

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

Semiannual Report to Congress

April 1, 2017 - September 30, 2017



A MESSAGE FROM THE INSPECTOR GENERAL

I am pleased to present this *Semiannual Report to Congress* summarizing activities of the Office of Inspector General (OIG), Department of Health and Human Services (HHS or the Department), for the 6-month period that ended September 30, 2017. OIG's mission is to protect the integrity of HHS programs and the health and welfare of the people they serve. We accomplish our mission by preventing and detecting fraud, waste, and abuse; identifying opportunities to increase the efficiency and effectiveness of HHS programs; and holding accountable those who do not meet program requirements or who violate Federal laws.

Our work during this reporting period reflects our heightened attention to delivering high-impact results while streamlining our approach to oversight. Data and our growing data analytics capabilities played a significant role in these efforts. We continue to cultivate a workforce with the skills and talents to excel in a data-driven oversight environment. This strategy is paying dividends for the American public. By leveraging advanced analytic

techniques to detect potential vulnerabilities and fraud trends, we are better able to target our resources at those areas and individuals most in need of oversight, leaving others free to provide care and services without unnecessary disruption. In July 2017, OIG and its law enforcement partners conducted the largest National Health Care Fraud Takedown in history. Sophisticated data analytics were critical. The end result—charges against more than 400 defendants in 41 Federal districts related to schemes involving about \$1.3 billion in false billings to Medicare and Medicaid—protected the programs and sent a strong signal that theft of taxpayer funds will not be tolerated. Notably, 120 defendants, including doctors, were charged for their roles in prescribing and distributing opioids and other dangerous narcotics, and 295 individuals were served with exclusion notices for conduct related to opioid diversion and abuse. Also in July we published a data brief describing concerns about extreme use and questionable prescribing of opioids in Medicare Part D.

Our heightened focus on prescription drug abuse, including the serious problem of opioid abuse, continues. Other continuing priorities include improving the safety and quality of children's services; strengthening care in noninstitutional settings, including home health care; and enhancing Medicaid program integrity. Looking forward, we anticipate our work to grow in key areas such as grants management, mental health services, managed care programs and value-based care, and the quality and safety of programs serving American Indian and Alaska Native beneficiaries. We will look at common



issues across all of these areas, including issues related to information technology, cybersecurity, and the completeness, accuracy, and timeliness of data.

Since Congress established OIG in 1976, we have worked collaboratively with our partners to protect and oversee HHS's vital health and human services programs. This collaboration across Federal agencies and among Federal, State, and local governments has never been more crucial or more fruitful. We remain open to appropriate opportunities to collaborate with the private sector to advance shared interests in effective, efficient, economical programs. We are adapting to an ever-evolving health and human services landscape. Today, as a modern OIG, we are using data and technology in innovative ways to enhance and target our oversight efforts. But none of the achievements of this office would be possible without the dedication and professionalism of OIG's employees. Once again, I would like to express my appreciation to Congress and to the Department for their sustained commitment to the important work of our office.

Daniel R. Levinson
Inspector General

TABLE OF CONTENTS

OIG’s Approach To Driving Positive Change	1
Highlights of OIG Accomplishments	4
OIG Participation in Congressional Hearings	11
Selected Acronyms and Abbreviations	12

Oversight Activities by Program Area	14
Centers for Medicare & Medicaid Services	14
Legal and Investigative Activities Related to the Medicare and Medicaid Programs	31
Public Health Agencies	47
Other HHS-Related Reviews and Investigations	56

Appendices	
A: Questioned Costs and Funds To Be Put to Better Use	66
B: Savings Decisions Supported by OIG Recommendations	73
C: Peer-Review Results	76
D: Summary of Sanction Authorities	78
E: Reporting Requirements in the Inspector General Act of 1978	81
F: Reporting Requirements in the Inspector General Empowerment Act of 2016	83
G: Anti-Kickback Statute—Safe Harbors	90

OlG's Approach to Driving Positive Change

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS or Department) Office of Inspector General (OlG) provides independent and objective oversight that promotes economy, efficiency, and effectiveness in HHS programs and operations. OlG'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 nationwide network of audits, investigations, and evaluations, OlG carries out its mission to protect the integrity of HHS programs and the health and welfare of the people served by those programs. OlG's work is conducted by three operating components—the Office of Audit Services, the Office of Evaluation and Inspections, and the Office of Investigations—with assistance from the Office of Counsel to the Inspector General and Executive Management.

OlG Organization

The Office of Audit Services (OAS). OAS conducts audits of HHS programs and operations through its own resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/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.

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

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

The Office of Counsel to the Inspector General (OCIG). OCIG provides legal services to OlG, 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 health care industry about the anti-kickback statute and other OIG enforcement authorities.

Executive Management (EM). EM is composed of the Immediate Office of the Inspector General and the Office of Management and Policy. EM 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. EM plans, conducts, and participates in a variety of cooperative projects within HHS and with other Government agencies. EM 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.

Top Management Challenges Facing HHS

To focus the Department’s attention on the most pressing issues, each year OIG identifies the [Top Management and Performance Challenges](#) facing the Department. 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.

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 the Department’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 the Department. Some of the projects described in the Work Plan are statutorily required.

Compendium of 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 [Compendium of Unimplemented Recommendations](#).

HHS OIG's Semiannual Report to Congress

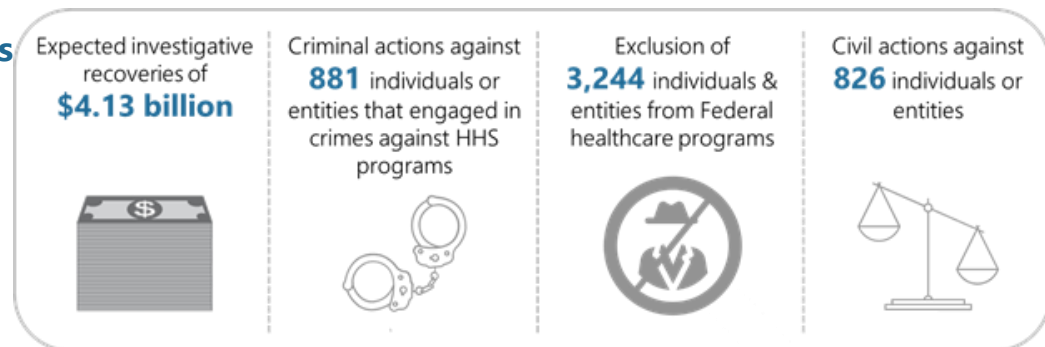
[HHS OIG's Semiannual Report\(s\) to Congress](#) (Semiannual Reports) describe OIG's work on identifying significant problems, abuses, deficiencies, remedies, and investigative outcomes relating to the administration of HHS programs and operations that were disclosed during the reporting period. In 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 2017. We also highlight some of our work completed during this semiannual reporting period, April 1, 2017, through September 30, 2017.

Highlights of OIG Accomplishments

HHS OIG'S SEMIANNUAL REPORT TO CONGRESS (Semiannual Report) describes OIG's work identifying significant risks, problems, abuses, deficiencies, remedies, and investigative outcomes relating to the administration of HHS programs and operations that were disclosed during the 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 for the entire FY 2017. We also highlight our most significant work completed during this semiannual reporting period, April 1, 2017, through September 30, 2017.

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. Not only does fraud increase HHS costs, it increases risk and potential harm to beneficiaries. During FY 2017, OIG reported the following.



To combat health care fraud, OIG partners with DOJ; the 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 health care fraud through a coordinated and data-driven approach. Since its inception in March 2007, the Medicare Fraud Strike Force has charged over 3,500 defendants who collectively have falsely billed the Medicare program for over \$12.5 billion.

The following examples highlight some of our significant enforcement accomplishments during this semiannual reporting period.

OIG and partners executed the largest national health care fraud takedown in history. In July 2017, OIG and our Federal and State law enforcement partners led the largest health care fraud takedown in history. More than 400 defendants in 41 Federal districts were charged with participating in fraud schemes involving about \$1.3 billion in false billings to Medicare and Medicaid.

Texas doctor sentenced to 35 years, \$268 million in restitution for massive home health fraud scheme. Dr. Jacques Roy was sentenced to 35 years in prison and,

jointly and severally with his co-defendants, ordered to pay \$268.1 million in restitution following his conviction on several counts of health care fraud. OIG's investigation found that Roy and his co-defendants were involved in a large-scale, sophisticated scheme to improperly recruit patients and bill Medicare for unnecessary home health services.

Drug manufacturer agreed to pay \$465 million and entered into corporate integrity agreement to resolve allegations of improper drug classification.

Mylan Inc. and Mylan Specialty L.P. (collectively, Mylan) agreed to pay \$465 million to resolve FCA liability associated with allegations that Mylan improperly classified EpiPen as a generic drug for purposes of the Medicaid drug rebate program, resulting in underpaid rebates to Medicaid and overcharges to covered entities participating in the 340B Drug Discount Program. Mylan also entered into a 5-year CIA with OIG.

Vendor of electronic health record software agreed to pay \$155 million to settle false claims allegations.

eClinicalWorks, LLC (ECW), and three of its senior executives agreed to pay \$155 million for allegedly causing health care providers to submit false claims in connection with the Medicare and Medicaid Electronic Health Record Incentive Programs by concealing from ECW's customers that ECW's software did not comply with the requirements for "meaningful use" certification. ECW also entered into a 5-year CIA with OIG.

Health center CEO sentenced to 18 years for fraud scheme.

Jonathan Wade Dunning, CEO of Birmingham Health Center, was convicted on 98 counts related to his embezzlement of Federal grant funds. Dunning was sentenced to 18 years in prison and ordered to pay \$13.5 million in restitution. He and his nine companies were also debarred for 10 years.

Curbing the Opioid Epidemic

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 alarming problem of prescription drug abuse, including opioids, as well as non-controlled substances that are often abused along with opioids (known as "potentiators"). We investigate opioid fraud and diversion cases and use advanced data analytics and tools to detect suspected problems for further review. Our work focuses on strengthening the integrity of HHS prescription drug and addiction treatment programs and protecting at-risk beneficiaries. Highlights from this semiannual reporting period include the following.

National takedown included largest number of opioid-related defendants.

OIG, along with our State and Federal law enforcement partners, participated in an unprecedented nationwide health care fraud takedown in July 2017. The takedown included opioid-related charges against 120 individuals—the largest number ever in a health care fraud takedown. The defendants included 27 doctors. In addition, OIG issued 295 exclusion notices related to the use and abuse of controlled substances.

OIG identified concerns about extreme use and questionable prescribing of opioids in Medicare Part D. In 2016, half a million beneficiaries received high amounts of opioids through Medicare Part D, and almost 90,000 of them were at serious risk of opioid misuse or overdose. Moreover, 401 prescribers had questionable prescribing patterns for the beneficiaries at serious risk. OIG and CMS are taking appropriate actions with respect to these prescribers. (See OIG's report, [OEI-02-17-00250](#).)

Pennsylvania doctor sentenced to 25 years for charges related to improper prescribing. Dr. Jeffrey Bado was convicted of 307 felony counts, including maintaining a drug-involved premises, drug distribution resulting in a death, health care fraud, and making false statements to Federal agents. Bado was sentenced to 25 years in prison.

Fraudulent medical practice and pharmacy co-conspirators sentenced. Three co-conspirators connected with health care provider Compassionate Doctors, PC, were convicted of charges resulting from their involvement in an unlawful prescription drug operation. The defendants—owner Sardar Ashrafkhan, Dr. Adelfo Pamatmat, and pharmacist Nadeem Iqbal—were sentenced to a combined 46 years and 4 months in prison and ordered to pay \$10.7 million in restitution.

Protecting Vulnerable Beneficiaries in Nursing Homes and Non- Institutional Settings

OIG's goal to promote quality, safety, and value includes a focus on protecting Medicare and Medicaid beneficiaries from substandard care, abuse, and neglect. We direct particular oversight attention to those who may be especially vulnerable to these risks, such as nursing home residents and beneficiaries with developmental disabilities who receive care from community-based providers. Significant OIG work during this semiannual period includes the following.

OIG uncovered over 100 instances of potential abuse or neglect of Medicare beneficiaries in skilled nursing facilities (SNFs). OIG's review of records from emergency room visits by Medicare beneficiaries residing in SNFs indicates that the injuries of 134 beneficiaries may have resulted from potential abuse or neglect. More than a quarter of these incidents may not have been reported to law enforcement at the time. OIG has referred all 134 incidents to appropriate law enforcement officials and CMS and suggested immediate actions for CMS to better protect beneficiaries. (See OIG's early alert, [A-01-17-00504](#).)

OIG identified deficiencies in Maine's oversight of critical incidents involving Medicaid beneficiaries with developmental disabilities. Maine failed to demonstrate that it has a system to ensure the health, welfare, and safety of its beneficiaries with developmental disabilities who are covered by its Medicaid waiver program. OIG found—among other problems—that Maine did not ensure that providers reported and reviewed all critical incidents; did not investigate and immediately report to law enforcement all incidents involving suspected abuse, neglect, or exploitation; and did

not ensure appropriate reporting, analysis, and investigation of all beneficiary deaths. (See OIG's report, [A-01-16-00001](#).)

Protecting the Health and Safety of Children in HHS Programs

OIG also prioritizes the health and safety of children served by HHS programs in directing our work toward our goal to promote health, safety, and value. Many of HHS's programs for children are operated by States and some require coordination with other agencies. During this reporting period, OIG's work included the following oversight of such programs.

OIG found that two States did not always properly handle allegations and referrals of abuse and neglect of children in foster care. In audits of Texas and California, OIG found that neither State always ensured that allegations and referrals of abuse and neglect of children in the Title IV-E foster care program were recorded and investigated. Further, California also did not always ensure that all such allegations and referrals were resolved. (See OIG's reports on Texas, [A-06-15-00049](#), and California, [A-09-16-01000](#).)

OIG noted improvements in the HHS Office of Refugee Resettlement's (ORR) coordination and outreach to protect unaccompanied alien children. OIG assessed HHS's progress in working with the Department of Homeland Security (DHS) to clarify their respective roles and responsibilities related to unaccompanied alien children after their release to sponsors, as OIG had recommended in 2008. We found that HHS and DHS have improved coordination and that ORR has increased its contact with the children and their sponsors after children are released from HHS custody. (See OIG's report, [OEI-09-16-00260](#).)

Improving Financial Management and Reducing Improper Payments in Medicare

OIG has identified reducing improper payments as a departmental priority necessary to ensuring the long-term health of HHS programs, especially Medicare. Highlights from this semiannual reporting period include the following.

OIG identified more than \$700 million in improper Medicare incentive payments designed to promote the adoption of electronic health records (EHR). In an audit of Medicare EHR incentive payments, OIG estimated that CMS paid \$729.4 million to providers who did not meet Federal requirements for "meaningful use." CMS also made \$2.3 million in incentive payments for the wrong payment year when providers switched between incentive programs. (See OIG's report, [A-05-14-00047](#).)

OIG recommended ways to improve recovery of Medicare overpayments identified by integrity contracts. OIG found that although CMS had improved its recovery rate since 2010 (7 percent collected), only 20 percent of the \$482 million in overpayments sought for collection based on integrity contractor referrals in 2014 were recouped, leaving \$386 million uncollected. OIG recommended several improvements to

contractors' overpayment identification, collection, and tracking. (See OIG's report, [OEI-03-13-00630](#).)

OIG found that data shortcomings may increase Medicare's and beneficiaries' costs for recalled and failed devices. Limitations in claims data impede CMS's ability to readily identify and effectively track Medicare's total costs related to the replacement of devices that were recalled or that failed prematurely. We estimated these costs totaled \$1.5 billion for Medicare and \$140 million for beneficiaries over the 10-year period ending on December 31, 2014, for seven recalled and prematurely failed cardiac devices. By including medical device-specific information on the claim forms, CMS could reduce Medicare and beneficiary costs by identifying poorly performing devices more quickly, which could also improve beneficiaries' chances of receiving appropriate followup care more quickly. (See OIG's report, [A-01-15-00504](#).)

Overseeing Programs Aimed at Improving Quality and Reducing Costs

In support of OIG's goal to promote value, we assess HHS programs aimed at improving quality while reducing costs. During this semiannual period, OIG's work in this area included the following.

OIG found that the Medicare Shared Savings Program (MSSP) shows potential to reduce spending and improve quality. Most Accountable Care Organizations (ACOs) in the MSSP were able to reduce spending and improve quality of care during the first 3 years of the program. A small subset of these ACOs showed substantial reductions in Medicare spending for key services. (See OIG's report, [OEI-02-15-00450](#).)

OIG found that CMS validated hospital-reported data on quality, but should use additional tools to identify gaming. CMS was validating hospital inpatient quality reporting data (used to adjust payments based on quality measures) according to the process it established in regulation, and most hospitals passed the validation. However, CMS made limited use of analytics, leaving it less likely to identify patterns that may indicate gaming of the data by hospitals. (See OIG's report, [OEI-01-15-00320](#).)

Protecting the Integrity of the Medicaid Program

Protecting the integrity of Medicaid is another key focus area 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 Medicaid Fraud Control Units to combat Medicaid fraud. Highlights of OIG's work during this reporting period include the following.

OIG identified continued concerns about national Medicaid data. Complete, accurate, and timely national data are essential for effective administration and oversight of

Medicaid; however, OIG identified continued concerns with the national Medicaid database known as T-MSIS. States and CMS reported challenges to States' submitting data to T-MSIS, CMS has postponed reporting deadlines multiple times, and CMS and States reported concerns about the completeness and reliability of submitted data. (See OIG's report, [OEI-05-15-00050](#).)

OIG found that Kentucky did not always determine Medicaid eligibility in accordance with Federal and State requirements. We estimated that Kentucky made Federal Medicaid payments on behalf of 69,931 potentially ineligible beneficiaries totaling \$72.8 million. (See OIG's report, [A-04-16-08047](#).)

OIG found that challenges limit States' use of Medicaid payment suspension. Payment suspensions are a program integrity tool for States to stop Medicaid payments as early as possible when there is a credible allegation of fraud against a provider. However, we found that most States imposed 10 or fewer suspensions in all of FY 2014, and States reported significant challenges with imposing payment suspensions. (See OIG's report, [OEI-09-14-00020](#).)

OIG initiated enhanced efforts to maximize the effectiveness of Medicaid Fraud Control Units. MFCUs play a primary role for Medicaid in investigating and prosecuting provider fraud as well as patient abuse or neglect in health care facilities. OIG collaborates with the MFCUs on joint cases and investigative initiatives and has oversight responsibility for MFCU operations. Supporting MFCU effectiveness is one of OIG's top priorities. During the semiannual reporting period, OIG piloted a new risk-based onsite review process, provided training for MFCU managers and staff, and partnered with 31 MFCUs in the July 2017 national health care fraud takedown.

Ensuring Integrity and Quality in Programs Serving American Indians and Alaskan Natives

OIG has focused significant attention on improving quality and integrity in HHS programs serving American Indians and Alaskan Natives (AI/AN). This includes improving the quality of care, management, and infrastructure of the Indian Health Service (IHS); combating fraud and misuse of funds; and ensuring adequate internal controls and training for AI/AN grantees. Highlights during this reporting period include the following.

OIG led training on quality of care, compliance, and combating fraud and abuse in programs serving AI/AN. In April 2017, OIG conducted a training program for IHS and tribal officials on health care and grants management compliance in South Dakota. The sessions focused on quality of care and service delivery, compliance programs and other tools for combating fraud and abuse, internal controls, and single audits.

