subsidiary, entered into a 5-year CIA.

Physicians

The following case example involves a physician:

- New York—Health Quest Systems, Inc., Health Quest Medical Practice, P.C. ("HQMP"), Health Quest Urgent Medical Care Practice, P.C., ("HQUC") (collectively "Health Quest"), and Putnam Health Center ("PHC") entered into a settlement agreement to resolve their FCA liability. From April 1, 2009, through June 23, 2015, Health Quest submitted claims for evaluation and management services but did not sufficiently document the services to support the level of service billed. As a result, the services were billed two levels higher than supported by the medical record. From April 1, 2011, through August 2014, Health Quest submitted claims for home health services that lacked sufficient medical records to support the claim, including

documentation of a face-to-face encounter with a physician. From March 1, 2014, through December 31, 2014, Health Quest subsidiary hospital, PHC, submitted allegedly false claims for inpatient and outpatient services referred to PHC by two orthopedic physicians, in alleged violation of the Physician Self-Referral Law. The two physicians had a direct financial relationship with PHC for providing administrative services and received compensation from PHC. The United States alleged their compensation exceeded the fair market value for the services, and thereby violated the Physician Self-Referral Law, which prohibits a hospital from billing Medicare for certain services referred by physicians with whom the hospital has an improper compensation arrangement. The United States further alleged that one purpose of the excessive compensation was to induce the above referrals to PHC, in violation of the Anti-Kickback Statute. Health Quest and PHC agreed to pay \$15.6 million and enter into a 5-year CIA.

Hospices

The following case example involves hospice care:

- Tennessee—Caris Healthcare LLC and Caris Healthcare, L.P. (collectively, “Caris”), a for-profit hospice chain, entered into a settlement agreement to resolve allegations that, from April 1, 2010, through December 31, 2013, Caris submitted false claims and improperly retained payments from Medicare for services provided to patients who were ineligible for hospice benefits because they were not terminally ill. Caris agreed to pay \$8.5 million to resolve its alleged liability.

Hospitals

The following case example involves a hospital:

- California—Prime Healthcare Services, Inc., Prime Healthcare Foundation, Inc., 14 hospitals owned and operated by the Prime entities, and Prime’s owner, Prem Reddy, M.D. (collectively, Prime and Dr. Reddy) entered into a settlement agreement to resolve allegations that Prime and Dr. Reddy submitted false claims to Medicare for medically unnecessary inpatient hospital stays from January 1, 2006, through September 20, 2013, and for upcoding inpatient diagnoses from January 1, 2006, through December 31, 2014. Prime and Dr. Reddy collectively agreed to pay \$65 million to resolve their FCA liability. Prime and Dr. Reddy also entered into a 5-year CIA, which includes a Claims Review and Inpatient Medical Necessity Review.

Clinics

The following case example involves a clinic:

- Iowa and Florida—Healogics, Inc. (Healogics) entered into two FCA settlement agreements to resolve allegations that: (1) from January 1, 2010, through December 31, 2015, Healogics submitted claims to Medicare for hyperbaric oxygen therapy that was not medically reasonable and/or necessary; and (2) from January 1, 2012, through June 30, 2017, Healogics, on behalf of

its Healogics Specialty Physicians Program, submitted claims to Medicare, Medicaid, and Tricare for evaluation and management services that improperly included modifier-25, which indicated that a significant, separately identifiable evaluation and management service was performed when, in fact, it was not. Healogics agreed to pay more than \$17.8 million to resolve its liability and entered into a 5-year CIA. The CIA addresses Healogics' distinct lines of business, including provisions related to both its employees and its independent contractors.

Healthcare Fraud Prevention and Enforcement

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>.

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, 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, 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.

In June 2018, OIG and our Federal and State law enforcement partners led the largest healthcare fraud takedown in history. More than 600 defendants in 58 Federal districts were charged with participating in fraud schemes involving about \$2 billion in false billings to Medicare and Medicaid. Since the last takedown, OIG also issued exclusion notices to 587 doctors, nurses, and other providers based on conduct related to opioid diversion and abuse. For more information on this takedown, visit our Strike Force website at <https://oig.hhs.gov/newsroom/media-materials/2018/takedown/>. During this semiannual reporting period, Strike Force efforts resulted in the filing of charges against 186 individuals or entities, 68 criminal actions, and more than \$217.2 million in investigative receivables.

The following case examples involve Strike Force cases:

- Florida—Nicholas Borgesano owned and operated numerous pharmacies and shell companies that he and his co-conspirators used to execute a fraud scheme involving prescription

compounded medications. Borgesano acquired and controlled multiple pharmacies, including A to Z Pharmacy. He admitted using these pharmacies to cause the submission of false claims for prescription compounded medications, chiefly pain creams and scar creams, to private insurance companies, Medicare, and Tricare. Borgesano admitted that he manipulated billing codes in the reimbursement claims and submitted claims for pharmaceutical ingredients they did not have. He also paid kickbacks and bribes in exchange for prescriptions and patient identifying information used to further the scheme, including to a physician in exchange for the physician signing prescriptions for patients he never saw. Borgesano admitted using A to Z Pharmacy as the hub of his operation on behalf of all his pharmacies. He disbursed proceeds of the fraud scheme through a variety of methods, including by check and wire transfer to co-conspirators' shell companies and through the purchase of assets. Borgesano pleaded guilty to conspiracy to commit healthcare fraud and conspiracy to engage in monetary transactions in property derived from specified unlawful activity, and was sentenced to 15 years in prison and ordered to pay \$54.5 million, joint and several.

- New York—Two co-conspirators connected with Prime Care on the Bay LLC and Bensonhurst Mega Medical Care P.C. in Brooklyn, New York, were convicted of charges resulting from their involvement in a scheme to defraud Medicare and Medicaid. The defendants—Prime Care and Bensonhurst manager Tatyana Schevchuk, and shell company owner Anna Dougherty—were sentenced to a combined 1 year and 6 months in prison, and ordered to pay \$17.6 million, joint and several. The investigation found that the defendants paid cash kickbacks to patients to induce them to attend the two clinics. The defendants then submitted fraudulent claims to Medicare and Medicaid for services that were induced by prohibited kickback payments to patients or that were unlawfully rendered by unlicensed staff. The defendants wrote checks from the clinics' bank accounts to third-party companies, which purported to provide services to the clinics, but which in fact were not providing services, and the payments were instead used to generate the cash needed to pay the illegal kickbacks to patients. Ten defendants involved in the scheme were previously sentenced to a combined 13 years, 6 months, and 2 days in prison. Schevchuk, Dougherty, and their 10 co-defendants were ordered to pay a total of \$48.5 million in restitution, joint and several.

Other Criminal and Civil Enforcement Activities

Special Assistant U.S. Attorney Program

During this reporting period, DOJ and OIG continued their participation in a program in which OIG attorneys, some of whom are special agents, serve as special assistant U.S. attorneys. These OIG attorneys are detailed full time to the fraud section of DOJ's Criminal Division for temporary assignments, including assignments to the Health Care Fraud Strike Force. Other attorneys prosecute matters on a case-by-case basis. Both arrangements offer excellent litigation training for OIG attorneys and enhance collaboration between the departments in their efforts to fight fraud. Under this program, OIG attorneys have successfully litigated important criminal cases relating to the fraudulent billing of medical equipment and supplies, infusion therapy, and physical therapy, as well as other types of Medicare and Medicaid fraud.

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/>.

The following is a case example involving a captured fugitive:

- One of OIG's Most Wanted Fugitives, Etienne Allonce, was captured during this reporting period. Etienne Allonce has been a fugitive for more than 10 years and was recently apprehended and taken into U.S. custody after being expelled from Haiti. He is being detained and will face charges stemming from his indictment. In December 2007, Allonce and his wife, Helene Michel, were indicted on charges of healthcare fraud. Allonce and Michel were owners of Medical Solutions Management, Inc. (MSM), a durable medical equipment (DME) company operating out of Hicksville, New York. Tri-State Surgical Supply (Tri-State) is a DME company that has a contract with numerous nursing homes in Long Island, Queens, and Brooklyn, to provide Medicare and Medicaid covered DME supplies to residents. According to the indictment, MSM employees allegedly posed as sub-contractors for Tri-State in order to gain access to several nursing homes. Once they entered the nursing homes under false pretenses, MSM employees allegedly accessed medical charts (containing private information protected by The Health Insurance Portability and Accountability Act of 1996 or HIPAA) for residents who required specialized wound care. MSM then allegedly billed Medicare Part B and/or Medicaid for wound care supplies that were never ordered or provided. It is also believed that MSM employees stole original documents containing HIPAA information from medical charts in facilities to "manufacture" fraudulent MSM charts in an effort to legitimize their medical billings. After Michel and Allonce were indicted on healthcare fraud charges for their participation in the scheme, Allonce fled the United States to avoid prosecution and was believed to be residing in Haiti. In April 2013, Michel was convicted on charges of healthcare fraud and wrongful disclosure of individually identifiable health information. She was sentenced to 12 years of incarceration and ordered to pay more than \$4.4 million 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 \$27 million as a direct result of cases originating from hotline complaints.

