

HHS OIG Semiannual Report to Congress

April 1, 2016 – September 30, 2016



OIG Organization

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), Office of Inspector General (OIG) provides independent and objective oversight that promotes economy, efficiency, and effectiveness in the programs and operations of HHS. OIG's program integrity and oversight activities are shaped by legislative and budgetary requirements and adhere to professional standards established by the Government Accountability Office (GAO), the Department of Justice (DOJ), and the Inspector General community. OIG carries out our mission to protect the integrity of HHS programs and the health and welfare of the people served by those programs through a nationwide network of audits, investigations, and evaluations. Our work is conducted by the following operating components with assistance from OIG counsel and management.

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 its grantees and contractors in carrying out their respective responsibilities and are intended to 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 general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, self-disclosure, and CMP cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements (CIA). 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 overseeing the activities of OIG's components; setting vision and direction, in collaboration with the components, for OIG's priorities and strategic planning; ensuring effective management of budget, finance, information technology (IT), human resources, 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.

Highlights of Our Accomplishments

HHS OIG'S *SEMIANNUAL REPORT TO CONGRESS (Semiannual Report)* describes 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 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 2016. We also highlight in this section some of our work completed during this semiannual reporting period, April 1, 2016, to September 30, 2016.

OIG Numbers At-A-Glance

For FY 2016, OIG reported expected recoveries of more than \$5.66 billion consisting of nearly \$1.2 billion in audit receivables¹ and about \$4.46 billion in investigative receivables.² The investigative receivables include about \$953 million in non-HHS investigative receivables, resulting from our work in areas such as the States' shares of Medicaid restitution.

Also during FY 2016, OIG reported 844 criminal actions against individuals or entities that engaged in crimes against HHS programs. Additionally, OIG reported 708 civil actions, which include false claims and unjust-enrichment lawsuits filed in Federal district court, CMP settlements, and administrative recoveries related to provider self-disclosure matters. Our CMP recoveries have increased almost five-fold over the past 3 years. We also reported exclusions of 3,635 individuals and entities from participation in Federal health care programs.

Health Care Fraud Strike Force Teams and Other Enforcement Actions

The Health Care Fraud Prevention and Enforcement Action Team (HEAT) was started in 2009 by HHS and DOJ to strengthen programs and invest in new resources and technologies aimed at preventing and combating health care fraud, waste, and abuse. HEAT has continued to identify and hold accountable those who seek to defraud Medicare and Medicaid. Health Care Fraud Strike Force teams, a key component of HEAT, coordinate law enforcement operations conducted jointly by Federal, State, and local law enforcement entities. The teams have a record of successfully analyzing data to quickly identify, investigate, and prosecute fraud.

¹ Audit receivables derive from OIG audits in which there were questioned costs and HHS program officials have agreed those questioned costs should not be charged to the Federal Government. Questioned costs relate to expenditures that OIG found in their audits were not supported by adequate documentation or because the expenditure was unnecessary or unreasonable.

² Investigative receivables are expected recoveries from criminal actions, civil and administrative settlements, civil judgments, or administrative actions that resulted wholly or in part from an OIG investigative activity. This does not represent actual collections but rather the amount of money that was ordered or agreed upon to be returned or paid to HHS and other Federal, State, and private individuals and entities.

The Strike Force model operates in Miami, Florida; Los Angeles, California; Detroit, Michigan; southern Texas; Brooklyn, New York; southern Louisiana; Tampa, Florida; Chicago, Illinois; and Dallas, Texas. During FY 2016, Strike Force efforts resulted in the filing of charges against 255 individuals or entities, 207 criminal actions, and \$321 million in investigative receivables. Below are examples of our Strike Force efforts during this semiannual reporting period:

Largest National Health Care Fraud Takedown Results in Charges Against 301 Individuals

In June 2016, the Health Care Fraud Strike Force led an unprecedented nationwide sweep in 36 Federal districts, with the assistance of 24 State Medicaid Fraud Control Units (MFCU). The sweep resulted in criminal and civil charges against 301 individuals, including 61 doctors, nurses, and other licensed medical professionals, for their alleged participation in health care fraud schemes involving approximately \$900 million in false billings. For more information on this takedown, visit our Strike Force website at <https://oig.hhs.gov/fraud/strike-force/highlights.html?width=600&height=540>.

Home Health Agency Owner Sentenced to 20 Years in Prison for Falsely Billing Medicare

Khaled Elbeblawy was the owner and manager of three Miami-area home health agencies. According to evidence presented at trial, Elbeblawy and his co-conspirators purported to provide home health services to Medicare beneficiaries, which were not medically necessary and often not provided. Elbeblawy and his co-conspirators paid kickbacks to doctors, patient recruiters, and staffing groups in return for referring beneficiaries to the home health agencies. Elbeblawy was convicted of conspiracy to commit health care fraud and wire fraud and conspiracy to defraud the United States and pay health care kickbacks. He was sentenced to 20 years in prison and ordered to pay \$36.4 million in restitution, joint and several.

Quality of Care

As Americans continue to live longer and with more chronic medical conditions, it is important that our Medicare and Medicaid beneficiaries, some of whom are our most vulnerable citizens, receive high-quality health care. OIG endeavors to ensure that providers offer HHS beneficiaries adequate quality care in the appropriate setting. The following are examples of our quality of care work during this semiannual reporting period:

Connecticut and Massachusetts Critical Incident Reporting

We are performing reviews in several States in response to a congressional request concerning a number of deaths and cases of abuse of developmentally disabled residents of group homes. We found that Connecticut and Massachusetts did not comply with Federal waiver and State requirements for critical incidents involving developmentally disabled Medicaid beneficiaries living in group homes. A critical incident is any actual or alleged event or situation that creates a significant risk of substantial or serious harm to the physical or mental health, safety, or well being of a beneficiary. Connecticut did not adequately safeguard 137 of 245 developmentally disabled Medicaid beneficiaries and Massachusetts did not adequately safeguard 146 out of 334 beneficiaries because the systems of reporting and

monitoring critical incidents did not work as expected. Neither State ensured that: (1) group homes reported all critical incidents to the appropriate agencies; (2) data on all critical incidents were obtained, analyzed, or reported; and (3) all reasonable suspicions of abuse or neglect were reported. Connecticut also did not ensure that group homes always reported incidents at the correct severity level. Both States concurred with our recommendations.

West Carroll Care Center Did Not Always Follow Care Plans for Residents Who Were Later Hospitalized with Potentially Avoidable Urinary Tract Infections

We found that the nursing home West Carroll Care Center did not always provide services to its residents in accordance with their care plans, as required by Federal regulations, before they were hospitalized with urinary tract infections. Specifically, the Nursing Home staff did not monitor and document residents' hydration status, monitor and document residents' conditions, or include appropriate progress notes for residents required by their care plans. West Carroll agreed to implement its newly developed policies and procedures requiring that its nursing staff follow residents' care plans and the director of nursing or a designee conduct reviews to ensure that the nursing staff follows residents' care plans. West Carroll stated that it has implemented corrective actions.

Prescription Drugs

Part D is the fastest growing component of the Medicare program, and Medicaid expenditures for prescription drugs are also increasing, influenced by Medicaid expansion and increasing expenditures for expensive specialty drug costs. HHS's oversight of its prescription drug programs faces numerous challenges, affecting beneficiary and community safety and the integrity of the benefit itself. In addition, pharmaceutical fraud and drug diversion are also major concerns on the rise. The following are examples of our prescription drug work during this semiannual reporting period:

High Part D Spending on Opioids and Substantial Growth in Compounding Drugs Raise Concerns

Medicare Part D spending for commonly abused opioids exceeded \$4 billion in 2015, and spending for compounded topical drugs increased more than 3,400 percent since 2006. This data brief builds on OIG's June 2015 data brief, which described trends in Part D spending and identified questionable billing by pharmacies. It updates information on spending for commonly abused opioids and provides data on the dramatic growth in spending for compounded drugs. OIG will continue to conduct investigations and reviews to address the ongoing problems created by opioid abuse and the emerging problems linked to compounded drugs. The Centers for Medicare & Medicaid Services (CMS) has taken steps to combat the problems associated with commonly abused opioids, such as identifying outlier prescribers. However, the data brief concluded that CMS needs to take additional action, including fully implementing OIG's previous recommendations. CMS also needs to assess the implications of the compounded drug trends identified in this data brief and take action where needed to protect the integrity of the program.

Recommendation Followup: CMS Should Address Medicare’s Flawed Payment System for DME Infusion Drugs

This review, following up on an earlier recommendation, investigated the impact of the current Part B payment methodology on provider reimbursement rates for two vital drugs: pump-administered insulin and milrinone lactate. We found that in 2015 Medicare paid suppliers 65 percent less than their cost for pump-administered insulin – hindering beneficiary access to the drug. Using the same reimbursement methodology, Medicare paid suppliers of milrinone lactate, an infusion drug used to treat congestive heart failure, 20 times the drug’s cost, thereby creating incentives for overutilization and improper billing. Therefore, OIG continued to recommend that CMS take action to ensure that payment amounts for infusion drugs more accurately reflect provider acquisition costs.

Pharmaceutical Company Enters into \$784.6 Million Settlement Agreement

Wyeth Inc. and Pfizer Inc. (the current owner of Wyeth) reached a \$784.6 million settlement agreement with the United States to resolve allegations that Wyeth reported false pricing information and underpaid rebates that were due under the Medicaid drug rebate program. The Government alleged that Wyeth failed to report deep discounts that it offered to hospitals for bundled sales of oral and intravenous versions of the drug Protonix. This conduct allegedly led Wyeth to report false pricing information to CMS and underpay rebates due to the States.

Provider Enrollment Safeguards and Oversight

To ensure that Medicare and Medicaid can continue to serve our Nation’s most vulnerable populations well into the future, it is critical to protect the financial integrity of these programs. One way to protect programs is through strong enrollment safeguards and robust ownership disclosure requirements. These forms of provider verification can fully identify information regarding the providers with whom HHS does business and can prevent ineligible providers from ever entering the Medicare or Medicaid programs. Strong provider safeguards at the beginning of the enrollment process, along with ongoing verification throughout to ensure that enrolled providers continue to meet Medicare and Medicaid requirements, allow CMS to better protect beneficiaries from harm and reduce to improper payments.

OIG examined both provider enrollment screenings and provider ownership databases in the Medicare and Medicaid programs and found that these screening tools can be effective mechanisms to ensure that illegitimate providers do not participate in either the Medicare or Medicaid programs, and to ensure that ineligible or disenrolled providers do not engage in fraudulent or abusive activities. CMS concurred with all OIG recommendations in all four reports analyzing provider screening and provider ownership disclosure (see below). The following are examples of our most recent provider enrollment work during this semiannual reporting period:

- **Enhanced Enrollment Screening of Medicare Providers: Early Implementation Results:** We found that CMS needs to strengthen implementation of its new enhanced enrollment

screening tools, which are intended to prevent illegitimate providers from enrolling in Medicare.

- **Medicare: Vulnerabilities Related to Provider Enrollment and Ownership Disclosure:** We found vulnerabilities that could allow potentially fraudulent providers to enroll in the Medicare program and limit CMS's ability to provide adequate oversight.
- **Medicaid: Vulnerabilities Related to Provider Enrollment and Ownership Disclosure:** We found that few State Medicaid programs requested that providers disclose all Federally required ownership information, that 14 State Medicaid programs reported that they did not verify the completeness or accuracy of provider ownership information, and that 14 State Medicaid programs reported that they did not check all required exclusions databases, which could allow providers with excluded owners to enroll in Medicaid.
- **Medicaid Enhanced Provider Enrollment Screenings Have Not Been Fully Implemented:** We found that State implementation of risk-based screening for Medicaid providers is incomplete, and that screening substitution and fingerprint-based criminal background checks remain challenges.

False Billings/Improper Payments

HHS policies or practices sometimes result in inefficiencies when unintended loopholes or other inherent problems invite exploitation or hinder consistent payment determinations. Improper payments and false billings occur when the programs do not effectively prevent, deter, identify, or address inappropriate and excessive billing by providers and suppliers. The following are examples of our improper payment work during this semiannual reporting period:

Medicare Improperly Paid Millions of Dollars for Unlawfully Present Beneficiaries for 2013 and 2014

In response to a congressional request regarding improper payments to unlawfully present beneficiaries, we found that when CMS's data systems indicated that at the time a claim was processed the beneficiary was unlawfully present, CMS followed its policies and procedures to prevent payment. However, when CMS's data systems did not indicate until after a claim had been processed that a beneficiary was unlawfully present, CMS did not follow its policies and procedures to detect and recoup payment. CMS determined that beneficiaries were liable for these improper payments, but it did not notify Medicare contractors to initiate recoupment activities. CMS concurred with our recommendations.

HIV Clinic Owner Ordered to Pay \$12.2 Million in Restitution for Health Care Fraud

Jorge Juvier was the owner and operator of multiple HIV/AIDS clinics in New York that purportedly provided injection and infusion treatments to Medicare-eligible HIV/AIDS patients. According to court documents, however, these clinics were, in reality, health care fraud mills. As part of the scheme, Juvier and his co-conspirators paid patients cash kickbacks for coming to the clinics; coached patients on lying to clinic doctors to enable fraudulent billing; and billed Medicare for medications that were never administered, administered at incorrect dosages, or were medically unnecessary. Juvier was sentenced

to over 5 years in prison and ordered to pay \$12.2 million in restitution, joint and several, for his guilty plea to conspiracy to commit health care fraud.

Grants Oversight

HHS is the largest grant-making organization in the Federal Government, with more than \$400 billion awarded in FY 2016. Responsible stewardship of these program dollars is vital to public health and well-being. Operating a financial management and administrative infrastructure that employs appropriate internal controls to minimize risk and protect resources remains a challenge for HHS. The following are examples of our grants oversight work during this semiannual reporting period:

More Effort is Needed to Protect the Integrity of the CCDF Block Grant Program

Past work on the Child Care and Development Fund (CCDF) block grant program identified fraud, found improper payments, and exposed health and safety concerns at childcare facilities. This recent report focused on how States and the Administration for Children and Families (ACF) ensure the integrity of the CCDF block grant program and the results of States' program integrity activities. This review found that States differed in the scope of their CCDF program integrity activities and varied substantially in the degree to which they conducted specific program integrity activities. Not all States performed important antifraud activities, and few States notified ACF and other States about suspected fraud. ACF does not have a process to ensure that States carry out planned program integrity activities nor does it collect information about the results of these activities. ACF concurred with all of our recommendations.

CDC Did Not Award President's Emergency Plan for AIDS Relief Funds for 2013 in Compliance with Applicable HHS Policies

We found that the Centers for Disease Control and Prevention (CDC) did not award President's Emergency Plan for AIDS Relief (PEPFAR) funds for FY 2013 in compliance with HHS and internal policies. We sampled 30 Funding Opportunity Announcements (FOAs) and found that, in some of the CDC FOA reviews that culminated in awards, CDC did not comply with one or more HHS or internal policies. As a result, CDC did not always adequately document its funding decisions to award \$1.9 billion over the 5-year project period, may have considered applications that it should not have considered, and sometimes treated applicants inconsistently. CDC concurred with our recommendations that it: (1) conduct quality assurance reviews of FOAs and funded grant applicant information to monitor compliance with HHS and internal policies when awarding PEPFAR funds and (2) address specific deficiencies that we identified in our review.

Health Information Technology

In support of its mission and operations, HHS maintains and uses expanding amounts of sensitive information. Complete, accurate, and timely data can help ensure efficient operations of HHS and its programs, as well as support proactive program oversight. Similarly, the American health care system increasingly relies on health information technology (health IT) and the electronic exchange and use of

health information. Health IT, including electronic health records (EHRs), offers opportunities for improved patient care, more efficient practice management, and improved overall public health. However, HHS continues to face a number of significant challenges in this information-rich environment. The following are examples of our health IT work during this semiannual reporting period:

Hospitals Largely Reported Addressing Requirements for EHR Contingency Plans

This evaluation provides information about the status of hospitals' contingency plans in light of evolving threats, including cyberattacks such as ransomware, to their electronic health information systems. We found that almost all hospitals reported having written EHR contingency plans, and most reported that their plans addressed four Health Insurance Portability and Accountability Act (HIPAA) requirements as well as recommended practices. This review provides baseline information on hospitals' contingency plans at a time when awareness of cybersecurity threats is growing, and reinforces previous OIG recommendations to the Office for Civil Rights (OCR) concerning its audit program, among others.

Public Summary Report: Wireless Penetration Test of Centers for Medicare & Medicaid Services' Data Centers

We performed a wireless penetration test of select CMS Data Centers and facilities to determine whether CMS's security controls over its wireless networks were effective. We found that, although CMS had security controls that were effective in preventing certain types of wireless cyberattacks, we identified four vulnerabilities at selected CMS Data Centers and facilities in security controls over its wireless networks. The vulnerabilities were collectively and, in some cases, individually significant. Although we did not identify evidence that the vulnerabilities had been exploited, exploitation could have resulted in unauthorized access to and disclosure of personally identifiable information, as well as disruption of critical operations. In addition, exploitation could have compromised the confidentiality, integrity, and availability of CMS's data and systems. We promptly shared detailed information with CMS about our preliminary findings. CMS concurred with our recommendations that it improve its security controls to address the wireless network vulnerabilities we identified.