In audits of two tribes, OIG identified improper administration of Low-Income Home Energy Assistance Program (LIHEAP) grant funds. Grant funds totaling \$1.2 million for one tribe and almost \$600,000 for the other tribe were not

administered in compliance with Federal laws, regulations, and guidance. These funds could have been used to provide additional benefits to eligible LIHEAP beneficiaries. Errors occurred because of insufficient internal controls, and in some cases, because staff circumvented existing internal controls. (See OIG reports on the Three Affiliated Tribes, [A-07-16-04230](#), and the Turtle Mountain Band of Chippewa Indians, [A-07-16-04233](#).)

Tribal member convicted of theft of federally provided welfare benefits, ordered to pay \$30,000 in restitution, and debarred for 3 years. James Leroy Emerson stole Temporary Assistance for Needy Families (TANF) and Supplemental Nutrition Assistance Program (SNAP) Tribal funds when he applied for and received benefit payments from the Blackfeet Tribe from 2007 through 2010, even though he was ineligible. He was convicted of theft of federally provided welfare benefits by fraud, Federal welfare assistance fraud, and theft from an Indian tribal organization, and ordered to pay \$30,000 in restitution. Emerson was also debarred for a period of 3 years following an OIG referral to HHS.

OIG Participation in Congressional Hearings

05/02/2017	Testimony of Christi A. Grimm , Chief of Staff, Office of Inspector General, U.S. Department of Health and Human Services	"Combating Waste, Fraud, and Abuse in Medicaid's Personal Care Services Program," House Committee on Energy and Commerce; Subcommittee on Oversight and Investigations
07/18/2017	Testimony of Erin Bliss , Assistant Inspector General for Evaluation and Inspections, Office of Inspector General, U.S. Department of Health and Human Services	"Examining HRSA's Oversight of the 340B Drug Pricing Program," House Committee on Energy and Commerce; Subcommittee on Oversight and Investigations

Selected Acronyms and Abbreviations

ACA	Patient Protection and Affordable Care Act
ACF	Administration for Children and Families
ACL	Administration for Community Living
ACO	Accountable Care Organizations
AMP	average manufacturer price
ASP	average sales price
CDC	Centers for Disease Control and Prevention
CIA	corporate integrity agreement
CMP	civil monetary penalty
CMS	Centers for Medicare & Medicaid Services
DHS	Department of Homeland Security
DOJ	Department of Justice
EHR	electronic health records
EMTALA	Emergency Medical Treatment and Labor Act
FCA	False Claims Act
FDA	Food and Drug Administration
FMAP	Federal medical assistance percentage
FPS	Fraud Prevention System
FY	fiscal year
GAO	Government Accountability Office
HCBS	home- and community-based services
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IT	information technology
LIHEAP	Low-Income Home Energy Assistance Program
MAC	Medicare Administrative Contractor
MCO	managed care organization
MFCU	Medicaid Fraud Control Unit
NIH	National Institutes of Health
OAS	Office of Audit Services
OCIG	Office of Counsel to the Inspector General
OEI	Office of Evaluation and Inspections
OI	Office of Investigations
OIG	Office of Inspector General

OMB	Office of Management and Budget
PCS	personal care services
PSC	Program Safeguard Contractors
SAMHSA	Substance Abuse and Mental Health Services Administration
SNAP	Supplemental Nutrition Assistance Program
SNF	skilled nursing facility
UPIC	Unified Program Integrity Contractor
ZPIC	Zone Program Integrity Contractor

Centers for Medicare & Medicaid Services

Medicare Program Reports and Reviews

Financial Management and Improper Payments

Enhancements Needed in the Tracking and Collection of Medicare Overpayments Identified by ZPICs and PSCs ([OEI-03-13-00630](#)), September 2017

Zone Program Integrity Contractors (ZPICs) and Program Safeguard Contractors (PSCs) referred a total of \$559 million in overpayments to Medicare Administrative Contractors (MACs) in FY 2014; however, the dollar amounts referred varied widely across ZPICs and PSCs. MACs did not collect 80 percent of the \$482 million they sought to collect from these overpayment referrals. MACs' collection rates varied, depending on the type of claim, with home health and hospice overpayments having a collection rate of just 11 percent. Furthermore, ZPICs, PSCs, and MACs continued to experience challenges in tracking referrals and collections of overpayments. Because CMS began transitioning PSCs and ZPICs to Unified Program Integrity Contractors (UPICs) in 2016, our recommendations included these new contractors.

CMS concurred with the following recommendations:

- share best practices across ZPICs and UPICs and address challenges that hinder their identification of overpayments;
- identify strategies to increase MACs' collection of ZPIC- and UPIC-referred overpayments;
- work with ZPICs, UPICs, and MACs to create a standard report format both for overpayment referral reports and overpayment collection reports; and
- require ZPICs, UPICs, and MACs to use a unique identifier for each overpayment.

CMS did not state whether it concurred or did not concur with our recommendation to implement the surety bond requirement for home health and consider the feasibility of requiring surety bonds for other providers based on their level of risk.

Medicare Inappropriately Paid Acute-Care Hospitals for Outpatient Services They Provided to Beneficiaries Who Were Inpatients of Other Facilities ([A-09-16-02026](#)), September 2017

Medicare did not appropriately pay acute-care hospitals any of the \$51.6 million for outpatient services that we reviewed, and beneficiaries were held responsible for unnecessary deductibles and coinsurance of \$14.4 million. Generally, Medicare should not pay an acute-care hospital for outpatient services provided to an inpatient of another facility. The services should be provided under arrangements between the two facilities,

and Medicare should pay the inpatient facility for all the services provided to the beneficiary.

Medicare overpaid the acute-care hospitals because the system edits that should have prevented or detected the overpayments were not working properly. If the system edits had been working properly since 2006, Medicare could have saved almost \$100 million, and beneficiaries could have saved \$28.9 million in deductibles and coinsurance.

CMS concurred with our recommendations that it do the following: direct the Medicare contractors to recover the \$51.6 million in identified improper payments to acute-care hospitals in accordance with CMS's policies and procedures; instruct the acute-care hospitals to refund beneficiaries up to \$14.4 million in deductible and coinsurance amounts that may have been incorrectly collected from them or from someone on their behalf; identify and recover any improper payments to acute-care hospitals after our audit period; correct the system edits to prevent overpayments to acute-care hospitals; and instruct the Medicare contractors to more effectively educate acute-care hospitals not to bill Medicare for outpatient services they provided to beneficiaries who were inpatients of other facilities.

Vulnerabilities Remain in Medicare Hospital Outlier Payments ([A-07-14-02800](#)), September 2017

The summarized results of our reviews of individual Medicare contractors revealed that for the period of October 2003 through March 2011, Medicare contractors did not always refer cost reports that qualified for reconciliation, and CMS did not always ensure that Medicare contractors reconciled the outlier payments associated with cost reports that had been referred. Our previous reviews identified 465 cost reports that qualified for reconciliation of outlier payments.

CMS concurred with our recommendations that it ensure that the Medicare contractors are continuing to take the corrective actions that we recommended in our previous series of reviews and that it maintain a system that identifies and tracks all cost reports Medicare contractors have referred for reconciliation and that it recalculates outlier payments on the basis of claim submissions made by hospitals.

CMS did not directly agree or disagree with our recommendations that it (1) determine whether the cost reports that had exceeded the 3-year reopening limit may be reopened and, if so, that it work with the Medicare contractors to reopen them, and (2) ensure that the Medicare contractors review all cost reports submitted since the end of the audit periods in our previous reviews and ensure that those whose outlier payments qualified for reconciliation are correctly identified, referred, and reconciled in accordance with Federal guidelines.

Shortcomings of Device Claims Data Complicate and Potentially Increase Medicare Costs for Recalled and Prematurely Failed Devices ([A-01-15-00504](#)), September 2017

We determined that the lack of medical device-specific information on the claim forms, along with the limited use of relevant condition codes, impedes CMS's ability to readily identify and effectively track Medicare's total costs related to the replacement of recalled or prematurely failed devices. Using claims data and other data in complex and labor-intensive auditing procedures, we estimated that services related to the replacement of seven recalled and prematurely failed medical devices cost Medicare \$1.5 billion and accrued \$140 million in beneficiary copayment and deductible liabilities during calendar years 2005 through 2014. By including medical device-specific information on the claim forms, CMS could more effectively identify and track Medicare's aggregate costs related to recalled or prematurely failed devices. This could help reduce Medicare costs by identifying poorly performing devices more quickly, which could also protect beneficiaries from unnecessary costs and improve their chances of receiving appropriate followup care more quickly.

CMS stated that it is taking under consideration our recommendation that it continue to work with the Accredited Standards Committee X12 to ensure that the medical device-specific information is included on the next version of claims forms.

CMS concurred with our recommendation "in cases where payment is impacted" that it require hospitals to use appropriate condition codes on claims for reporting a device replacement procedure.

Wisconsin Physicians Service Insurance Corporation Claimed Unallowable Medicare Part A Administrative Costs for Fiscal Year 2012 ([A-05-15-00046](#)), September 2017 and

Wisconsin Physicians Service Insurance Corporation Claimed Unallowable Medicare Part B Administrative Costs for Fiscal Year 2012 ([A-05-15-00047](#)), September 2017

Wisconsin Physicians Service Insurance Corporation (WPS) claimed \$2.5 million in unallowable Medicare Part A and B administrative costs for Federal FY 2012. CMS contracted with WPS, which was a Part A fiscal intermediary for selected providers in 49 States and was a Part B carrier for Illinois, Michigan, Minnesota, and Wisconsin. CMS requested that we audit WPS's Medicare final administrative cost proposal (FACP) for Federal FY 2012.

WPS concurred with our findings in Parts A and B on unallowable lobbying salaries, dues, and donations totaling \$15,874 (\$7,590 in Part A and \$8,284 in Part B) and provided limited comments on our recommendations for procedural improvements for Parts A and B.

WPS did not concur with our recommendations for Parts A and B that it reduce its FACP by \$2.5 million (\$1.2 million in Part A and \$1.3 million in Part B) related to unallowable residual home office expenses; employee incentive program bonuses and related Federal Insurance Contributions Act (FICA) taxes; and salary allocations.

Fox Rehabilitation Claimed Unallowable Medicare Part B Reimbursement for Outpatient Therapy Services ([A-02-16-01004](#)), August 2017

Medicare Part B covers outpatient therapy services, including occupational, physical, and speech therapy. Fox Rehabilitation (Fox), headquartered in New Jersey, was among the largest providers of outpatient therapy services in the country from July 2013 through June 2015.

We estimated that Fox improperly received at least \$29.9 million in Medicare reimbursement for services that did not comply with certain Medicare requirements. For 85 of the 100 claims in our random sample, Fox improperly claimed Medicare reimbursement for outpatient therapy services. From our medical review, we determined that all 85 claims had services that were not medically necessary. For nearly all of these claims, the amount, frequency, and duration of services were not reasonable and consistent with acceptable standards of practice. Further, some services did not require the skills of a licensed therapist or were not an effective treatment for the Medicare beneficiary's condition.

Fox disagreed with our recommendation that it refund \$29.9 million to the Federal Government and ensure that outpatient therapy services are provided and documented in accordance with Medicare requirements.

Medicare Paid Hundreds of Millions in Electronic Health Record Incentive Payments to Noncompliant Eligible Professionals ([A-05-14-00047](#)), June 2017

As an incentive for using certified EHR technology, the Federal Government makes payments to eligible professionals (EPs) and hospitals that attest to the "meaningful use" of EHRs. After reviewing a random sample of EPs who received at least one EHR incentive payment from May 2011 through June 2014, we estimated that CMS paid \$729.4 million in Medicare incentive payments to EPs who did not comply with Federal meaningful-use requirements. CMS also made \$2.3 million in incentive payments that were made for the wrong payment year when EPs switched between Medicare and Medicaid incentive programs.

CMS concurred with our recommendations that it recover payments made to the sampled EPs who did not comply with meaningful-use requirements, educate EPs on documentation requirements, recover \$2.3 million made to EPs after they switched programs, and use computer edits to ensure that an EP does not receive payments under both EHR incentive programs for the same program year.

CMS partially concurred with our recommendations that it review incentive payments to determine which EPs did not meet meaningful-use measures for each applicable program year to attempt recovery of the \$729.4 million, and that it review a random sample of EPs' documentation supporting their self-attestations to identify inappropriate incentive payments that may have been made after the audit period.

Quality of Care, Safety, and Access

A Few States Fell Short in Timely Investigation of the Most Serious Nursing Home Complaints: 2011–2015 ([OEI-01-16-00330](#)), September 2017

We found that nursing home complaints rose by one-third across States from 2011 to 2015. During the period we reviewed, States conducted nearly all the required onsite investigations for the two most serious levels of complaints. Although almost all States conducted most of their onsite investigations within required timeframes, a few States fell short. This data brief raises questions about how some States respond to complaints, as these responses could have serious consequences for nursing home residents in those States. To ensure the health and safety of nursing home residents, CMS must remain vigilant and assist the States that are falling short in meeting timeframes for investigations of complaints.

Early Alert: The Centers for Medicare & Medicaid Services Has Inadequate Procedures To Ensure That Incidents of Potential Abuse or Neglect at Skilled Nursing Facilities Are Identified and Reported in Accordance with Applicable Requirements ([A-01-17-00504](#)), August 2017

This memorandum alerted CMS to the preliminary results of our ongoing review of potential abuse or neglect of Medicare beneficiaries in SNFs. This audit is part of OIG's ongoing efforts to detect and combat elder abuse. We communicated these preliminary results because of the importance of detecting and combating elder abuse.

We identified 134 Medicare beneficiaries whose injuries may have been the result of abuse or neglect that occurred from January 1, 2015, through December 31, 2016. We also found that a significant percentage of these incidents may not have been reported to law enforcement. As a result, we determined that CMS has inadequate procedures to ensure that incidents of potential abuse or neglect of Medicare beneficiaries residing in SNFs are identified and reported. Accordingly, this Early Alert contained suggestions for immediate actions that CMS could take to ensure better protection of vulnerable beneficiaries.

Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing ([OEI-02-17-00250](#)), July 2017

We found that one out of every three beneficiaries received a prescription opioid through Medicare Part D in 2016. Half a million beneficiaries received high amounts of opioids during the year; of these, almost 90,000 beneficiaries were at serious risk of opioid misuse or overdose. These 90,000 beneficiaries either received extreme amounts of opioids or appeared to be "doctor shopping." Moreover, 401 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. OIG is committed to continuing investigations and evaluations to address this issue. In addition, we call on Part D sponsors to work with OIG and CMS to further improve efforts to combat opioid abuse and misuse in Medicare.

Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2017 ([OEI-05-17-00160](#)), June 2017

Overall, we found that the rate of Part D plan formularies' inclusion of the drugs commonly used by dual eligibles (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.

Round 2 Competitive Bidding for CPAP/RAD: Disrupted Access Unlikely for Devices, Inconclusive for Supplies ([OEI-01-15-00040](#)), June 2017

We found that Medicare payments for continuous positive airway pressure (CPAP) devices and respiratory assist devices (RADs) continued after the July 2013 implementation of Round 2 of the Competitive Bidding Program for almost all beneficiaries in both Round 2 bidding areas and non-bidding areas. Although payments for supplies declined more in Round 2 bidding areas, the decline may not indicate disruptions in beneficiaries' receiving needed supplies. For example, the decline may indicate that the program reduced the provision of unnecessary supplies, as CMS determined to be the case with Round 1 of the program.

This report was the first in a series of three examining the effect of Round 2 Competitive Bidding on Medicare beneficiary access to durable medical equipment. Subsequent reports will examine beneficiary access to enteral nutrition supplies and oxygen equipment and supplies.

Program Integrity

The Centers for Medicare & Medicaid Services Could Improve Performance Measures Associated with the Fraud Prevention System ([A-01-15-00509](#)), September 2017

The Fraud Prevention System (FPS), which was developed to meet a requirement in the Small Business Jobs Act of 2010, uses models that predict suspicious behavior to identify and prevent the payment of improper Medicare claims. When performing work to certify the actual and projected savings and the return on investment related to HHS's use of the FPS, we became aware that HHS might not have the capability to trace the savings from administrative actions back to the specific FPS model that generated the savings. CMS could not track those savings because, according to CMS, that capability was not built into the FPS. In addition, CMS did not make use of all pertinent performance results because CMS did not ensure that the contractors' adjusted savings reported to CMS reflected the amounts certified by OIG, and CMS did not evaluate FPS model performance on the basis of the amounts actually expected to be prevented or recovered. As a result, the FPS is not as effective as it could be in preventing fraud, waste, and abuse in Medicare.

CMS concurred with our recommendations that it make better use of its performance results to refine and enhance the predictive-analytics technologies of the FPS models by ensuring that the redesigned FPS is effective in allowing CMS to track savings from administrative actions back to individual FPS models, ensuring that contractors adjust savings reported to CMS to reflect only FPS-related savings amounts, and ensuring that evaluations of FPS model performance consider not only the identified savings but also the adjusted savings.

CMS Validated Hospital Inpatient Quality Reporting Program Data, But Should Use Additional Tools to Identify Gaming ([OEI-01-15-00320](#)), April 2017

For payment year 2016, CMS met its regulatory requirement by validating sufficient hospital inpatient quality reporting program data, which are used to adjust payments based on quality. However, CMS made limited use of analytics, which can help identify gaming of quality data. CMS concurred with our recommendation to make better use of analytics to ensure the integrity of hospital-reported quality data and the resulting payment adjustments.

Payment Policy and Trends

Medicare Payments for Clinical Diagnostic Laboratory Tests in 2016: Year 3 of Baseline Data ([OEI-09-17-00140](#)), September 2017

Medicare paid \$6.8 billion under Part B for clinical diagnostic laboratory tests (lab tests) in 2016, a total that changed very little in the 3-year period from 2014 through 2016. The top 25 tests by Medicare payments totaled \$4.3 billion and represented 63 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.

As part of legislation reforming Medicare's payment rates for lab tests under Part B, 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. Changes in the Medicare payment rates for these 25 tests could have a significant impact on overall Medicare spending for lab tests when the new payment system for lab tests goes into effect in 2018. Our data brief contained no recommendations.

Medicare Shared Savings Program: Accountable Care Organizations Have Shown Potential for Reducing Spending and Improving Quality ([OEI-02-15-00450](#)), August 2017

The Medicare Shared Savings Program is one of the largest alternative payment models in Medicare that reward providers for the quality and value of services. Over the first 3 years of the program, most ACOs in the Medicare Shared Savings Program reduced Medicare spending compared to their benchmarks, achieving a net spending reduction (i.e., total reduced spending minus total increased spending) of nearly \$1 billion. At the same time, ACOs generally improved the quality of care they provided, according to an analysis of

CMS data on quality measures. Further, our analysis of CMS data for the first 3 years revealed that a small subset of high-performing ACOs showed substantial reductions in Medicare spending while providing high-quality care, as compared to other Shared Savings Program ACOs and the national average for fee-for-service providers.

Medicare Market Shares of Mail-Order Diabetes Test Strips From October Through December 2016 ([OEI-04-16-00473](#)), June 2017

We found that from October through December 2016, sampled suppliers provided 19 types of diabetes test strips via the Medicare National Mail-Order program. The top 2 strip types accounted for 53 percent of the Medicare mail-order market, and the top 10 strip types accounted for 97.5 percent.