OIG Hotline Activity (04/01/18–09/30/18)

| | |
|--|--------|
| Contacts to 1-800-HHS-TIPS phone line, including callers seeking information | 60,390 |
| Total tips evaluated | 11,152 |
| Tips referred for action | 8,096 |
| Closed; no basis provided for further action | 4,148 |
| Closed; no HHS violation | 523 |

Sources of tips referred for action

| | |
|---------------|-------|
| Phone | 3,051 |
| OIG website | 3,618 |
| Letters/faxes | 1,200 |
| Other | 227 |

State Medicaid Fraud Control Units

OIG Oversight of State Medicaid Fraud Control Units

State MFCUs are key partners with OIG in the fight against fraud, waste, and abuse in State Medicaid programs. OIG has oversight responsibility for MFCUs and administers grants that provide Federal funding for their operations. The Federal Government reimburses 75 percent of the costs of operating all existing MFCUs, which are in 49 States and the District of Columbia. MFCUs investigate and prosecute Medicaid provider fraud and patient abuse and neglect in healthcare facilities or board and care facilities.

As part of training and technical assistance to the MFCUs, OIG issued a toolkit, *Statistical Sampling: A Toolkit for MFCUs*, in September 2018, which will assist MFCUs (and other law enforcement agencies) in effectively and correctly using statistical sampling to determine the overpayment amount in cases with a large number of claims (See [OEI-12-18-00160](#)).

OIG Onsite Reviews of MFCUs

In addition to an annual recertification review of each MFCU, OIG conducts reviews of a sample of MFCUs. OIG evaluates MFCU operations based on 12 performance standards and assesses compliance with laws, regulations, and OIG policy guidance. During the reporting period, OIG issued reports of onsite reviews of the following MFCUs:

- *Tennessee Medicaid Fraud Control Unit: 2017 Onsite Inspection* ([OEI-12-17-00230](#)), June 2018
- *New Hampshire Medicaid Fraud Control Unit: 2017 Onsite Review* ([OEI-09-17-00200](#)), September 2018
- *New York Medicaid Fraud Control Unit: 2017 Onsite Inspection* ([OEI-12-17-00340](#)), September 2018
- *New Jersey Medicaid Fraud Control Unit: 2017 Onsite Review* ([OEI-06-17-00520](#)), September 2018

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

- Texas—Mkrtich Yepremian and his co-defendants engaged in a \$13 million conspiracy to falsely bill Medicare and Medicaid for medically unnecessary diagnostic tests. According to court documents, from January 2006 through July 2015, Yepremian ran several false clinics in Houston and Conroe, Texas. He paid marketers to bring patients to the clinics for a battery of diagnostic tests and blood work, regardless of medical need. Yepremian paid the marketers approximately \$100 for each patient brought to his clinics; in turn, the marketers paid the patients approximately \$50 each. Yepremian employed a physician who approved the testing and allowed his physician number to be used in the Medicare billing process to support the tests. Yepremian pleaded guilty to conspiracy to commit healthcare fraud and kickbacks and was sentenced to 10 years in prison and ordered to pay \$9.0 million in restitution, joint and several. Seven defendants involved in the scheme were previously sentenced to a combined 7 years 4 months and 2 days in prison, and ordered to pay \$5.5 million in restitution, joint and several. One additional defendant is awaiting sentencing. This case was worked jointly with the Federal Bureau of Investigations and MFCU.

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 FY 2018, OIG received 41 requests for advisory opinions and issued 14 advisory opinions. OIG also rescinded one advisory opinion in FY 2018. On August 27, 2018, OIG issued a for Information (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.

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 1,247 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 1,124 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 case examples involve program exclusions:

- Michigan – Dr. Lawrence Gerard Nassar was excluded based on his convictions on multiple counts of criminal sexual conduct. From about July 1998 to about May 2015, Dr. Nassar sexually abused patients in his position as the lead doctor for the USA Women’s gymnastics team. It was his job to medically treat the gymnasts on the team, and during those treatment sessions, Dr. Nassar would sexually touch the victims. Nassar was sentenced to 40 to 175 years in prison based on his conviction in the 30th Judicial Circuit Court of Ingham County, Michigan, and 40 to 125 years in prison for his conviction in the 56th Judicial Circuit Court of Eaton County, Michigan. Dr. Nassar was also convicted in the United States District Court of Western Michigan of receipt and attempted receipt of child pornography, possession of child pornography and destruction and concealment of records and tangible objects. In addition, Dr. Nassar’s license to practice as an osteopath was revoked by the Michigan Department of Licensing and Regulatory Affairs. OIG excluded Nassar for a minimum period of 75 years; OIG had previously excluded Dr. Nassar in 2017 based on his suspension from the Michigan Department of Health and Human Services.
- California – Psychiatrist Samuel H. Albert engaged in a conspiracy to defraud the Office of Workers’ Compensation Program (OWCP). According to court documents, from about January 2008 to about March 2014, Dr. Albert engaged in a conspiracy to defraud the OWCP, which is a component of the Department of Labor, through the submission of millions of false claims. Dr. Albert and his co-conspirators would create templates and patient reports purportedly reflecting patients’ status, history, treatment, or progress that would be submitted

to OWCP randomly. These created records would then be used to bill OWCP for false claims for services that were never provided. Dr. Albert pleaded guilty to conspiracy to commit healthcare fraud and was sentenced to 10 months in prison and ordered to pay approximately \$2.3 million in restitution. OIG excluded Albert for a minimum period of 15 years.

Suspensions and Debarments

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

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

The following case examples involve debarment:

- Montana—Zachary Brooke Roberts and Martin Gasper Mazzara engaged in a scheme to steal funds from the Chippewa Creek Tribe. Roberts and Mazzara, through a backdated and inflated 15 percent fee agreement, were paid over \$3.5 million from the Chippewa Cree Tribe. Roberts and Mazzara then funneled money from Nevada back to Montana to Ideal Consulting. Ideal Consulting was a shell company used to distribute payments to tribal officials. This scheme was created to conceal from the tribal people the \$1.2 million in kickbacks to the tribal officials. These tribal officials were eventually sentenced for receiving bribes from Roberts and Mazzara. Roberts and Mazzara engaged in the scheme by inflating their invoices for “consulting services” from 10 percent to 15 percent, submitting those false invoices to the Chippewa Cree Tribe, and then funneling and concealing the 5 percent that went back to the shell company of Ideal Consulting. To perpetrate the scheme, Roberts and Mazzara generated false invoices from Encore Services, LLC, and they also accepted false invoices from Ideal Consulting. Roberts and Mazzara were convicted for conspiracy to commit wire fraud, and both were sentenced to 1 year and 8 months in prison and ordered to pay \$700,000 in restitution, joint and several. Roberts and Mazzara were debarred for 3 years on the basis of an OIG referral to HHS.
- Tennessee—Carolyn McCain-Davis was employed at Meharry Medical College (MMC) as a grants development specialist and was responsible for approving invoices and processing payment requests relating to MMC’s employees and vendors. MMC receives funding from HHS through NIH. McCain-Davis admitted that from about August 2009 to about May 2013, she devised and carried out a scheme to defraud the United States by submitting false invoices, as an agent for MMC, from companies that were not legitimate vendors, nor was a

service provided to MMC. The false invoices were often submitted under the names of companies set up by McCain-Davis, and she approved the submitted payment requests and directed payments to bank accounts under her control. McCain-Davis also processed reimbursement payments to herself for expenses that were never incurred and intercepted reimbursement payments to other employees, forged the signatures of the payees and deposited those checks into bank accounts under her control or under the control of a close relative. McCain-Davis pleaded guilty to embezzling funds from a Federal program while employed at MMC and was sentenced to 1 year and 1 day in prison and ordered to pay restitution of \$133,578. McCain-Davis was debarred for 3 years on the basis of an OIG referral to HHS.

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 \$30.5 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 example involves an affirmative litigation case 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 SNFs 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. OIG 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 example involves EMTALA:

- 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 that the on-call cardiologist come to the ED, nor did the on-call cardiologist go 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 had gone to Covenant’s ED. The receiving hospital placed a transvenous pacemaker on the patient, but he died shortly after. OIG alleged that Covenant’s on-call cardiologist was capable of providing a transvenous pacemaker.

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 \$25.8 million in HHS receivables.