OIG Participation in Congressional Hearings

09/28/2016	Abhijit Dixit, Special Agent in OIG's Office of Investigations, testified before the House Committee on Ways and Means: Subcommittee on Oversight: "Health Care Fraud Investigations"	
9/14/2016	Gloria Jarmon, Deputy Inspector General for Audit Services, testified before the House Committee on Energy and Commerce: Subcommittee on Oversight and Investigations and Subcommittee on Health: "The Affordable Care Act on Shaky Ground: Outlook and Oversight"	
5/24/16	Ann Maxwell, Assistant Inspector General for Evaluation and Inspections, testified before the House Committee on Energy and Commerce: Subcommittee on Oversight and Investigations: "Medicare and Medicaid Program Integrity: Combatting Improper Payments and Ineligible Providers"	

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Selected Acronyms and Abbreviations

- ACA Patient Protection and Affordable Care Act
- ACF Administration for Children and Families
- CDC Centers for Disease Control and Prevention
- CIA corporate integrity agreement
- CHIP Children’s Health Insurance Program
- CMP civil monetary penalty
- CMS Centers for Medicare & Medicaid Services
- CY calendar year
- DME durable medical equipment
- DOJ Department of Justice
- EHR electronic health record
- FBI Federal Bureau of Investigation
- FDA Food and Drug Administration
- FY fiscal year
- GAO General Accountability Office
- HHS Department of Health and Human Services
- HIPAA Health Insurance Portability and Accountability Act
- HRSA Health Resources and Services Administration
- MAC Medicare Administrative Contractors
- Marketplaces health insurance exchanges
- MFCU Medicaid Fraud Control Unit
- NIH National Institutes of Health
- OCR Office of Civil Rights
- OIG Office of Inspector General
- OMB Office of Management and Budget

Centers for Medicare & Medicaid Services

The Medicare Program

CMS Oversight of Medicare Contractor Performance

CMS relies on contractors to administer the Medicare program and is responsible for overseeing the contractors' performance. Medicare contractors are responsible for administering more than one-half of a trillion dollars in benefits each year. Medicare Administrative Contractors (MACs) process Parts A and B claims; Medicare Advantage plans provide managed care services under Part C; Part D plans provide prescription drug coverage under Part D; and various benefit integrity contractors serve to protect Medicare from fraud, waste, and abuse.

Medicare Payments, Policies, and Practices

Recommendation Followup: CMS Should Address Medicare's Flawed Payment System for DME Infusion Drugs (OEI-12-16-00340), September 2016

This review, following up on an earlier recommendation, built on previous OIG findings by illustrating the impact of the current Part B payment methodology on provider reimbursement rates for two vital drugs: pump-administered insulin and milrinone lactate. Unlike most other Part B drugs, Medicare payment amounts for DME infusion drugs are still based on list prices – known as average wholesale prices – from 2003. In February 2013, OIG issued a report to CMS recommending that the agency address payment issues associated with DME infusion drugs. Because CMS had not taken steps to address our recommendation, and payments continued to be misaligned with drug costs, OIG revisited this issue in a 2015 report.

In updating the two prior studies, we found that in 2015 Medicare paid suppliers 65 percent less than their cost for pump-administered insulin – hindering beneficiary access to the drug. Using this same reimbursement methodology, Medicare paid suppliers of milrinone lactate, an infusion drug used to treat congestive heart failure, 20 times the drug's cost, thereby creating incentives for overutilization and improper billing. Therefore, OIG continued to recommend that CMS take action to ensure that Medicare payment amounts for DME infusion drugs more accurately reflect provider acquisition costs. The agency could choose to seek a legislative change that would require payments for DME infusion drugs to be based on average sales price. CMS could also choose to use its existing authority to include DME infusion drugs in the competitive bidding program as soon as possible.

Incomplete and Inaccurate Licensure Data Allowed Some Suppliers in Round 2 of the Durable Medical Equipment Competitive Bidding Program That Did Not Have Required Licenses (A-05-13-00047), May 2016

To address market changes and increasing Medicare Part B expenditures for DME items, Congress required CMS to implement a Medicare competitive bidding program. The Medicare Improvements for Patients and Providers Act of 2008 contains a broad mandate requiring OIG to assess the process used

by CMS to conduct the competitive bidding and subsequent pricing determinations that are the basis for the single payment amounts under Rounds 1 and 2 of the competitive bidding program. In addition, we received congressional requests to look into complaints that some suppliers that were offered contracts for Round 2 of the competitive bidding program may not have met licensure requirements under the awarded contracts. Our objective was to determine whether suppliers that received contracts in Round 2 of the DME competitive bidding program and about whom CMS received complaints met licensure requirements.

We found that some contract suppliers in Round 2 of the Competitive Bidding Program had not met all of the competitive bidding licensure requirements. Specifically, of the 146 suppliers covered in our audit, 63 did not meet licensure requirements for some of the competitions for which they received a contract. Additionally, 14 suppliers need to be further researched by CMS and its contractors to determine if they met State licensure requirements. CMS concurred with our recommendations to: (1) complete the research required to determine whether 14 suppliers had a proper license and make a licensure determination regarding those suppliers, and (2) identify all applicable State licensure requirements to prevent suppliers that do not have all currently required licenses from receiving contracts in future rounds of the competitive bidding program. CMS did not concur with our recommendation to work with State licensing boards to better coordinate, identify, and maintain an accurate and complete licensure database of currently required State licenses.

Medicare Compliance Review of Home Health VNA for 2011 and 2012 (A-01-13-00518), August 2016

This review was part of a series of reviews of home health agencies (HHAs). Using computer matching, data mining, and data analysis techniques, we identified certain types of home health claims that were at risk for noncompliance with Medicare billing requirements. We determined that Home Health VNA (the Agency), located in Lawrence, Massachusetts, did not comply with Medicare billing requirements for 105 of the 497 home health claims we reviewed. As a result, the Agency received net overpayments of \$314,000 for calendar years (CYs) 2011 and 2012. Specifically, the Agency incorrectly billed Medicare because beneficiaries were not homebound; beneficiaries did not require skilled services; documentation from the certifying physicians was missing or insufficient to support the services the Agency provided; or, in one instance, a claim contained an incorrect payment code.

We estimated that the Agency received overpayments of at least \$15.5 million for the audit period. This overpayment amount includes claims with payment dates outside of the 3-year recovery period. The Agency did not concur with our recommendations to: (1) refund to the Medicare contractor \$6.3 million in estimated overpayments for claims incorrectly billed that are within the 3-year recovery period; (2) work with the contractor to refund net overpayments outside of the 3-year recovery period, which we estimate to be \$9.1 million for our audit period, in accordance with the 60-day repayment rule; (3) identify claims in subsequent years that did not meet Medicare payment requirements and refund any associated overpayments; and (4) take steps to strengthen its procedures.

Medicare Improperly Paid Hospitals for Beneficiaries Who Had Not Received 96 or More Consecutive Hours of Mechanical Ventilation (A-09-14-02041), June 2016

A previous OIG review found that hospitals did not fully comply with Medicare requirements for billing inpatient claims with certain Medicare Severity Diagnosis-Related Groups (MS-DRGs) that required beneficiaries to have received 96 or more consecutive hours of mechanical ventilation. A subsequent OIG review found that claims with longer lengths of stay were also at risk for billing errors. Our objective was to determine whether Medicare payments to hospitals for inpatient claims with certain MS-DRGs that required 96 or more consecutive hours of mechanical ventilation complied with Medicare requirements. We found that, for 63 of the 200 claims we reviewed, Medicare payments to hospitals were assigned incorrectly to MS-DRGs 207 and 870, resulting in \$1.5 million in overpayments. We estimated that the hospitals received overpayments of \$3.7 million for claims with a potential procedure length of 4 days or fewer and overpayments of \$15.9 million for claims with a potential procedure length of 5 days.

CMS concurred with our recommendations that it: (1) ensure that the Medicare contractors recover the \$1.5 million; (2) revise the length-of-stay edit to take into account the mechanical ventilation start date for claims with a potential procedure length of 4 days or fewer, which could result in savings of an estimated \$3.7 million over a 2-year period; (3) provide additional guidance to hospitals on the correct billing of mechanical ventilation claims, emphasizing correct billing of claims with a potential procedure length of 5 days, which could result in savings of an estimated \$15.9 million over a 2-year period; (4) review the remaining nonsampled claims and recover the overpayments to the extent feasible and allowed under the law; and (5) direct the Medicare contractors to review any claims for which procedure code 96.72 was used with a potential procedure length of 5 days or fewer and recover any overpayments after our audit period.

Medicare Improperly Paid Millions of Dollars for Unlawfully Present Beneficiaries for 2013 and 2014 – Mandatory Review (A-07-15-01159), September 2016

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires CMS to establish policies and implement claims edits to ensure that payments are not made for Medicare services rendered to individuals who are not lawfully present in the United States (unlawfully present). OIG must report on CMS's activities to ensure that Medicare payments are not made for unlawfully present beneficiaries. We found that, when CMS's data systems indicated that at the time a claim was processed the beneficiary was unlawfully present, CMS followed its policies and procedures to prevent payment. However, when CMS's data systems did not indicate until after a claim had been processed that a beneficiary was unlawfully present, CMS did not follow its policies and procedures to detect and recoup payment. CMS determined that beneficiaries were liable for these improper payments, but it did not notify Medicare contractors to initiate recoupment activities. Our review included 14,530 claims that were paid on behalf of 481 unlawfully present beneficiaries with \$9.3 million in associated Medicare payments during CYs 2013 and 2014.

CMS concurred with our recommendations to direct its Medicare contractors, to the maximum extent feasible, to initiate recoupment activities: (1) against the 481 unlawfully present beneficiaries on whose behalf Medicare made \$9.3 million in improper payments, and (2) for improper payments made after our audit period on behalf of any beneficiaries who are detected to be unlawfully present.

Enhanced Enrollment Screening of Medicare Providers: Early Implementation Results (OEI-03-13-00050), April 2016

To bill for services provided to beneficiaries, providers must enroll in Medicare and periodically revalidate this enrollment. Effective enrollment screening is an important tool in preventing Medicare fraud. CMS has sought to enhance the enrollment screening process with new antifraud tools, such as placing providers in risk categories, increasing site visits, requiring fingerprinting if applicable, implementing an Automated Provider Screening system, and denying enrollment to providers whose owners have existing Medicare overpayments. Our study examined CMS's early implementation of new screening tools intended to prevent illegitimate providers from enrolling in Medicare.

We found that CMS needs to strengthen the implementation of its new enhanced enrollment screening tools. We also found that CMS's enrollment data system does not contain the information needed for effective oversight and evaluation of the enhancements to the enrollment screening process. Maintaining a robust enrollment process is an important tool in preventing Medicare fraud and ensuring the program's integrity. CMS concurred with all of our recommendations to: (1) monitor contractors to determine whether they are verifying information on enrollment and revalidation applications as required, (2) validate that contractors are appropriately considering site visit results when making enrollment decisions, (3) revise and clarify site visit forms so they can be more easily used by inspectors to determine whether a facility is operational, (4) require the National Site Visit Contractor to improve quality-assurance oversight and training of site visit inspectors, and (5) ensure that CMS's enrollment data system contains the complete and accurate data needed to execute and evaluate CMS's enrollment-screening enhancements.

Medicare: Vulnerabilities Related to Provider Enrollment and Ownership Disclosure (OEI-04-11-00591), May 2016

CMS can prevent inappropriate payments, protect beneficiaries, and reduce time-consuming and expensive "pay and chase" activities by ensuring that providers that intend to engage in fraudulent or abusive activities are not allowed to enroll in Medicare. For CMS to identify potentially fraudulent providers, as well as those that may be associated with excluded individuals or entities, providers must disclose accurate and timely information about their owners. For selected providers, we compared three sets of owner names: (1) those on record with CMS for Medicare enrollment purposes, (2) those submitted by providers directly to OIG, and (3) those on record with State Medicaid programs. When we compared names, we found that over three-quarters of Medicare providers had owner names on record with CMS that did not match those that providers submitted to OIG. Further, nearly all providers in our review had owner names on record with CMS that did not match those on record with State

Medicaid programs. Additionally, 2 of the 11 CMS contractors did not check all required exclusions databases, which could allow providers with excluded owners to enroll in the Medicare program. Taken together, these findings reveal vulnerabilities that could allow potentially fraudulent providers to enroll in the Medicare program and limit CMS's ability to provide adequate oversight.

CMS concurred with our four recommendations to: (1) review providers that submitted nonmatching owner names and take appropriate action, (2) educate providers on the requirement to report changes of ownership, (3) increase coordination with State Medicaid programs on the collection and verification of provider ownership information in Medicare and Medicaid, and (4) ensure that its contractors check exclusions databases as required.

High Part D Spending on Opioids and Substantial Growth in Compounding Drugs Raise Concerns (OEI-02-16-00290), June 2016

Medicare Part D spending for commonly abused opioids exceeded \$4 billion in 2015, and spending for compounded topical drugs increased more than 3,400 percent since 2006. These striking trends raise concerns about misuse as well as fraud. This data brief builds on OIG's June 2015 data brief, "Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D," which described trends in Part D spending and identified questionable billing by pharmacies. It updates information on spending for commonly abused opioids and provides data on the dramatic growth in spending for compounded drugs. OIG will continue to conduct investigations and reviews to address the ongoing problems created by opioid abuse and the emerging problems linked to compounded drugs. CMS has taken steps to combat the problems associated with commonly abused opioids, such as identifying outlier prescribers. However, the data brief concluded that CMS needs to take additional action, including fully implementing OIG's previous recommendations. CMS also needs to assess the implications of the compounded drug trends identified in this data brief and take action where needed to protect the integrity of the program.

CMS is Taking Steps to Improve Oversight of Provider-Based Facilities, but Vulnerabilities Remain (OEI-04-12-00380), June 2016

We reviewed CMS's oversight of provider-based billing to ensure that only facilities that met provider-based requirements were receiving higher payments allowed by the provider-based designation. Under Medicare, payments for services performed in provider-based facilities are often more than 50 percent higher than payments for the same services performed in a freestanding facility. This increased cost is borne by both Medicare and its beneficiaries. We found that, nationwide, nearly half of hospitals owned at least one provider-based facility. While CMS is taking steps to improve its ability to monitor provider-based billing, vulnerabilities associated with provider-based billing remain. In addition, more than three-quarters of the 50 hospitals we reviewed that had not voluntarily attested for all their off-campus provider-based facilities owned off-campus facilities that did not meet at least one requirement. Finally, CMS reported challenges with the provider-based review process primarily because of difficulties

obtaining documentation. These findings demonstrate continued vulnerabilities associated with provider-based billing.

CMS partially concurred with our first recommendation to implement systems and methods to monitor billing by all provider-based facilities, but it did not concur with our second recommendation to require hospitals to submit attestations for all their provider-based facilities. CMS concurred with our other two recommendations to ensure that regional offices and MACs apply provider-based requirements appropriately when conducting attestation reviews and take appropriate action against hospitals and their off-campus provider-based facilities that we identified as not meeting requirements.

Quality of Care and Beneficiary Access

Adverse Events in Rehabilitation Facilities: National Incidence Among Medicare Beneficiaries (OEI-06-14-00110), July 2016

This report is part of a series on adverse events in health care settings, defined as harm resulting from medical care. Previous OIG work identified harm rates of about 30 percent in both acute-care hospitals and skilled nursing facilities, with an attendant toll on patient health and taxpayers' costs, the latter amounting to billions of dollars annually. This report extends our work by evaluating care provided in rehabilitation (rehab) hospitals, which are post-acute providers that specialize in intensive rehabilitative care for patients recovering from illness, injury, or surgery. We found that 29 percent of Medicare beneficiaries experienced adverse or temporary harm events during their rehab hospital stays, resulting in temporary harm, prolonged stays or transfers to other hospitals, permanent harm, life-sustaining intervention, or death. Physician reviewers determined that almost half (46 percent) of these events could have been prevented. Nearly one-quarter of the patients who experienced these harm events were transferred to an acute-care hospital for treatment, with an estimated cost to Medicare of more than \$7.7 million in a single month.

We recommended that the Agency for Healthcare Research and Quality (AHRQ) and CMS raise awareness of patient safety issues in rehab hospitals and seek to reduce patient harm. This effort should include: (1) creating a list of potential adverse events that occur in rehab hospitals and (2) adding information about potential adverse events in quality guidance to rehab hospitals. CMS and AHRQ concurred with our recommendations.