This was the third of three OIG reports addressing the Medicare market shares of diabetes test strips in 2016. This report provides additional information on the market shares of types of diabetes test strips provided by Medicare from October through December 2016. CMS will use the results from the second OIG report ([OEI-04-16-00471](#), February 2017) to determine bidders' adherence with the "MIPPA 50-percent rule" for the next round of competitive bidding. (The Medicare Improvements for Patients and Providers Act (MIPPA) prohibits CMS from awarding a contract to a supplier of diabetes test strips if the supplier's bid does not cover at least 50 percent, by volume, of all types of diabetes test strips on the market.) Contracts for the current round of the National Mail-Order program began on July 1, 2016, and expire on December 31, 2018.

Medicare Could Save Millions by Eliminating the Lump Sum Purchase Option for All Power Mobility Devices ([A-05-15-00020](#)), May 2017

Medicare Part B covers power mobility devices, which include power-operated vehicles and standard and complex power wheelchairs. Effective January 1, 2011, the Affordable Care Act (ACA) eliminated the lump-sum purchase option for standard rehabilitative power wheelchairs, requiring suppliers to provide these devices on a monthly rental basis. From 2011 through 2014, Medicare saved up to an estimated \$86 million by eliminating the lump-sum purchase option for standard power wheelchairs. However, the lump-sum purchase option remained available for nonstandard power mobility devices—i.e., power-operated vehicles and complex power wheelchairs.

Medicare could save millions by eliminating the lump-sum purchase option for all power mobility devices and requiring that all power mobility devices be provided to beneficiaries on a monthly rental basis. Medicare could have saved an additional \$10,245,539 from calendar years 2011 through 2014 if it had eliminated the lump-sum payment option for all power mobility devices.

CMS stated it would consider our recommendation that it seek legislation to eliminate the lump-sum payment option for all power mobility devices.

Drug Pricing and Reimbursement

CMS and Its Claims Processing Contractors Issued Conflicting Guidance on the Proper Use of the KX Modifier for Part B Immunosuppressive Drug Claims ([A-06-15-00018](#)), August 2017

Medicare Part B covers immunosuppressive drugs for beneficiaries who receive an organ transplant for which Medicare payment has been made. A record of fee-for-service transplant claims should be retained in the beneficiary's claims history. When Medicare cannot locate a fee-for-service claim in a beneficiary's history, a pharmacy can submit a claim for an immunosuppressive drug with a KX modifier to indicate that it has records showing that the beneficiary is eligible for Medicare coverage. In FY 2014, Part B paid almost \$353 million for immunosuppressive drugs and nearly 100 percent of the claims were submitted with the KX modifier. CMS intended the KX modifier to signify that the pharmacy had documentation proving that a beneficiary's organ transplant occurred when the beneficiary was eligible for Medicare coverage. However, CMS guidance is not clearly written and the guidance issued by claims processing contractors conflicted with CMS guidelines by indicating that claims without the KX modifier would be denied.

Part B paid for some immunosuppressive drugs billed with the KX modifier that were not eligible for Part B payment. Of the 75 claims in our random sample, pharmacies did not have documentation to support the KX modifier for 10 claims. On the basis of our sample results, we estimated that Part B paid \$4.6 million in reimbursement for immunosuppressive drugs billed with the KX modifier that did not comply with Medicare requirements.

CMS concurred with our recommendation that it clarify language in its guidance and instruct the claims processing contractors to process immunosuppressive drug claims without the KX modifier and educate pharmacies on the correct use of the modifier.

Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2015 Average Sales Prices ([OEI-03-17-00360](#)), September 2017

OIG is required to compare the average sales price (ASP) with the average manufacturer price (AMP) of drugs reimbursed under Medicare Part B. If OIG finds that the ASP for a drug exceeds the AMP by a certain percentage, CMS can substitute the ASP-based amount with the lower rate. In response to data provided by OIG, CMS lowered Part B reimbursement for 13 drugs, saving Medicare and its beneficiaries \$5.4 million over 1 year based on 2015 data. This finding highlights the success of OIG's mandated quarterly comparisons of average sales prices with AMPs 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 to expand the price-substitution policy and believes that more experience with this policy is needed before it can be expanded.

Calculation of Potential Inflation Indexed Rebates for Medicare Part B Drugs ([OEI-12-17-00180](#)), August 2017

In response to a congressional request, OIG found that if Medicare Part B were to implement a prescription drug rebate program similar to Medicaid's, it could have resulted in at least \$1.4 billion in rebates in 2015 for Part B drugs when prices increased faster than inflation. Any consideration of a rebate program should address several administrative issues that may hinder rebate collections. This report had no recommendations.

Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2014 Average Sales Prices ([OEI-03-16-00540](#)), August 2017

OIG is required to compare the ASP with the AMP of drugs reimbursed under Medicare Part B. If OIG finds that the ASP for a drug exceeds the AMP by a certain percentage, CMS can substitute the ASP-based amount with a lower rate. In response to data provided by OIG, CMS lowered Part B reimbursement for 14 drugs, saving Medicare and its beneficiaries \$24 million over 1 year based on 2014 data. This finding highlights the success of OIG's mandated quarterly comparisons of ASPs with AMPs 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 to expand the price-substitution policy and believes that more experience with this policy is needed before it can be expanded.

Medicaid Program Reports and Reviews

Financial Management and Improper Payments

Arkansas Did Not Make Supplemental Payments in Accordance with Federal Requirements ([A-06-15-00042](#)), September 2017

To encourage primary care providers to participate in Medicaid, the ACA required States to pay increased Medicaid payments (supplemental payments) to eligible providers in calendar years 2013 and 2014. The States received a Federal matching rate of 100 percent for any supplemental payment.

Arkansas did not always make the supplemental Medicaid payments in accordance with Federal requirements. Of the 120 supplemental payments in our stratified random sample, 88 were incorrectly calculated, made to ineligible providers, or both. We estimated that Arkansas improperly received at least \$7.1 million in additional Federal share, of which we recommended recovery of approximately \$3 million.

Arkansas concurred with our findings, which were the basis of our recommendation that it refund approximately \$3 million to the Federal Government for the Federal share associated with the inappropriate supplemental payments.

Texas Improperly Received Medicaid Reimbursement for School Based Health Service ([A-06-14-00002](#)), August 2017

To ascertain the portion of time and activities of a school-based health program that is related to the provision of Medicaid services, States may develop an allocation methodology that is approved by CMS. Random moment sampling, which makes use of random moment time studies, is an approved allocation methodology and must reflect all of the time used and activities performed by employees participating in a school-based health program. Not all of the direct medical service costs that the State agency claimed for Medicaid School Health and Related Services (SHARS) were reasonable, adequately supported, and otherwise allowable in accordance with applicable Federal and State requirements. Of the 3,161 random moments we reviewed, 274 were coded incorrectly. As a result of these errors, Texas received \$18.9 million in unallowable Federal reimbursement for the Medicaid SHARS program from October 2010 through September 2011.

Additionally, Texas's random moment sampling did not include all eligible sample moments in the random moment time studies. Also, we were unable to reproduce the sampling process or verify that Texas and the contractor did not make any unallowable changes to the sample. Thus, we are unable to verify whether the sample was valid.

Texas neither agreed nor disagreed with our recommendations that it refund the \$18.9 million Federal share of unallowable reimbursement that was claimed for the Medicaid SHARS program.

New York State Improperly Claimed Medicaid Reimbursement for Some Managed Long Term Care Payments ([A-02-15-01026](#)), August 2017

Medicaid Managed Long-Term Care (MLTC) plans under contract with New York receive fixed monthly payments to provide services to Medicaid beneficiaries who are chronically ill or disabled and who wish to stay in their homes and communities. In return, the plans agree to the terms of New York's MLTC contract, which was approved by CMS.

New York improperly claimed reimbursement for 36 of 100 payments made to MLTC plans that we reviewed. New York did not ensure that MLTC plans documented eligibility assessments of program applicants and reassessments of those already in the program or conducted these assessments in a timely manner. New York also did not ensure that the plans provided services to beneficiaries according to a written care plan or that the plans enrolled and retained only those beneficiaries who required community-based services and disenrolled beneficiaries in a timely manner. In addition, for 71 beneficiaries associated with the payments we reviewed, the beneficiaries' MLTC plans did not comply with New York's contract requirements for service planning and care management. As a result, there could have been health and safety risks to these beneficiaries.

New York did not concur or nonconcur with our recommendations that it (1) develop procedures to monitor MLTC plans for compliance with requirements in its contract and (2) ensure that future contracts include provisions that allow it to recover payments when plans do not comply with contract requirements. This measure could have saved Medicaid \$1.4 billion (\$717 million Federal share) during our 1-year audit period.

New Jersey Claimed Medicaid Reimbursement for Adult Partial Hospitalization Services That Did Not Comply with Federal and State Requirements ([A-02-14-01015](#)), April 2017

We identified a significant number of services provided by New Jersey on an outpatient basis to adults with mental illnesses, known as partial hospitalization services, that were improperly submitted for Federal Medicaid reimbursement.

New Jersey claimed at least \$30.7 million in Federal Medicaid reimbursement over 4 years for adult partial hospitalization services that were unallowable. Of the 100 New Jersey claims for reimbursement for these services that we sampled, all 100 did not comply with Federal and State requirements, and 92 contained more than 1 deficiency. We estimated that New Jersey improperly claimed at least \$30.7 million in Medicaid reimbursement for these services.

New Jersey did not concur or nonconcur with our recommendations that it ensure that partial hospitalization services are provided by appropriately licensed hospitals, issue guidance to providers on requirements for claiming Medicaid reimbursement for partial hospitalization services, improve its monitoring of partial hospitalization services providers, review and revise payment controls to ensure the correct rates are paid for partial hospitalization services, and work with CMS to identify claims outside of our audit period that were paid at an incorrect rate or for services that were not provided by an appropriate facility.

CMS did not concur with our recommendation that it refund \$30.7 million.

Ohio's and Michigan's Sales and Use Taxes of Medicaid Managed Care Organization Services Do Not Meet Broad Based Requirement ([A-03-16-00200](#)), April 2017

In 2016, Ohio and Michigan did not meet Federal requirements that taxes on Medicaid managed care organizations (MCOs) be broad-based. Specifically, they continued to tax only Medicaid MCOs under their sales and use tax programs. Ohio stated that it would work with CMS to address changes that might need to be made to its tax.

Our review covered eight States (California, Georgia, Kentucky, Michigan, Missouri, Ohio, Oregon, and Pennsylvania) that the National Conference of State Legislatures identified as continuing to tax only Medicaid MCOs as of June 2009. Two States—California and Pennsylvania—implemented new MCO tax programs effective July 1, 2016, to conform to the Deficit Reduction Act. Four States (Georgia, Kentucky, Missouri, and Oregon) discontinued collecting their Medicaid MCO-only tax on September 30, 2009, to conform to the Deficit Reduction Act. CMS granted Ohio a waiver that would bring Ohio's proposed MCO tax into compliance and became effective on July 1, 2017. Michigan discontinued its tax on December 31, 2016, as scheduled, and is now also in compliance.

CMS concurred with our recommendation that it monitor Ohio's and Michigan's use of revenues from their sales and use tax on Medicaid MCOs as part of the State share of Medicaid program expenditures after December 31, 2016, and verify that they conform to Federal requirements that such taxes be broad-based.

California Incorrectly Claimed Additional Medicaid Funding Authorized Under the Recovery Act When Reclaiming Overpayments Made to Bankrupt or Out of Business Providers (A-09-14-02030), April 2017

States are required to refund to the Federal Government the Federal share of a Medicaid overpayment at the end of the 1-year period following the date the overpayment is identified. If a State determines that the overpayment is uncollectable because the provider is bankrupt or out of business, the State is allowed to reclaim the Federal share of the overpayment.

For FYs 2010 through 2013, California claimed \$58.3 million in Federal reimbursement for Medicaid uncollectable overpayments. We reviewed California because the Federal reimbursement it claimed for uncollectible overpayments during this period represented approximately 70 percent of the total nation-wide.

California incorrectly used Federal medical assistance percentages (FMAPs) increased by the American Recovery and Reinvestment Act (Recovery Act) to claim additional Federal reimbursement of almost \$6.6 million for 250 uncollectible overpayments that were not originally made during the recession adjustment period or were not previously refunded to the Federal Government using the increased FMAPs.

California agreed with our recommendations that it refund almost \$6.6 million to the Federal Government and ensure that it uses the FMAPs in effect when the original

overpayments were made and refunded when claiming Federal reimbursement for uncollectible overpayments.

Medical Loss Ratio

Private health insurers, Medicare Advantage plans, and Medicare Part D sponsors are required to spend a fixed percentage of premium dollars to provide medical services and health quality improvement activities. This percentage is known as a medical loss ratio (MLR).

Review of Wisconsin Medicaid Managed Care Program Potential Savings With Minimum Medical Loss Ratio ([A-05-15-00040](#)), June 2017, and

Review of Pennsylvania Medicaid Managed Care Program Potential Savings With Minimum Medical Loss Ratio ([A-03-15-00203](#)), July 2017

These two reports are part of a series of reviews that OIG conducted to determine whether Medicaid could achieve savings if States required Medicaid MCOs to meet a minimum MLR standard and pay remittances if the MLR standard were not met.

In 2014, Wisconsin could have saved \$16.2 million (\$9.6 million Federal share) and Pennsylvania could have saved between \$8 million (\$4.3 million Federal share) on a contract and grant basis and \$81.4 million (\$42.3 million Federal share) on a rating category basis if the two States (1) required their Medicaid managed care plans to meet the minimum MLR standard similar to the Federal standards for other plans and (2) required remittances when Medicaid managed care plans did not meet the MLR standard.

Of the 11 managed care plans we reviewed in Wisconsin, 4 plans had MLRs that were less than 85 percent (the minimum MLR standard for large private insurers) during 2014. Of the 27 contracts and grants that we reviewed in Pennsylvania, 6 had MLRs that were less than 85 percent during 2014. After our reviews but before the issuance of our reports, CMS published a final rule requiring Medicaid MCOs to achieve a minimum MLR for rate-setting purposes.

Wisconsin and Pennsylvania agreed with our recommendations that they incorporate into their contracts with Medicaid MCOs the MLR standards adopted in the CMS final rule and consider implementing into their Medicaid MCO contracts a remittance requirement if appropriate.

Quality of Care, Safety, and Access

Maine Did Not Comply with Federal and State Requirements for Critical Incidents Involving Medicaid Beneficiaries with Developmental Disabilities ([A-01-16-00001](#)), August 2017

Maine did not comply with Federal Medicaid waiver requirements and State requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities. Maine did not ensure that community-based providers

reported all critical incidents to Maine; did not ensure that community-based providers conducted administrative reviews of all critical incidents involving serious injuries, dangerous situations, or suicidal acts and submitted their findings within 30 days; did not appropriately report all restraint usage and rights violations; did not review and analyze data on all critical incidents; did not investigate and report immediately to the appropriate office all critical incidents involving suspected abuse, neglect, or exploitation; and did not ensure that all beneficiary deaths were appropriately reported, analyzed, investigated, and reported to the appropriate office.

Maine failed to demonstrate that it has a system to ensure the health, welfare, and safety of the 2,640 Medicaid beneficiaries with developmental disabilities covered by the Medicaid waiver program.

Maine agreed or partially agreed with all our recommendations that it fully implement its regulations regarding the reporting and monitoring of critical incidents to fulfill the participant safeguard assurances it provided in its Medicaid waiver and help protect Medicaid beneficiaries from harm.

Program Integrity

Challenges Appear To Limit States' Use of Medicaid Payment Suspensions ([OEI-09-14-00020](#)), September 2017

When State Medicaid agencies determine an allegation of fraud against a provider is credible, they are required to suspend payments for health care items and services, unless good cause exists not to suspend payments. Most State Medicaid agencies (41 of 56) reported imposing 10 or fewer payment suspensions in FY 2014. Medicaid agencies reported significant challenges related to imposing payment suspensions, which appear to have limited States' use of this program integrity tool. CMS concurred with our recommendation to provide additional technical assistance to help Medicaid agencies fully utilize Medicaid payment suspensions as a program integrity tool.

T-MSIS Data Not Yet Available for Overseeing Medicaid ([OEI-05-15-00050](#)), June 2017

OIG's most recent review of the Transformed Medicaid Statistical Information System (T-MSIS) continues to identify concerns with T-MSIS data. Medicaid data are vital for the effective administration and oversight of the Medicaid program by States and the Federal Government, but problems with Medicaid data have hindered program integrity, research, budgeting, and policy.

After failing to meet the implementation deadline of January 2014, CMS and States reported that technological problems and competing priorities caused further delays with T-MSIS. Most recently, CMS indicated that it expects that all States will be reporting to T-MSIS by the end of 2017. As of December 2016, 21 States were submitting data.

As States and CMS work together to enter data into T-MSIS, they continue to raise concerns about the completeness and reliability of the data. Because of CMS's history of delaying target dates for implementation, OIG is concerned that CMS and States will delay further rather than address these outstanding challenges. OIG continues to support our 2013 recommendation that CMS establish a deadline for when T-MSIS data will be available for program analysis and other management functions. Without a fixed deadline, some States and CMS may not make T-MSIS a management priority.

Florida Did Not Suspend Medicaid Payments for Some Cases With Credible Fraud Allegations in Accordance with the Affordable Care Act ([A-04-14-07046](#)), April 2017

Florida did not always suspend Medicaid payments to providers that had credible fraud allegation cases in accordance with legal requirements. Of the 95 cases that we reviewed, Florida did not suspend Medicaid payments for 54 cases. For four cases, investigations into credible allegations of fraud were ongoing, but Florida did not suspend Medicaid payments. As such, the Federal share (\$8 million) of these payments was not eligible for Federal reimbursement. For one case with a completed investigation that resulted in a civil settlement, Florida did not provide documentation to support that it returned the Federal share of \$236,544 to the Federal Government. For 49 cases for which investigations were complete, Florida had not suspended Medicaid payments totaling \$40 million (Federal share) when the fraud investigations were pending.

Florida did not concur with our recommendations that it refund \$8 million to the Federal Government and update its policies and procedures to ensure that it suspends Medicaid payments to providers with credible allegations of fraud, which could have prevented \$40 million (Federal share) from being at risk.

Florida partially concurred with our recommendation that it refund \$236,544 to the Federal Government related to one case for which Florida did not provide documentation to support that it returned the Federal share to the Federal Government.

Payment Policy and Trends

Medicaid Eligibility Determinations

The ACA gave States the option to expand Medicaid coverage to low-income adults without dependent children and established a higher Federal reimbursement rate (FMAP) for services provided to these newly eligible beneficiaries. We examined whether Kentucky was determining Medicaid eligibility for all its beneficiaries in accordance with Federal and State requirements.

Kentucky Did Not Correctly Determine Medicaid Eligibility for Some Newly Enrolled Beneficiaries ([A-04-15-08044](#)), May 2017, and

Kentucky Did Not Always Perform Medicaid Eligibility Determinations for Non-Newly Eligible Beneficiaries in Accordance with State and Federal Requirements ([A-04-16-08047](#)), August 2017

Of our sample of 120 newly enrolled beneficiaries, Kentucky did not determine the eligibility for 9 in accordance with Federal and State requirements. For our sample of 120 non-newly

enrolled beneficiaries, Kentucky did not determine the eligibility in accordance with requirements for 7. Kentucky did not always electronically or manually verify income and citizenship or keep documentation of that verification. And although it did not violate an eligibility requirement, Kentucky did not perform, or maintain documentation of, identity-proofing for 40 newly enrolled beneficiaries or 13 non-newly enrolled beneficiaries in accordance with Federal requirements. The Federal identity-proofing requirements are intended to reduce the potential for identity theft.