The following case examples involve 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 software, agreed to pay \$155 million and entered into a CIA to resolve ECW’s alleged FCA 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, 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

Entities Generally Met Federal Select Agent Program Internal Inspection Requirements, but CDC Could Do More to Improve Effectiveness (OEI-04-15-00431), June 2018

We found that although most entities in our review conducted internal inspections as required, these inspections may not always be as thorough or well documented as they should be and that unclear inspection requirements and insufficient training challenge both the Division of Select Agents and Toxins' (DSAT) ability to oversee entities' internal inspections and entities' ability to conduct them. Entities' internal inspections are one critical safeguard to help protect public health and safety from select agent and toxin incidents, so it is important that CDC facilitate thorough, well documented entity inspections to ensure their effectiveness. CDC concurred with our recommendations to:

- clarify the internal inspection requirements;
- clarify the procedures for DSAT inspectors to assess entity compliance;
- for DSAT inspectors, develop and provide additional training; and
- for entities, develop and provide additional training and guidance.

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.

The National Institute of Health in Mozambique Did Not Always Manage and Expend the President's Emergency Plan for AIDS Relief Funds in Accordance With Award Requirements (A-04-16-04051), April 2018

The South African National Department of Health Did Not Always Manage and Expend the President's Emergency Plan for AIDS Relief Funds in Accordance With Award Requirements (A-04-17-01002), May 2018

Based on our sample results, we concluded that Mozambique and South Africa did not always manage and expend PEPFAR funds in accordance with award requirements.

Mozambique was unable to reconcile its accounting records to the \$8.5 million that it claimed on its Federal Financial Report (FFR) for the audit period. Mozambique claimed unsupported

personnel costs and classified transactions in the wrong budget category. Finally, Mozambique did not have a functioning accounting system and did not have a time and attendance system.

South Africa did not provide adequate supporting documentation, such as invoices or attendance rosters, or it paid unallowable value-added taxes with PEPFAR funds. Additionally, South Africa did not accurately identify expenses between cooperative agreements in its financial management reporting system, did not submit an accurate FFR, and filed one of its FFRs more than 5 months late. Furthermore, South Africa did not implement corrective actions for one of the nine recommendations from our prior audit.

Mozambique partially concurred with our recommendation that it refund to CDC \$431,458 of unallowable expenditures. It did not specifically concur with our recommendations that it: (1) implement an accounting system that allows it to accurately account for Federal funds; (2) work with CDC to determine the allowability of the \$1.3 million in personnel costs expended during the audit period; and (3) address other policy and procedural recommendations. Mozambique did describe actions it had taken or planned to take to address three recommendations.

South Africa did not specifically concur with our recommendations that it: (1) refund to CDC \$12,374 for transactions that were not adequately documented; (2) work with CDC to obtain \$343,930 of value-added taxes reimbursement; and (3) address recommendations from our prior audit, as well as procedural and policy issues in this audit.

Food and Drug Administration

FDA Should Further Integrate Its Review of Cybersecurity into the Premarket Review Process for Medical Devices (OEI-09-16-00220), September 2018

We found that FDA could take steps to more fully integrate its review of medical devices' cybersecurity risks and controls before clearing or approving devices for marketing in the United States. Researchers have shown that FDA-cleared or FDA-approved medical devices that use wireless, Internet, and network connectivity may be susceptible to cybersecurity threats, such as ransomware and unauthorized remote access, if they lack adequate security controls. FDA concurred with our recommendations, including to:

- promote the use of presubmission meetings to address cybersecurity-related questions;
- include cybersecurity documentation as a criterion in FDA's Refuse-To-Accept checklists; and
- include cybersecurity as an element in the Smart template, which FDA uses to guide its reviews of submissions.

Indian Health Service

The Indian Health Service's Controls Were Not Effective in Ensuring That Its Travel Card Program Complied with Federal Requirements and Its Own Policy (A-07-16-05091), April 2018

IHS's travel card program, under which IHS employees are to use Government charge cards for nearly all payments of expenses related to official Government travel, did not always comply with Federal requirements and IHS's own policy. We identified 16 transactions (out of the 151 sampled transactions) that did not comply with Federal requirements and IHS policy regarding proper travel card use. These errors occurred because, although IHS had controls in place to educate cardholders on the requirements for the use of the travel card, the controls did not always prevent misuse of the travel card. Additionally, whereas IHS had controls in place to monitor cardholders, those controls did not always identify noncompliance.

IHS concurred with our recommendations to: 1) re-emphasize the requirements for the use of the travel card to ensure that all travel cardholders are aware of the requirements; and 2) ensure that travel card usage is adequately monitored for compliance with the travel card requirements.

The Indian Health Service's Controls Were Not Effective in Ensuring That Its Purchase Card Program Complied with Federal Requirements and Its Own Policy (A-07-16-05090), July 2018

IHS's purchase card program, under which IHS employees are to use Government purchase cards for payments of expenses related to official Government needs, did not always comply with Federal requirements and IHS's own policy. We identified 25 transactions (out of the 136 sampled transactions) that were in error because they did not comply with Federal requirements and IHS's policy either for proper purchase card use or for supporting documentation. These errors occurred because IHS's controls for the administration of its purchase card program—controls that included monitoring as well as educating cardholders—were not adequate to ensure that transactions complied with Federal requirements and IHS's policy.

IHS concurred with our recommendations that it strengthen controls to ensure that purchase cardholders comply with Federal requirements and IHS's own policy by adequately monitoring purchase card usage and ensuring that all IHS purchase cardholders complete the required training on the use of the purchase card.

The Passamaquoddy Tribe's Pleasant Point Health Center Did Not Always Meet Federal and Tribal Health and Safety Requirements (A-01-17-01500), July 2018

In certain cases, the Federal Government permits Tribes to administer their own healthcare programs through Federally Qualified Health Centers, which receive Federal funding but limited Federal oversight in recognition of the independent Nation status of the Tribes.

The Passamaquoddy Tribe at Pleasant Point did not always meet Federal and Tribal health and safety requirements for the quality of care at the Passamaquoddy Tribe's Pleasant Point Health Center (PPHC). PPHC did not always have a physician who provided medical direction for the health center, clear lines of authority and responsibility between medical and administrative decision-making, medical policies and procedures (including pain-management treatment prioritization for opioid prescription and compliance monitoring), and other policies and procedures needed to comply with requirements.

The Passamaquoddy Tribe at Pleasant Point concurred with our recommendations, including that it: (1) ensures PPHC is under the medical direction of a physician; (2) establishes clear lines of authority and responsibility between medical and administrative decision-making; and (3) develops and implements medical policies.

The Indian Health Service Did Not Always Resolve Audit Recommendations in Accordance With Federal Requirements (A-07-17-03227), September 2018

IHS did not always resolve OIG audit recommendations in a timely manner during FYs 2015 and 2016. Specifically, IHS resolved 138 of the 651 recommendations that were outstanding during FYs 2015 and 2016. However, it did not resolve 123 of the 138 recommendations (89.1 percent) within the required 6-month resolution period. In addition, as of September 30, 2016, IHS had not resolved 513 audit recommendations that were past due for resolution.

IHS concurred with our recommendations that it follow, and where necessary update, its policies and procedures related to the non-Federal and Federal audit resolution processes; promptly resolve the 513 outstanding audit recommendations that were past due as of September 30, 2016; follow the reconciliation process that it implemented at the end of our audit period; and give higher priority to audit resolution in accordance with Federal requirements. IHS also described corrective actions that it had taken or planned to take.

National Institutes of Health

The University of Alabama at Birmingham Overstated Chilled Water Costs in Its Facilities and Administrative Cost Proposal (A-04-14-00095), May 2018

In its FY 2010 Facilities and Administrative (F&A) cost proposal, the University of Alabama at Birmingham (UAB) included \$8.6 million in chilled water costs that were not in accordance with Federal requirements. As a result, UAB's negotiated F&A rate was inflated by 1 percent per year for FYs 2012 through 2015, and it potentially received as much as \$5.9 million in overpayments from the Federal Government.

We recommended that UAB work with the Department's Cost Allocation Services to determine the portion of the \$5.9 million that was unallowable under Federal requirements, refund the unallowable portion (including any interest) to the Federal Government, and ensure that appropriate officials review future proposals for compliance with Federal requirements before submission. UAB acknowledged that it overstated chilled water costs but disagreed with the amount.

