

**OFFICE OF
INSPECTOR GENERAL**

U.S. Department of Health and Human Services

**SEMIANNUAL REPORT
TO CONGRESS**

April 1 – September 30, 2015

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, the Department of Justice (DOJ), and the Inspector General community. OIG carries out its 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 conducted by the following operating components with assistance from OIG counsel and management:

OAS
OEI
OI
OCIG
EM

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs, its grantees and contractors, all of the aforementioned, in carrying out their responsibilities—and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement, promoting economy and efficiency throughout HHS.

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

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in every State and the District of Columbia, OI actively coordinates with DOJ and other Federal, State, and local law enforcement authorities. 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) renders general legal services to OIG, rendering advice and opinions on HHS programs and operations and provides all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including the False Claims Act, program exclusion, and CMP cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry on the anti-kickback statute and other OIG enforcement authorities.

Executive Management (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, 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.

A Message From the Inspector General

This Semiannual Report to Congress, submitted pursuant to the Inspector General Act of 1978, as amended, summarizes the activities of the Office of Inspector General (OIG), Department of Health and Human Services (HHS or the Department), for the 6-month period that ended September 30, 2015.

OIG's mission is to protect the integrity of HHS programs, as well as the health and welfare of program beneficiaries. The work we perform to accomplish that mission directly affects an important measure of Government effectiveness: the improper payment rate. The improper payment rate, however, is more than just a measure of error; improper payments can degrade the integrity of Government programs.

OIG investigations, audits, and evaluations can help the Department reduce improper payments by providing information and recommendations designed to ensure that the Department can pay the right person the right amount for the right reasons and lessen the negative impact of improper payments.

Our work identifies improper payments, which sometimes may be caused by fraud, but may also indicate questionable billing patterns that could lead to waste or signal other problems, such as low quality of care. During this reporting cycle, OIG participated in the largest nationwide Strike Force operation in history. This operation involved over \$700 million in potential false billings to Medicare and Medicaid and resulted in charges against 243 defendants. In a recent report, OIG also identified 329 general dentists and 6 orthodontists in California's Medicaid program who had questionable billing patterns and received \$117.5 million in 2012. The patterns indicated that providers may be performing unnecessary procedures to increase profits and, in so doing, may be exposing patients to harm from medically unnecessary services.

OIG reports recommend improvements to correct problems that contribute to improper payments or policies that contribute to wasteful spending. One such report identified prepayment edits that Medicare contractors could implement to prevent overpayments for selected outpatient drugs. This report resulted in the majority of Medicare contractors educating providers to prevent similar future overpayments. Another report found that the payment system for skilled nursing facilities creates incentives for these facilities to bill for the highest level of therapy and recommended that the Centers for Medicare & Medicaid Services reevaluate this system.

OIG endeavors to examine new programs early in their implementation to pinpoint potential issues to curb or reduce the magnitude of improper payments. For example, as the Department continued its implementation of the health insurance marketplaces, OIG identified specific high-risk areas, such



*Daniel R. Levinson
Inspector General*

as eligibility and contractor oversight, that warranted heightened attention to better ensure the integrity of these new programs. A related report from this cycle found that internal controls did not effectively ensure the accuracy of nearly \$2.8 billion in aggregate financial assistance payments made to insurance companies offering plans on the health insurance marketplaces. With that information, the Department and other stakeholders can identify appropriate steps to address the risks identified by OIG.

OIG recognizes that individual vulnerabilities may also signal systemic issues in a program or across multiple programs. In June 2015, OIG released a “Portfolio Report” summarizing findings of OIG investigations, audits, evaluations, and legal guidance regarding Medicare Part D. The Portfolio Report offered recommendations to address systemic weaknesses in the use of data to identify vulnerabilities, as well as in the oversight provided by plan sponsors, program integrity contractors, and CMS. In September 2015, OIG issued a report that evaluated 13 awarding agencies within the Department. We found limitations in the variety of sources of information and communication that granting officials use to mitigate grantee risks. Those findings raise concerns about whether granting officials across multiple programs have all available information to assess and mitigate risks relating to poor performance and misuse of grant funds, which could lead to a higher risk of improper payments.

Since its establishment in 1976, OIG has worked diligently with its partners to protect HHS’s vital health and human services programs by, in part, addressing the negative impacts of improper payments. Since that time, OIG’s mission has expanded because of the rapidly changing health care economy and the Department’s \$1 trillion portfolio in programs and operations. The achievements of this office would not be possible without the dedication and professionalism of all OIG employees. Once again, I would also like to express my appreciation to Congress and to the Department for their sustained commitment to supporting the important work of our office.