Nationwide Analysis of Common Characteristics in OIG Home Health Fraud Cases (OEI-05-16-00031), June 2016

Home health has long been recognized as a program area vulnerable to fraud, waste, and abuse. During our review, we analyzed Medicare claims data from CYs 2014 and 2015 to assess the national prevalence and distribution of selected characteristics commonly found in OIG-investigated home health fraud cases. We identified home health agencies (HHAs) and supervising physicians that were statistical outliers with regard to those characteristics in comparison to their peers nationally. We also identified

geographic “hotspots” that were either statistical outliers compared to other areas nationally or contained significant numbers of HHA or physician outliers.

We identified a substantial number of providers—over 500 HHAs and over 4,500 physicians—that were outliers in comparison to their peers nationally with respect to multiple characteristics commonly found in OIG-investigated cases of home health fraud. While our analysis does not demonstrate that these providers were engaged in fraudulent activity, they may warrant further scrutiny. We also identified 27 geographic hotspots in 12 States—i.e., areas where characteristics commonly found in OIG-investigated cases of home health fraud are prevalent. Many of these hotspots are areas already recognized as having high rates of Medicare fraud. Along with OIG’s existing body of work, these results demonstrate that home health fraud in Medicare continues to warrant scrutiny and attention from OIG, its law enforcement partners, and CMS.

West Carroll Care Center Did Not Always Follow Care Plans for Residents Who Were Later Hospitalized With Potentially Avoidable Urinary Tract Infections (A-06-14-00073), June 2016

An OIG study found that in Federal FY 2011, nursing homes transferred about one-quarter of their Medicare beneficiary residents to hospitals for inpatient admissions. Medicare spent \$14.3 billion on these hospitalizations. One of the most frequent reasons for those hospitalizations was a urinary tract infection (UTI), a condition that a CMS study found is generally preventable and manageable in the nursing home setting. We reviewed West Carroll Care Center (the Nursing Home) because about 75 percent of its resident hospitalizations from October 1, 2011, through May 14, 2013, occurred because of conditions a CMS-sponsored study found to be associated with potentially avoidable hospitalizations. A UTI was the most frequent reason for the hospitalizations. We found that the Nursing Home did not always provide services to its residents in accordance with their care plans, as required by Federal regulations, before they were hospitalized with UTIs. Specifically, the Nursing Home staff did not monitor and document residents’ hydration status, monitor and document residents’ conditions, or document residents’ urine appearances as their care plans required.

During our audit, the Nursing Home developed policies and procedures requiring that the director of nursing or a designee conduct reviews to ensure that the nursing staff follows residents’ care plans. We recommend that the Nursing Home implement its newly developed policies and procedures requiring that its nursing staff follow residents’ care plans and the director of nursing or a designee conduct reviews to ensure that the nursing staff follows residents’ care plans. The Nursing Home agreed with our findings and stated that it has implemented corrective actions.

The Medicaid Program

Payments, Policies, and Practices

To fund their Medicaid programs, States receive Federal grant awards that pay for the Federal share of their Medicaid medical and administrative expenditures. OIG conducts audits on States’ withdrawals of

Federal Medicaid funds to determine whether a State submitted an improper claim for Federal reimbursement and, therefore, may owe money back to the Federal Government. If a State disagrees with our recommendation to refund questioned costs identified in an audit, CMS still has the authority to recoup those costs.

Medicaid Enhanced Provider Enrollment Screenings Have Not Been Fully Implemented (OEI-05-13-00520), May 2016

To bill for items and services provided to beneficiaries, providers must enroll, and periodically revalidate this enrollment, in Medicaid. To protect Medicaid against ineligible and fraudulent providers, the Patient Protection and Affordable Care Act (ACA) requires States to screen Medicaid providers according to their risk for fraud, waste, and abuse using enhanced screening procedures. To help States meet the demands of applying enhanced screening to all new and existing providers, CMS allows States to substitute Medicare or other State Medicaid agency or Children's Health Insurance Program (CHIP) screening results for their own. This review determined the extent to which States have screened high- and moderate-risk providers using risk-based screening. We found that State implementation of risk-based screening for Medicaid providers is incomplete. Most States report not having fingerprint-based criminal background checks while waiting for the requirement to take effect. We also found that screening substitution is challenging for many States.

CMS concurred with all of our recommendations to: (1) assist States in implementing fingerprint-based criminal background checks for all high-risk providers, (2) assist States in overcoming challenges in conducting site visits, (3) enable States to substitute Medicare screening data by ensuring the accessibility and quality of Medicare data, (4) develop a central system where States can submit and access screening results from other States, (5) strengthen minimum standards for fingerprint-based criminal background checks and site visits, and (6) work with States to develop a plan to timely complete their revalidation screenings.

Medicaid: Vulnerabilities Related to Provider Enrollment & Ownership Disclosure (OEI-04-11-00590), May 2016

States can prevent inappropriate payments, protect beneficiaries, and reduce time-consuming and expensive "pay and chase" activities by ensuring that providers that intend to engage in fraudulent or abusive activities are not allowed to enroll in Medicaid. Our review determined the extent to which States requested and verified provider ownership information and checked exclusions databases. We found that few State Medicaid programs requested that providers disclose all Federally required ownership information. In addition, 14 State Medicaid programs reported that they did not verify the completeness or accuracy of provider ownership information. We also found that 14 State Medicaid programs reported that they did not check all required exclusions databases, which could allow providers with excluded owners to enroll in Medicaid. Additionally, we found that most providers in our review had names on record with State Medicaid programs that did not match the names that providers submitted to OIG. Further, nearly all providers in our review had names on record with State Medicaid

programs that did not match those on record with CMS. Taken together, these findings reveal vulnerabilities that could allow potentially fraudulent providers to enroll in State Medicaid programs and that limit States' ability to provide adequate oversight.

CMS concurred with our seven recommendations to: (1) work with State Medicaid programs to identify and correct gaps in their collection of all required provider ownership information, (2) provide guidance to State Medicaid programs on how to verify the completeness and accuracy of provider ownership information, (3) require State Medicaid programs to verify the completeness and accuracy of provider ownership information, (4) ensure that State Medicaid programs check exclusions databases as required, (5) work with State Medicaid programs to educate providers on the requirement to report changes of ownership, (6) work with State Medicaid programs to review providers that submitted nonmatching owner names and take appropriate action, and (7) increase coordination with State Medicaid programs on collecting and verifying provider ownership information in Medicaid and Medicare.

Colorado Received Millions in Unallowable Bonus Payments (A-04-15-08039), August 2016

Under the Children's Health Insurance Program Reauthorization Act of 2009, Congress appropriated \$3.225 billion for qualifying States to receive performance bonus payments (bonus payments) for Federal FYs 2009 through 2013 to offset the costs of increased enrollment of children in Medicaid. We found that some of the bonus payments that Colorado received for FYs 2010 through 2013 were not allowable in accordance with Federal requirements. Colorado overstated its FYs 2010 through 2013 current enrollment in its bonus requests to CMS because it included individuals who did not qualify. As a result, CMS overpaid Colorado \$38.3 million in bonus payments. Colorado did not concur with our recommendation that it refund \$38.3 million to the Federal Government.

Washington State Claimed Federal Medicaid Reimbursement for Inpatient Hospital Services Related to Treating Provider-Preventable Conditions (A-09-14-02012), September 2016

Provider-preventable conditions (PPCs) are certain reasonably preventable conditions caused by medical accidents or errors in a health care setting. Federal regulations effective July 1, 2011, prohibit Medicaid payments for services related to PPCs. We conducted this review to determine whether Washington State (Washington) was in compliance with the new regulations for inpatient hospital services. We found that Washington claimed Federal Medicaid reimbursement for inpatient hospital services related to treating certain PPCs. From July 2012 through December 2013, we identified 463 claims that contained PPCs and: (1) a present-on-admission indicator code (POA code) indicating that the condition was not present on admission, (2) a POA code indicating that the documentation in the patient's medical record was insufficient to determine whether the condition was present on admission, or (3) no POA code. Washington did not determine the unallowable portion of \$18.3 million (\$10.8 million Federal share) that was for services related to treating PPCs and should not have been claimed for Federal Medicaid reimbursement. We set aside this amount for resolution by CMS and Washington.

Washington concurred with our recommendations that it work with CMS to determine what portion of the \$10.8 million claimed was unallowable for Federal Medicaid reimbursement and refund to the Federal Government the unallowable amount; refund to the Federal Government its share of any unallowable amounts for those paid claims reviewed; and ensure that its policy and procedure requiring a retrospective clinical review are fully implemented and effective in prohibiting unallowable payments for inpatient hospital services related to PPCs. Washington did not concur with our recommendation that it review paid claims before our audit period for certain inpatient hospital services to determine whether payments should be adjusted for any claims that contained PPCs that had certain POA codes or were missing POA codes.

The Medicaid Program Could Have Achieved Savings If Oregon Had Applied Medical Loss Ratio Standards Similar to Those Established by the Affordable Care Act (A-09-15-02033), April 2016

The objective of this review was to determine potential Medicaid program savings if Oregon required its Medicaid coordinated-care organization (CCO) plans to meet medical loss ratio (MLR) standards for its non-expansion population similar to those established by the ACA. The ACA set a standard for the amount of premium revenue that certain commercial health insurers and Medicare Advantage plans can spend on costs other than health-care-related expenses, which is known as the MLR. Insurers that do not meet these standards must pay rebates. Some States have applied similar standards to their contracts with Medicaid managed-care organizations. The Federal Government is entitled to the Federal share of the net amount recovered by a State with respect to its Medicaid program.

We determined that Medicaid could have saved \$10.1 million (\$6.4 million Federal share) during CY 2014 if Oregon had required its Medicaid CCO plans to meet MLR standards similar to those established by the ACA for those individuals who did not enroll through the Medicaid expansion program. Oregon concurred with our recommendation that it incorporate MLR standards into its contracts with Medicaid CCO plans for its non-expansion population.

State Governments May Unduly Benefit Financially From Publicly Owned but Privately Operated Entities (A-06-16-08005), August 2016

During our audit of Alabama's hospital certified public expenditures (CPEs) program for FY 2010, we noticed that Alabama had claimed, for FYs 2010 and 2011, more than \$5 million in Federal funds related to CPEs for three hospitals that appeared to be private hospitals. The three hospitals were owned but not operated by State or local governments. Alabama's definition of a public hospital indicates that a facility only has to be owned by a public entity, regardless of whether the facility is operated by a public entity or whether State or local government funds are used in its operation. As a result, Alabama received more than \$5 million in Federal funding by claiming CPEs from the three hospitals, even though no State or local government funding was used to operate the hospitals.

We are concerned that the Federal Government is matching funds from private entities with no true State or local government funds involved and that State Governments can benefit financially from

publicly owned but privately operated entities because the Federal Government has not provided a clear definition of “public funds” or “contributing public agency.” We suggest that CMS consider requiring that, to certify public expenditures as the State’s share of Medicaid expenditures, an entity be operated by a unit of government.

Utah Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs (A-07-14-06057), May 2016

We conducted a review to determine whether States are complying with Federal Medicaid requirements for billing manufacturers for rebates for physician-administered drugs. For a covered outpatient drug to be eligible for Federal reimbursement under Medicaid’s drug rebate requirements, manufacturers must pay rebates to the States for the drugs. States generally offset the Federal share of these rebates against their expenditures and bill the manufacturers for rebates to reduce the cost of drugs to the program. However, previous OIG reviews found that States did not always bill and collect all rebates due for drugs administered by physicians. We found that Utah did not invoice manufacturers for rebates associated with \$4.4 million in physician-administered drugs and \$1.2 million that did not have national drug codes in the utilization data or may have been otherwise ineligible for Federal reimbursement.

Utah concurred with our recommendations that it strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced and that it work with CMS to determine and refund the unallowable portion of Federal reimbursement for physician-administered drugs. Utah did not concur with our recommendations that it refund to the Federal Government \$4.4 million for claims for physician-administered drugs that were ineligible for Federal reimbursement and work with CMS to determine the unallowable portion of the \$1.2 million and refund that amount.

Texas Did Not Always Calculate Physician Supplemental Payments Made to the University of Texas Health Institutions in Accordance With Federal and State Requirements (A-06-11-00004), August 2016

Our objective was to determine whether the State agency calculated supplemental payments made to the University of Texas (UT) health institutions in accordance with Federal and State requirements. We determined that the State agency did not always calculate supplemental payments made to the UT health institutions in accordance with Federal and State requirements. Specifically, the supplemental payment calculations included overstated Medicare equivalent fees for claims that included payment modifiers and diagnostic test modifiers, Medicaid services that were performed by ineligible providers, and Medicaid services that did not have Medicare equivalent fees. As a result, the State agency claimed \$57.9 million in unallowable supplemental payments made to the UT health institutions from May 1, 2004, through September 30, 2007.

Texas stated it would review the physician supplemental payment calculation, refund the Federal share of any improper payments, and work with the UT health institutions in response to our recommendation that it refund to the Federal Government the \$57.9 million in improper supplemental payments made to the UT health institutions.

New York Overpaid Certain Medicaid Mental Health Services Providers (A-02-13-01021), June 2016

During a prior review of a Medicaid-funded mental health program in New York State, we observed that some providers were paid more than the Medicaid base rate for certain services. These providers participated in the State's Comprehensive Outpatient Program Services (COPS) and Community Support Program (CSP) programs and, as program participants, received supplemental (add-on) payments subject to annual payment thresholds in exchange for offering "enhanced services" to Medicaid beneficiaries. During this review, we identified overpayments due to the Federal Government totaling \$8.1 million (Federal share) from 2009 through 2012 for providers in New York's COPS and CSP programs. Although New York had credited to the Federal Government its share of reviewed overpayments that New York identified, New York continues to work to collect the \$92 million in final report overpayments due the Federal Government and \$27.4 million in preliminary report overpayments for 2003 through 2008. Further, New York said that \$2.7 million due to the Federal Government in other overpayments made during this period were not collectable because of provider bankruptcy or business closure.

New York agreed with our recommendations that it: (1) refund \$8.1 million for COPS and CSP overpayments for the period 2009 through 2012, (2) continue working to collect the additional overpayments for the period 2003 through 2008 and return \$27.4 million to CMS, (3) identify any overpayments made between December 2012 and October 2013 and refund the applicable Federal share, and (4) exhaust all legal efforts to collect the \$5.4 million (\$2.7 million Federal share) in overpayments that New York indicated were not collectable because of provider bankruptcy or business closure.

New Jersey Did Not Adequately Oversee Its Medicaid Nonemergency Medical Transportation Brokerage Program (A-02-14-01001), July 2016

Medicaid pays for nonemergency medical transportation (NEMT) services that a State determines to be necessary for beneficiaries to obtain medical care. Because OIG has consistently identified this area as vulnerable to fraud, waste, and abuse, OIG has conducted audits in multiple States since 2006. We selected New Jersey's NEMT services program for review because, in 2009, New Jersey transitioned from a fee-for-service program to one managed by a transportation broker. We determined that New Jersey did not adequately oversee its Medicaid NEMT brokerage program. As a result, we estimated that 2,538,674 claims totaling \$64.7 million did not comply with certain contract provisions and State requirements and 480,290 claims totaling \$11.3 million for services may not have complied. In addition, providers' noncompliance with certain contract and State requirements for the licensing and qualifications of vehicle safety and transport personnel could have jeopardized the health and safety of Medicaid beneficiaries.

New Jersey generally agreed with our recommendation that it improve its oversight and monitoring of its Medicaid NEMT brokerage program by requiring the contractor to strengthen its procedures to ensure that: (1) vehicles used to transport Medicaid beneficiaries meet New Jersey requirements, (2) transport personnel are licensed and qualified, (3) prior authorization is obtained and medical necessity

documented for beneficiaries who require certain transportation services, (4) transportation providers maintain required insurance coverages, (5) beneficiaries receive Medicaid-eligible medical services on the date of transportation, and (6) NEMT services are adequately documented. New Jersey did not directly agree or disagree with our recommendation that it ensure that its contract with the transportation broker contains provisions that: (1) consider improper claims submitted by transportation providers to the transportation broker when developing future capitated rates paid by New Jersey and (2) provide a means for New Jersey to recoup funds from the transportation broker when contract provisions and State requirements are not met—a measure that, if incorporated, could result in cost savings for Medicaid.

Alabama Claimed Millions in Unallowable School-Based Medicaid Administrative Costs (A-04-13-00094), July 2016

In prior reviews of school-based and community-based administrative costs that States allocated to Medicaid using random moment sampling (RMS), we identified significant overpayments. As part of our Medicaid risk assessment, we noted that the Alabama Medicaid Agency (Alabama) did not have an approved public assistance cost allocation plan (CAP). However, for Federal FYs 2010 through 2012, Alabama claimed school-based administrative costs, which are public assistance costs, totaling almost \$150.5 million (almost \$75.3 million Federal share). We conducted this audit because of the significant amount that Alabama claimed, its lack of an approved CAP, and our prior findings related to costs that States allocated to Medicaid using RMS.