The National Institutes of Health, Division of Financial Advisory Services Did Not Always Establish Final Indirect Cost Rates in Accordance With Federal Requirements (A-04-17-04059), May 2018

NIH's Division of Financial Advisory Services (DFAS) did not always establish final indirect cost rates for applicable organizations in accordance with Federal requirements during our audit period. DFAS had procedures to assess the allowability, allocability, and reasonableness of proposed indirect costs and identified unallowable costs that were excluded in its negotiations of rate agreements. However, DFAS did not always obtain adequate data demonstrating that: (1) organizations' proposed indirect costs were allowable, allocable, and reasonable in accordance with the Federal Acquisition Regulation (FAR); and (2) proposed direct cost bases were appropriate for the fair distribution of indirect costs to cost objectives; DFAS may not have established indirect cost rates as promptly as practical after receiving proposals; and DFAS used indirect cost rate ceilings in situations not covered by the FAR.

DFAS did not always comply with Federal requirements for establishing indirect cost rates because neither NIH nor HHS had adequately defined the extent of DFAS's roles and responsibilities as a cognizant Federal agency for indirect cost rates.

NIH did not concur with our recommendations that DFAS clarify its roles and responsibilities as a cognizant Federal agency for indirect cost rates and update its policies and procedures to comply with Federal requirements.

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, 10 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.

After being excluded for nonpayment of their HEAL debts, 2,745 individuals chose to enter into settlement agreements or completely repay their debts. That figure includes 17 individuals who entered into such settlement agreements or completely repaid their debts. More than \$218 million

is being repaid through settlement agreements or through complete repayment. Of that amount, more than \$2.5 million is attributable to this semiannual reporting period.

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

- Georgia—Tammie Small, chiropractor: \$165,780
- Texas—Lemuel L. Clanton, medical doctor: \$86,565

Human Services Agencies Reviews and Enforcement Activities

Administration for Children and Families

Heartland Human Care Services, Inc., Generally Met Safety Standards, But Claimed Unallowable Rental Costs (A-05-16-00038), September 2018

Heartland Human Care Services, Inc. (Heartland), generally met applicable safety standards for the care and release of UAC in its custody. Heartland met State licensure requirements and requirements for inspections, performed adequate oversight, and followed guidance when reviewing background investigations for employees who care for the children. However, we observed one classroom where the staff-to-child supervision ratio was significantly less than required, and we observed one classroom and hallway that lacked required monitoring equipment. We also found that some Heartland case files were missing documentation assuring that required records were provided upon the child's release to a family member or other sponsor.

Heartland claimed allowable expenditures for 119 of 120 transactions reviewed in our stratified random sample. For one transaction, it did not comply with Federal regulations related to less-than-arm's-length lease agreements. We also identified rental costs on two additional less-than-arm's-length leases that exceeded the amount allowable for such leases. The three leases resulted in unallowable rental costs of \$665,333 and associated indirect costs of \$103,127.

Heartland agreed with our recommendations that it adhere to classroom staffing-to-child ratios in accordance with State regulations and maintain children's case file documentation in accordance with ORR policy. Heartland did not agree with our recommendation that it refund \$768,460 to ORR for unallowable costs incurred under the less-than-arm's-length lease agreements and limit future rental costs under less-than-arm's-length lease agreements to the amount that would be allowed under Federal regulations.

Florence Crittenton Services of Orange County, Inc., Did Not Always Meet Applicable Safety Standards Related to Unaccompanied Alien Children (A-09-16-01005), June 2018

Florence Crittenton Services of Orange County, Inc. (Crittenton), did not always follow ORR policies on background checks or adequate documentation. We reviewed a sample of 100 children in Crittenton's care whom it had discharged during FYs 2014 and 2015. Crittenton released an

estimated 2 percent of UAC in its care to sponsors without conducting all required background checks and so could not be assured that sponsors were properly vetted. We also estimated that Crittenton did not properly document the care and release of approximately 9 percent of children released to sponsors in FYs 2014 and 2015. Without adequate documentation in the case files, ORR could not be assured that Crittenton had followed ORR policies. In addition, without accurate information on the number of released children, ORR did not have assurance that Crittenton ensured program integrity and that every child Crittenton released was accounted for.

Crittenton did not indicate concurrence or nonconcurrence with our recommendations that it:

- ensure that all required background checks are conducted and documented;
- provide periodic training to staff on maintaining documentation related to public records checks;
- increase oversight of its quality review for UAC case files to ensure that all required documentation is maintained in the files;
- develop policies and procedures for obtaining necessary documentation in the case files for children transferred from another shelter care provider; and
- develop a process to document the information used to prepare its quarterly performance reports and verify the information's accuracy.

Some New York City Childcare Providers Did Not Always Comply with Health and Safety Requirements (A-02-16-02003), June 2018

New York State did not ensure that selected New York City providers that received funding from the CCDF complied with applicable State and local requirements related to the health and safety of children. We found potentially hazardous physical conditions at all 11 locations operated by the 3 providers that we reviewed. Moreover, we found that the providers did not comply with requirements to obtain background checks on employees. The instances of noncompliance occurred because New York State had no written procedures regarding monitoring of legally exempt providers' compliance with physical condition and background check requirements. In addition, New York State's requirement that providers access a child abuse and maltreatment system to perform one required background check was inconsistent with current State law.

New York State concurred with our recommendations that it ensure that the health and safety issues noted in our report are corrected, develop written procedures to ensure that legally exempt providers' compliance with physical condition and background check requirements is regularly monitored, and seek a change to State law to allow providers access to the child abuse and maltreatment system or take other steps to ensure that required background checks are completed.

Illinois Implemented Most New Criminal Background Check Requirements for Childcare Providers, but Challenges Remain for Unimplemented Requirements (A-05-17-00047), June 2018

Georgia Implemented Most New Criminal Background Check Requirements for Childcare Providers, but Challenges Remain for Unimplemented Requirements (A-04-18-03578), July 2018

New Hampshire Implemented Most New Criminal Background Check Requirements for Childcare Providers, but Challenges Remain for Unimplemented Requirements (A-01-18-02500), July 2018
Colorado Implemented Many New Criminal Background Check Requirements for Childcare Providers, but Challenges Remain for Unimplemented Requirements (A-07-17-06076), September 2018
Nevada Implemented Some New Criminal Background Check Requirements for Childcare Providers, but Challenges Remain for Unimplemented Requirements (A-09-17-01003), September 2018

Illinois, Georgia, New Hampshire, Colorado, and Nevada implemented most of the new criminal background check requirements established under the Child Care and Development Block Grant Act. However, certain criminal background check requirements for childcare providers remained unimplemented in each State as of March 1, 2018. The States had until September 30, 2018, to implement those requirements, but significant challenges will delay full implementation until 2019 or 2020.

Illinois' challenges include unavailable finances and staff to process the background checks, data system limitations, and required changes to State laws or policies and procedures.

Georgia said that there does not appear to be a solution for resolving the issue of complying with the inter-State criminal background check requirement because other States do not have an incentive to respond to an applicant's request or Georgia's request for background check information. Another significant challenge is the cost of providing supervision of provisional childcare staff while background check results are pending.

New Hampshire's and Colorado's challenges include unavailable finances and staff to process the background checks, data system limitations, and required changes to State laws or policies and procedures. Nevada's challenges include decentralization of the background check processes. (Background checks are conducted by different entities, depending on the provider type.)

The Administration for Children and Families Did Not Always Resolve Audit Recommendations in Accordance With Federal Requirements (A-07-17-03225), July 2018

ACF did not always resolve audit recommendations in a timely manner during FYs 2015 and 2016. During FYs 2015 and 2016, it did not resolve 1,392 of the 1,570 recommendations (88.7 percent) within the required 6-month resolution period. In addition, as of September 30, 2016, ACF had not resolved 678 audit recommendations that were past due for resolution. The dollar amounts associated with these past-due recommendations totaled \$36.5 million. Without resolving all audit recommendations in a timely manner, ACF runs the risk of noncompliance with Federal requirements and mismanagement of Federal funds.

ACF concurred with our recommendations that it:

- follow its policies and procedures to ensure that management decisions are issued within the required 6-month resolution period;
- resolve the 678 outstanding audit recommendations that were past due as of September 30, 2016;

- follow its recently implemented procedures by reconciling each month the OIG stewardship reports with ACF's internal audit tracking and monitoring system and following up on any differences noted; and
- give higher priority to audit resolution so that the audit resolution process is conducted in accordance with Federal requirements.

Safety of Children in Foster Care

Ohio Did Not Always Comply with Requirements Related to the Case Management of Children in Foster Care (A-05-16-00022), May 2018

Ohio did not always comply with State requirements for maintaining documentation that Title IV-E-eligible children residing in group homes received required case management services and that case workers were qualified to provide those services. As a result, Ohio did not always have assurance that caseworkers provided all the required case management services appropriate for each child; were qualified to provide those services; and received the required criminal records checks. Without adequate documentation in the case files and caseworker personnel files, Ohio could not be assured that children received necessary case management services from qualified caseworkers.