Daniel R. Levinson
Inspector General

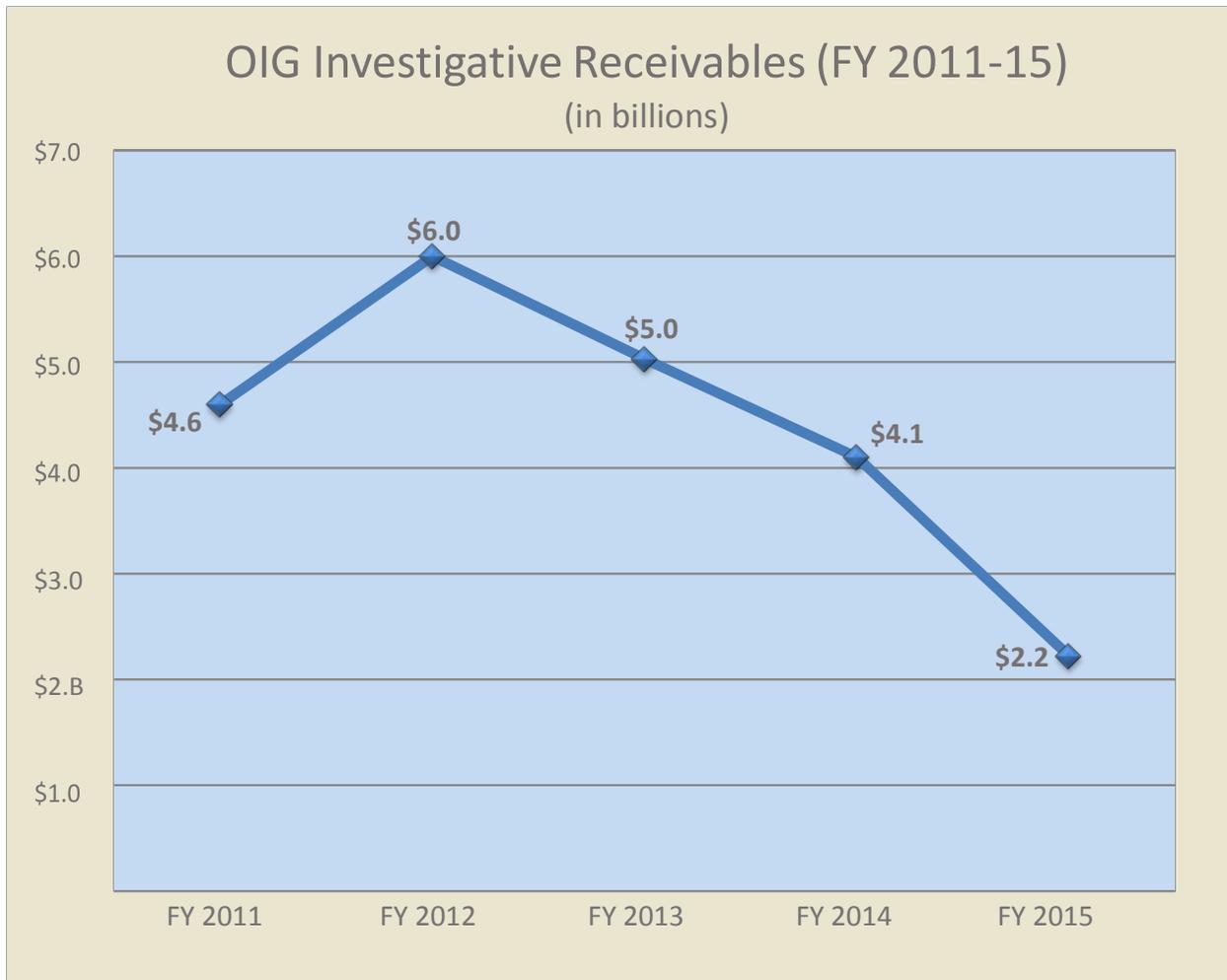
Highlights

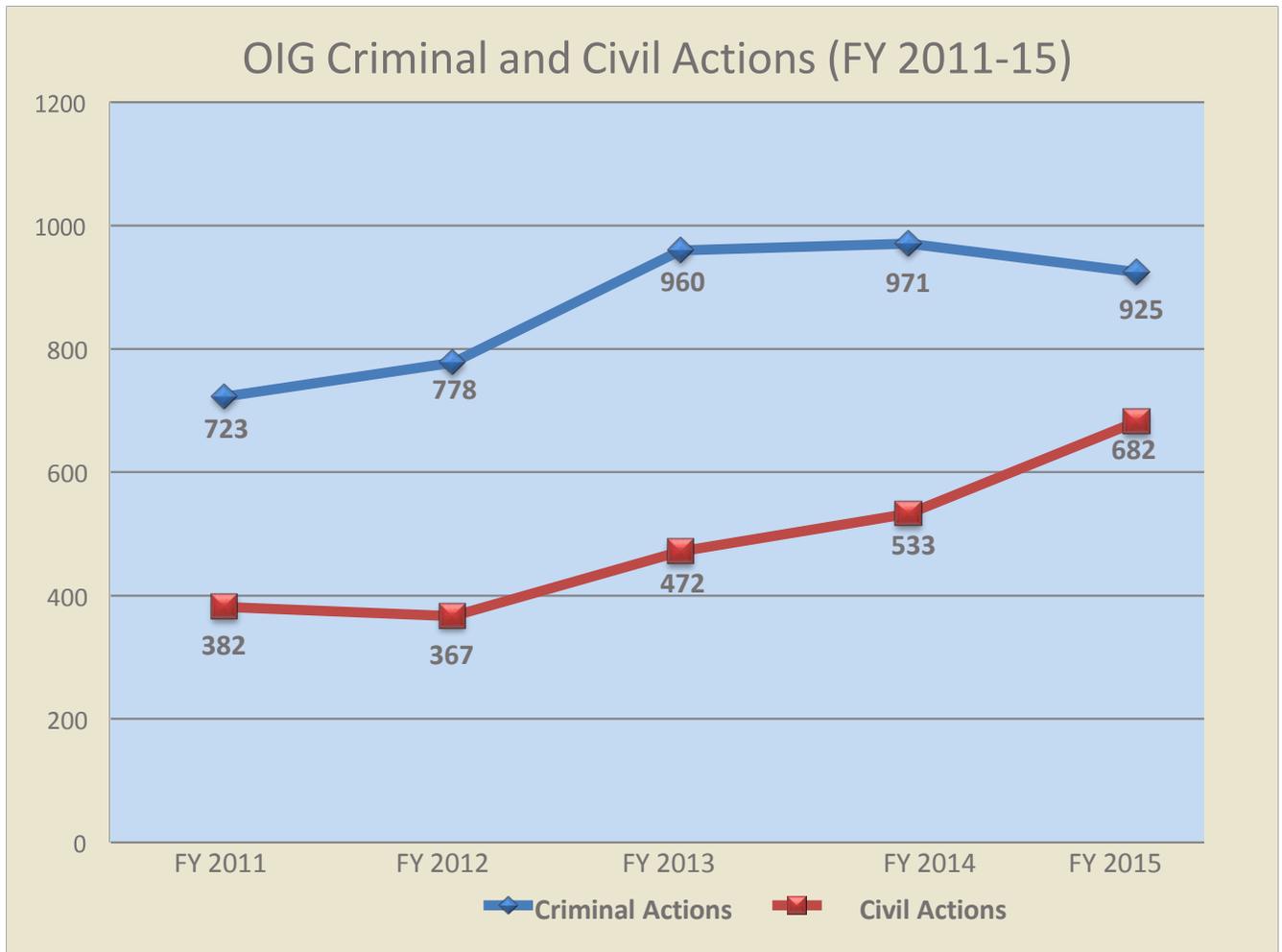
The Department of Health and Human Services (HHS or the Department) Office of Inspector General (OIG) *Semiannual Report to Congress (Semiannual Report)* describes significant problems, abuses, deficiencies, and investigative outcomes on the administration of HHS programs and operations that were disclosed during the reporting period. This edition addresses work completed during the second half of fiscal year (FY) 2015 (April to September) and summarizes key accomplishments during the period.

Accomplishments

For FY 2015, OIG reported expected recoveries of over nearly \$3.35 billion, consisting of nearly \$1.13 billion in audit receivables, and over \$2.22 billion in investigative receivables, which include over \$286.6 million in non-HHS investigative receivables resulting from our work in areas such as the States' shares of Medicaid restitution.

Also during FY 2015, OIG reported 925 criminal actions against individuals or entities that engaged in crimes against HHS programs; it also reported 682 civil actions, which include false claims and unjust-enrichment lawsuits filed in Federal district court, civil monetary penalties settlements, and administrative recoveries related to provider self-disclosure matters. We also reported exclusions of 4,112 individuals and entities from participation in Federal health care programs.