Kentucky made Federal Medicaid payments on behalf of 34,593 potentially ineligible newly enrolled beneficiaries totaling \$105 million. Kentucky made Federal Medicaid payments on behalf of 69,931 potentially ineligible non-newly enrolled beneficiaries totaling \$72.8 million. We did not include the identity-proofing errors in our estimate of potentially ineligible beneficiaries and payments, but we are highlighting the potential for identity theft if Kentucky does not correct these errors.

Kentucky agreed with our recommendation in both reports that it redetermine, if necessary, the current Medicaid eligibility status of the sample beneficiaries for whom income or citizenship verifications did not meet Federal and State requirements. For the newly enrolled beneficiaries, Kentucky also agreed with our recommendations that it ensure that the enrollment system used to determine eligibility verifies income and citizenship data using available electronic data sources and ensure that the enrollment system used verifies applicants' identity and maintains identity-proofing documentation.

Drug Pricing and Reimbursement

Previous OIG reviews found that States did not always bill and collect all rebates due for drugs administered by physicians to enrollees of Medicaid MCOs. For pharmacy and physician-administered drugs, Washington did not bill for and collect from manufacturers rebates of \$34.1 million (\$17 million Federal share), and Hawaii did not bill for and collect from manufacturers rebates of \$18.8 million (\$9.7 million Federal share).

Washington State Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations ([A-09-16-02028](#)), September 2017

Hawaii Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations ([A-09-16-02029](#)), September 2017

Washington and Hawaii concurred or partially concurred with our recommendations that they bill for and collect from manufacturers rebates for pharmacy drugs and refund \$34.1 million (Washington) and \$18.8 million (Hawaii); work with CMS to determine the amount of any rebates due for the 17,140 claim lines that we set aside (Washington) or whether the other physician-administered drugs were eligible for rebates and, if so, determine the rebates due (Hawaii); and improve oversight of the processes for determining drug rebate eligibility (Washington) and rebate billing and collection (Hawaii) to ensure that MCOs submit valid and complete drug utilization data for pharmacy and physician-administered drugs dispensed to MCO enrollees.

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,
- durable medical equipment, and
- diagnostic radiology and laboratory testing.

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

In addition to investigating Medicare and Medicaid fraud, OIG investigates fraud, waste, and abuse in other HHS programs, including ACF, IHS, the 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 health care programs involves filing false claims for reimbursement. False claims may be pursued under Federal and State criminal statutes and, when appropriate, under the 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 health care programs. Frequently used exclusion and penalty authorities are described on our website at <http://oig.hhs.gov/fraud/enforcement/cmp/>.

During this semiannual reporting period, we reported 373 criminal and 360 civil actions against individuals or entities that engaged in offenses related to health care. We also reported over \$1.62 billion in investigative receivables due to HHS and more than \$422.4 million in non-HHS investigative receivables, including civil and administrative settlements or civil judgments related to Medicare, Medicaid, and other Federal, State, and private health care programs.

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

Prescription Drugs

New York—Leopoldo Tejada and his codefendants conducted a scheme to defraud Medicaid, Medicare, and the New York State-funded AIDS Drug Assistance Program (ADAP) through the purchase and sale of illegally diverted prescription drugs. Specifically, from 2006 through August 2013 the defendants purchased prescription drugs, including high-cost medications used to treat HIV, that were obtained from patients who sold the drugs rather than use them to treat their illnesses. The drugs were then repackaged and resold to their customers, as if they were new drugs obtained from legitimate sources. The defendants requested and received reimbursement from Medicaid, Medicare, and ADAP in connection with these sales, even though these programs would not have been willing to reimburse the cost of secondhand drugs.

Tejada pleaded guilty to conspiracy to commit wire and health care fraud and was ordered to pay \$7.5 million in restitution, joint and several. Two defendants involved in the scheme were previously sentenced to a combined 3 years and 1 month in prison and ordered to pay \$7.5 million restitution, joint and several. To date, four codefendants have been excluded from participation in Federal health care programs for a combined 102 years.

Michigan—Three co-conspirators connected with the health care provider Compassionate Doctors, PC, were convicted of charges resulting from their involvement in an unlawful prescription drug operation. In all, they were sentenced to a combined 46 years and 4 months in prison, and ordered to pay \$10.7 million in restitution.

The defendants—Compassionate Doctors, PC, owner Sardar Ashrafkhan; Dr. Adelfo Pamatmat; and pharmacist Nadeem Iqbal—conspired to operate a fraudulent medical practice and pharmacy. Compassionate Doctors, PC, purported to be a visiting physician's practice; however, the actual scheme involved patient marketers bringing paid "patients" to residences to obtain fraudulent prescriptions for controlled substances. Medicare was billed for medical examinations and tests that were not conducted properly or were never conducted at all. At the cooperating pharmacy, patient marketers filled prescriptions for controlled substances to be sold on the street for profit.

Twenty-eight defendants involved in the scheme were previously sentenced to a combined 134 years and 11 months in prison and held responsible, both joint and several, for part of the \$10.7 million in restitution. To date, 27 codefendants in this matter have accounted for a cumulative 371 years towards exclusion from Federal health care programs.

Pharmaceutical Companies

Massachusetts—Mylan Inc. and Mylan Specialty L.P. (collectively, Mylan) agreed to pay \$465 million to resolve FCA liability associated with the drug EpiPen. Specifically, Mylan resolved allegations that from July 29, 2010, through March 31, 2017, it improperly classified EpiPen as a generic drug rather than a brand-name drug for purposes of the Medicaid drug rebate program. As a result, Mylan allegedly underpaid rebates to Medicaid for EpiPen and overcharged covered entities that purchased EpiPen under the 340B Drug Discount Program, which requires drug manufacturers to charge covered entities prices that are at or below ceiling prices. Concurrent with the FCA settlement, Mylan entered into a 5-year CIA, which requires an independent review organization to annually review multiple aspects of Mylan's practices relating to the Medicaid drug rebate program.

Physicians

Pennsylvania—Dr. Jeffrey Bado was a physician who owned a medical practice. Evidence at trial showed that Bado had prescribed large amounts of oxycodone and methadone to patients outside the usual course of professional practice and without medical necessity. By the time Bado's practice closed in 2013, he was charging new patients \$800 cash per visit, charging returning patients \$400 cash, and refusing to accept medical insurance. Bado's patients received at most a cursory physical examination and little other medical care or treatment. Even when Bado knew patients were addicted to oxycodone, were using illegal drugs, or were not taking the oxycodone prescribed, he continued to provide prescriptions for large amounts of oxycodone. Multiple former patients testified to becoming addicted to oxycodone prescribed by him. There was no evidence at trial suggesting that Bado had referred patients to opioid addiction treatment. Bado was convicted of 307 felony counts, including maintaining a drug-involved premises, drug distribution resulting in a death, drug distribution, health care fraud, and making false statements to Federal agents. He was sentenced to 25 years in prison.

Home Health

Texas—Dr. Jacques Roy was engaged in a large-scale, sophisticated home health care scheme to defraud Medicare and Medicaid. According to evidence presented at trial, from November 2004 through February 2012, Roy and his codefendants were involved in a scheme to recruit patients to receive unnecessary home visits and home health services. In some instances, the home health agencies paid recruiters kickbacks to find Medicare beneficiaries at a homeless shelter. The home health agency owners falsified documents to make it appear as though the beneficiaries qualified for home health care services, and Roy directed his staff to certify the beneficiaries for home health services, regardless of medical need. After an individual was certified for home health care services, the home health

nurses then falsified visit notes to make it appear as though skilled nursing services were being provided and continued to be necessary, and the home health agencies and Roy submitted fraudulent claims to Medicare.

Roy and his co-defendants were convicted of conspiracy to commit health care fraud, health care fraud, making a false statement relating to health care matters, and obstruction of justice. Roy was sentenced to 35 years in prison and ordered to pay \$268.1 million in restitution, joint and several with his codefendants. Five additional defendants involved in the scheme were previously sentenced to a combined 41 years and 6 months and ordered to pay joint and several portions of the \$268.1 million restitution.

Ohio—Delores Knight, owner of the home health agency Just Like Familee (JLF), and three of her employees were involved in a scheme to submit false claims to Medicare, Medicaid, and other Federal health programs. Together, the four individuals engaged in a conspiracy to prepare and submit forged or false records in support of previously submitted and reimbursed billings for patients they did not actually provide face-to-face services. Delores Knight and her son, Isaac Knight, the administrator of one of the JLF offices, were found guilty of conspiracy to commit health care fraud and health care fraud. Delores Knight was also convicted of money laundering. The defendants were ordered to serve a combined 17 years and 3 months in prison, and ordered to pay \$8.1 million in restitution, joint and several. Director of nursing Sonja Ferrell and biller Juliet Bonner pleaded guilty to health care fraud and were sentenced to serve a combined 1 year and 6 months in prison, and were ordered to pay \$1.4 million in restitution, joint and several.

Transportation

Pennsylvania—Yuriy Nesterov, owner of Triumph Ambulance, Inc., engaged in a scheme to defraud Medicare. Specifically, Triumph Ambulance employees, at the direction of Nesterov, transported Medicare beneficiaries by ambulance or in personally owned vehicles to regularly scheduled dialysis treatments. These patients were not medically eligible for ambulance transportation reimbursed by Medicare. Nesterov submitted false claims to Medicare for reimbursement and also provided kickbacks to Medicare beneficiaries. Nesterov pleaded guilty to 12 counts of health care fraud and was sentenced to 3 years' confinement and ordered to pay \$690,390 in restitution.

Durable Medical Equipment

New Jersey—Multiple businesses entered into two separate settlement agreements to resolve allegations that the defendants knowingly caused false claims to be submitted in connection with cardiac monitoring services. The first settlement agreement was with AMI Monitoring, Inc.; Spectacor, LLC; and Joseph Bogdan, and the second agreement was with Medi-Lynx Cardiac Monitoring, LLC (Medi-Lynx), and Medicalgorithmics S.A.

The defendants allegedly marketed cardiac monitoring services and designed a Web-based registration system that led to the submission of, or caused the submission of, false claims for cardiac monitoring services. Specifically, AMI Monitoring, Inc. and Medi-Lynx marketed

a cardiac monitoring device called the PocketECG. This device, created by Medicalgorithmics, S.A., is unique in that it is capable of performing as a short-term Holter monitor, a medium-term event monitor, or a longer term telemetry monitor. Although the PocketECG was capable of performing all three cardiac monitoring functions, the defendants allegedly designed the Web-based device registration system in such a way as to steer physicians to select telemetry—which provided the highest rate of reimbursement—for all Medicare patients, even when they wanted to select one of the less expensive services.

The defendants agreed to pay a total of \$13.4 million to resolve their FCA liability, and Medi-Lynx also agreed to a 5-year CIA.

Georgia—Barbara Wallace was the manager of MBA Diabetic Footwear Solutions, a Medicaid provider. The investigation disclosed that Wallace caused fraudulent claims to be submitted to Medicaid for medical equipment that was not medically necessary, not prescribed by a physician, and, on many occasions, never provided to a patient. Wallace then used the money defrauded from Medicaid for her own personal benefit. Wallace pleaded guilty to one count of health care fraud and was sentenced to 3 years and 5 months in prison and ordered to pay \$948,361 in restitution and forfeiture.

Laboratories

South Carolina—Berkeley Heartlab, Inc. (Berkeley) and its indirect owner, Quest Diagnostics, Inc. (Quest), entered into a settlement agreement to resolve that Berkeley knowingly submitted or caused to be submitted false or fraudulent claims to Medicare and TRICARE. From 1999 through January 2012, the defendant allegedly offered and/or paid illegal remuneration to health care providers through ‘process and handling’ payments related to the collection of blood to induce referrals in violation of the anti-kickback statute. To induce referrals to Berkeley for testing, Berkeley allegedly offered to waive and/or waived cost-sharing obligations (such as copayments and deductibles) for certain TRICARE beneficiaries, in violation of the anti-kickback statute. The defendant also allegedly submitted or caused to be submitted claims for payment to Medicare and TRICARE for tests that were not medically necessary or that were not reimbursable. Quest and Berkeley agreed to pay \$6 million to resolve Berkeley’s liability under the FCA.

Radiology

California—Valley Tumor Medical Group (Valley Tumor) entered into a settlement agreement to resolve allegations that from January 2006 through November 2015, the defendant billed Medicare, Medi-Cal (California’s Medicaid program), and TRICARE for radiation treatments at the Ridgecrest location without the requisite physician supervision. Specifically, radiation therapists employed by Valley Tumor allegedly administered regular radiation treatments when no doctor was present onsite and there was thus no doctor physically available to supervise such treatments. The defendant agreed to pay \$3 million to resolve its liability under the FCA.

Nursing Homes

California—Genesis Healthcare, Inc. (Genesis) entered into a settlement agreement to resolve allegations that it knowingly caused false claims to be submitted to Medicare. Genesis owns SNFs, assisted/senior living facilities, and a rehabilitation therapy business, which were all defendants. Specifically, the defendants were alleged to have submitted false claims to Medicare for hospice services provided to patients who were not eligible for the benefit; knowingly submitted claims to Medicare for services that were not medically necessary or unskilled in nature; billed for more therapy minutes than the patient received or at a higher level than medically necessary; and submitted claims to Medicare and Medi-Cal for services that were not rendered, grossly substandard or worthless. Genesis agreed to pay a total of \$52.1 million to resolve its FCA liability.

Identity Theft

New York—Davit Mirzoyan was a leader of the Mirzoyan-Terdjanian Crew, a criminal organization responsible for defrauding Medicare. According to the investigation, Mirzoyan and his codefendants stole the identities of doctors, set up fake medical clinics in their names, and then stole identities of patients so that Medicare could be billed for fictitious medical treatments. Mirzoyan pleaded guilty to racketeering, conspiracy to commit health care fraud, bank fraud, money laundering, and identity theft. He was sentenced to 17 years and 6 months in prison and ordered to pay \$20 million in restitution and \$20 million in forfeiture. Sixteen defendants involved in the scheme were previously sentenced to a combined 51 years and 1 month in prison.

Hospitals

California—Pacific Alliance Medical Center, an acute-care hospital, entered into a settlement agreement to resolve allegations that it engaged in improper financial relationships with referring physicians. Specifically, these relationships took the form of arrangements under which the hospital allegedly paid above-market rates to rent office space in physicians' offices, and marketing arrangements that allegedly provided undue benefit to physicians' practices. The hospital agreed to pay a total of \$42 million to resolve its FCA liability and enter into a 5-year CIA.

Kickbacks

New York—Giorgi Buleishvili was a patient recruiter when he took part in a scheme to defraud Medicare and Medicaid. According to the investigation, Buleishvili and his co-defendants recruited financially disadvantaged and homeless people insured by Medicare and/or Medicaid (the phony patients) to undergo unnecessary medical tests. The phony patients were recruited from soup kitchens and local welfare offices. They were coached on what to say on various medical forms in order to make it falsely appear that the medical tests to which the defendants intended to subject them were medically necessary. The tests were typically performed by unlicensed personnel at the clinics in exchange for cash. The clinics then billed Medicare and Medicaid for administering those unnecessary tests.

Buleishvili pleaded guilty to conspiracy to commit mail fraud, wire fraud, and health care fraud. He was sentenced to 2 years and 10 months in prison and was ordered to pay \$13.7 million in restitution, joint and several. Eleven defendants involved in the scheme were previously sentenced to a combined 18 years in prison and held jointly and severally responsible for various amounts of the total \$26.2 million restitution.

Health Information Technology

Vermont—eClinicalWorks, LLC (ECW), one of the nation's largest vendors of EHR software, and three senior executives agreed to pay \$155 million to settle allegations related to causing health care providers to submit false claims to the Medicare and Medicaid EHR Incentive Programs. Specifically, from August 2008 through February 1, 2017, ECW allegedly concealed from its customers that its software did not comply with the requirements for "meaningful use" certification. ECW's failure to comply with requirements to use standardized drug codes, to accurately record user actions in an audit log, and to always accurately record diagnostic imaging orders or perform drug interaction checks posed potential risks to patient safety. Concurrently with the settlement, ECW entered into a 5-year CIA that requires it to, among other things, retain an independent software quality oversight organization to assess ECW's software quality control systems and provide written semiannual reports to OIG; 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 risks to patient safety.

Managed Care

Florida—Freedom Health Inc. (FHI), a managed care service provider, and its related corporate entities agreed to pay more than \$31 million to resolve allegations that they violated the FCA by submitting or causing others to submit unsupported diagnosis codes to CMS, resulting in inflated reimbursements from 2008 to 2013 in connection with two Florida Medicare Advantage plans. FHI also allegedly made material misrepresentations to CMS regarding the scope and content of its provider networks in its Medicare Advantage applications to CMS to expand into new Florida counties and in other States. Concurrently with the settlement, FHI and Optimum HealthCare, Inc., as operators of Medicare Advantage plans, entered into a 5-year CIA containing a review of accuracy of the provider network information when the companies expand their service area or offer new plans under Medicare Advantage and an annual risk adjustment data and system review.

Health Care Fraud Prevention and Enforcement

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

HEAT Provider Compliance Training

OIG provides free training on our website for health care 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 health care community with OIG's message of compliance and prevention via free downloadable comprehensive training materials and podcasts. OIG's provider compliance training resources 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 health care 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 health care fraud data and investigative intelligence to quickly identify fraud and bring prosecutions. Strike Force teams operate in 10 areas: Miami, Orlando, and Tampa, Florida; Dallas and Houston, Texas; Los Angeles, California; Detroit, Michigan; Brooklyn, New York; southern Louisiana; and Chicago, Illinois.

In July 2017, the Medicare Fraud Strike Force led an unprecedented nationwide sweep in 41 Federal districts, with the assistance of 30 MFCUs. The sweep resulted in criminal and civil charges against 412 individuals—including 115 doctors, nurses, and other licensed medical professionals—for their alleged participation in health care fraud schemes involving approximately \$1.3 billion in false billings. In addition, OIG issued 295 exclusion notices related to the use and abuse of controlled substances. For more information on this takedown, visit our Strike Force website at <https://oig.hhs.gov/newsroom/media-materials/2017/2017-takedown.asp>.

During this semiannual reporting period, Strike Force efforts resulted in the filing of charges against 137 individuals or entities, 112 criminal actions, and more than \$504.6 million in investigative receivables.

Below are examples of Strike Force cases.

Michigan—Three colleagues at Advanced Care Services each pleaded guilty to conspiracy to commit health care fraud, and one of them also pleaded guilty to conspiracy to distribute and possess with intent to distribute controlled substances. They were sentenced to a combined 6 years and 5 months in prison and ordered to pay \$2.5 million in restitution, joint and several. The defendants—Jorge Azar, an owner of Advanced Care Services; Diontay Bradley, a patient recruiter; and Jellie Villalon, the administrative director—engaged in a conspiracy to unlawfully distribute controlled substances and to defraud Medicare by billing for services not rendered and billing for unnecessary services. According to the investigation, from June 2011 through October 2015, patient recruiters would recruit Medicare beneficiaries. After performing a cursory examination or no exam at all, a physician would write the beneficiary a prescription for a controlled substance. The

beneficiary would then fill the prescription and sell the medication back to the recruiter for illegal street trafficking. Another defendant, Dr. Rodney Moret, pleaded guilty and is awaiting sentencing.