We found that the \$150.5 million (\$75.3 million Federal share) that Alabama claimed in school-based Medicaid administrative costs for FYs 2010 through 2012 was unallowable. Alabama claimed these costs without submitting for Division of Cost Allocation review its public assistance CAP and certain amendments and, consequently, without having an approved CAP. Instead, Alabama claimed costs based on various versions of its implementation guides and plans that were being considered by and negotiated with CMS. Alabama also used statistically invalid RMS in allocating costs to Medicaid, and it did not maintain adequate support to validate its sample results and related extrapolations.

Alabama generally disagreed with our recommendations that it: (1) refund \$75.3 million to the Federal Government, (2) submit to CMS for review and approval its CAP and amendments, (3) ensure that its CAP addresses the statistical validity issues we identified, (4) implement policies and procedures to ensure that its RMS complies with Federal requirements for statistical validity, (5) maintain adequate support for its school-based administrative costs allocated to Medicaid, and (6) review school-based Medicaid administrative costs claimed after our audit period and refund unallowable amounts.

Alabama Did Not Comply With Federal and State Requirements for Claiming Medicaid Certified Public Expenditures for Federal Fiscal Year 2010 (A-06-15-00004), July 2016

Public entities (e.g., public hospitals) may certify that they have spent funds on Medicaid items or services that are eligible for Federal matching funds. These funds are referred to as certified public

expenditures (CPEs) and may be claimed as the State's share of Medicaid expenditures. The Alabama Medicaid Agency (Alabama) made a \$123.5 million adjustment to Medicaid hospital CPEs in Federal FY 2011 that more than doubled the CPEs claimed for FY 2010. We found that Alabama did not comply with Federal and State requirements for claiming \$209.5 million (\$162.5 million Federal share) in CPEs for FY 2010. Alabama incorrectly claimed \$27.5 million (\$21.3 million Federal share) because it made errors in its CPE calculation. We are setting aside the remaining \$182 million (\$141.2 million Federal share) Alabama claimed because it did not calculate the CPEs in accordance with the CMS-approved State plan. Of that amount, \$55.3 million (\$42.8 million Federal share) resulted from Alabama inappropriately applying a market inflation factor to 2010 costs, which essentially increased those costs to 2013 levels.

Alabama partially concurred with our recommendation that it work with CMS to determine whether any portion of the \$141.2 million in Federal share related to CPEs that were not calculated in accordance with the State plan should be refunded to the Federal Government, particularly the \$42.8 million Federal share associated with the increase from the application of the market inflation factor. Alabama did not concur with our recommendation that it refund to the Federal Government the \$21.3 million that related to the errors Alabama made when calculating CPEs.

Quality of Care and Beneficiary Access

Connecticut Did Not Comply With Federal and State Requirements for Critical Incidents Involving Developmentally Disabled Medicaid Beneficiaries (A-01-14-00002), May 2016

Also,

Massachusetts Did Not Comply With Federal and State Requirements for Critical Incidents Involving Developmentally Disabled Medicaid Beneficiaries (A-01-14-00008), July 2016

We are performing reviews in several States in response to a congressional request concerning the number of deaths and cases of abuse of developmentally disabled residents of group homes. We found that Connecticut and Massachusetts did not comply with Federal waiver and State requirements for critical incidents involving developmentally disabled Medicaid beneficiaries living in group homes. Connecticut did not adequately safeguard 137 of 245 developmentally disabled Medicaid beneficiaries living in group homes that we reviewed, and Massachusetts did not adequately safeguard 146 out of 334. Neither State ensured that: (1) group homes reported all critical incidents to the appropriate agencies; (2) data on all critical incidents were obtained, analyzed, or reported; and (3) all reasonable suspicions of abuse or neglect were reported. Connecticut also did not ensure that group homes always reported incidents at the correct severity level.

Both States concurred with our recommendations that they work with the appropriate State agencies to: (1) train staff of those agencies and group homes on how to identify and report critical incidents and reasonable suspicions of abuse or neglect, (2) develop a data-exchange agreement and related analytical procedures to ensure access to the Medicaid claims data to detect unreported and unrecorded critical incidents, (3) update Department of Developmental Services policies and procedures to clearly define

and provide examples of potential abuse or neglect that must be reported, and (4) ensure that any potential cases of abuse or neglect that are identified as a result of new analytical procedures are investigated as needed. Massachusetts concurred with our recommendation that it develop and provide training for staff of the State and group homes to ensure that action steps are identified in the incident reports to prevent similar critical incidents.

Health Information Technology

Arizona Made Incorrect Medicaid Electronic Health Record Incentive Payments to Hospitals (A-09-15-02036), August 2016

Also the following:

California Made Incorrect Medicaid Electronic Health Record Incentive Payments to Hospitals (A-09-16-02004), September 2016;

New Jersey Made Incorrect Medicaid Electronic Health Record Incentive Payments (A-02-14-01009), August 2016;

Oklahoma Made Incorrect Medicaid Electronic Health Record Incentive Payments to Hospitals (A-06-15-00032), August 2016;

Ohio Made Incorrect Medicaid Electronic Health Record Incentive Payments (A-05-13-00043), August 2016;

Pennsylvania Made Correct Medicaid Electronic Health Record Incentive Payments to Hospitals (A-03-15-00403), August 2016;

Washington State Made Incorrect Medicaid Electronic Health Record Incentive Payments to Hospitals (A-09-16-02015), September 2016; and

West Virginia Made Incorrect Medicaid Electronic Health Record Incentive Payments to Hospitals (A-03-14-00406), August 2016

Medicare and Medicaid EHR incentive programs promote the adoption of EHRs. As an incentive for using EHRs, the Federal Government makes payments to providers that attest to the “meaningful use” of EHRs. Because the incentive payment is calculated once and then paid out in the future, incorrect incentive payments mean that future payments will also be incorrect. We audited eight States for varying time periods.

We found that Arizona made incorrect Medicaid EHR incentive payments that resulted in a net overpayment of \$14.8 million, California made a net overpayment of \$22 million, New Jersey made a net overpayment of almost \$2.3 million, Oklahoma made a net overpayment of \$680,000, Ohio made a net overpayment of \$524,000, Washington State made incorrect EHR incentive payments totaling \$9.2 million, and West Virginia made incorrect EHR incentive payments totaling \$296,000. Pennsylvania made incentive payments in accordance with Federal and State requirements.

New Jersey, Oklahoma, Ohio, Washington, and West Virginia concurred, acknowledged, or partially concurred with our recommendations that they refund to the Federal Government the Federal share

received for the net overpayments. California, New Jersey, Ohio, Washington, and West Virginia concurred, acknowledged, or partially concurred with our recommendations that they review and adjust, if needed, remaining incentive payments of the hospitals in our samples to account for the incorrect calculations and those of other hospitals not included in our samples. California and Washington agreed or partially concurred with our recommendation that they review supporting documentation to help identify any errors in incentive payment calculations.

Oklahoma did not concur or nonconcur with our recommendations that it determine whether payment adjustments are needed for hospitals not in our audit and refund the Federal share received for any overpayments identified and educate hospitals to ensure that they follow Federal and State requirements for calculating their incentive payments. California disagreed with our recommendation that it refund the Federal share received for the overpayments. Arizona did not agree with our findings, which led to our recommendations that it: (1) refund \$14.8 million of the Federal share received for net overpayments, (2) adjust remaining incentive payments of the hospitals in our audit to account for the incorrect calculations, (3) review the calculations for the hospitals not included in our audit to determine whether payment adjustments are needed and refund to the Federal Government the Federal share received for any overpayments identified, (4) educate hospitals to ensure that they follow Federal and State requirements for calculating their incentive payments, and (5) review supporting documentation provided by all hospitals to help identify any errors in their incentive payment calculations. We did not have any recommendations for Pennsylvania.

Public Summary Report: Wireless Penetration Test of Centers for Medicare & Medicaid Services' Data Centers (A-18-15-30400), August 2016

We performed a wireless penetration test of select CMS Data Centers and facilities to determine whether CMS's security controls over its wireless networks were effective. We found that, although CMS had security controls that were effective in preventing certain types of wireless cyberattacks, we identified four vulnerabilities at selected CMS Data Centers and facilities in security controls over its wireless networks. The vulnerabilities were collectively and, in some cases, individually significant. Although we did not identify evidence that the vulnerabilities had been exploited, exploitation could have resulted in unauthorized access to and disclosure of personally identifiable information, as well as disruption of critical operations. In addition, exploitation could have compromised the confidentiality, integrity, and availability of CMS's data and systems. We promptly shared detailed information with CMS about our preliminary findings. CMS concurred with our recommendations that it improve its security controls to address the wireless network vulnerabilities we identified.

Public Summary Report: Washington State Implemented Security Controls Over the Web Site and Database for Its Health Insurance Exchange but Could Improve Protection of Personally Identifiable Information (A-09-15-03005), June 2016

Our objective was to determine whether the Washington Health Benefit Exchange (Washington marketplace) had implemented security controls to protect personally identifiable information on its

website and database in accordance with Federal requirements. We determined that the Washington marketplace had implemented many security controls, including policies and procedures, to protect personally identifiable information on its website and database. However, it did not always comply with Federal requirements. The Washington marketplace had not adequately secured its website and database and had not performed a vulnerability scan in accordance with Federal requirements. In addition, the Washington marketplace's plan of action and milestones did not meet some of CMS's minimum requirements for protection of marketplace systems. The Washington marketplace concurred with all our recommendations that it implement our detailed recommendations that address the specific findings we identified.

Public Summary Report: Information Technology Control Weaknesses Found at the Minnesota Health Insurance Exchange (A-06-15-00035), September 2016

Our objective was to determine whether MNsure, Minnesota's State-based marketplace, had implemented security controls to protect personally identifiable information on its website, database, and other supporting information systems in accordance with Federal and State requirements. We determined MNsure had implemented security controls, policies, and procedures intended to prevent vulnerabilities in its web applications (website), database, and other supporting information systems. However, it did not always comply with Federal and State IT requirements when it implemented those security controls, policies, and procedures, which increased MNsure's risk that personally identifiable information could have been exposed. Specifically, MNsure had not formalized procedures for analyzing and sharing information about vulnerabilities and had vulnerabilities related to penetration testing and website monitoring procedures. Additionally, our website and database vulnerability scans identified numerous weaknesses. Although we did not identify evidence that the vulnerabilities had been exploited, exploitation could have resulted in unauthorized access to and disclosure of personally identifiable information, as well as disruption of critical marketplace operations. The vulnerabilities were collectively and, in some cases, individually significant and could have potentially compromised the integrity of the marketplace.

We recommended that MNsure implement necessary corrective actions to address the specific security vulnerabilities that we identified during this audit.

The Department of Health and Human Services Security Management Practices for Computer Systems With Access to Personally Identifiable Information (A-18-16-30150), August 2016

HHS and its operating divisions (OPDIVs) have developed logical access policies and practices based on the National Institute of Standards and Technology standards. HHS and its OPDIVs use logical access controls to access all covered systems. HHS and its OPDIVs reported to us that multifactor authentication is required by privileged users to access nearly all of its covered systems, which includes the use of a personal identity verification card at the network/system level. Seven of HHS's 588 (about 1 percent) covered systems do not require privileged users to provide additional authentication to access those covered systems. The majority of OPDIVs have developed policies and procedures to conduct

inventories of software and licenses associated with covered systems. HHS and its OPDIVs use a variety of tools to monitor and detect exfiltration and other threats. All entities, including contractors that provide services to HHS, are required to follow HHS information security management practices for all covered systems.

Hospitals Largely Reported Addressing Requirements for EHR Contingency Plans (OEI-01-14-00570), July 2016

Disruptions, such as natural disasters or technical malfunctions, can make EHRs unavailable to hospital staff. Prior OIG work found that, for example, hospitals experienced substantial challenges responding to the effects of Superstorm Sandy, which included damage to health information systems and curtailed access to patient medical records. More recently, cyberattacks on hospitals have similarly prevented or limited access to EHRs. OCR enforces the HIPAA Security Rule, which requires all covered entities to have a contingency plan for responding to disruptions to electronic health information systems.

This evaluation provides information about the status of hospitals' contingency plans in light of evolving threats to their electronic health information systems. We found that almost all hospitals reported having written EHR contingency plans and most reported that their plans addressed four HIPAA requirements as well as recommended practices. This review provides baseline information on hospitals' contingency plans and reinforces previous OIG recommendations to OCR concerning its audit program, among others.

Legal and Investigative Activities Related to Medicare and Medicaid

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

Specific case types include fraud schemes related to:

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

OIG also conducts investigations involving organized criminal activity, including medical identity theft and fraudulent medical schemes established for the sole purpose of stealing Medicare dollars.

Investigators are seeing an increase in individuals, including both health care providers and patients, engaging in these health care fraud schemes. Those who participate in these schemes may face heavy fines, jail time, and exclusion from participating 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, Indian Health Service, Health Resources and Services Administration (HRSA), and Administration for Community Living. OIG also investigates potential misuse of grants and contracts funds awarded by CDC, National Institutes of Health (NIH), Substance Abuse and Mental Health Services Administration, and other HHS agencies. Under certain circumstances, OIG investigates noncustodial parents who fail to pay court-ordered child support. Additionally, OIG 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 False Claims Act (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/>.

From April 1, 2016, to September 30, 2016, we reported 381 criminal and 311 civil actions against individuals or entities that engaged in health-care-related offenses. We also reported over \$1.62 billion in investigative receivables due to HHS and over \$607.4 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 allegation or subject type:

Quality of Care

Kentucky – Dr. Jaime Guerrero was the owner and operator of Advanced Pain Management. According to court records, from November 2009 through May 2014, Dr. Guerrero distributed and dispensed narcotics to patients without a legitimate medical purpose and beyond the bounds of professional practice, leading to a patient's death. In addition, Dr. Guerrero falsely billed the health care benefit programs by submitting claims for office visits at a higher code than the services provided. Dr. Guerrero was sentenced to 8 years and 4 months in prison and ordered to pay \$827,000 in restitution for his guilty plea to conspiracy to unlawfully distribute and dispense Schedule II and III controlled substances, health care fraud, and money laundering.

Pharmacy

Florida – From November 2012 through February 2015, Zuzette De La Rua and her husband, Angel Sanchez, owned and operated three pharmacies in Miami, Florida. According to the investigation, Sanchez, De La Rua, and others committed fraud by paying kickbacks to patients and recruiters and for billing Medicare for medications not delivered to Medicare beneficiaries. Maria Sabater received compensation for recruiting patients to obtain pharmaceutical drugs at the pharmacies. De La Rua and Sabater pleaded guilty to conspiracy to commit health care fraud and were sentenced to a total of 6 years and 6 months in prison and ordered to pay \$5.9 million in restitution, joint and several. Sanchez pleaded guilty and is awaiting sentencing.

Florida – Sandy De La Fe, Jose Teijeiro, and Michel Cabral co-owned Goldenway Pharmacy Discount, Inc. (Goldenway), a retail pharmacy. From October 2011 through May 2013, the defendants conspired to defraud Medicare by submitting false claims for prescription drugs by using Medicare beneficiaries' ID numbers and forged doctors' signatures for medication that was either unnecessary or not provided. The conspirators also paid recruiters to entice Medicare beneficiaries to fill their prescriptions at Goldenway. De La Fe is a Cuban national who had been an OIG Most-Wanted Fugitive following his indictment in 2013 until his arrest in January 2016. De La Fe was sentenced to 1 year and 10 months in prison and ordered to pay \$2.8 million in restitution, joint and several, for his guilty plea to conspiracy to

commit health care fraud. Teijeiro and Cabral were previously sentenced to a combined 16 years and 1 month in prison.

Home Health

District of Columbia – Florence Bikundi and her husband, Michael Bikundi, Sr., were the owners of the home health agency Global Healthcare, Inc. According to evidence presented at trial, Florence fraudulently gained approval as a provider in the Medicaid program. From August 2009 through February 2014, the Bikundis led a scheme to bill Medicaid for services that were not provided, creating phony time sheets, patient files, and employment files. The Bikundis were sentenced for health care fraud, money laundering, and other charges stemming from this scheme. Florence was sentenced to 10 years in prison, while Michael was sentenced to 7 years in prison, and they were ordered to pay \$80.6 million in restitution, joint and several. Six defendants involved in the scheme were previously sentenced to a combined 6 months in prison and ordered to pay \$1.21 million in restitution, joint and several. One additional defendant has pleaded guilty and is awaiting sentencing.

Transportation

New York – New York City Fire Department (FDNY) agreed to pay \$4.3 million to resolve its liability under the False Claims Act. FDNY self-disclosed that, from October 2008 to October 2012, its billing contractor submitted claims to Medicare for emergency ambulance transport services FDNY knew were not medically necessary. These claims were submitted to obtain a formal denial to facilitate reimbursement from secondary insurers and/or beneficiaries. However, Medicare erroneously paid these claims, in part because FDNY coded them in a manner that was not consistent with the Medicare claims processing manual. FDNY failed to return the Medicare reimbursements it falsely received.