Ohio concurred with our recommendations that it:

- ensure that the appropriate internal controls are in place for maintaining the required documentation in the case files to substantiate that children in foster care are receiving the necessary services;
- improve controls to ensure that critical incidents involving children in foster care residing in group homes are reported timely to the county agencies;
- ensure that the county agencies maintain the required documentation in the caseworkers' personnel files; and
- implement controls to ensure that the appropriate criminal record checks are completed for the caseworkers upon hire and that the minimum training requirements are met and documented.

Treatment Planning and Medication Monitoring Were Lacking for Children in Foster Care Receiving Psychotropic Medication (OEI-07-15-00380), September 2018

None of the five States we reviewed fully complied with their own State requirements for treatment planning and medication monitoring for children in foster care receiving psychotropic medication. Improved compliance and stronger State requirements will help protect children who are at risk for inappropriate treatment and inappropriate prescribing practices.

ACF did not concur with the first recommendation and concurred with the second recommendation to:

- develop a comprehensive strategy to improve States' compliance with requirements related to treatment planning and medication monitoring for psychotropic medications; and
- assist States in strengthening their requirements for oversight of psychotropic medications by incorporating suggested professional practice guidelines for monitoring children at the individual level.

Low-Income Home Energy Assistance Program

The Fort Peck Assiniboine and Sioux Tribes Improperly Administered Some Low-Income Home Energy Assistance Program Funds for Fiscal Years 2011 Through 2015 (A-07-18-04106), August 2018

For FYs 2011 through 2015, the Fort Peck Assiniboine and Sioux Tribes (known collectively as the Fort Peck Tribes) did not administer \$436,765 of LIHEAP grant funds in compliance with Federal laws, regulations, and guidance. These errors occurred because the Fort Peck Tribes did not have policies and procedures or other internal controls in place to prevent the errors. The improperly administered LIHEAP grant funds could have been used to provide eligible households additional benefits, or the Fort Peck Tribes could have used them for other purposes such as crisis situations, residential weatherization, or energy-related home repairs.

The Fort Peck Tribes disagreed with most of our findings but did not comment on our recommendations to refund \$436,765 to the Federal Government and make procedural changes related to the development and implementation of internal controls and policies and procedures.

Health Resources and Services Administration

HRSA Helped Health Centers with Elevated Risks and Can Continue to Take Additional Steps (OEI-05-14-00470), May 2018

We found that HRSA intervened in multiple ways to help health centers reduce elevated risks, and while many health centers were able to do so, HRSA missed opportunities to further help these health centers. These findings raise concerns because HRSA's ability to provide comprehensive oversight is key to ensuring that medically underserved patients can access healthcare and that unnecessary risks to Federal grant funds are limited. HRSA outlined actions it took in response to our study that are consistent with our recommendations to:

- ensure that it uses its risk management interventions as intended, and
- explore additional steps it could take to help health centers reduce their elevated financial risks.

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 8 criminal actions and court-ordered restitution and settlements of \$859,107.

The following case examples involve child support enforcement:

- Michigan—In August 1989, Joseph Stroup was ordered to pay child support for his four children in the amount of \$100 per month. However, as a result of telling the court he was unemployed and medically disabled, his support was reduced to \$14 per month. In 1996, the court learned that Stroup was operating a successful Internet business, which he ultimately sold for more than \$2 million. The child support order was subsequently modified to account for the unreported income. From June 1996 to present, Stroup failed to pay any further child support. Stroup had been a fugitive for nearly 20 years and was recently located in Calgary, Canada, based on a tip from a Canadian national who identified the fugitive on the HHS OIG Child Support Enforcement website. Stroup pleaded guilty to failure to pay child support and was sentenced to 2 years in prison and ordered to pay \$533,624 in restitution.
- South Dakota—In July 1997, Joshua J. Layman was ordered to pay \$172 per month for the support of his child. Layman only sporadically made payments to the custodial parent of his child, and last made a payment in 2012. Layman pleaded guilty to felony failure to pay legal child support and was sentenced to 5 years of probation, 6 months in a residential re-entry center, and ordered to pay \$20,774.60 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 with regard to the more than 100 public health and human services programs carried out by more than 80,000 employees around the world. The size and scope of departmental awards make their operating effectiveness crucial to the success of programs designed to improve the health and well-being of the public.

Reviews

Grant Fraud Investigations

The following case examples relate to misuse of grant funds:

- Maryland—MassTech, Inc., its former CEO Arnold Lee, and its former CFO Richard Lee (collectively, "MassTech"), entered into an FCA settlement agreement to resolve allegations that, from January 2010 through December 2017, it falsely represented and certified to the National Science Foundation, National Aeronautics and Space Administration, and the NIH that MassTech was a Small Business Concern eligible to receive Small Business Innovation and Research (SBIR) awards. The certifications were allegedly false because MassTech was improperly affiliated with another company, Science and Engineering Solutions, Inc. (SESI), which had too many employees to qualify for SBIR grants. Evidence of this improper affiliation included common ownership and management between MassTech and SESI, a shared physical location, and shared employees. MassTech agreed to pay \$1.9 million to resolve its FCA liability.
- Oregon—Oregon Health and Sciences University (OHSU) entered into an FCA settlement agreement to resolve OHSU's FCA liability for charging improper costs to several NIH grants between January 1, 2005, and November 30, 2017. OHSU is a large research university that operates, among other centers, the Oregon National Primate Research Center (ONPRC) and the Vaccine Gene Therapy Institute (VGTI). ONPRC and VGTI both receive grants from NIH. In particular, the agreement resolves allegations that VGTI submitted claims for drawdowns from grants that improperly applied ONPRC's indirect cost rates, which were higher than the standard university indirect cost rates. This conduct resulted in OHSU receiving excess indirect cost recoveries. In addition, OHSU improperly retained and used program income generated by ONPRC under the NIH grant. Program income is gross income earned as a result of the NIH grant and must be used in a manner specified by NIH to support the grant purpose. Further, OHSU mischaracterized costs related to equipment and depreciation resulting in the calculation of an erroneous indirect cost rate which was applied to certain Federal awards,

resulting in excess indirect cost recoveries. OHSU agreed to pay \$1.32 million to resolve its liability.

Small Business Innovative Research Program

The National Defense Authorization Act for Fiscal Year 2012, § 5143, requires OIG to report annually on the number of cases referred to OIG to fraud, waste, or abuse in the Small Business Innovation Research/ Small Business Technology Transfer (SBIR/STTR) program. OIG must also report on the actions taken in each case; justification for not taking action on a case; and an accounting of funds used to address waste, fraud, and abuse in this program. In our November 2017 report delivered to the three congressional oversight committees, we reported that OIG spent approximately \$446,016 in salaries on oversight related to the SBIR/STTR program.

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 closed 0 investigations in which 0 instances of whistleblower retaliation were identified, declined 0 investigations, in which 0 instances of retaliation were identified, and received an extension on 1 whistleblower retaliation investigation.

Contract Audits

Pursuant to the National Defense Authorization Act for FY 2008, § 845, OIGs appointed under the Inspector General Act of 1978 are required to submit, as part of their semiannual report, pursuant to section 5 of the Inspector General Act, information on final completed contract audit reports issued during the period to the contracting activity. This information must contain significant audit findings.

OIG Reviews of Non-Federal Audits

OIG reviews audits conducted by non-Federal auditors of entities receiving Federal awards. During this semiannual reporting period, OIG's National External Audit Review Center reviewed 639 reports covering \$2.3 trillion in audited costs. Federal dollars covered by these audits totaled \$744.1 billion, of which about \$409 billion were HHS funds.

Office of Management and Budget (OMB) Circular A-133 and the more recent uniform guidance at 2CFR200 Subpart F establishes audit requirements for State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards. Under the circular and uniform guidance, covered entities must conduct annual organization-wide "single audits" of all Federal money they receive. These audits are conducted by non-Federal auditors, such as public accounting firms and State auditors. OIG reviews the quality of these audits and assesses the adequacy of the entities' management of Federal funds.

OIG’s oversight of non-Federal audit activity informs Federal managers about the soundness of management of Federal programs and identifies any significant areas of internal control weakness, noncompliance, and questioned costs for resolution or 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.

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

Non-Federal Audits, April 1, 2018, through September 30, 2018

| | |
|---|------------|
| Not requiring changes or having minor changes | 596 |
| Requiring major changes | 41 |
| Having significant technical inadequacies | 2 |
| Total Number of Non-Federal Audits | 639 |

The 639 reports included 1,928 recommendations for improving management operations. In addition, these audit reports provided information for 31 OIG special memorandums that identified concerns for increased monitoring by management.