Florida—Dr. Miguel Burgos was the medical director of four Orlando-area infusion clinics; Yosbel Marimon was an owner of one of the clinics. Burgos and Marimon admitted that they billed Medicare and private insurance companies for, among other things, expensive infusion therapy medications, including anticancer chemotherapeutic medications, despite never purchasing or dispensing the drugs. Burgos and Marimon also admitted to submitting false claims to Medicare and private insurance companies for physical therapy conducted at the clinics, even though there was no licensed physical therapist on staff at the clinics. In connection with the scheme, the defendants admitted that they billed Medicare and private insurers approximately \$13.7 million, of which approximately \$9.8 million was paid on the fraudulent claims. Burgos and Marimon both pleaded guilty to conspiracy to commit health care fraud and were sentenced to a combined 12 years and 10 months in prison. They were ordered to pay \$9.8 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 health care programs and stealing millions of taxpayer dollars. The Most Wanted Fugitives website is continually updated and features a profile for each fugitive as well as an online tip form and a hotline number for individuals to report fugitive-related information to OIG, in English or Spanish, 24 hours a day, 365 days a year. The Most Wanted Fugitives list can be accessed at <https://oig.hhs.gov/fraud/fugitives/>.

One of OIG's Most Wanted Fugitives, Hector Anca Soca, was captured during this reporting period. Anca Soca, who was the owner of M&K Home Health in Miami, Florida, was indicted on charges of health care fraud in January 2016 and fled the United States.

According to the indictment, from around October 2014 through around September 2015, he conspired to defraud Medicare by submitting false claims. Specifically, he obtained the names and Medicare identification numbers of Medicare beneficiaries, along with the names and provider numbers of physicians, in order to submit false claims to Medicare. Investigators believe that Anca Soca, through M&K, was paid approximately \$3.7 million for services that M&K did not render. Anca Soca was detained while trying to enter the United States from an inbound flight originating in Cuba. His capture is the result of the tireless effort and teamwork between HHS and the FBI.

Because of the success of OIG's Most Wanted Fugitives website, OIG launched its Most Wanted Deadbeat Parents website at <https://oig.hhs.gov/fraud/child-support-enforcement/index.asp>. The site identifies parents whose failure to pay court-ordered child support for their children places unnecessary strain on the custodial parents and the children as well as on agencies that enforce these matters. The Human Services Reviews section of this Semiannual Report provides examples.

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 \$9.9 million as a direct result of cases originating from hotline complaints.

OIG Hotline Activity (04/01/17–09/30/17)

Contacts to 1-800-HHS-TIPS phone line, including callers seeking information	58,510
Total tips evaluated	13,781
Tips referred for action	10,888
Closed; no basis provided for further action	1,492
Closed; no HHS violation	1,401

Sources of tips referred for action

Phone	5,815
OIG website	3,966
Letters/faxes	1,107

State Medicaid Fraud Control Units

OIG Oversight of State Medicaid Fraud Control Units

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

Medicaid Fraud Control Units Fiscal Year 2016 Annual Report
([OEI-09-17-00210](#)), May 2017

This annual report highlights statistics on the accomplishments of the 50 MFCUs during FY 2016. OIG found that FY 2016 continued a trend of increasing numbers of convictions. Just over one-third of the 1,564 MFCU convictions involved personal care services attendants. Fraud cases accounted for 74 percent of the MFCU convictions, while 26 percent involved patient abuse or neglect. MFCUs reported 998 civil settlements and judgments, almost half of which involved pharmaceutical manufacturers. MFCUs reported almost \$1.9 billion in criminal and civil recoveries. In an appendix to the report, OIG summarizes beneficial practices by the MFCUs that were identified in onsite review reports published during FYs 2011–2016.

OIG Onsite Reviews of MFCUs

In addition to an annual recertification review of each MFCU, OIG conducts periodic reviews of a sample of MFCUs. OIG evaluates MFCU operations on the basis of 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:

- *Wyoming State Medicaid Fraud Control Unit: 2016 Onsite Review*
([OEI-09-16-00530](#)), September 2017
- *Alaska State Medicaid Fraud Control Unit: 2016 Onsite Review*
([OEI-09-16-00430](#)), September 2017
- *Kentucky State Medicaid Fraud Control Unit: 2016 Onsite Review*
([OEI-06-17-00030](#)), September 2017
- *Colorado State Medicaid Fraud Control Unit: 2016 Onsite Review*
([OEI-06-16-00520](#)), August 2017
- *Wisconsin State Medicaid Fraud Control Unit: 2016 Onsite Review*
([OEI-07-16-00240](#)), May 2017

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

Pennsylvania—Dr. John Johnson owned multiple businesses, including a group of pain management clinics called Lighthouse Medical, LLC. According to the investigation, from May 2011 through November 2013, Dr. Johnson, through Lighthouse Medical, engaged in a pattern of fraudulent activity by receiving kickbacks from Universal Oral Fluids Lab in

exchange for sending oral swabs to Universal Oral Fluids Lab for testing that was paid for by Medicare, the Pennsylvania Medicaid program, or private insurance. Also, Dr. Johnson failed in 2013 to remit to the Internal Revenue Service (IRS) the payroll taxes he collected from his employees at two of his businesses. Dr. Johnson pleaded guilty to conspiracy and willful failure to remit employment taxes and was sentenced to 7 years in prison and ordered to pay \$2.3 million in restitution to CMS and \$722,476 in restitution to the IRS. This case was initiated on the basis of fraud tips provided to the HHS OIG hotline.

Advisory Opinions and Other Industry Guidance

As part of OIG's continuing efforts to promote the highest level of ethical and lawful conduct by the health care industry, we issue advisory opinions and other guidance to educate industry and other stakeholders on how to avoid fraud, waste, and abuse. Advisory opinions, which are developed in consultation with DOJ, are issued to requesting parties regarding the interpretation and applicability of certain statutes relating to Federal health care programs. The Health Insurance Portability and Accountability Act of 1996 (HIPAA), § 205, allows OIG to provide case-specific formal guidance on the application of the anti-kickback statute and safe harbor provisions and other OIG health care fraud and abuse sanctions. During FY 2017, OIG received 27 requests for advisory opinions and issued 4 advisory opinions and no modifications of advisory opinions.

Sanction Authorities and Other Administrative Actions

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

During this semiannual reporting period, OIG imposed 1,887 administrative sanctions in the form of program exclusions or administrative actions for alleged fraud or abuse or other activities that posed a risk to Federal health care programs and their beneficiaries. Exclusion and penalty authorities are described in Appendix D and on our website at <http://oig.hhs.gov/fraud/enforcement/cmp/index.asp>.

Program Exclusions

During this semiannual reporting period, OIG excluded 1,822 individuals and entities from Medicare, Medicaid, and other Federal health care programs. Most of the exclusions resulted from convictions for crimes relating to Medicare or Medicaid, for patient abuse or neglect, or as a result of license revocation. OIG is also responsible for reinstating providers who apply and have met the requirements of their exclusions. For a list of excluded individuals and entities, see <https://exclusions.oig.hhs.gov/>.

The following are examples of program exclusions:

Minnesota—George Sumo Kpingbah was certified as a nursing assistant. According to court documents, Kpingbah was employed as a nursing assistant at a nursing facility where he sexually assaulted an 83-year old patient. The patient had dementia and Alzheimer's disease and was completely dependent on her caretakers due to her advanced dementia. Kpingbah was sentenced to 8 years in prison based on his conviction for criminal sexual conduct. OIG excluded Kpingbah for a minimum of 20 years.

New York—Narco Freedom, Inc., a now-defunct provider of outpatient drug rehabilitation, agreed to resolve FCA allegations that it submitted claims to Medicaid for services predicated on illegal kickbacks and services not rendered. As a part of the settlement, Narco Freedom admitted that between 2006 and 2014, it induced beneficiaries to use its outpatient programs by providing the beneficiaries with subsidized housing. Narco Freedom also admitted that between 2008 and 2011, it paid operators of other short-term residences to condition residency at their residences on enrollment in and attendance at a Narco Freedom outpatient program. Narco Freedom also admitted that in 2010, it directed employees to falsify records to reflect that counselors had treated certain Medicaid beneficiaries. As part of the settlement, Narco Freedom, which is currently in Chapter 7 bankruptcy, agreed that the United States will receive a \$50.5 million bankruptcy claim. For its conduct, Narco Freedom is excluded from all Federal health care programs for 50 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 are debarment examples.

Alabama—Jonathan Wade Dunning was the CEO of Birmingham Health Center, a federally funded health care center. The investigation disclosed that Dunning engaged in a fraudulent scheme that embezzled approximately \$17 million in Federal grant funds. The money was meant to provide quality health care for the homeless and low-income

individuals. Instead, contrary to the stated purpose of the grant, funds were fraudulently diverted to Dunning's multiple corporations for personal use. Dunning was found guilty on 98 counts of conspiracy, wire fraud, bank fraud and money laundering. He was sentenced to 18 years in prison and ordered to pay \$13.5 million in restitution. Dunning and his nine companies were debarred for a period of 10 years, based on an OIG referral to the Department.

Montana—James Leroy Emerson stole tribal funds originally provided by the ACF to the Blackfeet Tribe of the Blackfeet Nation. Specifically, from 2007 through 2010, Emerson applied for and received TANF and SNAP benefit payments from the Blackfeet Tribe even though he was ineligible. Emerson failed to report receipt of the improper tribal TANF benefits as income to the Glacier County Office of Public Assistance. He withheld this information, misrepresenting his income, which resulted in overpayment of benefits. The defendant was convicted of theft of federally provided welfare benefits by fraud, Federal welfare assistance fraud, and theft from an Indian tribal organization, and was ordered to pay \$30,000 in restitution. Emerson was debarred for a period of 3 years as a result of an OIG referral to the Department.

Corporate Integrity Agreements

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

The following is a CIA enforcement example.

New York—Luitpold Pharmaceuticals, Inc. and American Regent, Inc.—subsidiaries of Daiichi Sankyo, Inc., a pharmaceutical company—paid just over \$1.2 million to settle Civil Monetary Penalties Law (CMPL) liability for conduct Daiichi disclosed to OIG under the Reportable Events Section of the Daiichi Sankyo, Inc., CIA. The settlement resolves allegations that the Daiichi subsidiaries provided illegal remuneration to a physician and her entity in the form of payments and free services, in connection with a "pilot program" for the management of iron deficiency anemia. Daiichi entered into the CIA in 2015 in connection with its settlement of FCA liability regarding the alleged provision of illegal remuneration to physicians to induce them to prescribe certain drugs. Certain Daiichi CIA requirements apply to Daiichi subsidiaries and other affiliates.

Civil Monetary Penalties and Affirmative Exclusions

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 health care program that the person knows, or should know, are false or fraudulent. The Exclusions Statute also authorizes OIG to exclude a person who violates the CMPL. When OIG excludes an individual under the Exclusions Statute for engaging in conduct that violates the CMPL, it is known as an affirmative exclusion. During this semiannual reporting period, OIG concluded cases involving more than \$22.8 million in CMPs and assessments.

The following is an example of a case under the CMPL.

Connecticut—Hartford Hospital and its sister hospital, Midstate Medical Center, agreed to pay more than \$2.8 million in assessments and penalties for submitting claims between February 2009 and March 2015 for home health services that patients received within 3 days of being released from Hartford Hospital, with the release improperly coded as a discharge rather than a post-acute care transfer.

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 are EMTALA case examples.

South Carolina—In the largest settlement under EMTALA in OIG's 30-year enforcement of the statute, AnMed Health, a 533-bed hospital in Anderson, South Carolina, agreed to pay \$1.2 million to resolve its potential liability. OIG alleged that between April 2012 and July 2013, AnMed Health violated EMTALA by failing to provide appropriate medical screening examinations and stabilizing treatment to patients who presented to the emergency department with psychiatric conditions. Specifically, OIG alleged that despite the availability of on-call psychiatrists and open beds in its psychiatric unit, AnMed Health kept 35 individuals in its emergency department pursuant to a longstanding policy of not admitting involuntary patients to its psychiatric unit. These 35 individuals, who suffered from serious psychiatric disorders, were kept in AnMed Health's emergency department for 6 to 38 days each until they were discharged or transferred to another medical facility.

Georgia—Monroe County Hospital agreed to pay \$25,000 to resolve its potential liability under EMTALA. OIG alleged that Monroe County Hospital violated EMTALA when it failed to provide an appropriate medical screening examination and stabilizing treatment for a woman who presented to the emergency department complaining she was 36 weeks pregnant and her water had broken. The patient told a nurse that she wanted to see her physician in Macon, Georgia. Without providing a medical screening examination, emergency department staff decided that the patient could go see her physician in Macon. The patient was then escorted to her car and told to call 911. Emergency medical services

arrived and found the patient in her car. She was brought to another hospital where she delivered her child within an hour of arriving.

Self-Disclosure Programs

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

Application processes for two additional self-disclosure programs were recently added to the OIG website for HHS contractors and grantees. The OIG contractor self-disclosure program provides contractors the opportunity to self-disclose when they have potentially violated the 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 \$12.6 million in HHS receivables.

The following are examples of provider self-disclosure settlements.

Louisiana—Madison Parish Hospital Service District d/b/a Madison Parish Hospital (MPH) agreed to pay \$1.8 million to resolve its liability under the CMPL for conduct it self-disclosed to OIG. Specifically, OIG alleged that MPH (1) improperly submitted claims to Medicare related to certain inpatient admissions; (2) received remuneration in the form of inpatient computed tomography equipment and services provided below fair market value (FMV) from an independent diagnostic testing facility (IDTF) and paid remuneration to the IDTF in the form of below-FMV medical office space and support services; and (3) improperly reported illegal remuneration from hospital vendors paid to a former CEO on MPH cost reports then used by the Medicare and Medicaid program to calculate reimbursement rates to MPH, resulting in overpayments.

Texas—After self-disclosing conduct to OIG, United Medical Center (UMC) Physicians agreed to pay more than \$3.3 million to resolve its liability under the CMPL. Specifically, OIG alleged that between January 1, 2011, through September 2, 2015, UMC Physicians improperly filed claims for (1) evaluation and management services and (2) Doppler and ultrasound testing services purportedly performed by a physician that were upcoded, not rendered, or otherwise not supported by the record.

Public Health Agencies

Public Health Agencies Reports and Reviews

Centers for Disease Control and Prevention

CDC Generally Met Its Inspection Goals for the Federal Select Agent Program; However, Opportunities Exist To Strengthen Oversight ([OEI-04-15-00430](#)), May 2017

We found that the Division of Select Agents and Toxins (DSAT) at the Centers for Disease Control and Prevention (CDC) generally met its Federal Select Agent Program inspection goals; however, opportunities exist to improve DSAT's oversight. The findings identify potential vulnerabilities in DSAT's oversight of entities possessing, using, or transferring select agents and toxins, which could pose a risk to public health and safety. This report contained no recommendations, but it did offer suggestions that CDC could consider in its ongoing efforts to improve oversight of the Federal Select Agent Program. This is the first of several OIG reports on the Federal Select Agent Program.

President's Emergency Plan for AIDS Relief

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

During the semiannual reporting period, OIG conducted three audits related to PEPFAR funding:

Management and Development for Health in Tanzania Did Not Always Manage the President's Emergency Plan for AIDS Relief Funds in Accordance with Award Requirements ([A-04-16-04045](#)), June 2017

Management and Development for Health (MDH), located in Dar es Salaam, Tanzania, did not always manage PEPFAR funds in accordance with award requirements. Of the 60 financial transactions in our sample, 9 transactions totaling \$181,000 were not allowable.

Additionally, MDH used \$23,000 in PEPFAR funds to pay unallowable Value-Added Taxes (VAT) on purchases that have not been reimbursed by the Tanzania Revenue Authority.

MDH generally concurred with our recommendations that it (1) refund to CDC \$101,000 for transactions that it could not fully support with adequate documentation and \$80,000 for unallowable PEPFAR expenditures and (2) work with CDC to obtain \$23,000 of VAT reimbursement from the Tanzanian Government. MDH also concurred with our procedural and policy recommendations and described some of the actions it has taken, or plans to take, to address them.

Ariel Foundation Against Pediatric AIDS Managed and Expended the President's Emergency Plan for AIDS Relief Funds in Accordance with Award Requirements ([A-04-16-04052](#)), June 2017

Our audit covered the budget periods from September 30, 2011, through September 29, 2015. These budget periods were for years 1 through 4 of a 5-year cooperative agreement. During the budget periods under review, CDC awarded Ariel \$35.8 million, of which Ariel expended \$29.6 million. From these PEPFAR fund expenditures, we selected a judgmental sample of 60 transactions totaling \$2.7 million. Our sample included transactions for travel expenses, vehicle purchases, salaries, and consultation fees.

Ariel managed PEPFAR funds in accordance with award requirements, so we made no recommendations.

The Ministry of Health and Social Welfare National AIDS Control Program Did Not Always Manage and Expend PEPFAR Funds in Accordance with Award Requirements ([A-04-16-04044](#)), August 2017

The Ministry of Health National AIDS Control Program (the Ministry), located in Dar es Salaam, Tanzania, did not always manage and expend PEPFAR funds in accordance with award requirements. Of the 52 financial transactions in our judgmental sample, 27 transactions totaling \$510,584 were allowable, but 27 transactions totaling \$495,379 were not. These transactions were unallowable because the Ministry did not provide adequate supporting documentation for the expenditures. In addition, the Ministry did not have a time and attendance system to support \$1.5 million in funded personnel costs, did not always record financial transactions correctly, filed an inaccurate Federal Financial Report (FFR), filed one of its FFRs more than 15 months late, did not maintain a United States dollar bank account, and paid unallowable value-added taxes.

The Ministry did not specifically concur or nonconcur with our recommendations that it (1) refund to CDC \$495,379 of unallowable expenditures from our sample review that it could not adequately support, (2) work with CDC to determine the allowability of the \$1.5 million in personnel costs awarded to the Ministry during the audit period, and (3) develop and implement adequate policies and procedures to ensure that it prepares and submits accurate FFRs on time. We also made other procedural and policy recommendations.

Food and Drug Administration

Drug Supply Chain Security: Wholesalers Exchange Most Tracing Information ([OEI-05-14-00640](#)), September 2017

Drug diversion, counterfeiting, and the importation of unapproved drugs may result in potentially dangerous drugs entering the drug supply chain, posing a threat to public health and safety. To enhance drug supply chain security, the Drug Supply Chain Security Act (DSCSA) requires trading partners in the drug supply chain to create a record of each drug product transaction. The Food and Drug Administration (FDA) can then use such tracing records to investigate suspect and illegitimate drug products and potential diversion to illegal use.

This first study, part of a series of examinations of drug supply chain security, examined wholesalers' implementation of the DSCSA. We found that all 31 selected wholesalers exchange drug product tracing information. Of these, 17 wholesalers—including the 3 largest wholesalers that account for more than 80 percent of drug distribution revenue—exchange all required drug product tracing information. The remaining 14 wholesalers exchange most elements of drug product tracing information but are missing a few of the required elements.

To ensure that all wholesalers comply with the DSCSA, we recommended that FDA offer technical assistance where appropriate. Specifically, we recommended that FDA provide technical assistance to wholesalers regarding direct purchase statements, exempt drugs, and exchanging drug product tracing information for transactions involving covered entities under the 340B Drug Discount Program and 340B contract pharmacies. FDA concurred with all of our recommendations.