Durable Medical Equipment

Utah – Orbit Medical is a DME supplier specializing in power wheelchairs. According to the investigation, the owner of Orbit, Jacob Kilgore, along with sales representatives Morgan Workman, David Evans, and Hunter Hartman, conspired to bill Medicare for power wheelchairs for which beneficiaries did not qualify. Specifically, they altered physician records and signatures in order for Medicare beneficiaries to qualify for and receive the wheelchairs, and for Orbit to receive payment. All four defendants pleaded guilty to health care fraud conspiracy and were sentenced to a combined 5 years and 10 months in prison and ordered to pay restitution of \$6.2 million, joint and several.

Laboratory

Tennessee – OPKO Health, Inc., Prost-Data, Inc., d/b/a OURLab, and Jonathan Oppenheimer, M.D., entered into a settlement agreement to resolve allegations that, from June 2007 to January 2015, the defendants submitted false claims to Medicare for drug testing that was referred to OURLab and, subsequently, to OPKO by physicians and physician practice groups to whom OURLab and Oppenheimer donated money toward the purchase of EHR systems, in violation of the anti-kickback statute and the

Limitation on Certain Physician Referrals. The defendants also allegedly submitted false claims to Medicare and TRICARE by billing for a non-covered form of fluorescence in situ hybridization (FISH) testing, the OURVision test, from June 2012 to January 2015. The defendants agreed to pay \$9.3 million, joint and several, to resolve their liability under the False Claims Act.

Radiology

New Jersey – Kirtish and Nita Patel were the owners of Biosound Medical Services (Biosound) and Heart Solutions (Heart), which provided mobile diagnostic testing services, such as ultrasounds, echocardiograms, and neurological testing. From 2006 to 2014, the Patels embarked on a fraud scheme whereby they forged thousands of test results that should have been interpreted by an appropriate medical doctor. Instead of paying the interpreting physician a reading fee, the Patels created test interpretations and falsely affixed a medical doctor's signature to the report. Those reports were then used by the referring providers to make medical decisions based upon those falsely reported results.

The Patels were sentenced to a combined 14 years and 10 months in prison and ordered to forfeit \$4.8 million for their guilty plea to health care fraud.

Clinics

New York – Jorge Juvier was the owner and operator of multiple HIV/AIDS clinics in New York that purportedly provided injection and infusion treatments to Medicare-eligible HIV/AIDS patients. According to court documents, however, these clinics were health care fraud mills. As part of the scheme, Juvier and his co-conspirators paid patients cash kickbacks for coming to the clinics; coached patients on lying to clinic doctors to enable fraudulent billing; and billed Medicare for medications that were never administered, administered at incorrect dosages, or were medically unnecessary. Juvier was sentenced to 5 years and 3 months in prison and ordered to pay \$12.2 million in restitution, joint and several, for his guilty plea to conspiracy to commit health care fraud. Two other defendants involved in the scheme were previously sentenced to a combined 8 years and 3 months in prison and ordered to pay \$9 million in restitution, joint and several.

Maryland – Dr. Paramjit Ajrawat and his wife Sukhveen Ajrawat co-owned and operated Washington Pain Management Center. According to evidence presented at trial, from January 2011 through May 2014, the Ajrawats filed claims for procedures that were not performed. Specifically, they performed less expensive procedures but falsely billed for procedures that provided higher reimbursement amounts. The Ajrawats also submitted claims for procedures that had not been performed at all, and caused the alteration or destruction of patient files to conceal the scheme from auditors and law enforcement. The charges against Mrs. Ajrawat were dismissed after her death. Paramjit Ajrawat was sentenced to 9 years and 3 months in prison and ordered to pay \$3.1 million in restitution after a Federal jury found him guilty of health care fraud, false statements relating to health care matters, obstruction of justice, and wire fraud.

Kickbacks

Massachusetts – Hollister Incorporated (Hollister) and Byram Healthcare, Inc. (Byram), entered into a settlement agreement to resolve allegations that Hollister and other manufacturers entered into arrangements with Byram, a DME supplier, to allegedly market ostomy products that violate the anti-kickback statute. Specifically, Hollister and Byram entered into “conversion campaigns” whereby Hollister agreed to pay Byram’s marketing costs, often by lowering the product price, in return for Byram’s agreement to recommend or even require that customers switch to the manufacturers’ products. Hollister also paid certain bonuses, called “spiffs,” directly to Byram’s marketing employees (and in one case regional vice presidents) as a means of incentivizing Byram’s employees to convert customers to Hollister’s products. Byram also solicited kickbacks from Hollister in the form of a \$200,000 per year cost defrayment of Byram’s product catalogue. The defendants agreed to pay a total of \$20.9 million to resolve their liability under the False Claims Act.

Hospital

South Carolina – Lexington County Health Services District, Inc., d/b/a Lexington Medical Center (LMC) entered into a settlement agreement to resolve allegations that LMC had compensation arrangements within the meaning of the Stark law in the form of asset purchase arrangements and employment arrangements with certain physicians that did not satisfy all the requirements of any applicable exception to Stark’s referral and billing prohibition. These alleged problematic arrangements led LMC, which operates the Lexington Medical Center hospital and associated office-based clinics, to submit fraudulent claims to Medicare for designated health services referred by these physicians in violation of the False Claims Act. LMC agreed to pay \$17 million and enter into a CIA with OIG to resolve its liability under the False Claims Act.

Pharmaceutical Company

Massachusetts – Wyeth Inc. and Pfizer Inc. (the current owner of Wyeth), entered into a settlement agreement to resolve allegations that Wyeth reported false pricing information and underpaid rebates that were due under the Medicaid drug rebate program. Specifically, between 2001 and 2006, Wyeth Inc., allegedly failed to report to CMS the correct best price for its product Protonix. Protonix is a proton pump inhibitor used to treat symptoms of, among other things, acid reflux. The Government alleged that Wyeth failed to report deep discounts that it offered to hospitals for bundled sales of oral and intravenous versions of Protonix. This conduct allegedly led Wyeth to report false pricing information to CMS and underpay rebates due to the States for Protonix. Wyeth Inc. and Pfizer agreed to pay \$784.6 million to resolve their liability under the False Claims Act.

Psychiatric and Psychological Services

Texas – Sharon Iglehart was a psychiatrist at Riverside General Hospital (Riverside). According to evidence presented at trial, from 2006 until 2012, Iglehart and others engaged in a scheme to defraud Medicare by submitting through Riverside approximately \$158 million in false claims for partial

hospitalization program (PHP) services, an intensive outpatient treatment for severe mental illness. Beneficiaries for whom Riverside billed Medicare did not receive PHP services; in fact, beneficiaries rarely saw a psychiatrist and did not receive intensive psychiatric treatment at all. A jury convicted Iglehart of conspiracy to commit health care fraud, health care fraud, and making false statements relating to health care matters. She was sentenced to 12 years in prison and ordered to pay \$6.3 million in restitution. Six defendants involved in the scheme were previously sentenced to a combined 120 years in prison and ordered to pay \$46.7 million in restitution, joint and several. Six additional defendants either pleaded guilty or were found guilty and are awaiting sentencing.

Health Care Fraud Prevention and Enforcement

On May 20, 2009, former HHS Secretary Kathleen Sebelius and former Attorney General Eric Holder 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: <http://oig.hhs.gov/compliance/provider-compliance-training/index.asp>.

Health Care Fraud Strike Force Activities

Health Care Fraud Strike Force teams began in 2007 in an effort to combine the resources of Federal, State, and local law enforcement entities to prevent and combat health care fraud, waste, and abuse. These partnerships between OIG and HHS, DOJ, U.S. Attorneys' Offices, FBI, and State and local law enforcement have a common goal: successfully analyze health care fraud data and investigative intelligence to quickly identify fraud and bring prosecutions. Strike Force teams currently operate in nine areas: Miami, Florida; Los Angeles, California; Detroit, Michigan; Houston, Texas; Brooklyn, New York; southern Louisiana; Tampa, Florida; Chicago, Illinois; and Dallas, Texas.

From April 1, 2016, to September 30, 2016, Strike Force efforts resulted in the filing of charges against 168 individuals or entities, 107 criminal actions, and more than \$204.2 million in investigative receivables.

Below are examples of Strike Force cases:

Florida – Khaled Elbeblawy was the owner and manager of three Miami-area home health agencies. According to evidence presented at trial, from approximately 2006 to 2013, Elbeblawy and his co-

conspirators purported to provide home health services to Medicare beneficiaries that were not medically necessary and often were not provided. Elbeblawy and his co-conspirators paid kickbacks to doctors, patient recruiters, and staffing groups in exchange for referring beneficiaries to his home health agencies. Elbeblawy was convicted of conspiracy to commit health care fraud and wire fraud and conspiracy to defraud the United States and pay health care kickbacks. He was sentenced to 20 years in prison and ordered to pay \$36.4 million in restitution, joint and several. One other defendant involved in the scheme was previously sentenced to 8 months in prison and ordered to pay \$49,000 in restitution, joint and several, and another defendant has pleaded guilty and is awaiting sentencing.

Florida – Dr. Henry Lora and Isabel Medina co-owned the medical clinic Merfi Corp. Lora, who was also the medical director, admitted that in exchange for kickbacks and bribes, he and his co-conspirators ordered home health care and other services for Medicare beneficiaries that were not medically necessary and also falsified patient records to make it appear as if the beneficiaries qualified for these services. Lora was sentenced to 9 years in prison and ordered to pay \$30.2 million in restitution for his guilty plea to conspiracy to commit health care fraud and conspiracy to defraud the United States, namely, to receive health care kickbacks and make false statements regarding health care matters. Medina was previously sentenced to 9 years in prison and ordered to pay \$8.4 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 DOJ's Criminal Division, Fraud Section, 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.

Below is a related case example:

Texas – Dr. Augustine Egbunike owned PrimeCare Medical Associates, while Loretta Mbadugha owned Bayou Rehab and Family Services, Inc. Both companies purportedly provided vestibular diagnostic testing, which is used to evaluate a person for vertigo or dizziness. From 2006 to 2010, the conspirators falsely billed Medicare and Medicaid for numerous, unnecessary vestibular diagnostic tests. The evidence demonstrated that the testing was either not performed, not medically necessary, or not performed by licensed individuals. Both defendants pleaded guilty to conspiracy to commit health care

fraud. Egbunike was sentenced to 4 years and 9 months in prison and ordered to pay \$2 million in restitution, joint and several. Mbadugha was sentenced to 2 years and 6 months in prison and ordered to pay \$404,157 in restitution, joint and several. One other defendant involved in the scheme was previously sentenced to 2 years and 9 months in prison and ordered to pay \$896,100 in restitution, joint and several.

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/index.asp>. During this reporting period, four fugitives were captured.

One of OIG's Most Wanted Fugitives who was captured during this reporting period was Robert Allen Lopez. Lopez pleaded guilty to Medicare fraud in 1995 and then went on the run for 20 years, fleeing the country before sentencing. According to the indictment, from July 1991 through June 1994, Lopez and others conspired to defraud Medicare by filing false claims and structuring cash transactions to evade Federal currency-reporting requirements. The fraudulent claims totaled more than \$4 million. OIG investigators found that Lopez established numerous companies in Miami, using sham owners to conceal that he was the true owner. These companies filed false Medicare claims on behalf of beneficiaries for services that were either medically unnecessary or were not provided. Lopez also recruited friends and relatives to assist him as sham owners. He directed them to open bank accounts where the fraudulently obtained Medicare reimbursements were deposited. To avoid reporting requirements for cash transactions exceeding \$10,000, it is believed that Lopez directed the sham owners to make structured cash withdrawals from the accounts. OIG investigators found that Lopez established numerous companies in Miami, using sham owners to conceal that he was the true owner. These companies filed false Medicare claims on behalf of beneficiaries for services that were either medically unnecessary or were not provided. Lopez fled the country and was arrested in Nicaragua. He is currently in custody and will face charges stemming from his indictment.

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 who fail to pay court-ordered child support for their children; as a result, an unnecessary strain is placed on the custodial parents and the children as well as on agencies that enforce these matters. Examples are provided in the Human Services Reviews section of this *Semiannual Report*.

HHS OIG Hotline

The mission of the HHS OIG Hotline is to support OIG in oversight responsibilities to safeguard the integrity of all programs and personnel under purview of HHS and protect them from fraud, waste and abuse. We achieve this through our dedication to timely intake and evaluation of information received from various sources, such as the “Report Fraud” website portal on the HHS OIG Internet page and telephone calls to 1–800–HHS–TIPS. Strategically located within the Office of Investigations, the OIG Hotline is the public facing division for the intake of fraud tips. The OIG Hotline is motivated by the constant awareness that our work impacts all Americans, including some of our most vulnerable citizens, such as the elderly and others who are often unable to help themselves.

OIG Hotline Activity (4/1/16–9/30/16):

Total HHS TIPS Received via Phone-Evaluated for Action: 11,196

Total HHS TIPS Received via Phone – Referred: 8,957

Total HHS TIPS Received via Internet: 5,201

Total HHS TIPS Received via Letters/Faxes: 1,697

Total Viable HHS TIPS Evaluated: 11,196

Total Contacts to the HHS OIG Hotline Calls: 15,855

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 a Unit; the States contribute the remaining 25 percent. 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 2015 Annual Report (OEI-07-16-00050), September 2016

OIG’s MFCU FY 2015 Annual Report highlights statistical achievements from the investigations and prosecutions the 50 MFCUs conducted in FY 2015. OIG found that nearly one-third of the 1,533 MFCU convictions involved personal care services attendants. Fraud cases accounted for 71 percent of the MFCU convictions. MFCUs reported 731 civil settlements and judgements, with pharmaceutical manufacturers making up over a third of its settlements. Additionally, MFCUs reported \$744 million in criminal and civil recoveries. OIG also found that, in FY 2015, MFCUs reported the highest number of convictions in the last 5 years, and OIG exclusions resulting from its conviction referrals have grown since 2011. Civil settlements and judgments have decreased modestly over the last 5 years, and civil recovery

amounts have decreased significantly. Finally, many MFCUs made operational improvements in response to OIG recommendations.

OIG Onsite Reviews of MFCUs

In addition to an annual recertification review of each MFCU, OIG conducts periodic in-depth reviews of a sample of MFCUs. OIG evaluates MFCU operations in accordance with 12 [performance standards](#) and assesses compliance with laws, regulations, and OIG policy guidance. OIG issued reports of onsite reviews of the following MFCUs during the reporting period:

- Maryland State Medicaid Fraud Control Unit: 2016 Onsite Review, [OEI-07-16-00140](#), September 2016.
- North Carolina State Medicaid Fraud Control Unit: 2016 Onsite Review, [OEI-07-16-00070](#), September 2016.
- South Dakota State Medicaid Fraud Control Unit: 2016 Onsite Review, [OEI-07-16-00170](#), September 2016.
- Washington State Medicaid Fraud Control Unit: 2016 Onsite Review, [OEI-09-16-00010](#), August 2016.
- Virginia State Medicaid Fraud Control Unit: 2015 Onsite Review, [OEI-07-15-00290](#), August 2016.
- Massachusetts State Medicaid Fraud Control Unit: 2015 Onsite Review, [OEI-7-15-00390](#), June 2016.
- Pennsylvania State Medicaid Fraud Control Unit: 2015 Onsite Review, [OEI-07-15-00360](#), June 2016.
- Florida State Medicaid Fraud Control Unit: 2015 Onsite Review, [OEI-07-15-00340](#), June 2016.
- Oklahoma State Medicaid Fraud Control Unit: 2014 Onsite Review, [OEI-06-14-00630](#), April 2016.

The following is a case example of joint efforts with MFCUs:

Virginia – Beth Palin and Joseph D. Webb, Jr., were the owners of Bristol Laboratories LLC. According to the investigation, from May 2009 to April 2012, Palin and Webb conspired with Dr. Charles Wagner to bill medically unnecessary and excessive urine drug screen (UDS) tests to Federal and private health insurances. Wagner was an opioid addiction therapy doctor who directed all of his patients to be tested at Bristol. Investigators found that Palin and Webb determined the types of drug screens that were ordered and their frequency. Patients who were uninsured would have a basic UDS; however, insured patients would have much more expensive testing performed. Dr. Wagner died during the course of this investigation and was not charged. Palin and Webb, Jr., were each sentenced to 3 years in prison and ordered to pay \$1.4 million in restitution, joint and several, for their guilty plea to conspiracy to commit health care fraud and health care fraud. This was a joint investigation with the Virginia Medicaid Fraud Control Unit.

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. 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. From April 1, 2016, to September 30, 2016, OIG received 20 requests for advisory opinions and issued 6 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 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 2,092 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 1,973 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:

California – Hsiu Ying Lisa Tseng was a doctor of osteopathy. According to court documents, Tseng prescribed massive quantities of controlled substances to patients with no legitimate need. Tseng was sentenced to 30 years in prison based on her conviction of second degree murder, unlawful controlled substance prescription, and obtaining a controlled substance by fraud. In addition, her license to practice as a doctor was suspended by the Osteopathic Medical Board of California. OIG excluded Tseng for a minimum period of 50 years.