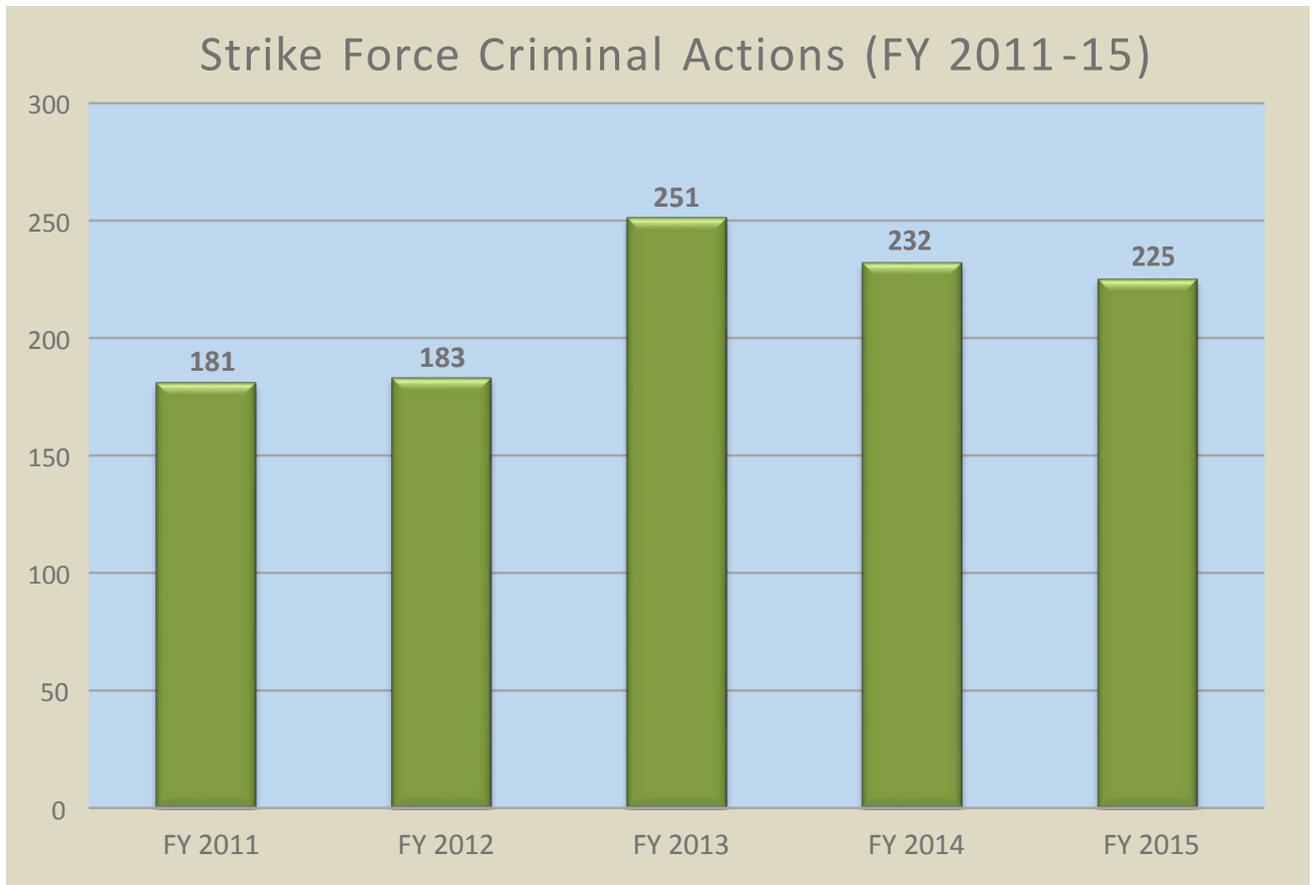


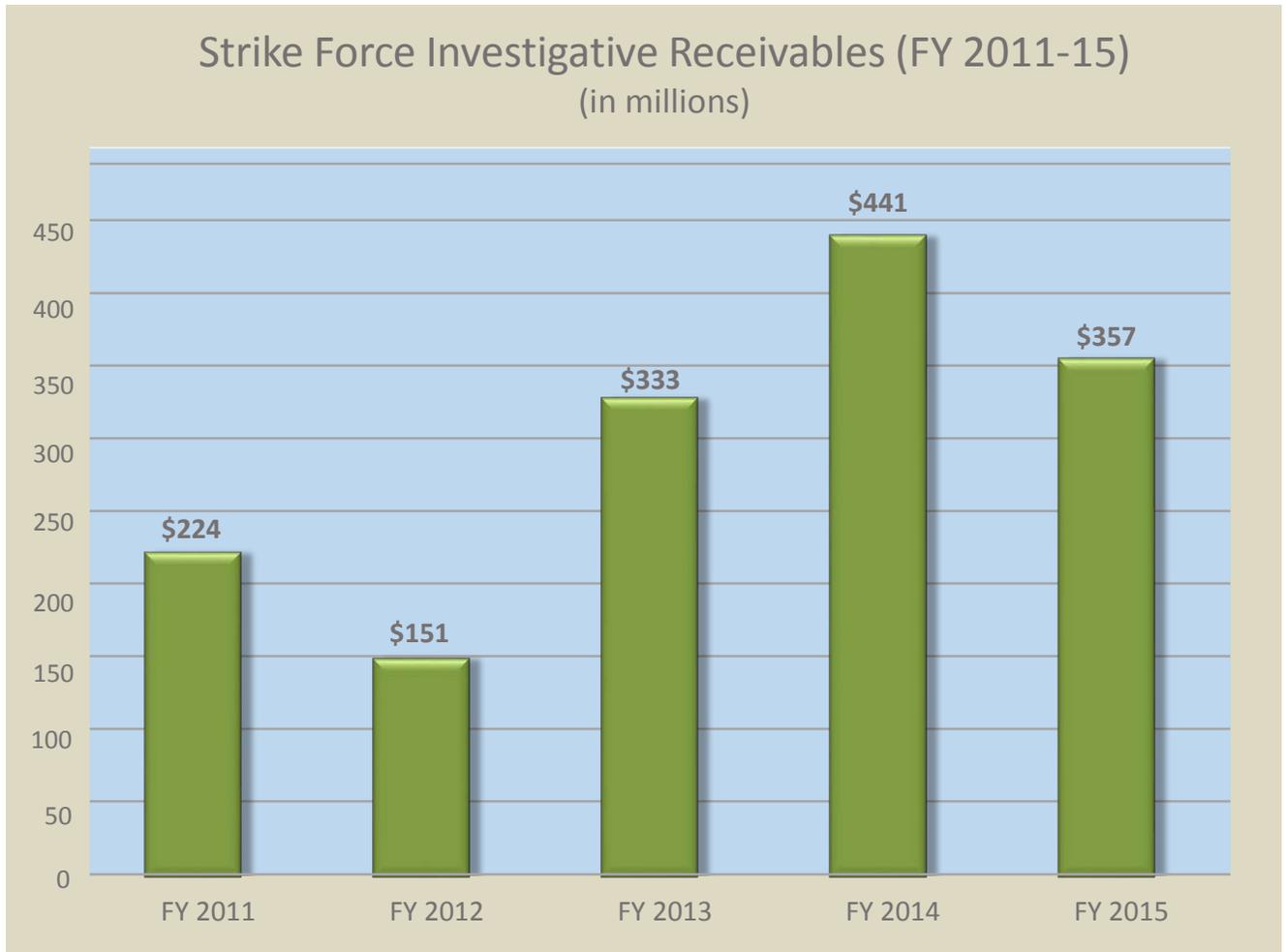


Strike Force and other fraud accomplishments

The Health Care Fraud Prevention and Enforcement Action Team (HEAT) was started in 2009 by HHS and the U.S. Department of Justice to strengthen programs and to invest in new resources and technologies aimed at preventing and combatting health care fraud, waste, and abuse. HEAT has continued to identify and hold accountable those who seek to defraud Medicare and Medicaid.

Medicare 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. Launched in March 2007, the Strike Force model now 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 2015, Strike Force efforts resulted in the filing of charges against 232 individuals or entities, 225 criminal actions, and over \$357.8 million in investigative receivables, as shown on the next page.





Strike Force case examples –

Fraudulent Part D claims – Nationwide

In June 2015, a nationwide takedown led by the Medicare Fraud Strike Force resulted in charges against 243 defendants, including doctors, nurses, and other licensed medical professionals. These defendants were charged in various health care fraud-related crimes, including conspiracy to commit health care fraud, violations of the anti-kickback statute, money laundering, and aggravated identity theft. The charges were based on a variety of alleged fraud schemes; these involved various medical treatments and services, including home health care, psychotherapy, physical and occupational therapy, durable medical equipment, and pharmacy fraud. More than 44 of the defendants were charged with fraud related to the Medicare prescription drug benefit program, known as Part D, the fastest-growing component of the Medicare program. According to court documents, the defendants participated in alleged schemes to submit claims to Medicare and Medicaid for treatments that were medically unnecessary—and often never provided. In many cases, patient recruiters, Medicare beneficiaries, and other co-conspirators allegedly were paid cash kickbacks in return for supplying beneficiary information to providers. The providers then submitted fraudulent bills to Medicare for services that were medically unnecessary or never performed. The takedown, the largest in Strike Force history, was part of a

coordinated operation across 17 districts and potentially involved over \$700 million in false billings to Medicare and Medicaid.

Fraudulent health care claims – Southern Texas Strike Force

Earnest Gibson III, Earnest Gibson IV, Mohammad Kahn, and Regina Askew were sentenced to a combined 117 years of incarceration. They were also ordered to pay more than \$46 million in joint and several restitution after being convicted of conspiracy to commit health care fraud and conspiracy to pay and receive kickbacks. Gibson III and Gibson IV also were convicted of conspiracy to commit money laundering. The scheme involved more than \$158 million in false claims to Medicare for partial hospitalization program (PHP) services that were medically unnecessary, not eligible for reimbursement, and were not provided. To facilitate the scheme, the defendants offered and paid kickbacks, including cash, cigarettes, and food, to patient recruiters, group home owners, and assisted living facility owners in exchange for sending Medicare beneficiaries to Riverside General Hospital and its satellite facilities. Here, the patients watched television, played games, and engaged in other non-PHP activities rather than receive the PHP services for which the hospital billed Medicare.

Michigan – Oncologist Farid Fata was sentenced to 45 years in prison and ordered to forfeit more than \$17 million after pleading guilty to charges of health care fraud, conspiracy to pay or receive kickbacks, and money laundering. Fata, who owned and operated the cancer treatment clinic Michigan Hematology Oncology, P.C., admitted that he prescribed and administered aggressive chemotherapy, cancer treatments, intravenous iron, and other infusion therapies to 553 patients who did not need these therapies, in order to increase his billings to Medicare and other insurance companies. He then submitted fraudulent claims to Medicare and other insurers for these unnecessary treatments. In total, Fata submitted approximately \$34 million in fraudulent claims to Medicare and private insurance companies.

Prescription Drug Fraud Scheme

New York – Kevin Lowe was convicted of conspiracy to distribute and possess with intent to distribute oxycodone. Lowe owned and operated Astramed, a series of purported medical clinics with multiple locations in the Bronx, New York. Astramed doctors were paid cash in exchange for writing tens of thousands of medically unnecessary prescriptions for large quantities of oxycodone. These prescriptions were then filled at pharmacies by co-conspirators who, in turn, resold and distributed the drugs at vastly inflated rates. Patient recruiters would bring beneficiaries to the clinic, where they would receive a “doctor visit” that typically lasted just a minute or two without any actual physical examination, but consistently resulted in a prescription for a large dose of oxycodone. On a daily basis, crowds of up to 100 people gathered outside the clinics waiting to see one of the doctors and receive a prescription for oxycodone. The “patient” would often be escorted by a patient recruiter, or crew member, to a pharmacy to fill the prescription. The crew member would then pay the patient and take possession of and ultimately sell the oxycodone on the street. In total, Astramed issued approximately 31,500 medically unnecessary prescriptions for oxycodone, comprising nearly 5.5 million tablets with a street value of up to \$165 million. Lowe is awaiting sentencing in November 2015.

International Health Care Fraud Scheme

Miami – Mirna Blanco was sentenced to 2 years in prison and ordered to pay \$16 million in joint and several restitution after pleading guilty to conspiracy to commit health care fraud and wire fraud. Blanco submitted fraudulent Medicare and Medicaid enrollment applications for beneficiaries, which claimed that the beneficiaries resided in Florida. However, these applicants actually resided in Nicaragua and the Dominican Republic. To falsely represent that the foreign residents lived in Florida, Blanco and her co-conspirators used nonresidential addresses, addresses belonging to the relatives and friends of these foreign residents, and addresses associated with the defendants.

Inefficient payments, policies, and practices

Medicare and Medicaid policies or practices sometimes result in inefficiencies when unintended loopholes or other inherent problems invite exploitation or hinder consistent payment determinations. Improper payments occur when the programs do not effectively prevent, deter, identify, or address inappropriate and abusive billing by providers and suppliers. Some, but not all, abusive billing is fraudulent.

Examples of our work follow:

- *Texas Paid Millions for Unallowable Medicaid Orthodontic Services (A-06-11-00048*
<http://oig.hhs.gov/oas/reports/region6/61100048.pdf>) June 2015

Texas did not ensure that requests for prior authorization of Medicaid orthodontic services were approved in accordance with State Medicaid guidelines. We estimated that Texas paid at least \$133.4 million for unallowable orthodontic services. Of 106 sampled orthodontic prior-authorization requests, 89 were improperly approved: 78 did not qualify for orthodontic services, and 11 did not have sufficient documentation to determine whether they qualified.