Challenges Remain in FDA's Inspections of Domestic Food Facilities ([OEI-02-14-00420](#)), September 2017

We found that FDA is on track to meet the inspection timeframes mandated by the Food Safety Modernization Act (FSMA) for the initial cycles; however, challenges remain as FSMA requires FDA to conduct future inspections in timeframes that are 2 years shorter than the timeframes for the initial cycles. Also, inaccuracies in FDA's domestic food facility data result in FDA's attempting to inspect numerous facilities that are either out of business or otherwise not in operation at the time of the visit. Although FDA is on track to meet the FSMA mandates during the initial cycles, this did not result in a greater number of facilities being inspected. In fact, the overall number of food facilities FDA inspected decreased over time. In addition, FDA did not always take action when it uncovered significant inspection violations. When it did take action, it commonly relied on facilities to voluntarily correct the violations. Also, it rarely took advantage of the new administrative tools provided by FSMA. Moreover, FDA's actions were not always timely, nor did they always result in the correction of these violations. Further, FDA consistently failed to conduct timely followup inspections to ensure that facilities corrected significant inspection violations. FDA concurred with all four recommendations to:

- improve how it handles attempted inspections to ensure better use of resources,
- take appropriate action against all facilities with significant inspection violations,
- improve the timeliness of its actions so that facilities do not continue to operate under harmful conditions, and
- conduct timely followup inspections to ensure that significant inspection violations are corrected.

FDA Oversight of Tobacco Manufacturing Establishments ([OEI-01-15-00300](#)), August 2017

We found that 171 domestic tobacco manufacturing establishments registered with FDA in the first 6 years it has been authorized to regulate tobacco, and that FDA largely met its requirement to inspect the establishments biennially. In addition, through its routine surveillance of marketing activities for tobacco products, FDA issued 14 warning letters to

manufacturers mostly for violations of advertising and labeling requirements. Complete and accurate information on registrants will aid FDA in fulfilling its oversight role.

National Institutes of Health

As Funding for BPA Research Increased, the National Institute of Environmental Health Sciences (NIEHS) Followed Its Peer Review Process While Also Exercising Its Discretion ([OEI-01-15-00150](#)), August 2017

We found that NIEHS followed its peer review processes as it increased funding for bisphenol A (BPA) research and that it used its discretion to fund applications with less favorable scores more often for BPA grants than non-BPA grants. Such discretion is allowed and enables NIEHS to be responsive to emerging threats to public health; however, applying it frequently or disproportionately in one research area may invite added scrutiny of NIEHS's funding decisions.

Legal Actions and Investigations Related to Public Health Agencies

Health Education Assistance Loan Program

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

HEAL Exclusions

During this semiannual reporting period, 57 individuals and related entities were excluded as a result 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, 2,682 individuals chose to enter into settlement agreements or completely repay their debts. That figure includes 23 individuals who entered into such settlement agreements or completely repaid their debts during this semiannual reporting period. More than \$212 million is being repaid through settlement agreements or through complete repayment. Of that amount, more than \$1.9 million is attributable to this semiannual reporting period.

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

- Florida—osteopath - \$428,075
- California—dentist - \$88,880

Human Services Agencies Reviews and Enforcement Activities

Administration for Children and Families

HHS's Office of Refugee Resettlement Improved Coordination and Outreach to Promote the Safety and Well-Being of Unaccompanied Alien Children ([OEI-09-16-00260](#)), July 2017

Since OIG's 2008 report on the topic, HHS has improved its coordination with DHS and increased its efforts to promote the safety and well-being of unaccompanied alien children (UAC) after their release from HHS custody. In light of these developments, OIG considers its prior recommendation—that the departments clarify their roles and responsibilities related to UAC—to be implemented. However, we recognize that current efforts do not guarantee that all UAC are protected from harm. Although this report contained no recommendations, we encouraged HHS's Office of Refugee Resettlement to:

- continue its efforts to contact these children after their release to sponsors and provide case management services for the most vulnerable;
- continue to report any concerns about the safety and well-being of UAC to the local law enforcement and child protective service agencies that have jurisdiction to address such concerns, and to support these agencies in any ways possible; and
- continue its efforts to share information and coordinate with DHS.

Safety of Children in Foster Care

Texas Did Not Always Ensure That Allegations and Referrals of Abuse and Neglect of Children Eligible for Title IV-E Foster Care Payments Were Recorded and Investigated in Accordance with Federal and State Requirements ([A-06-15-00049](#)), May 2017

California Did Not Always Ensure That Allegations and Referrals of Abuse and Neglect of Children Eligible for Title IV-E Foster Care Payments Were Properly Recorded, Investigated, and Resolved ([A-09-16-01000](#)), September 2017

Texas and California did not always ensure that allegations and referrals of abuse and neglect for children in foster care covered by Title IV-E were recorded (both States), investigated (both States), and resolved (California) in accordance with Federal and State requirements.

Texas agreed that our findings accurately reflect the conditions that were found, but it did not directly address our recommendations that it (1) revise its policy of requiring a 30-day timeframe for submitting an investigation report to a period that ensures both quality and

timeliness in completing the investigation and (2) ensure that interim meetings between investigators and supervisors are held and documented within the required timeframes.

California agreed with our recommendations that it develop an action plan to ensure that complaint investigations are completed in a timely manner; develop additional policies and procedures as necessary and follow existing policies and procedures; ensure that the complaint system currently under development includes functionality that addresses our findings; and provide analysts and their supervisors with periodic mandatory complaint investigation training to reinforce their knowledge of the laws, regulations, policies and procedures, and best practices related to complaint investigations.

Some Ohio Group Homes Did Not Always Comply With Foster Care Health and Safety Requirements ([A-05-16-00049](#)), September 2017

Some Oklahoma Group Homes Did Not Always Comply With State and Federal Requirements ([A-06-16-07004](#)), September 2017

Although Ohio and Oklahoma conducted the required inspections at all the group homes that we reviewed in each State (30 group homes in Ohio and 22 in Oklahoma), this monitoring did not ensure that the group homes complied with State and Federal requirements related to the health and safety of children in foster care. Nineteen of the 30 group homes in Ohio and 17 of the 22 group homes in Oklahoma did not comply or did not always comply with 1 or more requirements in these areas: physical and environmental safety (17 group homes in Ohio); transportation (12 in Oklahoma); building, utilities, and grounds (12 in Oklahoma); fire safety (10 in Oklahoma and 4 in Ohio); criminal records checks (5 in Ohio); food service (4 in Oklahoma); safety and emergency preparedness (4 in Oklahoma); staff records (3 in Ohio); and physical facility and equipment (1 in Oklahoma).

Ohio and Oklahoma concurred with our recommendations that they consider additional outreach programs for the group homes, such as training. Oklahoma concurred with our recommendation that it ensure that monitoring staff document and resolve all issues of noncompliance of group homes in a timely manner.

Ohio said that it was “in accordance” with our recommendations that it ensure that all instances of noncompliance are documented and corrected; ensure that the group homes adhere to all requirements for the health and safety of children by continuing onsite visits; and ensure that group homes obtain the required criminal records checks for all employees who provide direct care to children.

Oklahoma did not concur with our recommendation that it revise Oklahoma licensing requirements for the monitoring of vehicles used to transport children.

Low-Income Home Energy Assistance Program

Three Affiliated Tribes Improperly Spent Low Income Home Energy Assistance Program Funds for FYs 2010–2014 ([A-07-16-04230](#)), July 2017, and

The Turtle Mountain Band of Chippewa Indians Improperly Administered Some Low-Income Home Energy Assistance Program Funds for Fiscal Years 2010 through 2013 ([A-07-16-04233](#)), September 2017

The Three Affiliated Tribes (TAT) and the Turtle Mountain Band of Chippewa Indians (TMT) are both federally recognized American Indian tribes, located in North Dakota, that receive HHS grant funds from several sources, including LIHEAP. ACF administers LIHEAP for HHS. In FYs 2010 through 2014 (TAT) and FYs 2010 through 2013 (TMT), the tribes did not administer LIHEAP grant funds in compliance with Federal laws, regulations, and guidance: \$1.2 million for TAT and \$587,248 for TMT. Also, TMT could not determine whether an additional \$96,932 was subject to repayment.

TAT and TMT did not directly agree or disagree with our recommendations that they refund to the Federal Government \$1.2 million and \$587,248, respectively, for unallowable or unsupported grant funds and develop and implement policies and procedures to address internal control deficiencies.

TAT did not directly agree or disagree with our recommendation that it formalize its definition of income in ways that conform to Federal requirements and guidelines and train staff to understand that applicants who are homeless do not qualify for crisis assistance for lodging.

TMT did not directly agree or disagree with our recommendation that it determine how much of the \$96,932 that energy suppliers returned to the tribe should be repaid to the Federal Government.

Disaster Response and Recovery

Economic Opportunity Commission of Nassau County, Inc., Claimed Some Unallowable Hurricane Sandy Disaster Relief Act Fund ([A-02-15-02009](#)), April 2017

HHS had approximately \$800 million in funding for disaster response and recovery and other expenses directly related to Hurricane Sandy. Of this amount, ACF received \$577.2 million, of which \$95 million was allocated to assist Head Start and Early Head Start grantees with program response, recovery, and other activities related to the impact of Hurricane Sandy. ACF awarded \$8.1 million of these funds to the Economic Opportunity Commission of Nassau County, Inc. (EOC), for construction and other expenses resulting from Hurricane Sandy.

EOC claimed costs that did not comply with Federal requirements. Of the \$3.6 million in costs that we reviewed, \$3 million complied with applicable Federal requirements.

However, EOC claimed \$614,278 in unallowable costs because it (1) claimed construction costs, salaries, and fringe benefits on the basis of budgeted, not actual, costs; (2) claimed construction management and design costs that were not allocable to the grant; and (3) claimed costs that had been separately reimbursed by insurance.

ACF partially concurred with our recommendation that it ensure that EOC refund \$614,278 to the Federal Government for costs that did not comply with Federal requirements.

ACF concurred with our recommendation that it ensure that the \$1.1 million in costs associated with EOC's ongoing work that we did not review complies with Federal requirements.

Child Support Enforcement Activities

OIG Investigations

OIG investigates noncustodial parents who violate 18 U.S.C. § 228 by failing to pay court-ordered child support. OIG works with ACF's Office of Child Support Enforcement; DOJ; U.S. Attorneys' Offices; the U.S. Marshals Service; and Federal, State, and local partners to address egregious child support enforcement cases with appropriate law enforcement and prosecutorial action. During this semiannual reporting period, OIG investigations of child support enforcement cases nationwide resulted in nine criminal actions and court-ordered restitution and settlements of \$445,970.

The following are examples of child support enforcement cases.

Florida—In 2000, Khanh Hung Nguyen was ordered to pay \$429.00 per month for the support of his child. Nguyen only occasionally made payments to the custodial parent of his child, and last made a payment in 2008. Nguyen was sentenced to 3 years of probation and ordered to pay restitution of \$82,225.13 after pleading guilty to failure to pay legal child support obligations.

South Dakota—In 2008, Charles Lee VanWardhuizen was ordered to pay \$585.94 per month for the support of his child. This amount of ordered support was later raised to \$591.57 in 2009. VanWardhuizen only occasionally made payments to the custodial parent of his child. VanWardhuizen was sentenced to 2 years of probation and ordered to pay restitution of \$31,184.01 after pleading guilty to failure to pay legal child support obligations.

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 2017, HHS awarded more than \$481 billion in grants and over \$24 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 70,000 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

Human Subjects Protections

OHRP Should Inform Potential Complainants of How They Can Seek Whistleblower Protections ([OEI-01-15-00351](#)), September 2017

We found that fear of reprisal may prevent potential complainants from disclosing allegations of noncompliance to the Office for Human Research Protections (OHRP). This raises concerns that some instances of noncompliance may go unreported and unresolved. Although whistleblower protections are not available for complainants who make disclosures of noncompliance only to OHRP, protections may be available if complainants disclose such noncompliance to other entities, such as OIG or the HHS grant-awarding agency. The Office of the Assistant Secretary for Health (OASH) concurred with all of our recommendations, which were for OHRP to:

- inform potential complainants of how they can seek whistleblower protections and
- request that HHS consider the adequacy of whistleblower protections for complainants making disclosures about human subjects protections to OHRP.

OHRP Generally Conducted Its Compliance Activities Independently, But Changes Would Strengthen Its Independence ([OEI-01-15-00350](#)), July 2017

We found that OHRP appeared to carry out its compliance activities for protecting human subjects in HHS-funded research while maintaining its independence from the HHS agencies that fund the research and the institutions conducting the research. However, certain factors may limit or appear to limit OHRP's ability to operate independently. OASH provided HHS's response and neither concurred nor nonconcurred with our recommendation that HHS should address factors that may limit OHRP's ability to operate independently. OASH said that HHS would consider our recommendation as part of a comprehensive review of HHS's structure and functions that is currently underway and may identify revisions to OHRP's organizational location, mission, and budget. OHRP concurred with our recommendation to post the following on its website: (1) a description of its

approach to oversight and (2) data (in aggregate) on the full array of its compliance activities.

2016 Performance Data for the Senior Medicare Patrol Projects ([OEI-02-17-00220](#)), June 2017

The Senior Medicare Patrol projects receive grants from ACL to recruit and train retired professionals and other senior citizens to prevent, recognize, and report health care fraud, errors, and abuse. In 2016, the 53 Senior Medicare Patrol projects had a total of 6,126 total active team members who conducted a total of 26,220 group outreach and education events, reaching an estimated 1.5 million people. The projects reported \$163,904 in cost avoidance on behalf of Medicare, Medicaid, beneficiaries, and others. Savings to beneficiaries and others totaled \$53,449. Expected Medicare recoveries totaled \$2,672.

Grant Fraud Investigations

The Program Support Center Did Not Identify and Report HHS Antideficiency Act Violations ([A-03-13-03002](#)), May 2017

During our audit period (October 2011 through March 2013), PSC, a component of HHS, awarded or modified 216 contracts that had an estimated contract value that exceeded \$5 million each. We randomly selected 30 of these contracts, totaling \$498.3 million, for review. The PSC did not always obligate and expend funds for 13 of the 30 contracts we reviewed in accordance with appropriations law and Federal acquisition requirements, resulting in unreported Antideficiency Act obligation violations totaling \$20.3 million and expenditure violations totaling \$29.2 million. For 4 of the 30 contracts reviewed, the PSC incorrectly extended the period of performance and the fiscal year funding beyond its 12-month period of availability. In addition, the PSC did not always submit contracts to the appropriate offices for appropriations funding reviews before awarding the contracts.

The PSC generally agreed with our recommendations that it work with the HHS Office of the Secretary to report Antideficiency Act obligation violations totaling \$20.3 million and Antideficiency Act expenditure violations totaling \$29.2 million and that it make procedural changes that should help prevent violations of the Antideficiency Act and the Federal Acquisition Regulation in the future.

The following are case examples related to misuse of grant funds.

Massachusetts—Brigham and Women’s Hospital, a subsidiary of Partners HealthCare System, Inc. (collectively, BWH), entered into a settlement agreement to resolve allegations that a BWH stem cell research laboratory fraudulently obtained grant funding from NIH. The settlement resolves allegations that Dr. Piero Anversa, along with Dr. Annarosa Leri and Dr. Jan Kajstura, knew or should have known that their laboratory promulgated and relied upon manipulated and falsified information in applications submitted for NIH research grant awards concerning the purported ability of stem cells to repair damage to the heart.

The Government alleged that problems with the work of the laboratory included improper protocols, invalid and inaccurately characterized cardiac stem cells, reckless or deliberately misleading recordkeeping, and discrepancies and/or fabrication of data and images included in applications and publications. The Government contends that, at the direction of these BWH scientists, the laboratory included false scientific information in claims to NIH to obtain and use funds from NIH grants. BWH agreed to pay \$10 million to resolve their liability under the FCA.

South Carolina—Jian Yun Dong was the president and CEO of Genphar, Inc., and owner of Vaxima, Inc., federally funded research laboratories. The investigation disclosed that Dong founded Genphar and Vaxima to perform research and produce a vaccine for diseases such as Ebola, Marburg, and dengue. From August 2004 through April 2011, Federal grant money (including a cooperative agreement and Small Business Innovative Research funds) was obtained by Genphar and Vaxima for biodefense research and vaccine development but was used for other purposes, including the construction of a commercial office building and to pay lobbyists and others who were seeking to secure more Federal funding for the defendants. Approximately \$3 million was diverted from federally funded research into the construction of the facility. A jury found Dong guilty of 24 counts and sentenced him to 5 years and 10 months in prison and ordered him to pay \$3.2 million in restitution. Genphar, Inc., and Vaxima, Inc., were sentenced to pay a fine of \$6.4 million each.

Small Business Innovative Research Program

The National Defense Authorization Act for Fiscal Year 2012, § 5143, requires OIG to annually report on the number of cases that were referred with relation to fraud, waste, or abuse in the Small Business Innovative Research/Small Business Technology Transfer (SBIR/STTR) program. OIG must also report on the actions taken in each case; justification for not taking action on a case; and an accounting of funds used to address waste, fraud, and abuse in this program. In our December 2016 report delivered to the three congressional oversight committees, we reported that OIG spent approximately \$151,182 in salaries on oversight related to the SBIR/STTR program. In FY 2017, 6 new SBIR/STTR cases were referred to OIG.

Recovery Act Retaliation Complaint Investigations

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

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 to the contracting activity” during the period. This information must contain significant audit findings. OIG issued no final reports meeting § 845 criteria during this semiannual period.

OIG Reviews of Non-Federal Audits

OIG reviews audits conducted by non-Federal auditors of entities receiving Federal awards. During this semiannual reporting period, OIG’s National External Audit Review Center reviewed 552 reports covering \$2.2 trillion in audited costs. Federal dollars covered by these audits totaled \$697.8 billion, of which about \$365.1 billion were HHS funds.

The regulation at 45 CFR, subpart F, establishes audit requirements for certain State and local governments, colleges and universities, and nonprofit organizations receiving HHS awards. Entities subject to part 75’s single-audit requirements must conduct annual organization-wide “single audits.” These audits are conducted by non-Federal auditors, such as public accounting firms and State auditors. OIG reviews the quality of these audits and assesses the adequacy of the entities’ management of Federal funds.

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

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

Non-Federal Audits, April 1, 2017, through September 30, 2017

Number of Non-Federal Audits:	
Not requiring changes or having minor changes	516
Requiring major changes	26
Having significant technical inadequacies	10
Total	552

The 552 reports included 1,962 recommendations for improving management operations. In addition, these audit reports provided information for 16 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 [Compendium of 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.

Initial Review of the Centers for Medicare & Medicaid Services' Automated System for Processing Financial Assistance Payments ([A-02-17-02001](#)), May 2017

The House Committee on Energy and Commerce's Subcommittee on Oversight and Investigations and Subcommittee on Health requested that the HHS OIG provide information regarding CMS's automated system for processing financial assistance payments (e.g., advance premium tax credits and cost-sharing reductions). This briefing document presents our initial review of the design and implementation of CMS's automated system from May through October 2016. As of May 2016, CMS had fully implemented the automated system for the Federal marketplace and planned to fully transition issuers operating through State marketplaces to the automated system in 2018.

CMS Did Not Provide Effective Oversight To Ensure That State Marketplaces Always Properly Determined Individuals' Eligibility for Health Plans and Insurance Affordability Programs ([A-09-16-01002](#)), September 2017

Our prior reviews of seven State marketplaces found that not all were effective in ensuring that individuals were properly determined eligible for qualified health plans (QHPs) and insurance affordability programs. CMS did not ensure that all State marketplaces had the system functionality to verify individuals' eligibility for QHPs and insurance affordability programs and resolve inconsistencies in eligibility data according to Federal requirements, had or used the system functionality to perform the process for determining ineligibility for individuals who had not filed a tax return to reconcile the premium tax credit, and completed required independent audits. We also identified three weaknesses in CMS's procedures for SMART reviews. (The SMART—State Marketplace Annual Reporting Tool—is a reporting document that State marketplaces must submit annually to CMS to demonstrate that they meet program integrity standards.)