Florida – Enemisis Torres was the owner and registered representative of Comprehensive Care Clinic (CCC). Torres conspired with CCC employees to pay kickbacks to Medicare beneficiaries for allowing them to use their Medicare information for fraudulent purposes. Torres was sentenced to 4 years and 3 months in prison and ordered to pay \$20 million in restitution based on his conviction of conspiracy to commit health care fraud and wire fraud. OIG excluded Torres for a minimum period of 55 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, misused grant funds, or are otherwise not presently responsible. Because these are Governmentwide sanctions, an individual or entity that has been suspended or debarred by HHS or any other agency is ineligible from participating 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:

South Dakota – Samone Milk, Heather Garcia, Joe Garcia, and Wayne Cortier were each involved in the Oglala Sioux Tribe. According to the investigation, the defendants organized a scheme to divert Oglala Sioux Tribe/Low Income Home Energy Assistance Program funds from legitimate projects. On at least 30 occasions, they fraudulently generated documents such as requests for assistance, invoices, and vouchers on behalf of real or fictional tribal members, and they unlawfully converted the Federal funds for their own personal use. The defendants were each convicted of conspiracy to commit theft concerning programs receiving Federal funds and were debarred for a 3-year period based on OIG referrals to the Department.

Mississippi – Linda Harvey-Irvin was the deputy director of the Mississippi Gulf Coast Community Action Agency (GCCAA), a nonprofit organization partially funded by Federal grants, which are used to fund the Head Start preschool program. Harvey-Irvin accepted bribes from Donald Walton, owner and operator of Walton Construction, in exchange for construction contracts worth more than \$400,000. Harvey-Irvin was also charged in a second indictment with accepting bribes from Markuntala Croom, owner and operator of Croom Consulting, in exchange for awarding more than \$520,502 in consulting work to Croom. Walton paid Harvey-Irvin \$31,000 in kickbacks as a reward for his contracts, and Croom paid Harvey-Irvin \$69,911 in kickbacks as a reward for her contracts. All three defendants were convicted of

theft or bribery concerning programs receiving Federal funds and were debarred for a 3-year period based on 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. Many civil settlements include CIAs with OIG.

The following is a CIA example:

Louisiana – Amedisys, Inc., entered into a settlement agreement to resolve allegations that it submitted claims for home health services provided at six different locations that were medically unnecessary and/or in violation of other Medicare requirements. Amedisys reported this conduct to OIG under the terms of its CIA and agreed to pay \$4.6 million to resolve their liability.

Civil Monetary Penalties Law

The Civil Monetary Penalties Law (CMPL) authorizes OIG to impose administrative penalties on and assessments 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. During this semiannual reporting period, OIG concluded cases involving more than \$38.4 million in CMPs and assessments.

The following is a CMP example:

California – Enloe Medical Center (Enloe) entered into a settlement agreement to resolve allegations that it submitted claims for emergency ambulance transportation to destinations such as skilled nursing facilities and patient residences that should have been billed at the lower non-emergency rate. Enloe agreed to pay \$570,912 to resolve its liability.

Patient Dumping

Some of the CMPL cases that OIG resolved between April 1, 2016, and September 30, 2016, were pursued under the Emergency Medical Treatment and Labor Act (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:

Georgia – Grady Memorial Hospital Corporation d/b/a/ Grady Health System (Grady) entered into an agreement to resolve allegations that it failed to provide an adequate medical screening examination and stabilizing treatment to a patient. Specifically, a patient was extracted from his apartment by a SWAT team and brought to Grady’s emergency department (ED) by a police officer because of complaints of suicidal and homicidal ideations. While at Grady, two Licensed Professional Counselors (LPCs) evaluated the patient and determined that the patient should be held involuntarily for further evaluation and treatment. Approximately 5 hours after the patient’s arrival in the ED, the ED physician discharged the patient without consulting the LPCs or the on-call psychiatrist. Grady agreed to pay a penalty of \$40,000 to resolve its potential liability under EMTALA.

Tennessee – Regional One Health (ROH) entered into an agreement to resolve allegations that it failed to provide an adequate medical screening examination and stabilizing treatment to a patient. Specifically, OIG alleged that a patient with complaints of sudden pain in the lower right quadrant of his abdomen presented to ROH, and ROH failed to fully evaluate the severity and cause of the patient’s emergency medical condition and did not provide stabilizing treatment for sepsis before ROH transferred the patient to another hospital. The patient died of septic shock and respiratory failure within a week of his transfer by ROH. ROH agreed to pay a penalty of \$45,000 to resolve its potential liability under EMTALA.

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, to voluntarily disclose self-discovered evidence of potential fraud. The self-disclosure program may give providers the opportunity to potentially avoid costs or possible 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 enables contractors the opportunity to self-disclose when they have potentially violated the False Claims Act or other Federal criminal laws prohibiting fraud, conflict of interest, bribery, or gratuity. This self-disclosure process is 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 sub-recipients and provides the opportunity for voluntarily 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, self-disclosure cases resulted in more than \$39.1 million in HHS receivables.

The following are examples of provider self-disclosure settlements:

California – Five Star Quality Care-CA, LLC d/b/a Lancaster Healthcare Center entered into an agreement with OIG to resolve allegations that, during the period of January 2010 through July 2014, it submitted

claims for skilled nursing services without proper certifications and recertifications for services, establishment and content of therapy plans, and/or maintenance of clinical records. In addition, during the period of September 2014 through December 2014, it paid remuneration to a medical director for referrals. The company agreed to pay \$8.6 million to resolve its liability under the CMPL for conduct it disclosed to OIG.

Virginia – Planned Parenthood Health Systems, Inc. (Planned Parenthood), entered into an agreement with OIG to resolve allegations that, between November 2004 and February 2015, it submitted claims to Medicaid in North Carolina, South Carolina, Virginia, and West Virginia for services using a provider number different than the medical professional who provided the services and billed for the services of non-physician practitioners who were not properly enrolled in their State Medicaid program. Planned Parenthood agreed to pay \$1.5 million to resolve its liability under the CMPL for conduct it disclosed to OIG.

Public Health Agencies Reviews and Enforcement Activities

Centers for Disease Control and Prevention

President's Emergency Plan for AIDS Relief

The President's Emergency Plan for AIDS Relief (PEPFAR) program 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. Additional funds were authorized to be appropriated through 2018. OIG is required to provide oversight of PEPFAR. To meet this requirement, OIG has conducted a series of audits of CDC's PEPFAR grant administration and of organizations receiving PEPFAR funds from CDC.

The Centers for Disease Control and Prevention Did Not Award President's Emergency Plan for AIDS Relief Funds for 2013 in Compliance With Applicable HHS Policies (A-04-14-04021), May 2016

Also, Medical Access Uganda Limited Generally Managed the President's Emergency Plan for AIDS Relief Funds in Accordance With Award Requirements (A-04-15-04040), June 2016

We found that CDC did not award PEPFAR funds for FY 2013 in compliance with HHS and internal policies. For all 30 Funding Opportunity Announcements (FOAs) in our judgmental sample, CDC did not comply with one or more HHS or internal policies in some awards. As a result, CDC did not always adequately document its funding decisions to award \$1.9 billion over the 5-year project period and may have considered applications that it should not have or treated applicants inconsistently. CDC concurred with our recommendations that it: (1) conduct quality assurance reviews of FOAs and funded grant applicant information to monitor compliance with HHS and internal policies when awarding PEPFAR funds, and (2) address specific deficiencies that we identified in our review.

CDC awarded PEPFAR funds of \$105 million for September 30, 2011, through September 29, 2014, to Medical Access Uganda Limited (Medical Access). Medical Access expended \$103.8 million during that period. Medical Access managed PEPFAR funds in accordance with award requirements except that it used these funds to pay \$751,000 in value-added tax (VAT) that the Ugandan Government has not reimbursed. This payment of VAT and lack of reimbursement occurred because of a disagreement over the interpretation of a provision of a bilateral agreement in effect between the United States and the Government of Uganda. CDC believed that grantees were exempt from the payment of VAT and that the exemption would occur through reimbursement. However, the Government of Uganda recognized only State Department purchases as exempt or reimbursable of VAT under the bilateral agreement. Medical Access concurred with our recommendation that it work with CDC to obtain \$751,000 in VAT reimbursement from the Ugandan Government.

Centers for Disease Control and Prevention's Property System Data Were Neither Accurate Nor Complete (A-04-14-03546), June 2016

CDC has various types of accountable property stored in the United States and overseas. As of September 30, 2013, CDC's property system showed that CDC had 60,241 property items with a total cost of \$451 million. Our audit of data in the property system determined that the data were neither accurate nor complete in FY 2013. Of the 250 items we sampled from the system, we located 245. CDC had classified the remaining five items as missing. We also found 14 items that were not barcoded or accurately recorded in the system. We estimated that \$29.2 million of CDC property was at risk of being lost or misplaced. CDC did not record in the system all newly acquired property. Of 128 sampled payments that CDC made for property, CDC incorrectly barcoded and added to its system property items associated with 114 payments. We estimated that the cost of property purchased (\$96.7 million) was understated by approximately \$5.9 million. Also, although CDC performed a monthly reconciliation of its system, the reconciliation was not complete because it included only property items with costs of \$25,000 or more, so CDC excluded 95 percent of its property items (41 percent of inventory costs in the system). Furthermore, CDC did not always remove from its system property that it had identified as missing, so the cost of property included in the system could be overstated by as much as \$23.1 million.

CDC concurred or partially concurred with our recommendations that it: (1) complete Reports of Survey within HHS's 90-day time limit and remove property from the system that the Reports of Survey identify as missing; and (2) ensure that all property is added correctly to the system, that the system is reconciled, and that the system is adjusted to resolve any discrepancies. CDC did not concur with our recommendation that it ensure that existing property is barcoded and correctly identified in the system.

World Trade Center Health Program: Review of Medical Claims (A-02-14-02008), September 2016

The World Trade Center Health Program (WTCHP) was established in January 2011 and is administered by CDC through its National Institute for Occupational Safety and Health (NIOSH). Under the WTCHP, pharmacy benefits and medical services are provided to eligible responders and survivors with certified health conditions related to the September 11, 2001, terrorist attacks. OIG is required to review WTCHP expenditures to detect inappropriate billing and payment for services. For this review, we found that not all of CDC's internal controls were effective in ensuring that claims for WTCHP pharmacy benefits and medical services were paid in accordance with Federal requirements.

CDC generally concurred with our recommendations that it: (1) establish a procedure for collecting and transmitting New York Metro area members' prescription drug insurance coverage information to pharmacy benefit managers (PBMs) for benefits coordination, (2) establish a procedure to ensure that Nationwide Network members' prescriptions are written by authorized WTCHP prescribers, (3) require PBMs to establish procedures to prevent the authorized number of refills from being exceeded, (4) establish a procedure for ensuring that pharmacy benefit claims are reimbursed at or below appropriate payment rates, and (5) determine whether medical service claims processed before October 22, 2012, were reimbursed at or below the appropriate payment rate and recoup any overpayments.

Food and Drug Administration

Early Alert: The Food and Drug Administration Does Not Have an Efficient and Effective Food Recall Initiation Process (A-01-15-01500), June 2016

FDA generally relies on firms to voluntarily recall harmful articles of food. Before 2011, FDA did not have the authority to require a firm to recall certain articles of food. However, in 2011 FDA gained the authority to order a firm to recall certain articles of food after FDA determines that there is a reasonable probability that the food is adulterated or misbranded and that it will cause serious adverse health consequences or death to humans or animals.

Our ongoing audit of FDA's food recall program found that FDA did not have an efficient and effective food recall initiation process that helps ensure the safety of the Nation's food supply. Specifically, FDA did not have policies and procedures to ensure that firms or responsible parties initiated voluntary food recalls promptly. As a result, consumers remained at risk of illness or death for several weeks after FDA was aware of a potentially hazardous food in the supply chain. We suggest that FDA update its policies and procedures to instruct its recall staff to establish set timeframes for FDA to request that firms voluntarily recall their products and for firms to initiate voluntary food recalls.

National Institutes of Health

The National Institute of Environmental Health Sciences Generally Administered Its Superfund Appropriations During Fiscal Year 2014 in Accordance With Federal Requirements (A-04-15-04035), April 2016

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 established the Hazardous Substance Response Trust Fund, commonly known as the Superfund. NIH's National Institute of Environmental Health Sciences (NIEHS) receives an annual Superfund appropriation to carry out functions mandated by the Act. The Act also requires OIG to audit all uses of the fund in the prior fiscal year. The objective of this audit was to determine whether NIEHS administered its Superfund appropriations during FY 2014 in accordance with applicable Federal requirements.

We found that NIEHS generally administered its Superfund appropriations during FY 2014 in accordance with applicable Federal requirements. However, it did not always obligate Superfund appropriations in accordance with applicable Federal laws. Specifically, NIEHS improperly used \$7,500 from expired Superfund appropriations. NIEHS improperly used expired Superfund appropriations because it did not follow its standard operating procedure on the use of prior-year funds. By not ensuring that obligations were made within the 1-year period of availability, NIEHS violated Federal appropriations law. If appropriate FY funding is not available to correct the improper obligations, an Antideficiency Act violation will have occurred. NIEHS partially concurred with our recommendation that it, as applicable, deobligate the \$7,500 of improper obligations and obligate \$7,500 using available appropriations from the correct fiscal year or determine whether any Antideficiency Act violations occurred and take appropriate action.

Public-Health-Related Legal Actions and Investigations

Health Education Assistance Loan Program

OIG excludes individuals who have defaulted on Health Education Assistance Loan (HEAL) loans from participation in Federal health care programs. Under the HEAL program, which stopped making loans in 1998, HRSA guaranteed commercial loans to students seeking education in health-related fields.³ 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 indebtedness. After PSC has exhausted efforts to secure repayment of a debt, it declares an individual in default. The Social Security Act permits exclusion thereafter of such individuals from Medicare, Medicaid, and all other Federal health care programs for nonpayment of the loans.

Exclusion means that the individual may not receive reimbursement under these programs for professional services rendered, nor may any other provider receive reimbursement for services ordered or prescribed by the excluded individual. OIG is responsible for excluding individuals who have defaulted on HEAL loans from participation in Federal health care programs.

HEAL Exclusions

During this semiannual reporting period, 48 individuals and related entities were excluded as a result of PSC referral of their cases to OIG. Individuals who have been excluded as a result 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, 2,637 individuals chose to enter into settlement agreements or completely repay their debts. That figure includes 20 individuals who entered into such settlement agreements or completely repaid their debts during this semiannual reporting period. More than \$209 million is being repaid through settlement agreements or through complete repayment. Of that amount, more than \$2.2 million is attributable to this semiannual reporting period.

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

- Ohio: Dentist – \$281,872
- California: Medical Doctor – \$124,177
- Florida: Medical Doctor – \$116,633
- California: Medical Doctor – \$52,343

³ The HEAL Program, noted in previous *Semiannual Reports*, was permanently transferred from HHS to the U.S. Department of Education as required by the Consolidated Appropriations Act, 2014 (Pub. L. 113-76). The transfer was completed on July 1, 2014.

Human Services Agencies Reviews and Enforcement Activities

Administration for Children and Families

Hurricane Sandy — Response Preparedness and Oversight of Funds

Hurricane Sandy made landfall on October 29, 2012, devastating portions of the mid-Atlantic and northeastern United States and leaving victims of the storm and their communities in need of disaster relief aid. On January 29, 2013, the President signed into law the Disaster Relief Appropriations Act of 2013, P.L. No. 113-2 (Disaster Relief Act), which, in part, provided HHS with approximately \$800 million in funding (\$759.5 million after sequestration, of which \$577.2 million was allocated to ACF) for disaster response and recovery and other expenses directly related to Hurricane Sandy. The Disaster Relief Act mandated OIG to perform oversight, accountability, and evaluation of programs, projects, or activities supported with Disaster Relief Act funds.

Superstorm Sandy Block Grants: Funds Benefited States' Reconstruction and Social Service Efforts, Though ACF's Guidance Could Be Improved (OEI-09-15-00200), September 2016

Five States received almost \$475 million in Social Services Block Grant (SSBG) funding to help cover social service and reconstruction expenses resulting directly from Superstorm Sandy. When Congress made funds available to States to help pay for expenses related to Superstorm Sandy, Congress noted that such funds were "susceptible to significant improper payments." This evaluation examined States' experiences using Superstorm Sandy SSBG funds and ACF oversight of these funds. We found that although Sandy SSBG funds assisted States' recovery, ACF's guidance limited the effectiveness of State planning and use of the funds. The initial deadline that ACF established did not allow States the time they needed to use the Sandy SSBG funds. States also reported wanting more direction from ACF on allowable Sandy SSBG activities and more clarity about the type of documentation that ACF would expect during program integrity reviews. To take full advantage of available funding for future disasters, States and grantees must receive appropriate guidance about when funds expire, how they may use the funds, and what documents or other evidence they must maintain for program integrity purposes. Nonetheless, ACF worked closely with States as they planned and implemented their activities and conducted required reviews of States' use of the Sandy SSBG funds.