Other Reporting Requirements and Reviews

Legislative and Regulatory Reviews

Pursuant to the Inspector General Act, § 4(a)(2), OIG is required to review existing and proposed legislation and regulations relating to HHS’s programs and operations and make recommendations concerning their impact on economy and efficiency or the prevention and detection of fraud and abuse. Most audits and other reviews that we conduct are designed to test compliance with and/or assess the administration and oversight of existing laws and regulations. Our reports of such reviews describe findings, which include questioned costs, inefficiencies, vulnerabilities to fraud, inconsistencies, errors in application, or weaknesses in oversight or supporting systems. Our corresponding recommendations tell HHS and its 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 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 HHS 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.

Health Insurance Marketplaces

Key focus areas for our oversight of the Health Insurance Marketplaces include payment accuracy, eligibility, management and administration, and security. In developing our work plan, we coordinate with GAO and other Federal and State oversight agencies.

Colorado Did Not Always Comply with Federal Requirements When Expending Federal Establishment Grant Funds Allocated for Its Shared Eligibility System Costs (A-07-16-02804), April 2018

Connect for Health Colorado (Colorado marketplace), the health insurance exchange established by Colorado under the Patient Protection and Affordable Care Act (ACA), did not always comply with Federal requirements when expending Federal establishment grant funds allocated for Shared Eligibility System (SES) costs.

SES costs were not always properly allocated to the Colorado marketplace because it did not have written policies that explained how to develop a Cost Allocation Plan (CAP) based on relative benefits received and because it did not maintain documentation for the cost allocation ratio. In addition, the marketplace did not have adequate internal controls to ensure that these costs were properly allocated to it by the Colorado Department of Health Care Policy and Financing (HCPF) using the cost allocation ratios in effect for the appropriate CAP period.

The Colorado marketplace neither agreed nor disagreed with our recommendations that it: (1) develop and implement a cost allocation methodology and written policies, reinforced by adequate internal controls, that explain how to develop a CAP, how to provide formal input to HCPF and CMS during the development of cost allocation ratios, and how to adequately document the development of those ratios; and (2) develop and implement written policies and procedures to ensure that future Federal grant award costs are allocated to it in accordance with Federal requirements.

The Colorado Health Insurance Marketplace's Financial Management System Did Not Always Comply with Federal Requirements (A-07-17-02808), July 2018

The Colorado marketplace did not always comply with Federal requirements with respect to the administration of its financial management system for the establishment grant funds it was awarded. Specifically, the marketplace improperly transferred grant costs totaling almost \$2 million. The marketplace also transferred costs between grants that may not have been allowable, in part, due to a lack of certifications that the new charges were correct. In addition, the marketplace made payments that were unallowable because the marketplace used grant funds from its first two grants to pay for expenditures outside of those grant periods. The marketplace also engaged in a number of financial management procedures and practices that did not provide for effective control over and accountability for establishment grant funds.

The Colorado marketplace did not agree with our recommendation that it refund to the Federal Government \$2 million in improperly transferred costs and \$568,987 in payments related to obligations that were not incurred during the grant period. It agreed with our recommendations that it: (1) work with CMS to certify the cost transfers associated with the remaining expenditures; (2) ensure that each expenditure transferred was allowable; (3) refund any unallowable expenditures to the Federal Government; and (4) address procedural recommendation regarding the development and implementation of written policies and procedures for the administration of the marketplace's financial management system.

CMS Did Not Always Accurately Authorize Financial Assistance Payments to Qualified Health Plan Issuers in Accordance With Federal Requirements During the 2014 Benefit Year (A-02-15-02013), August 2018

Of the 140 policies in our sample, CMS did not accurately authorize financial assistance payments in accordance with Federal requirements for 26 policies. For five policies, CMS authorized potentially improper financial assistance payments to qualified health plan (QHP) issuers that did not provide documentation to support that enrollees had paid their premiums, a requirement for receiving these payments. Based on our sample results, we estimated that CMS authorized improper financial assistance payments totaling almost \$434.4 million for 461,127 policies that were not in accordance with Federal requirements and authorized potentially improper financial assistance payments totaling almost \$504.9 million for 183,983 policies during the 2014 benefit year. In 2016, CMS fully transitioned QHP issuers operating through the Federal marketplace to an automated payment system that makes financial assistance payments on an individual policy-level basis.

CMS partially concurred with our recommendations that it: (1) work with the U.S. Department of the Treasury and QHP issuers to collect improper financial assistance payments; and (2) work with Treasury and QHP issuers to resolve potentially improper financial assistance payments. CMS concurred with our recommendation that it clarify guidance with QHP issuers on Federal requirements for terminating an enrollee's coverage when the enrollee fails to pay his or her monthly premium.

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

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

Audit Reports with Questioned Costs

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

Table 1—Audit Reports with Questioned Costs

| Description | Number of Reports | Dollar Value Questioned | Dollar Value Unsupported |
|---|-------------------|-------------------------|--------------------------|
| Section 1 | | | |
| Reports for which no management decisions had been made by the beginning of the reporting period ¹ | 155 | \$1,037,381,000 | \$38,786,000 |
| Issued during the reporting period | 41 | \$1,345,749,000 | \$504,902,000 |
| Total Section 1 | 196 | \$2,383,130,000 | \$543,688,000 |
| Section 2 | | | |
| Reports for which management decisions were made during the reporting period ^{2, 3} | | | |
| Disallowed costs | 136 | *\$333,565,000 | \$14,698,000 |
| Costs not disallowed | 6 | \$84,500,000 | \$23,265,000 |
| Total Section 2 | 142 | \$418,065,000 | \$37,963,000 |
| *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) | 54 | \$1,965,065,000 | \$505,725,000 |
| Section 4 | | | |
| Reports for which no management decisions were made within 6 months of issuance ⁴ | 24 | \$644,289,000 | \$823,000 |

Audit Reports With Funds Recommended To Be Put to Better Use

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

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 | 8 | \$16,460,871,000 |
| Reports issued during the reporting period | 3 | \$666,138,000 |
| Total Section 1 | 11 | \$17,127,009,000 |
| Section 2 | | |
| Reports for which management decisions were made during the reporting period | | |
| Value of recommendations agreed to by management | | |
| Based on proposed management action | 5 | \$1,300,979,000 |
| Based on proposed legislative action | 0 | \$0 |
| Value of recommendations not agreed to by management | | \$0 |
| Total Section 2 | 5 | \$1,300,979,000 |
| 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 | \$15,826,030,000 |

End Notes

Table 1 End Notes

¹ The opening balance was adjusted upward by \$54.6 million because of a reevaluation of previously issued recommendations.

² Revisions to previously reported management decisions:

- *A-02-16-01004 Fox Rehabilitation Claimed Unallowable Medicare Reimbursement for Outpatient Therapy Services.* CMS conducted a subsequent review and concluded that the medical records complied with Medicare coverage and payment requirements. As result, CMS nonconcurred with the previously sustained amount of \$29,902,452.
- *A-02-07-01028 Review of Medicaid Outpatient Drug Expenditures in the State of New York for the Period October 1, 2003, Through September 30, 2005.* Due to additional documentation provided by the State and the age of the remaining records in question, CMS reduced the previously sustained amount by \$16,189,125.

- A-01-12-02507 *Connecticut Often Did Not Comply with Federal Adoption Assistance Requirements*. ACF reduced the sustained amount by \$6,921,914 due to the receipt of additional documentation from the State.
- A-07-14-06057 *Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs*. CMS made an agreement with the State resulting in a refund of \$554,807. As a result, the original sustained amount was reduced by \$3,832,477.
- **Not detailed are reductions to previously disallowed management decisions totaling \$5.7 million.**

³ Included are management decisions to disallow \$38.5 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 24 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-02-15-01010 | 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-09-16-02034 | Medicare Improperly Paid Providers for Specimen Validity Tests Billed in Combination with Urine Drug Tests, February 2018, \$66,309,751 |
| 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-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-02-14-02012 | Visiting Nurse Service of New York Budgeted Costs That Were Not Appropriate and Claimed Some Unallowable Hurricane Sandy Disaster Relief Act Funds, November 2016, \$3,771,672 |

| | |
|------------------------------------|--|
| 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-05-12-00089 | The Council on Rural Service Programs, Inc., Claimed Unallowable Head Start Costs, November 2013, \$1,074,352 |
| A-02-15-01014 | New York Did Not Comply with Federal Grant Requirements for Claiming Marketplace Contract Costs to Medicaid and the Childrens Health Insurance Program, March 2018, \$954,521 |
| A-09-14-01007 | Nevada Misallocated Costs for Establishing a Health Insurance Marketplace to Its Establishment Grants, February 2016, \$893,464 |
| 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-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-01-10-02505 | Results of Limited Scope Review Of CTE, Inc., May 2011, \$239,975 |
| A-04-15-04039 | Mild may 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 |
| A-09-11-01014 | Hawaii Claimed Unallowable Community Services Block Grant Costs for Hawaii County Economic Opportunity Council's Expenditures Under the Recovery Act, July 2012, \$22,602 |
| TOTAL CINS: 24 | |
| TOTAL AMOUNT: \$644,289,431 | |