- *Medicare Part B Overpaid Millions for Selected Outpatient Drugs (A-09-14-02024*
<http://oig.hhs.gov/oas/reports/region9/91402024.asp>) July 2015

Medicare contractors in 13 jurisdictions overpaid providers \$35.8 million for selected outpatient drugs from July 1, 2009, through June 30, 2012. For 88 percent of the overpayments, providers billed either incorrect units of service or, otherwise, a combination of incorrect units of service and incorrect Healthcare Common Procedure Coding System codes. The Medicare claims processing systems did not have sufficient prepayment edits in place to prevent all overpayments. CMS said that, as of May 4, 2015, Medicare contractors had recovered 63 percent of the \$35.8 million in overpayments, and 10 of the 13 Medicare contractors had used the results of our audits in ongoing provider education activities.

- *Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered*
Drugs (A-07-14-06051 <http://oig.hhs.gov/oas/reports/region7/71406051.pdf>) April 2015

Missouri did not always comply with Federal Medicaid requirements for billing drug manufacturers for rebates for physician-administered drugs. Missouri did not collect the National Drug Codes (NDCs) that were required for it to invoice manufacturers for rebates associated with about \$34.8 million in physician-administered drugs. In addition, Missouri did not capture the utilization and coding data necessary to collect rebates for all physician-administered drugs. Without the NDCs, we were unable to determine whether Missouri improperly claimed Federal reimbursement for an additional \$13.2 million

for other physician-administered drug claims. Federal reimbursement for covered outpatient drugs administered by a physician is not available to States that do not comply with Federal requirements for capturing data to bill and collect rebates.

- *Questionable Billing for Medicaid Pediatric Dental Services in California (OEI-02-14-00480 <http://oig.hhs.gov/oei/reports/oei-02-14-00480.pdf>) May 2015*

We identified 329 general dentists and 6 orthodontists in California with questionable billing. Medicaid paid these providers \$117.5 million for pediatric dental services in 2012. These 335 dental providers—representing 8 percent of the California general dentists and orthodontists we reviewed—provided either a large number of services or certain services to an extremely large number of children, among other practices. Half of the dental providers with questionable billing worked for dental chains. The California Department of Health Care Services concurred with all of our recommendations, which were for the State agency to:

- increase its monitoring of dental providers to identify patterns of questionable billing;
- closely monitor billing by providers in dental chains;
- review its payment processes for orthodontic services; and
- take appropriate action against the dental providers identified as having questionable billing.

- *Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D (OEI-02-15-00190 <http://oig.hhs.gov/oei/reports/oei-02-15-00190.pdf>) June 2015*

Spending for Part D drugs, especially commonly abused opioids, has grown substantially. We identified questionable billing by 1,400 pharmacies that may indicate fraudulent activity. Each of these pharmacies billed for extremely high amounts for one or more of our billing measures. We also identified geographic hotspots for certain drugs that point to possible fraud and abuse. These findings and previous OIG work demonstrate that more needs to be done to address fraud and abuse in Part D. This goal requires CMS to fully implement OIG's previous recommendations, which are summarized in the OIG portfolio highlighted below.

- *Ensuring the Integrity of Medicare Part D (OEI-03-15-00180 <http://oig.hhs.gov/oei/reports/oei-03-15-00180.pdf>) June 2015*

This portfolio presents an overview of OIG investigations, audits, evaluations, and legal guidance related to Part D. It synthesizes numerous OIG reports that have identified weaknesses in Part D program integrity, and provides updates on Departmental efforts to address these weaknesses. In particular, OIG has identified weaknesses in the use of data to identify vulnerabilities, as well as in the oversight by all parties responsible for protecting Part D: CMS, Part D plan sponsors, and the Medicare Drug Integrity Contractor. OIG has made recommendations to strengthen Part D program integrity, and progress has been made. However, Part D remains vulnerable to fraud, as evidenced by ongoing investigations. To fully protect Part D from fraud, waste, and abuse, CMS should take further action and implement OIG's previous recommendations including:

- require plan sponsors to report all potential fraud and abuse to CMS, the Medicare Administrative Contractor, or both;
- expand drug utilization review programs to include additional drugs susceptible to fraud, waste, and abuse;
- implement an edit to reject prescriptions written by excluded providers;

- seek authority to restrict certain beneficiaries to a limited number of pharmacies or prescribers;
- develop and implement a mechanism to recover payments from plan sponsors when law enforcement agencies do not accept case referrals; and
- determine the effectiveness of plan sponsors' fraud and abuse detection programs.

Quality of care and beneficiary protection

Gaps in program safeguards intended to ensure medical necessity, patient safety, access to services, and quality of care present significant challenges to the Medicare and Medicaid programs. OIG is committed to continuing its quality-of-care and beneficiary protection oversight across all HHS programs and services. Examples of our work follow:

■ *CMS's Reliance on New York Qualification Requirements Could Not Ensure the Quality of Care Provided to Medicaid Beneficiaries Receiving Home Health Services (A-02-11-01013 <http://oig.hhs.gov/oas/reports/region2/21101013.pdf>) May 2015*

■ *CMS's Reliance on New Jersey Qualification Requirements Could Not Ensure the Quality of Care Provided to Medicaid Beneficiaries Receiving Home Health Services (A-02-11-01019 <http://oig.hhs.gov/oas/reports/region2/21101019.pdf>) June 2015*

CMS could not rely on New York's or New Jersey's qualification requirements to ensure quality of care was provided to Medicaid beneficiaries receiving home health services. Some New York and New Jersey home health agencies did not meet certain Federal and State requirements for employee health screenings and training, among other issues. We estimated that \$31.9 million in Federal Medicaid reimbursement was associated with HHA workers who did not meet Federal and State requirements (\$27.9 million in New York and \$4 million in New Jersey).

■ *The Medicare Payment System for Skilled Nursing Facilities Needs to Be Reevaluated (OEI-02-13-00610 <http://oig.hhs.gov/oei/reports/oei-02-13-00610.pdf>) September 2015*

The findings of this and prior OIG reports demonstrate the need for CMS to reevaluate the skilled nursing facility (SNF) payment system. Medicare payments for therapy greatly exceeded SNFs' costs for therapy. Combined with the current method of paying for therapy, this large difference between therapy payments and costs creates a strong financial incentive for SNFs to bill for higher levels of therapy than necessary. Under this system, SNFs increasingly billed for the highest level of therapy even though key beneficiary characteristics remained largely the same. Increases in SNF billing—particularly for the highest level of therapy—resulted in \$1.1 billion in Medicare payments in FYs 2012 and 2013. Payment reform could save Medicare billions of dollars and encourage SNFs to provide services that are better aligned with beneficiaries' care needs.

CMS concurred with our recommendations to:

- evaluate the extent to which Medicare payment rates for therapy should be reduced;
- change the method for paying for therapy;
- adjust Medicare payments to eliminate any increases that are unrelated to beneficiary characteristics; and
- strengthen oversight of SNF billing.

- *Providers Terminated From One State Medicaid Program Continued Participating in Other States (OEI-06-12-00030 <http://oig.hhs.gov/oei/reports/oei-06-12-00030.pdf>) August 2015*

The Affordable Care Act (ACA) requires States to terminate providers who were already terminated for cause in another State, yet States face challenges complying with this mandate. OIG found continued participation from providers terminated in one State in other States' Medicaid program, specifically, about one-third of providers continued to receive payments for services provided to Medicaid beneficiaries after being terminated for cause. Continued participation of providers after their terminations for cause presents a vulnerability to Medicaid and raises concern that these providers could continue to treat Medicaid beneficiaries. This report built on previous work that found weaknesses in the CMS process for sharing termination information among the States. OIG found that not all State Medicaid agencies were reporting to the database and that not all submitted records met the definition of a "for cause termination."

CMS concurred with our recommendations from both reports to:

- require each State Medicaid agency to report all providers terminated for cause;
- ensure that the shared information contains only records that meet CMS's criteria for terminated for cause;
- work with States to develop uniform terminology to clearly denote terminations for cause;
- require that State Medicaid programs enroll all providers participating in Medicaid managed care; and
- furnish guidance to State Medicaid agencies that termination is not contingent on the provider's active licensure status.

Affordable Care Act implementation

The Patient Protection and Affordable Care Act (ACA) of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, made changes to HHS programs and enacted a range of new programs that affect the Department. Our work related to the ACA encompasses the health insurance marketplaces, Medicaid expansion, use of State establishment grants, and financial assistance payments.

IT Security

- *Public Summary Report: The Centers for Medicare & Medicaid Services' Implementation of Security Controls Over the Multidimensional Insurance Data Analytics System Needs Improvement (A-06-14-00067 <http://oig.hhs.gov/oas/reports/region6/61400067.asp>) September 2015*

Regarding CMS's Multidimensional Insurance Data Analytics System (MIDAS) and consumer's personally identifiable information (PII) data in the systems and databases we reviewed, CMS had not accomplished the following tasks: disabled unnecessary generic accounts in its test environment, encrypted user sessions, conducted automated vulnerability assessments that simulate known attacks, or used a shared read-only account for access to the database housing the PII. Serving as a central repository for insurance-related data, Multidimensional Insurance Data Analytics System is intended to provide

reporting and performance metrics to HHS for various initiatives mandated by the Affordable Care Act. Our database vulnerability scans identified 22 high, 62 medium, and 51 low vulnerabilities.