CMS did not concur with our recommendations that it set firm deadlines for marketplaces to fully develop system functionality for verifying applicants' eligibility and resolving inconsistencies, assess potential enforcement mechanisms that would ensure that marketplaces meet those deadlines, and, if such mechanisms are identified, seek legislative authority to establish them.

CMS did not state whether it concurred with our recommendation that it require marketplaces to submit additional data elements.

CMS concurred with our recommendations that it monitor marketplaces' progress in developing and using current and future system functionality; ensure that marketplaces complete required independent programmatic audits annually; complete its review of SMART documentation; and continue to work with marketplaces to develop the reporting capability to ensure that all required data elements are submitted.

CMS Oversight Must Continue Because All Remaining Consumer Operated and Oriented Plans Were Not Profitable and May Not Be Viable and Sustainable ([A-05-16-00027](#)),
August 2017

The ACA authorized the Secretary of HHS to make startup and solvency loans to new consumer-governed, nonprofit health insurance issuers, known as Consumer Operated and Oriented Plans (CO-OPs). In 2015 and 2016, CMS placed 10 of the 11 CO-OPs on a corrective action plan or an enhanced oversight plan because of financial, operational, or market strategy concerns. CMS conducted the required oversight of the CO-OP program, but this did not prevent the CO-OPs from ceasing or planning to cease operations.

Five of the eleven CO-OPs operating on January 1, 2016, had ceased or planned to cease operations by the end of the 2016 plan year, and each of the remaining six CO-OPs reported net losses, had drawn down nearly all available CO-OP loan amounts as of December 31, 2016, and did not appear to be financially viable and sustainable based on the reported net income and available capital and surplus. When a CO-OP ceases operations during the plan year, health plan participants can be significantly affected.

CMS agreed with our recommendations that it (1) continue to work with operational CO-OPs to improve their financial condition; (2) continue the use of corrective action and enhanced oversight plans, especially for those CO-OPs with net losses and no remaining CO-OP loan funds to be drawn down; and (3) continue to work with States to ensure that CO-OP plan participants receive continuous coverage and access to plan providers and services.

Information Security

These summaries do not include details of the vulnerabilities that we identified because of the sensitive nature of the information.

Public Summary Report: Information Technology Control Weaknesses Found in the New Mexico Human Services Department's Medicaid Eligibility Systems ([A-06-16-05000](#)),
August 2017

New Mexico had not adequately secured its Medicaid data and information systems in accordance with Federal requirements. Although New Mexico adopted a security program for its eligibility systems, we identified system vulnerabilities that potentially placed New Mexico's operations at risk. Although we did not identify evidence that the vulnerabilities had been exploited, exploitation could have resulted in unauthorized access to, and

disclosure of, sensitive information, as well as in disruption of New Mexico's critical operations. As a result, the vulnerabilities were collectively and, in some cases, individually significant and could have potentially compromised the confidentiality, integrity, and availability of New Mexico's eligibility systems.

New Mexico concurred with our findings and most of our recommendations that it implement our detailed recommendations to address the findings we identified in its eligibility system security program, but it did not concur with one recommendation.

Public Summary Report: The State of North Carolina Did Not Ensure That Federal Information System Security Requirements Were Met for Safeguarding Its Medicaid Claims Processing Systems and Data ([A-07-16-00469](#)), August 2017

North Carolina had not ensured that CSRA, Inc., which operates North Carolina's Medicaid claims processing systems, implemented adequate information system general controls over the North Carolina Medicaid claims processing systems in accordance with Federal requirements. The vulnerabilities that we identified increased the risk to the confidentiality, integrity, and availability of North Carolina's Medicaid data.

Although we did not identify evidence that the vulnerabilities had been exploited, exploitation could result in unauthorized access to and disclosure of sensitive information, as well as disruption of critical North Carolina Medicaid operations. As a result, the vulnerabilities are collectively and, in some cases, individually significant and could potentially compromise the confidentiality, integrity, or availability of North Carolina's Medicaid claims processing data and systems. In addition, without proper safeguards, systems are not protected from individuals and groups with malicious intent to obtain access in order to commit fraud or abuse or launch attacks against other computer systems and networks.

North Carolina concurred with our recommendations that it improve the protection of sensitive data on its Medicaid claims processing systems by working with CSRA to address the vulnerabilities identified during our audit to ensure compliance with Federal requirements.

Public Summary Report: Virginia Did Not Adequately Secure Its Medicaid Data ([A-04-15-05066](#)), May 2017

Virginia did not adequately secure its Medicaid data and information systems in accordance with Federal requirements. Although Virginia had adopted a security program for its Medicaid Management Information System, numerous significant system vulnerabilities remained because Virginia neither implemented sufficient controls over its Medicaid data and information systems nor provided sufficient oversight to ensure that its contractor implemented contract security requirements. Although we did not identify evidence that anyone had exploited these vulnerabilities, exploitation could have resulted in unauthorized access to and disclosure of Medicaid beneficiary data, as well as the disruption of critical Medicaid operations. These vulnerabilities were collectively and, in

some cases, individually significant and could have compromised the integrity of Virginia's Medicaid program.

Virginia concurred with our recommendations that it improve its Medicaid security program to secure Medicaid data and information systems in accordance with Federal requirements, provide adequate oversight to its contractor, and address the vulnerabilities identified during our audit.

Alabama Did Not Adequately Secure Its Medicaid Data and Information Systems ([A-04-15-05065](#)), September 2017

Alabama did not adequately secure its Medicaid data and information systems in accordance with Federal requirements. Although Alabama had adopted a security program for its Medicaid Management Information System, numerous significant system vulnerabilities remained because Alabama neither implemented sufficient controls over its Medicaid data and information systems nor provided sufficient oversight to ensure that HP, Alabama's Medicaid fiscal agent, implemented contract security requirements. Although we did not identify evidence that anyone had exploited these vulnerabilities, exploitation could have resulted in unauthorized access to and disclosure of Medicaid data, as well as the disruption of critical Medicaid operations. These vulnerabilities were collectively and, in some cases, individually significant and could have compromised the integrity of Alabama's Medicaid program.

Alabama concurred with our recommendations that it improve its Medicaid security program to secure Medicaid data and information systems in accordance with Federal requirements, provide adequate oversight to its contractors, and address the vulnerabilities identified during our audit.

Readiness of CDC's Strategic National Stockpile Could Be at Risk in Case of a Public Health Emergency ([A-04-16-03554](#)), July 2017

The Strategic National Stockpile (Stockpile) is a repository of vaccines, antibiotics, antidotes, antitoxins, medications, and supplies, in addition to certain controlled substances, meant to supplement and resupply State and local public health agencies in the event of a national emergency. Two primary systemic issues may prevent CDC from ensuring that Stockpile sites are adequately protected and that inventory is readily deployable in a public health emergency: although CDC's Division of Strategic National Stockpile (DSNS) is no longer responsible for providing Stockpile security, DSNS still controls security funding, and the Stockpile automated inventory system did not always accurately track the movement of all inventory or accurately record inventory locations.

These systemic issues could place at risk approximately \$7 billion of Stockpile inventory and negatively affect Stockpile readiness during a national emergency.

CDC concurred with our recommendations that it consider directly funding the Stockpile security mission of CDC's Office of Safety, Security, and Asset Management and improve its

automated inventory system so that it can accurately identify inventory movements and locations at all times.

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

Table 1

	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	151	\$605,454,000	\$18,196,000
Reports issued during the reporting period	49	\$240,582,000	\$596,000
Total Section 1	200	\$846,036,000	\$18,792,000
Section 2			
Reports for which management decisions were made during the reporting period ^{2, 3}			
Disallowed costs	116	\$296,434,000	\$0
Costs not disallowed	5	\$38,032,000	\$0
Total Section 2	121	\$334,466,000	\$0
*Audit receivables (expected recoveries).			
Section 3			
Reports for which no management decisions had been made by the end of the reporting period (Section 1 minus Section 2)	79	\$511,570,000	\$18,792,000
Section 4			
Reports for which no management decisions were made within 6 months of issuance ⁴	53	\$363,497,000	\$18,195,000

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

	Reports	Dollar Value
Section 1		
Reports for which no management decisions had been made by the beginning of the reporting period ¹	8	\$15,439,476,000
Reports issued during the reporting period	5	\$2,392,492,000
Total Section 1	13	\$17,831,968,000
Section 2		
Reports for which management decisions were made during the reporting period		
Value of recommendations agreed to by management		
Based on proposed management action	3	\$20,264,000
Based on proposed legislative action	0	0
Value of recommendations not agreed to by management	1	\$50,728,000
Total Section 2	4	\$70,992,000
Section 3		
Reports for which no management decisions had been made by the end of the reporting period ² (<i>Section 1 minus Section 2</i>)	9	\$17,760,976,000

End Notes

Table 1 End Notes

¹ The opening balance was adjusted upward by \$57.5 million because of a reevaluation of previously issued recommendations.

² Revisions to previously reported management decisions:

- A-05-11-00016 *National Government Services, Inc., Did Not Always Refer Medicare Cost Reports and Reconcile Outlier Payments.*
Based on subsequent review, CMS determined that no reconciliation or recoupment would be completed and that the \$51,513,196 would be allowable cost.
- A-02-09-01017 *The New Jersey Department of Human Services Claimed Medicaid Disproportionate Share Hospital payments to Five Hospitals That Did Not Meet Federal Eligibility Requirements.*
Based on the HHS Departmental Appeals Board decision, CMS reviewed the questioned cost totaling \$50,063,977 and determined that \$45,011,013 was allowable cost, reducing disallowed cost to \$5,052,964.
- A-05-12-00057 *Hoveround Corporation Claimed Millions in Federal Reimbursement for Power Mobility Devices That did not Meet Medicare Requirements.*
Subsequent review by CMS determined that \$12,296,045 in overpayments were allowable cost, reducing disallowed cost to \$14,731,534.
- A-01-13-00506 *Incorrect Place-of-Service Coding Resulted in Potential Medicare Overpayments Costing Millions.*

Based on subsequent review of supporting documentation, CMS determined that the \$7.1 million in questioned costs was allowable.

- **Not detailed are reductions to previously disallowed management decisions totaling \$14 million.**

³Included are management decisions to disallow \$27.7 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.

⁴Because of administrative delays, some of which were beyond management control, resolution of the following 53 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:

CIN: A-02-14-02017	NEW YORK MISALLOCATED COSTS TO ESTABLISHMENT GRANTS FOR A HEALTH INSURANCE MARKETPLACE, NOV 2016, \$149,654,512
CIN: A-01-02-00006	REVIEW OF RATE SETTING METHODOLOGY MEDICAID SCHOOL-BASED CHILD HEALTH PROGRAM COSTS CLAIMED BY THE CONNECTICUT DEPARTMENT OF SOCIAL SERVICES JULY 1997 THROUGH JUNE 2001, MAY 2003, \$32,780,146
CIN: A-01-14-02503	MARYLAND MISALLOCATED MILLIONS TO ESTABLISHMENT GRANTS FOR A HEALTH INSURANCE MARKETPLACE, MAR 2015, \$28,400,000
CIN: A-07-13-01125	MEDICARE IMPROPERLY PAID MEDICARE ADVANTAGE ORGANIZATIONS MILLIONS OF DOLLARS FOR UNLAWFULLY PRESENT BENEFICIARIES FOR 2010 THROUGH 2012, APR 2014, \$26,150,043
CIN: A-04-14-07050	KENTUCKY ESTABLISHMENT GRANTS AUDIT, FEB 2017, \$25,530,429
CIN: A-02-12-02016	PUERTO RICO IMPROPERLY CLAIMED SOME CHILD CARE AND DEVELOPMENT TARGETED FUNDS, JAN 2016, \$12,471,385
CIN: A-01-15-02500	VERMONT DID NOT PROPERLY ALLOCATE MILLIONS TO ESTABLISHMENT GRANTS FOR A HEALTH INSURANCE MARKETPLACE, SEP 2016, \$11,243,006
CIN: A-02-14-02024	NEWARK PRESCHOOL COUNCIL, INC., DID NOT ALWAYS COMPLY WITH HEAD START REQUIREMENTS, FEB 2017, \$9,950,556
CIN: A-07-15-01159	MEDICARE IMPROPERLY PAID MILLIONS OF DOLLARS FOR UNLAWFULLY PRESENT BENEFICIARIES FOR 2013 AND 2014, SEP 2016, \$9,267,392
CIN: A-07-14-02801	COLORADO HEALTH EXCHANGE ESTABLISHMENT GRANT, DEC 2016, \$4,398,333
CIN: A-03-12-00004	REVIEW OF HORIZON'S 2009 AND 2010 BONA FIDE SERVICE FEES, MAR 2013, \$4,344,417
CIN: A-02-12-02012	NEW YORK IMPROPERLY CLAIMED SOME CHILD CARE AND DEVELOPMENT TARGETED FUNDS, JUL 2015, \$3,827,836
CIN: 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, NOV 2016, \$3,771,672
CIN: A-05-13-00014	OHIO EXCEEDED THE 5-PERCENT LIMIT FOR CLAIMING CHILD CARE DEVELOPMENT FUND ADMINISTRATIVE EXPENDITURES, NOV 2013, \$3,164,630
CIN: A-03-13-00024	REVIEW OF NEW ORLEANS REGIONAL PHYSICIAN HOSPITAL ORGANIZATION, INC.'S 2009, 2010, AND 2011 BONA FIDE SERVICE FEES, APR 2014, \$2,880,698
CIN: A-03-13-00025	REVIEW OF UAB HEALTH SYSTEM'S 2009, 2010, AND 2011 BONA FIDE SERVICE FEES, JAN 2014, \$2,812,109

CIN: A-03-13-00026	REVIEW OF USABLE MUTUAL'S (ARKANSAS BLUE CROSS BLUE SHIELD) 2009, 2010, AND 2011 BONA FIDE SERVICE FEES, JAN 2014, \$2,763,821
CIN: A-03-11-00002	REVIEW OF NEW ENGLAND JOINT ENTERPRISE 2009 DIR REPORTS, APR 2012, \$2,710,732
CIN: A-03-12-00006	REVIEW OF TAHMO'S 2009 AND 2010 BONA FIDE SERVICE FEES, MAR 2013, \$2,355,532
CIN: A-03-13-00020	REVIEW OF CAPITAL DISTRICT PHYSICIANS' HEALTH PLAN, INC.'S 2009, 2010, AND 2011 BONA FIDE SERVICE FEES, JAN 2014, \$2,070,605
CIN: A-03-12-00007	REVIEW OF ARCADIAN'S 2009 AND 2010 BONA FIDE SERVICE FEES, FEB 2013, \$2,048,967
CIN: A-03-12-00005	REVIEW OF WINDSOR'S 2009 AND 2010 BONA FIDE SERVICE FEES, JAN 2013, \$1,948,737
CIN: A-03-13-00018	REVIEW OF AMERIGROUP CORPORATION'S 2009, 2010, AND 2011 BONA FIDE SERVICE FEES, JAN 2014, \$1,943,251
CIN: A-03-13-00019	REVIEW OF BLUECROSS BLUESHIELD OF SOUTH CAROLINA'S 2009, 2010, AND 2011 BONA FIDE SERVICE FEES, DEC 2013, \$1,799,096
CIN: A-05-16-00014	REVIEW OF PHYSICIAN-ADMINISTERED DRUG REBATES AT WISCONSIN, MAR 2017, \$1,732,222
CIN: 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, JUN 2013, \$1,419,524
CIN: A-04-13-01022	COSTS NORMALLY TREATED AS ADMINISTRATIVE AND CLERICAL CHARGED DIRECTLY TO HHS AWARDS AT THE UNIVERSITY OF LOUISVILLE, DEC 2016, \$1,311,067
CIN: A-05-14-00045	REVIEW OF MN STATE AGENCY PROCESS FOR DESIGN & IMPLEMENTATION OF THE STATE'S HEALTH INSURANCE EXCHANGE, NOV 2016, \$1,279,677
CIN: A-03-13-00021	REVIEW OF FALLON COMMUNITY HEALTH PLAN'S 2009, 2010, AND 2011 BONA FIDE SERVICE FEES, JAN 2014, \$1,079,578
CIN: A-05-12-00089	THE COUNCIL ON RURAL SERVICE PROGRAMS, INC., CLAIMED UNALLOWABLE HEAD START COSTS, NOV 2013, \$1,074,352
CIN: A-03-13-00022	REVIEW OF MD CARE, INC.'S 2009, 2010, AND 2011 BONA FIDE SERVICE FEES, JAN 2014, \$1,040,501
CIN: A-03-13-00023	REVIEW OF NATIONAL RURAL ELECTRIC COOPERATIVE ASSOCIATION'S 2009, 2010, AND 2011 BONA FIDE SERVICE FEES, JAN 2014, \$957,921
CIN: A-09-14-01007	NEVADA MISALLOCATED COSTS FOR ESTABLISHING A HEALTH INSURANCE MARKETPLACE TO ITS ESTABLISHMENT GRANTS, FEB 2016, \$893,464
CIN: A-04-15-04040	MEDICAL ACCESS UGANDA LIMITED GENERALLY MANAGED THE PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF FUNDS IN ACCORDANCE WITH AWARD REQUIREMENTS, JUN 2016, \$751,399
CIN: A-09-11-01007	HAWAII CLAIMED UNALLOWABLE COMMUNITY SERVICES BLOCK GRANT COSTS FOR HONOLULU COMMUNITY ACTION PROGRAM, INC.'S EXPENDITURES UNDER THE RECOVERY ACT, FEB 2013, \$513,649
CIN: 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, JUN 2014, \$352,843
CIN: A-02-15-02011	HURRICANE SANDY DISASTER RELIEF ACT FUNDS AWARDED TO THE CLEVELAND CLINIC LERNER COLLEGE OF MEDICINE, MAR 2017, \$299,170
CIN: A-01-10-02505	RESULTS OF LIMITED SCOPE REVIEW OF CTE, INC., MAY 2011, \$293,870
CIN: A-02-11-02015	PUERTO RICO CLAIMED UNALLOWABLE COMMUNITY SERVICES BLOCK GRANT RECOVERY ACT COSTS FOR INSTITUTO SOCIO-ECONÓMICO, INC., APR 2013, \$285,412

CIN: A-02-11-02017	NEW JERSEY CLAIMED UNALLOWABLE COMMUNITY SERVICES BLOCK GRANT COSTS INCURRED BY CHECK-MATE INC., UNDER THE RECOVERY ACT, AUG 2014, \$246,359
CIN: A-09-09-00045	RISK ADJUSTMENT DATA VALIDATION OF PAYMENTS MADE TO PACIFICARE OF CALIFORNIA FOR CALENDAR YEAR 2007 (CONTRACT H0543), NOV 2012, \$224,388
CIN: A-04-15-04039	REVIEW OF MILD MAY UGANDA COOPERATIVE AGREEMENT U2GPS002909 FOR FYS 2010-2014, MAR 2017, \$209,480
CIN: A-05-12-00012	ROCKFORD HUMAN SERVICES DID NOT ALWAYS CHARGE ALLOWABLE COSTS TO THE COMMUNITY SERVICES BLOCK GRANT - RECOVERY ACT PROGRAM, JUL 2013, \$205,296
CIN: A-06-09-00012	RISK ADJUSTMENT DATA VALIDATION OF PAYMENTS MADE TO PACIFICARE OF TEXAS FOR CALENDAR YEAR 2007 (CONTRACT NUMBER H4590), MAY 2012, \$183,247
CIN: A-04-11-01004	NORTHEAST FLORIDA COMMUNITY ACTION AGENCY, INC.'S CSBG FUNDS AWARDED UNDER THE AMERICAN RECOVERY AND REINVESTMENT ACT OF 2009, SEP 2012, \$165,795
CIN: A-04-11-01008	CENTRAL FLORIDA COMMUNITY ACTION AGENCY, INC., DID NOT ALWAYS CHARGE ALLOWABLE COSTS TO THE COMMUNITY SERVICES BLOCK GRANT - RECOVERY ACT PROGRAM, APR 2013, \$160,404
CIN: A-07-11-02766	NOT ALL COMMUNITY SERVICES BLOCK GRANT COSTS CLAIMED ON BEHALF OF THE CARBON COUNTY COMMUNITY ACTION COMMITTEE FOR THE PERIOD OCTOBER 1, 2008, THROUGH SEPTEMBER 30, 2010, WERE ALLOWABLE, AUG 2013, \$143,588
CIN: A-09-11-01013	OREGON CLAIMED SOME POTENTIALLY UNALLOWABLE COMMUNITY SERVICES BLOCK GRANT COSTS FOR MULTNOMAH COUNTY'S EXPENDITURES UNDER THE RECOVERY ACT, APR 2013, \$115,911
CIN: A-06-11-00058	CROWLEY'S RIDGE DEVELOPMENT COUNCIL, INC., CLAIMED UNALLOWABLE COSTS UNDER A RECOVERY ACT GRANT, AUG 2012, \$115,420
CIN: A-02-13-02005	PUERTO RICO'S CONTROLS FOR ITS CHILD CARE AND DEVELOPMENT PROGRAM CLAIMS WERE NOT EFFECTIVE, JAN 2017, \$82,544
CIN: A-02-15-02005	NEW JERSEY CLAIMED SOME UNALLOWABLE COSTS UNDER A HURRICANE SANDY DISASTER RELIEF ACT GRANT, FEB 2017, \$36,547
CIN: A-09-11-01014	HAWAII CLAIMED UNALLOWABLE COMMUNITY SERVICES BLOCK GRANT COSTS FOR HAWAII COUNTY ECONOMIC OPPORTUNITY COUNCIL'S EXPENDITURES UNDER THE RECOVERY ACT, JUL 2012, \$22,602
CIN: A-05-11-00053	THE COLUMBUS URBAN LEAGUE CLAIMED SOME UNALLOWABLE COSTS TO HEAD START, SEP 2012, \$13,102
TOTAL CINS:	53
TOTAL AMOUNT:	\$363,497,000

Table 2 End Notes

¹ The opening balance was adjusted upward by \$34.5 million to reflect prior period adjustments of previously issued recommendations.