Table 2 End Notes

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

² Because of administrative delays, some of which were beyond management control, 4 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-03-14-00010 | CMS Did Not Adequately Address Discrepancies in The Coding Guidelines for Kwashiorkor, November 2017, \$102,000,000 |
| A-03-13-03002 | HHS Did Not Identify and Report Antideficiency Act Violations, May 2017, \$49,445,025 |
| A-09-16-02034 | Medicare Improperly Paid Providers for Specimen Validity Tests Billed in Combination with Urine Drug Tests, February 2018, \$12,146,760 |
| TOTAL CINS: 4 | |
| TOTAL AMOUNT: \$15,163,591,785 | |

Appendix B: Savings Decisions Supported by OIG Recommendations

The table below lists policy decisions reflected in legislation, regulations, or other directives from prior years that are supported by OIG recommendations and for which cost savings were estimated, usually by third parties, such as the Congressional Budget Office (CBO) or HHS actuaries. Of the savings estimated for the decisions below, \$25.6 billion was attributed to FY 2018. This figure reflects the most recent available savings estimates issued by the third-party appraiser; actual savings may be higher or lower.

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

To quantify the value of administrative decisions, we use estimates developed by, or in consultation with, HHS operating or staff divisions. To quantify the value of legislative decisions, we generally use estimates developed by CBO. CBO projects the annual increases or reductions in Federal spending that it expects would result from enacting the legislation. The policy decisions shown on the table beginning on the next page mirror not only OIG’s recommendations but also the contributions of others, such as HHS staff and operating divisions, congressional committees, and the GAO.

| Centers for Medicare & Medicaid Services (CMS) Programs | | |
|--|--|------------------------------|
| OIG Recommendations | Policy Decisions | Estimated Savings (millions) |
| Medicare Lab Test Payment Rates Seek legislation that would allow CMS to establish lower payment rates for lab tests. The recommendation reflected findings in OIG report numbers OEI-07-11-00010 and OEI-05-08-00400. | Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) changed the way that Medicare sets payments for clinical lab tests. PAMA requires that Medicare set payments for lab tests based on the median rates paid by private payers, updated every 3 years using data reported by labs. Previously, Medicare based lab test payments on lab charges from 1984 to 1985, adjusted annually for inflation. CBO estimated savings of \$3.9 billion over 10 years with \$400 million attributed to FY 2018. | \$400 |
| Medicare Part C Prepayments Modify monthly capitated payments to a level fully supported by empirical data. The recommendation reflected findings in OIG report number A-14-00-00212. | Section 3201 of the ACA changed the Medicare Advantage benchmark percentages that are applied to Medicare fee-for-service and imposed a cap on the benchmarks, resulting in cost savings for Medicare Part C as compared to prior law. CBO estimated Part C savings | \$23,200 |

| | | |
|---|---|---------|
| | through FY 2019, including \$23.2 billion for FY 2018. CBO produced its estimate in 2010, prior to two significant implementation decisions by HHS that affect the actual savings; however, neither CBO nor HHS has calculated a revised estimate. | |
| <p>Reductions in Medicare Bad Debt Reimbursement</p> <p>Seek legislative authority to eliminate (or reduce) Medicare payments to hospitals for bad debt associated with beneficiaries' failure to pay their deductibles and coinsurance. The recommendations reflected findings in OIG report number A-14-90-00339 and subsequent reviews.</p> | Section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012 applied percentage reductions in bad debt reimbursement to all providers eligible to receive bad debt reimbursement. CMS estimated savings to Medicare of \$10.92 billion over 10 years with \$1.21 billion attributed to FY 2018. (77 Fed. Reg. 67450, 67523 (November 9, 2012)) | \$1,210 |
| <p>Payments for Prescription Drugs Provided to Incarcerated Beneficiaries</p> <p>Work with prescription drug plan sponsors to identify and resolve improper Medicare Part D payments made for prescription drugs provided to incarcerated beneficiaries. The recommendation reflected findings in OIG report number A-07-12-06035.</p> | CMS issued a final rule about the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug programs. The eligibility requirements to enroll in Medicare Advantage and Part D are outlined in Sections 1851(a)(3)(B) and 1860D-1(a)(3)(A) of the Act. To enroll in Medicare Advantage, a beneficiary must be entitled to Part A and enrolled in Part B. To enroll in Part D, a beneficiary must be entitled to Part A and/or enrolled in Part B. An incarcerated beneficiary is not precluded from meeting the eligibility requirements for Part A and Part B, but in general, no Medicare Payment is made for these individuals. CMS promulgated regulations to require Part D plans to disenroll incarcerated beneficiaries. CMS estimated savings of \$1.6 billion over 10 years with \$129 million attributed to FY 2018. (79 Fed. Reg. 29844, 29953 (May 23, 2014)) | \$129 |
| <p>Medicare Payments for Vacuum Erection Systems</p> <p>Seek legislative authority to include vacuum erection systems (VES) in the Competitive Bidding program and then implement a National Mail-Order Competitive Bidding program for VES. The recommendation reflected findings in OIG report number A-07-12-05024.</p> | Section 203 of the Achieving A Better Life Experience Act of 2014 implements changes to treat VES prosthetic devices and related accessories as statutorily noncovered in the same manner that erectile dysfunction drugs are treated in Medicare Part D. CBO estimated savings of \$444 million over 10 years. | \$44.4 |
| <p>Additional Rebates for Brand-Name Drugs with Multiple Versions</p> <p>OIG recommended that CMS continue to seek legislative authority to modify the rebate formula calculation to ensure that manufacturers cannot circumvent additional rebates by bringing new versions of existing brand-name drugs to</p> | Section 2501(d) of the ACA, as amended by section 1206(a) of the Health Care and Education Reconciliation Act of 2010, addresses this issue. CBO estimated savings of \$300 million for FY 2018. | \$300 |

| | | |
|--|---|--------------|
| <p>market. The recommendation reflected findings in OIG report number A-06-09-00033.</p> | | |
| <p>Medicaid Provider Reimbursement for Durable Medical Equipment OIG recommended that CMS seek legislative authority to limit State Medicaid DME reimbursement rates to Medicare program rates and encourage further reduction of Medicaid reimbursement rates through competitive bidding or manufacturer rebates. OIG also recommended that that CMS work with State Medicaid agencies to determine whether the use of manufacturer rebates and lower provider reimbursement rates could achieve net savings for the purchase of test strips. The recommendations reflected findings in OIG reports A-05-15-00025 and A-05-13-00033.</p> | <p>In December 2015, the Consolidated Appropriations Act, 2016 section 503, Congress added section 1903(i)(27) to the Social Security Act (the Act) which prohibits federal Medicaid reimbursement to States for certain DME expenditures that are, in the aggregate, in excess of what Medicare would have paid for such items. The requirement was scheduled to effect January 1, 2019. The 21st Century Cures Act Section 5002 moved up the effective date to January 1, 2018 when it was passed in December 2016. CBO estimated savings of \$275 million for FY 2018.</p> | <p>\$275</p> |
| <p>Excessive Medicaid Payments to New York State Ensure that expenditures related to developmental centers and other intermediate care facilities and any revised payment methodology be consistent with efficiency and economy. The recommendation reflected findings in OIG reports A-02-11-01029, A-02-13-01008, and other reviews.</p> | <p>Agreement between CMS and the State of New York, dated March 20, 2015, to repay \$1.95 billion over 12 years with \$100 million attributed to FY 2018.</p> | <p>\$100</p> |

Appendix C: 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 | United States 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, no peer review involving OI was completed. Listed below is information concerning OI’s peer-review activities during prior reporting periods.

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

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

| OI | Date | Reviewing Office | Office Reviewed |
|----|-------------|------------------|-----------------|
| | August 2015 | DOL OIG | HHS OIG, OI |

The system of internal safeguards and management procedures for the investigative function of HHS OIG in effect through June 2014, 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, we conducted two peer reviews in accordance with the Council of the Inspectors General on Integrity and Efficiency (CIGIE) *Guide for Conducting Peer Reviews of Inspection and Evaluation Organizations of Federal Offices of Inspector General* (January 2017). The onsite visits for these reviews were conducted from October 2 through November 17, 2017.