Financial Assistance Payments

- *CMS's Internal Controls Did Not Effectively Ensure the Accuracy of Aggregate Financial Assistance Payments Made to Qualified Health Plan Issuers Under the Affordable Care Act (A-02-14-02006 <http://oig.hhs.gov/oas/reports/region2/21402006.pdf>) June 2015*

CMS did not effectively ensure the accuracy of nearly \$2.8 billion in aggregate financial assistance payments made to insurance companies under the Affordable Care Act during the first 4 months that these payments were made. CMS's reliance on issuer attestations did not ensure that advance cost-sharing reduction payment rates identified as outliers were appropriate; CMS did not have systems in place to ensure that financial assistance payments were made on behalf of confirmed enrollees and in the correct amounts and to ensure that State marketplaces could submit enrollee eligibility data for financial assistance payments. Also, CMS did not always follow its guidance for calculating advance cost-sharing reduction payments and does not plan to perform a timely reconciliation of these payments.

Consumer Operated and Oriented Plan

- *Actual Enrollment and Profitability Was Lower Than Projections Made by the Consumer Operated and Oriented Plans and Might Affect Their Ability to Repay Loans Provided Under the Affordable Care Act (A-05-14-00055 <http://oig.hhs.gov/oas/reports/region5/51400055.pdf>) July 2015*

The Consumer Operated and Oriented Plan (CO-OP) program, established by the Affordable Care Act, directs the Secretary of HHS to provide loans to help establish new consumer-governed, nonprofit health insurance issuers, or CO-OPs, in every State. Factors such as low enrollments and net losses could limit the ability of some CO-OPs to repay startup and solvency loans and to remain viable and sustainable. Member enrollment for 13 of the 23 CO-OPs that provided health insurance in 2014 was considerably lower than the CO-OPs initial projections, and as such, 21 of the 23 CO-OPs had incurred net losses as of December 31, 2014. Although CMS recently placed four CO-OPs on enhanced oversight or corrective action plans and two CO-OPs on low-enrollment-warning notifications, CMS had not established guidance or criteria to assess whether a CO-OP was viable or sustainable.

Enrollment

- *Not All of the Federally Facilitated Marketplace's Internal Controls Were Effective in Ensuring That Individuals Were Properly Determined Eligible for Qualified Health Plans and Insurance Affordability Programs (A-09-14-01011 <http://oig.hhs.gov/oas/reports/region9/91401011.pdf>) August 2015*

The Federal marketplace had deficiencies related to verifying applicants' eligibility for qualified health plans and related to resolving and expiring inconsistencies. ("Expiring" an inconsistency means making a determination about an applicant's eligibility generally on the basis of available data sources when a marketplace is unable to resolve the inconsistency.) The Federal marketplace (1) resolved inconsistencies related to annual household income based on applicants' responses to income

discrepancy questions, using a higher threshold than the threshold used to initially verify income and (2) extended inconsistency periods indefinitely for the CY 2014 coverage period based on applicants' good-faith efforts to obtain required documentation.

Contracting

- *CMS Did Not Always Manage and Oversee Contractor Performance for the Federal Marketplace as Required by Federal Requirements and Contract Terms (A-03-14-03001 <http://oig.hhs.gov/oas/reports/region3/31403001.pdf>)* September 2015

In contracts awarded for the development, implementation, and operation of the Federal marketplace, contracting officers and contracting officer's representatives did not always manage and oversee contractor performance as required by Federal requirements and contract terms. Moreover, CMS did not always comply with Federal regulations. For example, contractor delays and performance issues were not always identified; contractor-incurred unauthorized costs that increased the cost of the contract; contracting officers in all Government agencies did not have access to contractor past-performance evaluations when making contract awards; or critical deliverables and management decisions were not properly documented.

Oversight of HHS grants

HHS is the largest grant-making organization in the Federal Government, and its funding of health and human services programs touches the lives of almost all Americans. The size and scope of Departmental awards make the operating effectiveness of these grants crucial to the success of programs designed to improve the health and well-being of the public. Yet, OIG has noted weaknesses in the oversight of grantees year after year.

An example of our work follows:

- *HHS Oversight of Grantees Could Be Improved Through Better Information-Sharing*
(*OEI-07-12-00110* <http://oig.hhs.gov/oei/reports/oei-07-12-00110.pdf>) September 2015

Awarding agencies' grant officials use various sources of information and communication to mitigate grantee risks. However, grant officials noted limitations in some instances. Our findings raise concerns about whether awarding agencies' grant officials have all available information to assess and mitigate risks relating to poor performance and misuse of grant funds. The HHS Assistant Secretary for Financial Resources concurred with all three of our recommendations, which included:

- analyzing whether to implement the use of integrated databases that contain adverse information on grantees' past performance;
- establishing a departmentwide source of adverse information from audits of grantees; and
- facilitating departmentwide information-sharing about grantees that have past performance issues.

OIG participation in congressional hearings

09-11-2015 — “Strengthening Medicaid Program Integrity and Closing Loopholes”



Testimony of John Hagg, Director of Medicaid Audits, Office of Inspector General, U.S. Department of Health and Human Services before the House Committee on Energy and Commerce, Subcommittee on Health

07-28-2015 — "Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax"



Testimony of Gregory Demske, Chief Counsel to the Inspector General, Office of Counsel to the Inspector General, Office of Inspector General, U.S. Department of Health and Human Services before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations

07-14-2015 — “Medicare Part D: Measures Needed to Strengthen Program Integrity”



Testimony of Ann Maxwell, Assistant Inspector General, Office of Evaluation and Inspections, Office of Inspector General, U.S. Department of Health and Human Services before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations

Contents

Highlights	i
Centers for Medicare & Medicaid Services	1
CMS oversight of Medicare contractor performance	1
Contractor overpayments and errors	1
Medicare cost reports reconciliation	3
Contractor administrative and pension costs	4
Ensuring Medicare Integrity	4
Medicare payments, policies, and quality	5
Medicare questionable claims and payments	5
Medicare payments, policies, and practices	7
Medicare quality of care and beneficiary access	8
Medicaid payments, policies, and quality	10
Improper and unallowable State claims for Federal reimbursement	10
Medicaid payments, policies, and practices	15
Medicaid quality of care and beneficiary access	17
Medicaid managed care – Encounter data	18
Legal and investigative activities related to Medicare and Medicaid	19
Patient harm	20
Quality of care	21
Prescription drugs	21
Identity theft	22
Home health	23
Physicians	23
Personal care services	24
Electronic health records	24
Kickbacks	25
Pharmacies	25
Laboratories	25
Pharmaceutical companies	26
Hospitals	26
Psychiatric and psychological services	26
Community mental health center	27
Durable medical equipment	27
International health care fraud scheme	28
Health care fraud prevention and enforcement	28
HEAT provider compliance training	28

Medicare Fraud Strike Force	28
Other criminal and civil enforcement activities	30
Special Assistant U.S. Attorney Program	30
Corporate Integrity Agreements	30
OIG’s Most Wanted Fugitives	30
OIG Hotline Operations	31
State Medicaid Fraud Control Units	32
OIG oversight of State Medicaid Fraud Control Units	32
OIG onsite reviews of MFCUs	32
Advisory opinions and other industry guidance	33
Sanction authorities and other administrative actions	33
Program exclusions	34
Suspensions and debarments	35
Civil Monetary Penalties Law	36
Patient Dumping	36
Provider self-disclosure protocol	37
Public health agencies and enforcement activities	39
Public health agencies	39
Food and Drug Administration	39
Health Resources and Services Administration	39
Indian Health Service	40
National Institutes of Health	40
Substance Abuse and Mental Health Services Administration	40
Information Technology Infrastructure and Operations Office	41
Public health-related legal actions and investigations	41
Health Education Assistance Loan Program	41
HEAL Exclusions	42
Human services agencies and enforcement activities	43
Administration for Children and Families	43
Family child day care centers and State health and safety requirements	43
Child support enforcement activities	45
OIG investigations	45
Engaging the public in capturing deadbeat parents	45
IT infrastructure reviews	46
Other HHS-related reviews	47
Grants and Contracts	47
Improper payments and misuse of grant funds	47
Misuse of grant funds case examples	49
Small Business Innovative Research Program	49

Recovery Act retaliation complaint investigations.....	50
Hurricane Sandy.....	50
Office for Civil Rights.....	50
Contract audits.....	51
OIG reviews of non-Federal audits.....	52
Other reporting requirements and reviews.....	54
Government Charge Card Abuse Prevention Act.....	54
Legislative and regulatory reviews.....	54
Affordable Care Act implementation.....	55
Marketplaces.....	55
Medicaid payment suspension.....	58
Information technology.....	58
Establishment grants.....	59
Community Health Center Fund.....	60
Eligibility.....	60
Consumer Operated and Oriented Plan.....	61
Appendixes.....	63
Appendix A: Savings decisions supported by OIG recommendations.....	64
Appendix B: Monetary recommendations.....	69
Appendix C: Peer review results.....	75
Appendix D: Summary of Sanction authorities.....	77
Appendix E: Reporting requirements in the Inspector General Act of 1978.....	80
Appendix F: Anti-kickback statute—Safe harbors.....	82