² Revisions to previously reported management decisions:

- A-07-13-02795 *Palmetto Government Benefits Administrator Did Not Always Refer Medicare Cost Reports and Reconcile Outlier Payments in Jurisdiction 1.*
 Subsequent review by CMS determined that cost savings totaling \$34,897,819 were outside the three year window for reopening.

³ Because of administrative delays, some of which were beyond management control, 4 of the 9 audits open at end of the period were not resolved within 6 months of issuance of reports. OIG is working with management to reach resolution on these recommendations before the end of the next semiannual reporting period:

CIN: 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, APR 2014, \$15,000,000,000
CIN: A-09-14-02033	NATIONWIDE REVIEW OF CHIROPRACTIC SERVICES, OCT 2016, \$358,800,549
CIN: A-01-13-00511	NATIONWIDE REVIEW OF CARDIAC CATHETERIZATIONS AND HEART BIOPSIES FOR CY2010 THRU 2012, MAR 2017, \$7,629,229
CIN: A-09-14-02037	MEDICARE DID NOT PAY SELECTED INPATIENT CLAIMS FOR BONE MARROW AND STEM CELL TRANSPLANT PROCEDURES IN ACCORDANCE WITH MEDICARE REQUIREMENTS, FEB 2016, \$2,054,306
TOTAL CINS:	4
TOTAL AMOUNT:	\$15,368,484,000

Appendix B: Savings Decisions Supported by OIG Recommendations

The table below lists policy decisions reflected in legislation, regulations, or other directives from prior years that are supported by OIG recommendations and for which cost savings were estimated, usually by third parties, such as the Congressional Budget Office (CBO) or HHS actuaries. Of the savings estimated for the decisions below, nearly \$24.4 billion was attributed to FY 2017. 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 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 Programs		
OIG Recommendations	Policy Decisions	Estimated Savings (millions)
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 through FY 2019, including \$21.3 billion for FY 2017. 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.	\$21,300
Excessive Medicaid Payments to New York Developmental Centers. Ensure that New York's Medicaid daily rate for State-operated developmental centers meets the Federal requirement that payment for services be consistent with efficiency and economy. The recommendation reflected findings in OIG report number A-02-11-01029.	New York's Medicaid State Plan Amendment 12-03, effective April 1, 2013, limits payment to costs with projected annual savings of nearly \$799 million.	\$799
Part B Drugs Average Sales Price. Adopt an alternate calculation of volume-weighted ASP that is consistent with the results set forth in section 1847A (b)(3) of the Social Security Act. The recommendation reflected findings in OIG report number OEI-03-05-00310.	Section 112 of the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Extension Act of 2007 establishes a revised method for calculating volume-weighted ASPs for Medicare Part B drugs that comports with OIG's recommendation. CBO estimated savings of \$400 million for FY 2017.	\$400
Reductions in Medicare Bad Debt Reimbursement. Seek legislative authority to eliminate (or reduce) Medicare payments to hospitals for bad debt associated with beneficiaries' failure to pay their deductibles and coinsurance. The recommendations reflected findings in OIG report number A-14-90-00339 and subsequent reviews.	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 \$1.14 billion attributed to FY 2017. (77 Fed. Reg. 67450, 67523 (November 9, 2012))	\$1,140
Additional Rebates for Brand-Name Drugs with Multiple Versions. 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 market. The recommendation reflected findings in OIG report number A-06-09-00033.	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 2017.	\$300

<p>Medicare Secondary Payer. Implement stronger followup procedures for employers who fail to respond to data requests, exercise civil monetary penalty authority, and seek necessary legislative authority for mandatory data reporting. The recommendations reflected findings in the following OIG reports: A-02-98-01036, A-02-02-01037, A-02-02-01038, A-04-01-07002, A-09-89-00100</p>	<p>Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 amended the Medicare secondary payer provisions of the Social Security Act, § 1862(b), to provide for mandatory reporting for various categories. CBO estimated savings of \$200 million for FY 2017.</p>	<p>\$200</p>
<p>Medicare Payments for Vacuum Erection Systems. Seek legislative authority to include vacuum erection systems (VES) in the Competitive Bidding program and then implement a National Mail-Order Competitive Bidding program for VES. The recommendation reflected findings in OIG report number A-07-12-05024.</p>	<p>Section 203 of the Achieving a Better Life Experience Act of 2014 implements changes to treat VES prosthetic devices and related accessories as statutorily noncovered in the same manner that erectile dysfunction drugs are treated in Medicare Part D. CBO estimated savings of \$444 million over 10 years.</p>	<p>\$44.4</p>
<p>Payments for Prescription Drugs Provided to Incarcerated Beneficiaries. 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>	<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 Social Security 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 \$108 million attributed to FY 2017. (79 Fed. Reg. 29844, 29953 (May 23, 2014))</p>	<p>\$108</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 2017.</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
	May 2015	Department of Transportation OIG	HHS OIG, OAS

The system of quality control for the audit organization of HHS OIG in effect for the year ending September 30, 2014, has been suitably designed and complied with to provide HHS OIG with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Federal audit organizations can receive a rating of pass, pass with deficiencies, or fail. HHS OIG received a peer-review rating of pass.

OAS	Date	Reviewing Office	Office Reviewed
	December 2015	HHS OIG, OAS	U.S. Department of Agriculture (USDA) OIG

The system of quality control for the audit organization of USDA OIG in effect for the year ending March 31, 2015, has been suitably designed and complied with to provide USDA OIG with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Federal audit organizations can receive a rating of pass, pass with deficiencies, or fail. USDA OIG received a peer-review rating of pass.

Office of Investigations

During this semiannual reporting period, one peer review involving OI was completed. Listed below is information concerning 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 HHS 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
	June 2014	HHS OIG, OI	Treasury Inspector General for Tax Administration (TIGTA)

The system of internal safeguards and management procedures for the investigative function of TIGTA, 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 OEI initiated a peer review of certain Department of Defense (DoD) OIG Inspection and Evaluations (I&E) units, at the request of DoD OIG. Results of this peer review will be reported in January 2018.

OEI	Date	Reviewing Office	Office Reviewed
	September 2017	HHS OIG	DoD OIG, I&E units

Appendix D: Summary of Sanction Authorities

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

Program Exclusions

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

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

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

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

Civil Monetary Penalties Law

The CMPL of the Social Security Act, 1128A (42 U.S.C. § 1320a 7a), imposes penalties, assessments, and exclusion from participation in Federal health care programs for engaging in certain activities. For example, a person who submits, or causes to be submitted, to a Federal health care program a claim for items and services that the person knows, or should know, is false or fraudulent is subject to a penalty of up to \$15,270 for each item or service falsely or fraudulently claimed, an assessment of up to 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 health care program (including Medicare and Medicaid managed care programs and Medicare Part D); the ACA authorizes a penalty of up to \$55,262 for each false statement, as well as activities relating to fraudulent marketing by managed care organizations, their employees, or their agents.

The 21st Century Cures Act (enacted on December 13, 2016) added more grounds for imposing CMPs, assessments, and exclusion from Federal health care programs for fraudulent conduct in an HHS grant, contract, or other agreement. OIG may assess CMPs of up to \$10,000 per claim and assessments of up to 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 health care programs or (2) purchasing, leasing, or ordering, or arranging for or recommending the purchasing, leasing, or ordering, of any good, facility, service, or item payable under the Federal health care programs (Social Security Act, § 1128B(b) (42 U.S.C. § 1320a-7b(b))).

Individuals and entities 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	<i>OIG Compendium of Unimplemented Recommendations (Compendium)</i>
(a)(4)	Matters referred to prosecutive authorities	"Legal and Investigative Activities Related to the Medicare and Medicaid Programs" section
(a)(5)	Summary of instances in which information requested by OIG was refused	None for this reporting period
(a)(6)	List of audit reports	Submitted to the Secretary under separate cover
(a)(7)	Summary of significant reports	Throughout this report
(a)(8)	Statistical Table 1—Reports with Questioned Costs	Appendix A
(a)(9)	Statistical Table 2—Funds Recommended To Be Put to Better Use	Appendix A
(a)(10)	Summary of previous audit reports without management decisions, in which no establishment comment was returned within 60 days, and in which there are any outstanding unimplemented recommendations	Appendix A
(a)(11)	Description and explanation of revised management decisions	Appendix A
(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

Section	Requirement	Location
(a)(14)-(16)	Results of peer reviews of HHS OIG conducted by other OIGs or the date of the last peer review, outstanding recommendations from peer reviews, and peer reviews conducted by HHS OIG of other OIGs	Appendix C
(a)(17)	Investigative statistical tables	Appendix F
(a)(18)	Metrics description for statistical tables	Appendix F
(a)(19)	Investigations on Senior Government Employees	Appendix F
(a)(20)	Description of whistleblower retaliation instances	Appendix F
(a)(21)	Description of attempts to interfere with OIG independence	Appendix F
(a)(22)	Description of closed and nondisclosed reports and investigations regarding Senior Government Employees	Appendix F

Other Reporting Requirements

Section	Requirement	Location
845	Significant contract audits required to be reported pursuant to the National Defense Authorization Act for FY 2008 (P.L. No. 110-181), § 845.	"Other HHS-Related Reviews and Investigations" section
205	Pursuant to HIPAA (P.L. No. 104-191), § 205, the Inspector General is required to solicit proposals annually via a 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 2017, OIG had 126 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 is able to 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 10 additional audit reports with overdue management decisions from FY 1990 through FY 2010.

OIG is actively tracking 1,344 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 fiscal year:

Fiscal Year (2011–2017)	Number of Reports with Unimplemented Recommendations	Number of Unimplemented Recommendations	Dollar Value of Aggregate Potential Cost Savings
2011	20	39	\$444,267,108
2012	39	66	\$350,705,539
2013	53	124	\$872,462,968
2014	57	117	\$15,164,610,238
2015	61	138	\$536,392,445
2016	112	322	\$440,555,639
2017	139	538	\$2,553,368,595
Totals	481	1344	\$20,362,362,532

OIG annually produces a [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. The Compendium’s appendix is a list of 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 DOJ and/or State/local prosecuting authorities for criminal prosecution during the reporting period ³	1,453
Total number of indictments and criminal informations during the reporting period that resulted from any prior referral to prosecuting authorities	519

(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 is a document that 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 operating division or staff division, 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 makes a decision 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.

Currently, OIG’s case management system does not have the capability to distinguish between a Federal and State presentation. Consequently, the information provided in the table represents presentations to both Federal and State/local prosecuting jurisdictions. Beginning in FY 2018, OIG will have the capability to separate Federal from State/local presentations and will begin reporting this information accordingly.

Regarding (17)(D), the table 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 presentation in a previous period. In certain situations, the presentation and charging dates are in the same reporting period. Also, as mentioned above, beginning in FY 2018, OIG will have the capability to separate Federal from State/local indictments/criminal informations and will begin reporting this information accordingly.

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

³ OIG counts “persons” as both individuals and entities.

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

Description of Investigation	Status	Disposition	DOJ Referral	DOJ Referral Date	DOJ Declination	DOJ Declination Date
A senior Government employee was alleged to have given the winner of an IT contract pre-bidding information in exchange for potential post-government employment.	Closed	Voluntary Dismissal/ Nolle Prosequi	Yes	09/2015	N/A	N/A
A senior Government employee was alleged to have demonstrated a lack of oversight regarding an employee this person supervised who allegedly	Closed	Written Reprimand	No	N/A	N/A	N/A

spent the majority of his time in another country.						
A senior Government employee was alleged to have revoked an employee's clearance following a disclosure of the senior employee's gross mismanagement	Closed	Written Reprimand/ Resigned After Investigation	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.

Under this system, OIG submitted two reports that included findings of retaliation to the HHS Office of the Secretary prior to October 1, 2016 (both prior to the semiannual reporting period). Because these reports are still under review by the Department, OIG will not comment about them at this time. OIG will include information about these reports in OIG's Semiannual Report following the Department's resolution of the matter.

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 the Department interfered with the independence of OIG during this reporting period. OIG would immediately notify Congress if it were unable to resolve these issues within the Department.

(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, 2017, to September 30, 2017

Category/Description	Number of Reports
IT security reviews (involve IT systems, e.g., penetration test audits)	9
Homeland security issues (involve particularly sensitive topics, e.g., bioterrorism, emergency preparedness, and classified or potentially classified information)	1
Recipient Capability Audits (primarily in Head Start/Early Head Start programs)	0
Reimbursable audits performed for other Federal agencies (primarily contract audits)	0
Confidential or proprietary information (e.g., Medicare Part B drug claims/imaging services, Medicare investment income)	3
Medicare Adverse Event Reviews (required by law not to disclose)	0
Medicare Prescription Drug Event Reviews	0
Other	2
Departmental technical assistance reports ⁴	1
Finance-related attestation reviews	3
Total	19

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

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

⁴ OIG routinely provides technical assistance to the Department. 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.

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

Description of Investigation	Status	Disposition	DOJ Referral	DOJ Referral Date	DOJ Declination	DOJ Declination Date
A senior Government employee was alleged to have changed their duty location in order 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 in order 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

Anti-Kickback Statute – Safe Harbors

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

In crafting safe harbors for a criminal statute, it is incumbent upon the OIG to engage in a complete and careful review of the range of factual circumstances that may fall within the proposed safe harbor subject area to uncover all potential opportunities for fraud and abuse by unscrupulous providers. Having done so, OIG must then determine, in consultation with DOJ, whether it can develop effective regulatory limitations and controls—not only to foster beneficial or innocuous arrangements but also to protect the Federal health care programs and their beneficiaries from abusive practices.

Public proposals for new and modified safe harbors

In response to the 2016 annual solicitation, OIG received the following proposals related to safe harbors:

Proposal	OIG Response
A new safe harbor that would protect value-based payment arrangements that bundle products and related services and allow for price adjustments if a measurable clinical and/or cost outcome is not achieved.	OIG is not adopting this suggestion at this time, as it requires further study. In the meantime, questions about the application of the anti-kickback statute to such arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.
A new safe harbor that would protect value-based warranties offered by manufacturers or suppliers of products that provide certain assurances about clinical and/or cost outcomes and appropriate remedies where such outcomes are not achieved.	OIG is not adopting this suggestion at this time, as it requires further study. In the meantime, questions about the application of the anti-kickback statute to such arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.

A new safe harbor that would protect value-based payment arrangements generally.	OIG is not adopting this suggestion at this time, as it requires further study. In the meantime, questions about the application of the anti-kickback statute to such arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.
A new safe harbor that would protect arrangements that support patient adherence to a treatment regimen that has been recommended by the patient's health care provider.	OIG is not adopting this suggestion at this time, as it requires further study. In the meantime, questions about the application of the anti-kickback statute to such arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.
A new safe harbor that would protect arrangements that pay for, or provide, data analytics.	OIG is not adopting this suggestion at this time, as it requires further study. In the meantime, questions about the application of the anti-kickback statute to such arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.
The modification of the personal services and management contracts safe harbor, 42 C.F.R. § 1001.952(d), to protect personal services arrangements involving part-time or periodic services that lack an exact schedule of services or precise length of intervals.	OIG is not adopting this suggestion at this time, as it requires further study. In the meantime, questions about the application of the anti-kickback statute to such arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.
The modification of the discounts safe harbor, 42 C.F.R. § 1001.952(h), to include exceptions for value-based arrangements within the existing definition of discount; to protect certain discounts offered in connection with value-based arrangements; and to define "value-based arrangement" to capture appropriate and beneficial arrangements while excluding arrangements that are abusive or result in inappropriate financial incentives.	OIG is not adopting this suggestion at this time, as it requires further study. In the meantime, questions about the application of the anti-kickback statute to such arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.
The modification of the discounts safe harbor, 42 C.F.R. § 1001.952(h), to expand upon the subcategories of buyers potentially protected by the safe harbor; to specify under what circumstances a discount or rebate arrangement may involve the performance of services or activities; and to clarify the disclosure obligations that arise under the safe harbor.	OIG is not adopting this suggestion at this time, as it requires further study. In the meantime, questions about the application of the anti-kickback statute to such arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.
The modification of the warranties safe harbor, 42 C.F.R. § 1001.952(g), to protect remuneration	OIG is not adopting this suggestion at this time, as it requires further study. In the meantime, questions

paid to cover certain services and items that are related to the item that is the subject of the warranty in the context of value-based arrangements.	about the application of the anti-kickback statute to such arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.
The modification of the warranties safe harbor, 42 C.F.R. § 1001.952(g), to protect manufacturer-issued refunds in circumstances in which the manufacturer's products do not work as specified for individual patients or patient populations, particularly in outcomes or value-based arrangements.	OIG is not adopting this suggestion at this time, as it requires further study. In the meantime, questions about the application of the anti-kickback statute to such arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.
The modification of the price reductions offered to health plans, price reductions offered to eligible managed care organizations, and price reductions offered by contractors with substantial financial risk to managed care organizations safe harbors, 42 C.F.R. § 1001.952(m), (t), and (u), to clarify the circumstances under which drug manufacturer rebate agreements with managed care organizations or pharmacy benefit managers would be protected.	OIG is not adopting this suggestion at this time, as it requires further study. In the meantime, questions about the application of the anti-kickback statute to such arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.