The External Peer Review Team (Team) conducted a primary review of the extent to which the Inspection and Evaluation (I&E) components of the Department of Defense’s Office of Inspector General (DoD OIG) adhered to seven standards described in CIGIE’s *Quality Standards for Inspection and Evaluation* (Blue Book), specifically: Quality Control, Planning, Data Collection and Analysis, Evidence, Records Maintenance, Reporting, and Followup. A supplemental review focused on two additional Blue Book standards: Timeliness and Independence.

The Team determined that the DoD OIG I&E components’ policies and procedures generally met the Blue Book standards addressed in these peer reviews. In addition, the ten reports reviewed for these peer reviews generally met the applicable Blue Book standards.

The draft reports, issued August 20, 2018, set forth specific findings, recommendations, and observations identified during the reviews. DoD OIG management officials provided a response to our draft reports in which they agreed with our two recommendations. Their response was incorporated into the final reports issued September 25, 2018.

Appendix D: Summary of Sanction Authorities

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

Program Exclusions

The Social Security Act, § 1128 (42 U.S.C. § 1320a-7), provides several grounds for excluding individuals and entities from participation in Medicare, Medicaid, and other Federal 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 E: Reporting Requirements in the Inspector General Act of 1978

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

| Section | Requirement | Location |
|------------------|---|--|
| Section 4 | | |
| (a)(2) | Review of legislation and regulations | "Other HHS-Related Reviews and Investigations" section |
| Section 5 | | |
| (a)(1) | Significant problems, abuses, and deficiencies | Throughout this report |
| (a)(2) | Recommendations with respect to significant problems, abuses, and deficiencies | Throughout this report |
| (a)(3) | Prior significant recommendations on which corrective action has not been completed | Solutions to Reduce Fraud, Waste, and Abuse in HHS Programs: Top Unimplemented Recommendations (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 |

| Section | Requirement | Location |
|--------------|--|---|
| (a)(11) | Description and explanation of revised management decisions | Appendix A |
| (a)(12) | Management decisions with which the Inspector General disagrees | None for this reporting period |
| (a)(13) | Information required by the Federal Information Security Management Act. | 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 E |
| (a)(18) | Metrics description for statistical tables | Appendix E |
| (a)(19) | Investigations on senior Government employees | Appendix E |
| (a)(20) | Description of whistleblower retaliation instances | Appendix E |
| (a)(21) | Description of attempts to interfere with OIG independence | Appendix E |
| (a)(22) | Description of closed and nondisclosed reports and investigations regarding senior Government employees | Appendix E |

Other Reporting Requirements

| Section | Requirement | Location |
|---------|--|---|
| 845 | Significant contract audits required to be reported pursuant to the National Defense Authorization Act for FY 2008 (P.L. No. 110-181), § 845. | "Other HHS-Related Reviews and Investigations" section |
| 205 | Pursuant to HIPAA (P.L. No. 104-191), § 205, the Inspector General is required to solicit proposals annually via a 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 F: 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 2018, OIG had 91 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.

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

OIG is actively tracking 1,133 unimplemented open recommendations made in reports issued since FY 2011. Given the volume of recommendations OIG makes each year, the table below reflects summary data by FY:

| FY (2011–2018) | Number of Reports with Unimplemented Recommendations | Number of Unimplemented Recommendations | Dollar Value of Aggregate Potential Cost Savings |
|----------------|--|---|--|
| 2011 | 15 | 27 | \$434,404,003 |
| 2012 | 30 | 36 | \$397,825,976 |
| 2013 | 41 | 77 | \$264,181,505 |
| 2014 | 35 | 69 | \$15,170,192,492 |
| 2015 | 44 | 88 | \$359,882,015 |
| 2016 | 51 | 132 | \$193,929,887 |
| 2017 | 60 | 247 | \$1,896,324,293 |
| 2018 | 114 | 457 | \$2,527,665,306 |
| Totals | 390 | 1,133 | \$21,244,405,477 |

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 |
| Total number of persons referred ² to Federal prosecuting authorities for criminal prosecution during the reporting period ³ | 1,301 |
| Total number of persons referred to State and local prosecuting authorities for criminal prosecutions during the reporting period | 179 |
| Total number of Federal indictments and criminal informations during the reporting period that resulted from any prior referral to prosecuting authorities | 524 |
| Total number of State and local indictments and criminal informations during the reporting period that resulted from any prior referral to prosecuting authorities | 123 |

(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 information cannot be limited to only those that occurred as a result of a

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

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

presentation in a previous period. In certain situations, the presentation and charging dates are in the same reporting period.

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

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

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

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

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

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

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

For this section, OIG describes investigations during this reporting period, both criminal and administrative, involving senior Government employees for whom allegations of misconduct were substantiated. The descriptions below include a level of detail appropriate for each investigation, depending on whether the case details were available in public documents. During this reporting period, OIG investigated 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 proactive analysis revealed an IP address associated with the transfer of child exploitation material on peer-to-peer networks, which was also used for VPN access to HHS networks. | Closed | Eighteen months in prison suspended; 3 years supervised probation with | Yes | 9/6/2016 | N/A | N/A |

| | | | | | | |
|--|--------|---|----|-----|-----|-----|
| | | special conditions, and court costs. Removal. | | | | |
| Request for assistance was received from the Montgomery County, Maryland Department of Police regarding an investigation of a HRSA employee who has been allegedly communicating with an undercover detective posing as a male teenager. | Closed | Removal. | No | N/A | N/A | N/A |

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 April 1, 2018, through September 30, 2018, 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, April 1, 2018, to September 30, 2018

| Category/Description | Number of Reports |
|--|-------------------|
| IT security reviews (involve IT systems, e.g., penetration test audits) | 5 |
| 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 | 2 |
| Total | 7 |

- (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

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.

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 |
|--|--------|------------------------------------|--------------|-------------------|-----------------|----------------------|
| It was alleged that a chief operating officer kept a former director on the payroll for three months after the individual resigned. The chief operating officer allegedly instructed a management official to secretly move the former director without alerting other administrative officials across the agency. | Closed | No evidence to support allegations | No | N/A | N/A | N/A |
| A senior Government employee was alleged to have changed their duty location to receive per diem and other travel benefits such as plane tickets to travel home each week. | Closed | No evidence to support allegations | Yes | 12/2016 | Yes | 12/2016 |
| A senior Government employee was alleged to have conflicts of interest with contractors, abused their authority, and mismanaged personnel matters. | Closed | No evidence to support allegations | Yes | 05/2016 | Yes | 05/2016 |
| A senior Government employee was alleged to have colluded with a contractor to escalate billing costs. | Closed | No evidence to support allegations | No | N/A | No | N/A |
| A senior Government employee was alleged to have falsely grown their division into an office to acquire grants and Senior Executive Service title. | Closed | No evidence to support allegations | No | N/A | No | N/A |

Appendix G: Anti-Kickback Statute—Safe Harbors

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

In crafting safe harbors for a criminal statute, it is incumbent upon OIG to engage in a complete and careful review of the range of factual circumstances that may fall within the proposed safe harbor subject area to uncover all potential opportunities for fraud and abuse by unscrupulous providers. Having done so, OIG must then determine, in consultation with DOJ, whether it can develop effective regulatory limitations and controls—not only to foster beneficial or innocuous arrangements but also to protect the 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 |
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| <p>New safe harbors to facilitate coordinated care and promote alternative payment models so physicians can pursue integration options that are not hospital driven.</p> | <p>On August 27, 2018, OIG issued a 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.</p> |
| <p>New or modified safe harbors for incentive payment arrangements between hospitals and other providers operating under current, proposed, and new CMS alternative payment models.</p> | <p>On August 27, 2018, OIG issued a 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</p> |

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| | 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 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. | OIG is considering modifying this safe harbor to address the concerns described in this proposal. |
| 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. | On August 27, 2018, OIG issued a 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. |
| A new safe harbor to protect arrangements that support patient adherence to a prescribed treatment or medication regimen. | On August 27, 2018, OIG issued a 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. |
| 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. | On August 27, 2018, OIG issued a 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 current managed care safe harbor (42 C.F.R. § 1001.952(t)) to add Medicare Part D Sponsors to the list of | On August 27, 2018, OIG issued a RFI seeking input from the public on how to address any regulatory provisions that may act as barriers to coordinated care or value- |

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| <p>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>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>New or modified safe harbors to protect donations to independent charitable foundations and to enable financial assistance from both charitable entities and directly from drug manufacturers.</p> | <p>OIG is not adopting this suggestion. Financial assistance programs could vary greatly and should be addressed on a 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 a 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 a 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</p> | <p>On August 27, 2018, OIG issued a RFI seeking input from the public on how to address any regulatory provisions</p> |

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| <p>electronic health record software (42 C.F.R. § 1001.952(y)) and expand the scope of covered technologies under the safe harbor.</p> | <p>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> |
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