ACF concurred with all of our recommendations to: (1) take additional steps to ensure, within the scope of the legislation, that States are given an appropriate amount of time to expend any future supplemental SSBG awards; (2) conduct a post-grant review to identify lessons learned and best practices; and (3) prepare guidance about supplemental SSBG documentation requirements.

New York Implemented Effective Internal Controls Over Hurricane Sandy Social Services Block Grant Funds and Appropriately Budgeted and Claimed Allowable Costs (A-02-14-02009), May 2016

ACF awarded \$235.4 million in Disaster Relief Act funding to New York for Social Services Block Grant (SSBG) activities, including social, health, and mental health services for individuals and for the repair, renovation, and rebuilding of health care, mental health, and childcare facilities. We found that New York implemented effective internal controls over the awarding, monitoring, and reporting of Hurricane Sandy SSBG funds and appropriately budgeted and claimed allowable costs as of March 31, 2014. Accordingly, this report does not contain recommendations.

Bayview Nursing and Rehabilitation Center Claimed Allowable Hurricane Sandy Disaster Relief Act Funds (A-02-15-02010), April 2016

We reviewed New York's awarding of approximately \$2.8 million of Disaster Relief Act funds to Bayview Nursing and Rehabilitation Center (Bayview) for construction and equipment expenses resulting from Hurricane Sandy. We found that Bayview claimed allowable Hurricane Sandy Disaster Relief Act costs. Specifically, Bayview used Disaster Relief Act funds to offset costs it had incurred repairing its facility and replacing damaged equipment before receiving its Disaster Relief Act grant award. Accordingly, this report does not contain recommendations.

Columbia University Claimed Allowable Hurricane Sandy Disaster Relief Act Funds (A-02-15-02007), May 2016

NIH awarded \$299,000 to Columbia University (Columbia) to replace research resources lost or damaged by Hurricane Sandy. We found that Columbia claimed allowable Hurricane Sandy Disaster Relief Act costs for the period January 31, 2014, through February 28, 2015. Accordingly, this report does not contain recommendations.

Childcare and Head Start Programs

ACF provides Federal grants through several programs, including Head Start and the Child Care and Development Fund (CCDF). CCDF (authorized by the Child Care and Development Block Grant Act and the Social Security Act § 418) assists low-income families, families receiving temporary public assistance, and families transitioning from public assistance to obtain childcare so that they may work or obtain training or education.

Child Care and Development Fund

More Effort Is Needed to Protect the Integrity of the CCDF Block Grant Program (OEI-03-16-00150), July 2016

The CCDF block grant program is a Federal–State partnership to provide eligible, low-income families with help paying for childcare at a provider of their choice. Within the CCDF program, OIG has previously identified fraud, found improper payments, and exposed health and safety concerns at childcare facilities. This report focuses on how States and ACF ensure the integrity of the CCDF block grant program and the results of States' program integrity activities. We found that States differed in the scope of CCDF program integrity activities and varied substantially in the degree to which they conducted specific program integrity activities. Not all States performed important antifraud activities,

and few States notified ACF and other States about suspected fraud. Many States reported no results or did not know the results of their CCDF program integrity efforts in 2015, including their numbers of program violations and errors, referrals to law enforcement, and client and provider disqualifications. States identified payment error rates ranging from less than 1 percent to 36 percent, but almost half of the States did not expect to recover any improper payments identified as a result of their error rate reviews. States identified limitations in technology, resources, and coordination as top challenges to ensuring CCDF program integrity. In its oversight of State activities, ACF focuses more on technical assistance than compliance. ACF does not have a process to ensure that States carry out planned program integrity activities nor does it collect information about the results of these activities.

ACF concurred with all of our recommendations to: (1) request that States examine the effectiveness of their program integrity and fraud fighting activities, (2) examine with States the benefits of expanding program integrity and fraud fighting activities, (3) establish routine communication to share program integrity and fraud-fighting best practices, and (4) determine the feasibility of requiring all States to report information about the results of their program integrity and fraud-fighting activities.

Head Start

Head Start Grant Recompensation: Early Implementation Results Suggest Opportunities for Improvement (OEI-12-14-00650), August 2016

The Head Start program is the largest Federal investment in early childhood education. The Improving Head Start for School Readiness Act of 2007 required ACF to begin awarding 5-year grants for Head Start and to require grantees that ACF determines are not providing a high-quality and comprehensive Head Start program to “recompete” or participate in open competition for funding renewal. In response, ACF began to implement the Designation Renewal System (DRS), which uses seven “trigger conditions” to assess a subset of grantees (known as a cohort) each year and determine which grantees will be required to recompete.

We reviewed ACF’s DRS for Head Start grantees and assessed the early results of Head Start grant recompensation. In late 2011, ACF began assessing grantees through the DRS to determine which grantees would have their grants automatically renewed and which would be required to participate in open competition for renewal—a process known as “recompensation.” We found that one-third of grantees were required under the DRS to recompete for funding renewal. Grantees’ DRS determinations were not linked to the number of Head Start enrollees they served, the types of areas (i.e., rural or urban) where their centers were located, the proportion of their enrollees who were from non-English-speaking families, or the proportion of their enrollees who were from very poor households. Of grantees required to recompete, approximately three-quarters had their grants renewed for an additional 5-year term. More than half of these grantees were the sole applicants for their respective grants. We also found that DRS determinations were largely inconsistent with other ACF performance data. Additionally, few grantees with lower performance on a hybrid of 10 DRS and non-DRS performance measures left the

Head Start program through the DRS and recompetition processes. Overall, 92 percent of Head Start grantees had their grants renewed.

We recommend that ACF proactively monitor grantees' performance results to verify that grantees designated under the DRS for automatic, noncompetitive renewal perform better than their peers. Additionally, ACF should take steps to increase the number of applicants for recompeted grants. ACF concurred with both recommendations.

Child Support Enforcement Activities

OIG Investigations

OIG investigates noncustodial parents who fail 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 reporting period, OIG investigations of child support enforcement cases nationwide resulted in 16 criminal actions and court-ordered restitution and settlements of \$956,546.

The following are examples of child support enforcement cases:

Pennsylvania – In July 2002, Mark Matsinger was ordered to pay \$1,300 per month for the support of his two children. Matsinger made inconsistent payments to the custodial parent of his children; his last payment was made in 2006. Matsinger was sentenced to 8½ months in prison (time served), 6 months of location monitoring, and ordered to pay \$170,000 in restitution after pleading guilty to willful failure to pay child support. In addition, Matsinger pleaded guilty to mail fraud and was ordered to pay \$40,002 to the Social Security Administration.

Virginia – Between 1999 and 2016, Raymond Dyrek Payne unlawfully failed to pay child support for his minor children, and he was placed on the OIG Child Support Enforcement Most Wanted list in January 2015. Payne moved from State to State knowingly eluding payments by working under aliases and fraudulent Social Security numbers while convincing businesses in several States that he had professional training in various fields including a country music singer/songwriter, pastry chef, real estate agent, graphic artist, and brewmaster. Payne has no professional training or certifications. He was sentenced to 5 years of supervised probation and ordered to pay restitution in the amount of \$67,087 following a guilty plea for failure to pay child support.

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 is 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 2016, HHS awarded more than \$463.5 billion in grants and over \$21.1 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. Recent appropriations increased OIG's discretionary funding for public health and human services oversight.

Grant Fraud Investigations

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

Kentucky – Vesta Brue is the owner, president, and chief executive officer of Care Team Solutions LLC (Care Team), and LifeTechniques, Inc. (LifeTechniques). LifeTechniques and Care Team allegedly submitted applications to NIH to obtain Small Business Innovation Research grants to fund the development of various medical devices, and were awarded five grants. The Government alleges that Brue, on behalf of LifeTechniques and Care Team, created phony invoices that grossly overstated expenses and manufactured products in China when all products were supposed to be produced domestically. As a result of these false claims, NIH paid Federal grant funds to LifeTechniques and Care Team to which neither company was entitled. Brue, Care Team, and LifeTechniques agreed to pay \$4.5 million, joint and several, to resolve their liability under the False Claims Act.

Illinois – Bishop Herman Jackson was the owner and pastor of the Ark of Safety Apostolic Faith Temple. He and his wife Jannette Faria operated three daycare centers from 2002 to 2011 and received childcare subsidies from ACF Block Grants. The investigation found that Jackson enrolled children who did not financially qualify to receive subsidized daycare services. Also, many of the children attended daycare for a short period of time but were continuously billed long after they stopped attending. In addition, some children never attended. Jackson and Faria were found guilty of mail fraud, wire fraud, and false statements. Jackson was sentenced to 5 years in prison, and Faria was sentenced to 1 year and 1 month in prison. Both were ordered to pay \$896,590 in restitution, joint and several.

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 2015 report delivered to the three congressional oversight committees, we reported that OIG spent approximately \$236,239 in salaries on oversight related to the SBIR/STTR program. HHS referred two new SBIR/STTR cases to OIG in FY 2016.

Recovery Act Retaliation Complaint Investigations

The American Recovery and Reinvestment Act (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 Reports to Congress 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 Reports to Congress* pursuant to section 5 of such Act, information on final completed contract audit reports issued during the period to the contracting activity containing significant audit findings. OIG issued no final reports meeting § 845 criteria during this semiannual period.

OIG Reviews of Non-Federal Audits

OIG reviews audits conducted by non-Federal auditors of entities receiving Federal awards. In this semiannual period, OIG's National External Audit Review Center reviewed 595 reports covering \$2.1 trillion in audited costs. Federal dollars covered by these audits totaled \$689 billion, of which about \$366 billion were HHS funds.

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

OIG's oversight of non-Federal audit activity informs Federal managers about the soundness of management of Federal programs and identifies any significant areas of internal control weakness, noncompliance, and questioned costs for resolution or followup. We identify entities for high-risk monitoring, alert program officials to any trends that could indicate problems in HHS programs, and

profile non-Federal audit findings of a particular program or activity over time to identify systemic problems. We also provide training and technical assistance to grantees and members of the auditing profession. OIG maintains a process to assess the quality of the non-Federal reports received and the audit work that supports the selected reports.

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

Non-Federal Audits, April 1, 2016, through September 30, 2016	
Number of Non-Federal Audits:	
■ <i>Not requiring changes or having minor changes</i>	579
■ <i>Requiring major changes</i>	16
■ <i>Having significant technical inadequacies</i>	0
Total	595

The 595 reports included 2,137 recommendations for improving management operations. In addition, these audit reports provided information for 20 OIG special memorandums that identified concerns for increased monitoring by management.

Other Reporting Requirements and Reviews

Government Charge Card Abuse Prevention Act

Letter to Office of Management and Budget Director to Meet Requirements of Government Charge Card Abuse Prevention Act of 2012 Regarding Agency Progress Implementing Recommendations on Charge-Card-Related Findings (A-04-14-06175), January 2015.

This letter report describes the progress that HHS has made in implementing previous purchase and travel card audit recommendations and the status of OIG's annual risk assessment. The letter was issued to meet the requirements of the Government Charge Card Abuse Prevention Act of 2012 (P.L. No. 112-194) (Charge Card Act) to report to the OMB Director on agency progress in the implementation of recommendations on charge-card-related findings. In addition, while not required for this report, we also explain how we intend to conduct required annual risk assessments of agency purchase cards.

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 annual [Work Plan and Mid-Year Update](#) 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 us and its operating and other staff divisions in the review and development of HHS regulations through a well-established HHS process. Our audits, evaluations, and investigations are sometimes cited in regulatory preambles as influencing HHS regulations. In addition, we provide independent, objective technical assistance on a bipartisan, bicameral basis to congressional committees and members who request it.

Implementation of Health Insurance Marketplaces

OIG continues to review programs implemented pursuant to the ACA. OIG's ACA oversight strategy focuses on the health insurance marketplaces, reforms in the Medicare and Medicaid programs, and public health programs. Key focus areas for our marketplace oversight 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.

State-Based Marketplaces

The ACA requires the establishment of a health insurance exchange (marketplace) in each State and the District of Columbia. A marketplace is designed to serve as a "one-stop shop" at which individuals get information about their health insurance options; are evaluated for eligibility for a qualified health plan and, when applicable, eligibility for insurance affordability programs; and enroll in the qualified health plan of their choice. A previous OIG review found that not all internal controls implemented by the Federally Facilitated Marketplace and the State marketplaces in California and Connecticut were effective in ensuring that individuals were enrolled in qualified health plans according to Federal requirements. The review below is part of an ongoing series that looks at seven State marketplaces across the Nation and determines whether their marketplaces' internal controls were effective in ensuring that individuals were enrolled in qualified health plans according to Federal requirements.

Vermont Did Not Properly Allocate Millions to Establishment Grants for a Health Insurance Marketplace (A-01-15-02500), September 2016

We found that Vermont did not always follow Federal requirements on allocating costs to its establishment grants for implementing a health insurance marketplace and drawing down establishment grant funds. Vermont allocated \$10.5 million using a cost allocation methodology that included a material defect, may not have allocated \$13.9 million in costs in accordance with the relative benefits that each grant program received, and drew down establishment grant funds that exceeded actual program costs by \$736,000.

Vermont did not fully address our first recommendation but stated it would work with CMS to determine the appropriate action to amend its Cost Allocation Plan and either refund \$10.5 million or work with CMS to determine the appropriate allocation to the establishment grants.

Payments and Policies

Conversions of Startup Loans Into Surplus Notes by Consumer Operated and Oriented Plans Were Allowable but Not Always Effective (A-05-16-00019), August 2016

CMS established loan agreements with Consumer Operated and Oriented Plans (CO-OPs) to provide startup and solvency loan funding. CMS issued a memo to the CO-OPs in July 2015 allowing the CO-OPs to convert startup loans into surplus notes. A surplus note is a bondlike instrument issued to provide needed capital. Under the terms of a surplus note, CO-OPs are not required to make any repayment on the surplus note that could lead to financial distress or default. We determined that the CO-OPs complied with CMS guidance and applicable accounting principles when converting startup loans into surplus notes. However, CMS did not adequately document the potential impact of the conversions on the Federal Government's ability to recover the loan payments if the CO-OPs were to fail. Although the conversions provided increased levels of capital and surplus, 4 of the 12 CO-OPs approved for conversions ceased operations within 6 months after the conversion. Despite the conversions allowing CO-OPs to record the startup loans as capital and surplus instead of debt, risk-based capital percentages were at levels below the CMS requirement of 500 percent for four of the eight operational CO-OPs as of December 31, 2015.

CMS concurred with our recommendations that it perform the following steps prior to approving additional conversions of startup loans to surplus notes: (1) document any potential negative impact from changes in distribution priority and (2) quantify the likely impact on the Federal Government's ability to recover loan payments.

Appendixes

- A Savings Decisions Supported by OIG Recommendations
- B Monetary Recommendations
- C Peer Review Results
- D Summary of Sanction Authorities
- E Reporting Requirements in the Inspector General Act of 1978
- F Anti-Kickback Statute – Safe Harbor

Appendix A

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 \$22.1 billion was attributed to FY 2016. This figure reflects the most recent available savings estimates issued by the third-party appraiser; actual savings may be higher or lower.

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

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

Centers for Medicare & Medicaid Services (CMS) Programs		
OIG Recommendations	Policy Decisions	Estimated Savings (millions)
Medicare 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 \$19.2 billion for FY 2016. CBO produced its estimate in 2010, prior to two significant implementation decisions by HHS that	\$19,200

	affect the actual savings; however, neither CBO nor HHS has calculated a revised estimate.	
<p>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.</p>	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
<p>Part B Drugs Average Sales Price. Adopt an alternate calculation of volume-weighted average sales price (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.</p>	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 2016.	\$400
<p>Reductions in Medicare Bad Debt Reimbursement. Seek legislative authority to eliminate (or reduce) Medicare payments to hospitals for bad debt associated with beneficiaries' failure to pay their deductibles and coinsurance. The recommendations reflected findings in OIG report number A-14-90-00339 and subsequent reviews.</p>	Section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012 applied percentage reductions in bad debt reimbursement to all providers eligible to receive bad debt reimbursement. CMS estimated savings to Medicare of \$10.92 billion over 10 years with \$1.06 billion attributed to FY 2016. (77 Fed. Reg. 67,450, 67,523 (November 9, 2012))	\$1,060
<p>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</p>	Section 2501(d) of the ACA, as amended by section 1206(a) of the Health Care and Education Reconciliation Act of 2010, addresses this issue. CBO estimated savings of \$200 million for FY 2016.	\$200

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.		
<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:</p> <p>A-02-98-01036</p> <p>A-02-02-01037</p> <p>A-02-02-01038</p> <p>A-04-01-07002</p> <p>A-09-89-00100</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 2016.	\$200
<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>	Section 203 of the Achieving a Better Life Experience Act of 2014 implements changes to treat VES prosthetic devices and related accessories as statutorily noncovered in the same manner that erectile dysfunction drugs are treated in Medicare Part D. CBO estimated savings of \$444 million over 10 years.	\$44.4
Payments for Prescription Drugs Provided to Incarcerated Beneficiaries.	CMS issued a final rule about the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare	\$90

<p>Work with prescription drug plan sponsors to identify and resolve improper Medicare Part D payments made for prescription drugs provided to incarcerated beneficiaries. The recommendation reflected findings in OIG report number A-07-12-06035.</p>	<p>Prescription Drug programs. The eligibility requirements to enroll in Medicare Advantage and Part D are outlined in Sections 1851(a)(3)(B) and 1860D-1(a)(3)(A) of the Act. To enroll in Medicare Advantage, a beneficiary must be entitled to Part A and enrolled in Part B. To enroll in Part D, a beneficiary must be entitled to Part A and/or enrolled in Part B. An incarcerated beneficiary is not precluded from meeting the eligibility requirements for Part A and Part B, but in general, no Medicare Payment is made for these individuals. CMS promulgated regulations to require Part D plans to disenroll incarcerated beneficiaries. CMS estimated savings of \$1.6 billion over 10 years with \$90 million attributed to FY 2016. (79 Fed. Reg. 29,844, 29,953 (May 23, 2014))</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 2016.</p>	<p>\$100</p>

Appendix B

Monetary Recommendations

The tables below summarize OIG’s monetary recommendations and HHS responses. 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 with the Supplemental Appropriations and Rescissions Act of 1980.