Selected Acronyms

ACA	Patient Protection and Affordable Care Act of 2010, P.L. No. 111-148 (as amended by the Health Care Education and Reconciliation Act of 2010)
ACF	Administration for Children and Families
CBO	Congressional Budget Office
CIA	corporate integrity agreement
CMP	civil monetary penalty
CMPL	Civil Monetary Penalties Law
CMS	Centers for Medicare & Medicaid Services
CO-OP	Consumer Operated and Oriented Plan
CY	calendar year
DME	durable medical equipment
DOJ	Department of Justice
EHR	electronic health record
EMTALA	Emergency Medical Treatment and Labor Act, § 9121 of the Consolidated Omnibus Reconciliation Act of 1985, P.L. No. 99-272
FBI	Federal Bureau of Investigation
FCA	False Claims Act (31 U.S.C. §§ 3729–3733)
FDA	Food and Drug Administration
FISMA	Federal Information Security Modernization Act
FY	fiscal year
HEAT	Health Care Fraud Prevention and Enforcement Action Team
HEAL	Health Education Assistance Loan
HHA	home health agency
HIPAA	Health Insurance Portability and Accountability Act of 1996, P.L. No. 104-191 HHS Department of Health and Human Services
HRSA	Health Resources and Services Administration
ITIO	Information Technology Infrastructure and Operations Office
marketplaces	health insurance exchanges
MA	Medicare Advantage
MAC	Medicare Administrative Contractor
MFCU	Medicaid Fraud Control Unit
NDC	National Drug Code
NIH	National Institutes of Health
OIG	Office of Inspector General
OMB	Office of Management and Budget
PHP	partial hospitalization program
SNF	skilled nursing facility
TANF	Temporary Assistance for Needy Families

Centers for Medicare & Medicaid Services

CMS oversight of Medicare contractor performance

The Centers for Medicare & Medicaid Services (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 a half-trillion dollars in benefits each year. Medicare Administrative Contractors (MACs) process Parts A and B claims; Medicare Advantage (MA) 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.

Contractor overpayments and errors

- *Incorrect Place-of-Service Claims Resulted in Potential Medicare Overpayments Costing Millions* (A-01-13-00506 <http://oig.hhs.gov/oas/reports/region1/11300506.pdf>) May 2015

Physicians did not always correctly code nonfacility places of service on Part B claims submitted to, and paid by, Medicare contractors nationwide. Medicare contractors potentially overpaid physicians about \$33.4 million for incorrectly coded services provided from January 2010 through September 2012. Physicians performed these services in facility locations but incorrectly coded the services as having been performed in nonfacility locations.

CMS concurred with all of our recommendations, which were to:

- direct its Medicare contractors to recover or monitor the recovering of \$33.4 million in potential overpayments;
- continue to educate physicians and billing personnel on the importance of internal controls to ensure the correct place-of-service coding; and
- expand and strengthen efforts to perform coordinated data matches of nonfacility-coded physician services and facility claims and to identify physician services that are at a high risk for place-of-service miscoding and recover overpayments.

- *First Coast Service Options, Inc., Paid Some Unallowable Sleep Study Claims* (A-04-13-07039 <http://oig.hhs.gov/oas/reports/region4/41307039.pdf>) May 2015

First Coast Service Options, Inc., the MAC for Jurisdiction 9 (Florida, Puerto Rico, and the U.S. Virgin Islands) made some payments to providers for sleep study services that were not in accordance with Medicare reimbursement requirements. Of the 100 sampled beneficiaries, First Coast made payments that did not meet Medicare requirements for 61 beneficiaries, resulting in overpayments totaling \$68,000. We estimated that First Coast overpaid providers about \$15.7 million for sleep study services during our audit period. These errors occurred because First Coast did not have adequate claim-processing edits to prevent the incorrect payment of Medicare claims or because providers did not understand the Medicare requirements.

First Coast concurred with all of our recommendations, which were to:

- recover \$68,000 in identified overpayments;
- develop and implement claim-processing edits that would prevent payment of incorrectly billed polysomnography services; and
- use the results of this audit in its provider education activities.

- *Medicare Part B Overpaid Millions for Selected Outpatient Drugs (A-09-14-02024*
<http://oig.hhs.gov/oas/reports/region9/91402024.pdf>) July 2015

Medicare contractors in 13 jurisdictions overpaid providers \$35.8 million for selected outpatient drugs during our audit period (July 1, 2009, through June 30, 2012). For 88 percent of the overpayments, providers billed either incorrect units of service—or a combination of incorrect units of service and incorrect Healthcare Common Procedure Coding System codes. The Medicare claims processing systems did not have sufficient prepayment edits in place to prevent all overpayments. The 13 Medicare contractors concurred with our recommendations in the individual reports to recover the identified overpayments and to use the results of our audits in ongoing provider education. CMS informed us that, as of May 4, 2015, Medicare contractors had recovered 63 percent of the \$35.8 million in overpayments, and 10 of the 13 Medicare contractors had used the results of our audits in ongoing provider education activities.

CMS concurred with our recommendations, which were to:

- ensure that Medicare contractors collect the remaining overpayments identified in our individual reviews;
- continue to educate providers on correct billing of outpatient drugs;
- instruct Medicare contractors to review payments to providers for outpatient drugs billed after our audit period, which could represent overpayments of \$11.5 million; and
- continue to implement prepayment edits for additional outpatient drugs.

- *CGS Administrators, LLC, Made Medicare Payments for Diabetic Test Strips When Beneficiaries Had Not Nearly Exhausted Previously Dispensed Supplies (A-09-14-02015*
<http://oig.hhs.gov/oas/reports/region9/91402015.pdf>) July 2015

CGS Administrators, LLC, made payments in 2012 to suppliers that dispensed diabetic test strips when the beneficiaries had not nearly exhausted test strips previously dispensed by different suppliers. We estimated that \$7.6 million, or 74 percent, of the \$10.3 million that CGS paid to suppliers may have been unallowable for Medicare reimbursement.

CGS did not concur with our recommendation, which were to:

- identify for review those claims submitted by multiple suppliers with overlapping service dates for test strips dispensed to the same beneficiary. Implementing this edit could have saved Medicare an estimated \$7.6 million for CY 2012.

Medicare cost reports reconciliation

- *Cahaba Government Benefit Administrators, LLC, Did Not Always Refer Medicare Cost Reports and Reconcile Outlier Payments (A-05-11-00019 <http://oig.hhs.gov/oas/reports/region5/51100019.pdf>) March 2015*
- *Novitas Solutions, Inc. (Formerly Highmark Medicare Services, Inc.), Did Not Always Refer Medicare Cost Reports and Reconcile Outlier Payments (A-05-11-00023 <http://oig.hhs.gov/oas/reports/region5/51100023.pdf>) March 2015*
- *First Coast Service Options, Inc., Did Not Always Refer Medicare Cost Reports and Reconcile Outlier Payments (A-05-11-00022 <http://oig.hhs.gov/oas/reports/region5/51100022.pdf>) March 2015*
- *Palmetto Government Benefits Administrator Did Not Always Refer Medicare Cost Reports and Reconcile Outlier Payments in Jurisdiction 11 (A-07-10-02775 <http://oig.hhs.gov/oas/reports/region7/71002775.pdf>) April 2015*
- *National Heritage Insurance Corporation Did Not Always Refer Medicare Cost Reports and Reconcile Outlier Payments (A-05-11-00024 <http://oig.hhs.gov/oas/reports/region5/51100024.pdf>) April 2015*
- *CGS Administrators, LLC, Did Not Always Refer Medicare Cost Reports and Reconcile Outlier Payments (A-07-13-02791 <http://oig.hhs.gov/oas/reports/region7/71302791.pdf>) May 2015*

Medicare contractors Cahaba Government Benefit Administrators, Novitas Solutions, First Coast Service Options, Palmetto Government Benefits, National Heritage Insurance Corporation, and CGS Administrators did not always refer Medicare cost reports whose outlier payments qualified for reconciliation to CMS. In addition, the six contractors did not always reconcile the outlier payments associated with cost reports whose outlier payments qualified for reconciliation. The financial impact to Medicare of the unreconciled outlier payments and cost reports was about \$10.2 million (Cahaba), \$3.6 million (Novitas Solutions), \$6.3 million (First Coast), \$48.2 million (Palmetto), \$25.6 million (National Heritage Insurance), and \$18.7 million (CGS). Medicare supplements basic prospective payments for inpatient hospital services by making outlier payments for unusually high-cost cases. Medicare contractors refer hospital cost reports to CMS for reconciliation of outlier payments.

Cahaba and Novitas generally concurred, and First Coast and National Government Services, Inc. (NGS) (the Medicare contractor that assumed National Heritage's responsibilities) partially concurred with our recommendations to:

- review the cost reports that qualified for referral, and if applicable, determine whether the cost reports may be reopened, reconcile the associated outlier payments, and refund the amounts due to Medicare and due to providers;
- reconcile the outlier payments associated with the cost reports that were referred and, if applicable;
- determine whether these cost reports may be reopened, work with CMS to reconcile the associated outlier payments, finalize these cost reports, and ensure the return of funds to Medicare and to the providers;
- work with CMS to resolve the outlier payments—that is, \$114,000 (Cahaba), \$747,000 (First Coast), \$1.1 million (Palmetto), and \$236,099 (NGS)—that we could not recalculate;

- ensure that control procedures are in place so that all cost reports with qualifying outlier payments are referred and reconciled; and
- review all cost reports submitted since the end of our audit period, and ensure that those whose outlier payments qualified for reconciliation are referred and reconciled in accordance with Federal guidelines.

Palmetto disagreed with our recommendations. However, CGS did not concur with our recommendations to reconcile outlier payments.

Contractor administrative and pension costs

- *National Government Services Claimed Allowable Administrative Costs for Fiscal Year 2010 and the First Quarter of Fiscal Year 2011 Under Medicare Contract 00130 (A-05-14-00024 <http://oig.hhs.gov/oas/reports/region5/51400024.pdf>) August 2015*

National Government Services of Indianapolis, Indiana, claimed allowable administrative costs of \$51.4 million for FY 2010 and the first quarter of FY 2011 under Medicare Part A contract 00130. Accordingly, this report contained no recommendations.

- *National Government Services, Inc., Understated Its Allocable Pension Costs for Calendar Years 2006 Through 2009 (A-07-14-00453 <http://oig.hhs.gov/oas/reports/region7/71400453.pdf>) May 2015*

National Government Services, Inc., a Medicare contractor, understated its allocable pension costs for the “Medicare” and the “Other” segments by \$1.6 million and \$5.0 million, respectively, for CYs 2006 through 2009.

NGS concurred with our recommendations to:

- increase the “Medicare segment” pension costs used to calculate its indirect cost rates by \$1.6 million for CYs 2006 through 2009 and
- increase the “Other segment” pension costs used to calculate its indirect cost rates by \$5.0 million for CY 2006.

Ensuring Medicare Integrity

- *Ensuring the Integrity of Medicare Part D (OEI-03-15-00180 <http://oig.hhs.gov/oei/reports/oei-03-15-00180.pdf>) June 2015*

This portfolio presents an overview of Office of Inspector General (OIG) investigations, audits, evaluations, and legal guidance related to Part D. It synthesizes numerous OIG reports that have identified weaknesses in Part D program integrity, and provides updates on Departmental efforts to address these weaknesses. In particular, OIG has identified weaknesses in the use of data to identify vulnerabilities, as well as in the oversight by all parties responsible for protecting Part D: Part D plan sponsors, the Medicare Drug Integrity Contractor, and CMS. OIG has made recommendations to strengthen Part D program integrity, and progress has been made. However, Part D remains vulnerable

to fraud, as evidenced by ongoing OIG investigations. To fully protect Part D from fraud, waste, and abuse, CMS should take further action and implement OIG's previous recommendations including:

- require plan sponsors to report all potential fraud and abuse to CMS, the Medicare Administrative Contractor, or both;
- expand drug utilization review programs to include additional drugs susceptible to fraud, waste, and abuse;
- implement an edit to reject prescriptions written by excluded providers;
- seek authority to restrict certain beneficiaries to a limited number of pharmacies or prescribers;
- develop and implement a mechanism to recover payments from plan sponsors when law enforcement agencies do not accept case referrals; and
- determine the effectiveness of plan sponsors' fraud and abuse detection programs.

- *Performance Data for the Senior Medicare Patrol Projects: July 2015 Performance Report (OEI-02-15-00100 <http://oig.hhs.gov/oei/reports/oei-02-15-00100.pdf>) July 2015*

The Senior Medicare Patrol projects receive grants from the Administration for Community Living to recruit and train retired professionals and other senior citizens to recognize and report instances or patterns of health care fraud. In 2014, the 53 projects had 5,294 active volunteers, a slight decrease from 2013. The volunteers conducted slightly fewer group education sessions (14,692), but conducted significantly more one-on-one counseling sessions (202,862). Results attributable to their efforts included \$661,333 in expected Medicare and Medicaid recoveries and total savings to beneficiaries and others of about \$80,000.

Medicare payments, policies, and quality

Medicare questionable claims and payments

- *CMS Should Use Targeted Tactics to Curb Questionable and Inappropriate Payments for Chiropractic Services (OEI-01-14-00200 <http://oig.hhs.gov/oei/reports/oei-01-14-00200.pdf>) September 2015*

In 2013, \$76 million in Medicare payments for chiropractic services were questionable, half of which were paid to just 2 percent of chiropractors. Medicare inappropriately paid \$20 million for chiropractic services that lacked a primary diagnosis covered by Medicare. These findings raise concerns about CMS's ability to curb improper payments for chiropractic services. CMS concurred with our recommendations to:

- develop and use measures to identify questionable payments for chiropractic services;
- take appropriate action on the chiropractors with questionable payments;
- collect overpayments based on inappropriately paid claims; and
- ensure that claims are paid only for Medicare-covered diagnoses.

CMS did not concur with our recommendation to establish a more reliable control for identifying active treatment, citing significant obstacles and stating that new medical review requirements would address our concerns; we disagree because the requirements target a narrow group of chiropractors who are not necessarily receiving payments for maintenance therapy.

■ *Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D (OEI-02-15-00190 <http://oig.hhs.gov/oei/reports/oei-02-15-00190.pdf>) June 2015*

Spending for Part D drugs, especially commonly abused opioids, has grown substantially. We identified questionable billing by 1,400 pharmacies that may indicate fraudulent activity. Each of these pharmacies billed for extremely high amounts for one or more of our billing measures. We also identified geographic hotspots for certain drugs that point to possible fraud and abuse. These findings and previous OIG work demonstrate that more needs to be done to address fraud and abuse in Part D. This goal requires CMS to fully implement OIG's previous recommendations, which are summarized in an OIG portfolio—*Ensuring the Integrity of Medicare Part D* (OEI-03-15-00180).

■ *Questionable Billing for Medicare Ophthalmology Services (OEI-04-12-00280 <http://oig.hhs.gov/oei/reports/oei-04-12-00280.pdf>) September 2015*

While most providers did not demonstrate questionable billing on any of our measures in 2012, 4 percent of providers billing Medicare for ophthalmology services demonstrated at least one of our nine measures of questionable billing. Overall, Medicare paid these 1,726 providers \$768 million for ophthalmology services in 2012, of which \$171 million was for services associated with the measures on which these providers demonstrated questionable billing. The findings in this report raise concerns that certain providers may be billing for services that are not medically necessary or were never provided. CMS concurred with our recommendations to:

- increase monitoring of billing for ophthalmology services and
- review providers with questionable billing for ophthalmology services identified by this evaluation and take appropriate action.

■ *Inappropriate Payments and Questionable Billing for Medicare Part B Ambulance Transports (EI-09-12-00351 <http://oig.hhs.gov/oei/reports/oei-09-12-00351.asp>) September 2015*

We found that Medicare paid \$24 million in the first half of 2012 for ambulance transports that did not meet certain program requirements justifying payments, and that about one in five ambulance suppliers had questionable billing. Our findings indicate that inappropriate, questionable billing for ambulance transports poses vulnerabilities to Medicare program integrity. Our report made five recommendations. CMS concurred or partially concurred with our recommendations to:

- determine whether a temporary moratorium on ambulance supplier enrollment in additional geographic areas is warranted;
- require ambulance suppliers to include the National Provider Identifier (NPI) of the certifying physician on transport claims that require certification;
- implement new claims processing edits or improve existing edits to prevent inappropriate payments for ambulance transports;
- increase its monitoring of ambulance billing; and

- determine the appropriateness of claims billed by ambulance suppliers identified in the report and take appropriate action.

Medicare payments, policies, and practices

- *The Medicare Payment System for Skilled Nursing Facilities Needs to Be Reevaluated* (OEI-02-13-00610 <http://oig.hhs.gov/oei/reports/oei-02-13-00610.pdf>) September 2015

The findings of this and prior OIG reports demonstrate the need for CMS to reevaluate the skilled nursing facility (SNF) payment system. Medicare payments for therapy greatly exceeded SNFs' costs for therapy. Combined with the current method of paying for therapy, this large difference between therapy payments and costs creates a strong financial incentive for SNFs to bill for higher levels of therapy than necessary. Under this system, SNFs increasingly billed for the highest level of therapy even though key beneficiary characteristics remained largely the same. Increases in SNF billing—particularly for the highest level of therapy—resulted in \$1.1 billion in Medicare payments in FYs 2012 and 2013. Payment reform could save Medicare billions of dollars and encourage SNFs to provide services that are better aligned with beneficiaries' care needs. CMS concurred with our recommendations to:

- evaluate the extent to which Medicare payment rates for therapy should be reduced;
- change the method for paying for therapy;
- adjust Medicare payments to eliminate any increases that are unrelated to beneficiary characteristics; and
- strengthen oversight of SNF billing.