Table 1 – Audit Reports with Questioned Costs

	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	146	\$644,920,000	\$19,315,000
Reports issued during the reporting period	67	\$320,514,000	\$55,000
Total Section 1	213	\$965,434,000	\$19,370,000
Section 2			
Reports for which management decisions were made during the reporting period ^{2, 3}			
Disallowed costs	120	*\$575,846,000	\$1,169,000
Costs not disallowed	6	\$26,868,000	\$0
Total Section 2	126	\$602,714,000	\$1,169,000
Section 3			
Reports for which no management decisions had been made by the end of the reporting period (Sec. 1 minus Sec. 2)	87	\$362,720,000	\$18,201,000
Section 4			
Reports for which no management decisions were made within 6 months of issuance ⁴	46	\$151,589,000	\$18,145,000

*Audit receivables (expected recoveries).

Audit Reports With Funds Recommended To Be Put to Better Use

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

Table 2 – Audit Reports with Funds To Be Put to Better Use

	Reports	Dollar Value
Section 1		
Reports for which no management decisions had been made by the beginning of the reporting period ¹	5	\$15,020,135,000
Reports issued during the reporting period	7	\$37,149,000
Total Section 1	12	\$15,057,284,000
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	1	\$6,388,000
Based on proposed legislative action		\$0
Value of recommendations not agreed to by management	1	\$28,000
Total Section 2	2	\$6,416,000
Section 3		
Reports for which no management decisions had been made by the end of the reporting period ² (Sec. 1 minus Sec. 2)	10	\$15,050,868,000

End Notes

Table 1 End Notes

¹ The opening balance was adjusted upward by \$211.3 million because of a reevaluation of previously issued recommendations.

² Revisions to previously reported management decisions:

- A-01-13-00506 *Nationwide Review of Place of Service Coding for Physician Services Processed by Part B Contractors for Calendar Years 2010 through 2012*. Subsequent review by CMS determined that the \$1,408,649 of the \$7.3 million were allowable cost.
- A-04-12-07032 *Medicare Compliance Review at JFK Medical Center*. Subsequent review by CMS of the OIG’s extrapolation led to a downward adjustment in unallowable claims totaling \$4,183,075.

- A-05-14-00023 *Review of Illinois Medicaid Payments for Drug Herceptin*. Subsequent review by CMS determined additional offsets, increasing disallowed cost by \$496,038.
- A-06-14-00022 *Outpatient Dental Claims – National Government Services*. Subsequent review by CMS determined most of the claims identified were canceled by providers, reducing disallowed cost by \$1,973,933.
- Not detailed are net reductions to previously disallowed management decisions totaling \$5.6 million.

³ Included are management decisions to disallow \$39.9 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 OMB Circular A-133. OIG is currently ensuring that work performed by these non-Federal auditors complies with Federal audit standards; accordingly, OIG tracks, resolves, and reports on recommendations in these audits.

⁴ Because of administrative delays, some of which were beyond management control, resolution of the following 46 audits was 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-01-02-00006	REVIEW OF RATE SETTING METHODOLOGY FOR MEDICAID SCHOOL BASED HEALTH SERVICES - CT, MAY 2003, \$32,780,146
CIN: A-01-14-02503	REVIEW OF MD STATE AGENCY PROCESSES FOR DESIGN & IMPLEMENTATION OF THE STATE'S HEALTH INSURANCE EXCHANGE, MAR 2015, \$28,400,000
CIN: A-07-13-01125	MEDICARE PART C UNLAWFULLY PRESENT ENROLLEES, APR 2014, \$26,150,043
CIN: A-02-12-02016	PUERTO RICO IMPROPERLY CLAIMED SOME CHILD CARE AND DEVELOPMENT TARGETED FUNDS, JAN 2016, \$12,471,385
CIN: A-09-14-02037	REVIEW OF INPATIENT BONE MARROW AND STEM CELL TRANSPLANTS, FEB 2016, \$4,574,228
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-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-07-11-06013	INDIRECT COSTS CLAIMED AS DIRECT COSTS - UNIVERSITY OF COLORADO DENVER, JUN 2013, \$1,419,524
CIN: A-03-12-00008	REVIEW OF XL HEALTH DIR, JAN 2013, \$1,410,342
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-06-15-00013	MEDICARE OUTPATIENT DENTAL CLAIMS - FCSO (JN), MAR 2016, \$1,065,486
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	REVIEW OF NEVADA HEALTH EXCHANGE ESTABLISHMENT GRANTS, FEB 2016, \$893,464
CIN: A-09-11-01007	REVIEW OF CSBG RECOVERY ACT COSTS CLAIMED BY HI FOR HCAP, FEB 2013, \$513,649
CIN: A-04-13-01024	ALLOWABILITY OF SELECTED COSTS CHARGED TO FEDERAL GRANTS AND CONTRACTS UNC, JUN 2014, \$352,843
CIN: A-03-15-00006	CORNERSTONE HOSPITAL OF BOSSIER CITY INCORRECTLY BILLED MEDICARE INPATIENT CLAIMS WITH KWASHIORKOR, MAR 2016, \$321,971
CIN: A-01-10-02505	RESULTS OF LIMITED SCOPE REVIEW OF CTE, INC., MAY 2011, \$293,870
CIN: A-02-11-02015	REVIEW OF INSEC, INC. CSBG ARRA COSTS CLAIMED BY THE COMMONWEALTH OF PUERTO RICO, 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-05-12-00012	REVIEW OF IL CSBG RECOVERY ACT COSTS CLAIMED - ROCKFORD, JUL 2013, \$205,296
CIN: A-06-09-00012	RISK ADJUSTMENT DATA VALIDATION - PACIFICARE 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	FLORIDA'S ADMINISTRATION OF CSBG RECOVERY ACT PROGRAM AND COSTS CLAIMED BY CENTRAL FLORIDA COMMUNITY ACTION AGENCY, INC., APR 2013, \$160,404
CIN: A-07-11-02766	REVIEW OF WY CSBG RECOVERY ACT COSTS CLAIMED - CARBON COUNTY, AUG 2013, \$143,588
CIN: A-09-11-01013	REVIEW OF OREGON'S HOUSING AND COMMUNITY SERVICES DEPARTMENT, APR 2013, \$115,911
CIN: A-06-11-00058	REVIEW OF CSBG ARRA COSTS CLAIMED BY CROWLEY'S RIDGE DEVELOPMENT COUNCIL, AUG 2012, \$115,420
CIN: A-07-12-02779	REVIEW OF NATRONA COUNTY CSBG RECOVERY ACT COSTS CLAIMED, JUN 2013, \$104,971
CIN: A-02-14-02013	LINK2HEALTH SOLUTIONS, INC., BUDGETED COSTS THAT WERE NOT APPROPRIATE AND CLAIMED SOME UNALLOWABLE HURRICANE SANDY DISASTER RELIEF ACT FUNDS, MAR 2016, \$54,822
CIN: A-04-14-04028	AUDIT OF NC DHHS PPHF GRANTS AND COOPERATIVE AGREEMENTS AWARDED BY CDC, JAN 2016, \$50,485
CIN: A-02-11-02000	DIRECT COST REVIEW - SUNY ALBANY, OCT 2011, \$27,384
CIN: A-09-11-01014	REVIEW OF CSBG RECOVERY ACT COSTS CLAIMED BY HI FOR THE HAWAII COUNTY ECONOMIC OPPORTUNITY COUNCIL, 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:	46
TOTAL AMOUNT:	\$151,589,000

Table 2 End Notes

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

² Because of administrative delays, some of which were beyond management control, 4 of the 10 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	Comparison of Surgical Services Provided in the ASC Setting to Other Outpatient Settings, APRIL 2014, \$15,000,000,000
CIN: A-07-13-02795	Review of Palmetto Medicare Outlier Processing Timeliness for J1, JUL 2015, \$15,792,301
CIN: A-09-14-02037	Review of Inpatient Bone Marrow and Stem Cell Transplants, FEB 2016, \$3,821,519
CIN: A-04-14-04028	Audit of NC DHHS PPHF Grants and Cooperative Agreements Awarded by CDC, JAN 2016, \$493,401
TOTAL CINS:	4
TOTAL AMOUNT:	\$15,020,107,000

Appendix C

Peer Review Results

The Inspector General Act of 1978, as amended, requires OIGs to report the results of peer reviews of their operations conducted by other OIGs, the date of the last peer review, outstanding recommendations from peer reviews, and peer reviews conducted by the 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). The required information follows.

Office of Audit Services

During this semiannual reporting period, no peer reviews involving the Office of Audit Services (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	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)

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

Office of Investigations

During this semiannual reporting period, no peer reviews involving Office of Investigations (OI) were completed. Listed below is information concerning OI's peer review activities during prior reporting periods.

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

The system of internal safeguards and management procedures for the investigative function of HHS OIG in effect 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	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.

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

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

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

Civil Monetary Penalties Law

The CMPL of the Social Security Act, 1128A (42 U.S.C. § 1320a-7a), imposes penalties, assessments, and exclusion from participation in Federal health care programs for engaging in certain activities. For example, a person who submits, or causes to be submitted, to a Federal health care program a claim for items and services that the person knows, or should know, is false or fraudulent is subject to a penalty of up to \$10,000 for each item or service falsely or fraudulently claimed, an assessment of up to three times the amount falsely or fraudulently claimed, and exclusion.

For the purposes of the CMPL, “should know” is defined to mean that the person acted in reckless disregard or deliberate ignorance of the truth or falsity of the claim. The law and its implementing regulations also authorize actions for a variety of other violations, including submission of claims for items or services furnished by an excluded person; requests for payment in violation of an assignment agreement; 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 \$50,000 for each false statement, as well as activities relating to fraudulent marketing by managed care organizations, their employees, or their agents.

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 \$25,000 against small hospitals (fewer than 100 beds) and up to \$50,000 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 \$50,000 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 False Claims Act, as amended by the False Claims Amendments Act of 1986 (FCA) (31 U.S.C. §§ 3729–3733), a person or an entity is liable for up to treble damages and a penalty between \$5,500 and \$11,000 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 Issues” 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	OIG <i>Compendium of Unimplemented Recommendations</i>
(a)(4)	Matters referred to prosecutive authorities	“Legal and Investigative Activities” section
(a)(5)	Summary of instances in which information requested by OIG was refused	None
(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	Appendix A
(a)(11)	Description and explanation of revised management decisions	Appendix A
(a)(12)	Management decisions with which the Inspector General disagrees	None
(a)(13)	Information required by the FISMA	Reported annually in the spring <i>Semiannual Report to Congress</i> , “Other HHS-Related Issues” section
(a)(14)-(16)	Results of peer reviews of HHS OIG conducted by other OIGs or the date of the last peer review, outstanding recommendations from peer reviews, and peer reviews conducted by HHS OIG of other OIGs	Appendix B

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 Issues” 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 <i>Semiannual Report</i> . Appendix F
1553	Pursuant to the American Recovery and Reinvestment Act of 2009, § 1553, OIG reports to Congress the retaliation complaint investigations it decided not to conduct or continue during the period.	“Other HHS-Related Issues” section

Appendix F

Anti-Kickback Statute – Safe Harbors

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

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

Public proposals for new and modified safe harbors

In response to the 2065 annual solicitation, OIG received the following proposals related to safe harbors:

Proposal	OIG Response
A new safe harbor that would allow non-unit-based rebate arrangements between biopharmaceutical manufacturers and payers to promote arrangements tying pricing of drugs to value and protect the provision of data analytic support to Medicare and Medicaid providers and suppliers.	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 permit value-based purchasing arrangements between biopharmaceutical manufacturers and purchasers that would promote patient outcome-based pricing, indication-specific pricing, and patient-specific pricing models.	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 to protect financial arrangements between payers, providers,	OIG is not adopting this suggestion at this time, as it requires further study. In the meantime, questions

and/or manufacturers to support coverage and payment methodologies that reward or penalize items and services based on their achievement of value and/or cost savings. Parties would be permitted to provide investments to design agreements and infrastructure, monitor patient outcomes, and analyze clinical information.	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 to protect and encourage 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.
Extend existing safe harbor for donation and financial support of EHR software, related technology, and training beyond 2021 and modify safe harbor to ensure the range of relevant and appropriate technologies are included based on the evolving technological environment.	OIG is not adopting the suggestion to extend the safe harbor. With respect to modifying the safe harbor to ensure the range of relevant and appropriate technologies are included based on the evolving technological environment, we are not adopting this suggestion at this time, as it requires further study.
A new safe harbor for financial arrangements that involve risk sharing and gainsharing in alternative payment models when appropriate safeguards are in place.	OIG is not adopting this suggestion at this time. Waivers of certain fraud and abuse laws, including the anti-kickback statute, have been issued or are being considered as needed in connection with the Medicare Shared Savings Program and specific models sponsored by the Centers for Medicare and Medicaid Innovation. See Fraud and Abuse Waivers available at https://oig.hhs.gov/compliance/accountable-care-organizations/index.asp . Whether safe harbors are appropriate for the types of arrangements involved in these demonstrations requires further study.
A new safe harbor to broadly protect participants of Centers for Medicare and Medicaid Innovation programs from liability under the anti-kickback statute.	OIG is not adopting this suggestion at this time. Waivers of certain fraud and abuse laws, including the anti-kickback statute, have been issued or are being considered as needed in connection with specific models sponsored by the Centers for Medicare and Medicaid Innovation. See Fraud and Abuse Waivers available at https://oig.hhs.gov/compliance/accountable-care-organizations/index.asp . Whether safe harbors are appropriate for the types of arrangements involved in these demonstrations requires further study.
A new safe harbor to permit incentive payment arrangements, including direct or	OIG is not adopting this suggestion at this time. Waivers of certain fraud and abuse laws, including the

<p>indirect monetary remuneration or financial arrangements to support startup costs and support contributions, between hospitals and other providers who participate in advanced payment models, as defined by CMS.</p>	<p>anti-kickback statute, have been issued or are being considered as needed in connection with the Medicare Shared Savings Program and specific models sponsored by the Centers for Medicare and Medicaid Innovation. See Fraud and Abuse Waivers available at https://oig.hhs.gov/compliance/accountable-care-organizations/index.asp. Whether safe harbors are appropriate for the types of arrangements involved in these demonstrations requires further study.</p>
<p>Modification of the personal services and management contracts safe harbor to deem incentive payment arrangements between providers participating in alternative payment models to be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties, when the compensation methodology is based on the achievement of objective, evidence-based, quality measures and cost savings.</p>	<p>OIG is not adopting this suggestion at this time, as it requires further study. Waivers of certain fraud and abuse laws, including the anti-kickback statute, have been issued or are being considered as needed in connection with the Medicare Shared Savings Program and specific models sponsored by the Centers for Medicare and Medicaid Innovation. See Fraud and Abuse Waivers available at https://oig.hhs.gov/compliance/accountable-care-organizations/index.asp. Whether modification of the personal services and management contracts safe harbor is appropriate for the types of arrangements involved in these demonstrations requires further study.</p>
<p>A new safe harbor that would protect items and services provided to patients by a health care provider or supplier that are reasonably related to a patient's medical needs.</p>	<p>OIG is not adopting this suggestion at this time. We note that, on a related point, some arrangements under the proposal may be covered by the exception to the definition of remuneration for purposes of the civil monetary penalties law (CMPL) at section 1128A. A final rule regarding the implementation of an exception to the definition of remuneration for purposes of the CMPL under section 1128A(i)(6)(F) of the Act, 42 U.S.C. §1320a-7a(i)(6)(F) is under review. OIG is considering whether a safe harbor to the anti-kickback statute is appropriate to protect the remuneration to beneficiaries in the same circumstances. Any such safe harbor would be proposed in a new notice of proposed rulemaking. 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.</p>