- *Skilled Nursing Facility Billing for Changes in Therapy: Improvements Are Needed* (OEI-02-13-00611 <http://oig.hhs.gov/oei/reports/oei-02-13-00611.pdf>) June 2015

OIG has recommended that CMS reevaluate and change the way it pays SNFs for therapy services. This review identified concerns about SNF billing for changes in therapy that should be addressed if CMS continues its current payment system. In FYs 2011 and 2012, CMS introduced three types of SNF therapy assessments to more quickly capture when beneficiaries start therapy, end therapy, and decrease or increase therapy. However, SNF billing for changes in therapy increased only slightly. In addition, SNFs used assessments very differently when decreasing therapy than when increasing it, costing Medicare \$143 million over 2 years. Further, SNFs frequently used the new start-of-therapy assessment incorrectly. For example, SNFs often used a start-of-therapy assessment but billed for no therapy during the stay. CMS's new policies are complex and create challenges for effective oversight. CMS concurred with our recommendations to:

- reduce the financial incentive for SNFs to use assessments differently when decreasing and increasing therapy and
- strengthen the oversight of SNF billing for changes in therapy.

- *Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data* (OEI-09-15-00210 <http://oig.hhs.gov/oei/reports/oei-09-15-00210.pdf>) September 2015

Medicare Part B paid \$7.0 billion for clinical laboratory (lab) tests in 2014. The top 25 lab tests, based on Medicare payments, accounted for \$4.2 billion of the total payments for lab tests. The Protecting Access

to Medicare Act of 2014 requires reform of the payment system for lab tests—the first such reform in 3 decades. To provide oversight, Congress mandated that OIG monitor Medicare payments for lab tests and the new payment system. As part of the mandate, OIG is required to publicly release an annual analysis of the top 25 lab tests based on Medicare payments. This data brief provides baseline data on the top 25 lab tests for 2014, 3 years before the new payment system goes into effect in 2017. Our data brief contains no recommendations.

- *Implementing OIG Recommendation Could Have Reduced Payments for DME Infusion Drugs by Hundreds of Millions of Dollars (OEI-12-15-00110 <http://oig.hhs.gov/oei/reports/oei-12-15-00110.pdf>) April 2015*

We found that Medicare expenditures for infusion drugs administered in conjunction with durable medical equipment could have been reduced by \$251 million in an 18-month period if the average sales price-based payment methodology previously recommended by OIG had been implemented in April 2013. Our findings illustrate that Medicare’s payment methodology for durable medical equipment (DME) infusion drugs, which relies on average wholesale prices (AWPs), which were “list prices” published in 2003, has resulted in payments that bear little or no resemblance to provider acquisition costs. Specifically, at least 42 percent of DME infusion drugs had Medicare payment amounts that were more than twice their estimated acquisition costs. In contrast, approximately one-quarter of these drugs had payment amounts that were below costs. This report contains no recommendations.

- *Overlap Between Physician-Owned Hospitals and Physician-Owned Distributors (OEI-01-14-00270 <http://oig.hhs.gov/oei/reports/oei-01-14-00270.pdf>) August 2015*

In response to a request from CMS to conduct additional analysis based on our 2013 report *Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use (OEI-01-11-00660 <http://oig.hhs.gov/oei/reports/oei-01-11-00660.asp>)*, we identified one physician with an ownership interest both in 1 of the 12 physician-owned hospitals we examined and in a physician-owned distributorship that sold spinal devices to that hospital. However, we cannot determine whether this was the only physician with such ownership interests because data to identify such interests is not readily available. This work demonstrated the limited transparency of ownership information for spinal device suppliers and, to a lesser extent, hospitals. This analysis did not include any recommendations.

Medicare quality of care and beneficiary access

- *Home Health Agencies Conducted Background Checks of Varying Types (OEI-07-14-00130 <http://oig.hhs.gov/oei/reports/oei-07-14-00130.pdf>) May 2015*

All home health agencies (HHAs) conducted background checks on prospective employees; however, our review of six employees with convictions for crimes against persons found that three have convictions that appear—based on available data—to disqualify them from employment in HHAs. Our findings raise concerns about whether HHA employees undergo a minimum level of background screening. CMS concurred with our recommendation:

- to promote minimum standards in background check procedures.

- *Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles (OEI-05-15-00120 <http://oig.hhs.gov/oei/reports/oei-05-15-00120.pdf>) June 2015*

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

- *CMS's Reliance on Puerto Rico's Certification Surveys Could Not Ensure the Quality of Care Provided to Medicare Hospice Beneficiaries by Servicios Suplementarios de Salud, Inc. (A-02-11-01028 <http://oig.hhs.gov/oas/reports/region2/21101028.pdf>) June 2015*

CMS's reliance on Puerto Rico's certification surveys could not ensure the quality of hospice care that Servicios Suplementarios de Salud, Inc., provided to Medicare beneficiaries. Servicios did not always meet certain Federal and Commonwealth requirements for professional licensing and certification, criminal background checks, health certificates, and training. Of 170 workers, 130 workers' personnel records did not contain documentation to support compliance with one or more of the requirements. Servicios also did not have any personnel records for five workers who provided direct care to Medicare beneficiaries. Puerto Rico's most recent certification survey did not find any of the types of deficiencies we identified. So CMS's reliance on State and Commonwealth surveys could not ensure quality of care or adequate protection of Medicare beneficiaries.

Although Puerto Rico did not address our findings, CMS concurred with our recommendation, which was:

- to work with Puerto Rico to ensure that Servicios meets all Federal and Commonwealth requirements for professional licensing and certification, criminal background checks, health certificates, and training.

- *CMS's Reliance on Accreditation Surveys Could Not Ensure the Quality of Care Provided to Medicare Hospice Beneficiaries by The Community Hospice, Inc. (A-02-11-01027 <http://oig.hhs.gov/oas/reports/region2/21101027.pdf>) June 2015*

CMS's reliance on accreditation surveys could not ensure the quality of hospice care that The Community Hospice, Inc., provided to Medicare beneficiaries. Community did not meet certain Federal and State requirements for criminal background checks, health assessments, professional licensing and experience, training, and performance evaluations. Of the 100 workers in our random sample, Community could not document that 51 complied with 1 or more of these requirements. We estimated that 194 workers were not in compliance with Federal and State requirements.

The April 2009 Community Health Accreditation Partner (CHAP) accreditation survey did not find any of the deficiencies we identified, so CMS's reliance on CHAP surveys could not ensure quality of care or adequate protection of Medicare beneficiaries.

CMS concurred with our recommendation, which was to:

- work with CHAP and New York to ensure that Community meets all Federal and State requirements for criminal background checks, health assessments, professional licensing and experience, training, and performance evaluations.

New York stated that it has no oversight authority over CHAP and that it does not survey Community.

- *CMS's Reliance on Puerto Rico's Certification Surveys Could Not Ensure the Safety of Medicare Beneficiaries Who Received Home Health Care Services Provided by St. Luke's Home Health Agency—Juana Diaz (A-02-11-01030 <http://oig.hhs.gov/oas/reports/region2/21101030.pdf>) September 2015*

CMS's reliance on Puerto Rico's certification surveys of St. Luke's Home Health Agency-Juana Diaz could not fully ensure the safety of Medicare beneficiaries. None of the 43 Juana Diaz employees had a certification from Puerto Rico indicating that he or she was not a registered sex offender.

Puerto Rico conducted a validation survey of Juana Diaz on July 21, 2010. However, surveyors did not determine whether Diaz had verified the sex offender status of its employees.

Puerto Rico acknowledged that this discrepancy occurred because the health department did not have procedures for periodically reviewing the enacted Commonwealth laws. Therefore, an administrative order was not created in a timely manner to require the survey unit to incorporate compliance with sex offender registration requirements in the certification surveys.

CMS concurred with our recommendation, which was to:

- work with Community Health Accreditation Partner and Puerto Rico to ensure that Juana Diaz and other HHAs meet Commonwealth requirements for ensuring that their employees are not registered sex offenders.

Medicaid payments, policies, and quality

Improper and unallowable State claims for Federal reimbursement

- *Washington State Did Not Always Verify Correction of Deficiencies Identified During Surveys of Nursing Homes Participating in Medicare and Medicaid (A-09-13-02039) July 2015*

The Washington State Department of Social and Health Services, Aging and Long-Term Support Administration, Residential Care Services Division (State agency), did not always verify nursing homes' correction of deficiencies identified during surveys in 2012 in accordance with Federal requirements. For the 100 sampled deficiencies, the State agency verified the nursing homes' correction of 30 deficiencies but did not have documentation supporting that it had verified the nursing homes' correction of the remaining 70 deficiencies. We estimated that the State agency did not verify nursing homes' correction of deficiencies in accordance with Federal requirements for 1,164 (84 percent) of the 1,390 deficiencies identified during surveys in 2012.

Washington concurred with our recommendations that it:

- provide guidance and training to its surveyors and establish standardized practices for them to follow;

- improve internal controls over retaining documentation to support that it has verified the correction of deficiencies; and
- follow all Federal requirements to appropriately verify and document nursing homes' correction of deficiencies before certifying their substantial compliance with Federal participation requirements.

■ *Missouri Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs (A-07-14-06051 <http://oig.hhs.gov/oas/reports/region7/71406051.pdf>) April 2015*

Missouri did not always comply with Federal Medicaid requirements for billing drug manufacturers for rebates for physician-administered drugs. To collect these rebates, States submit to the manufacturers the National Drug Codes (NDCs) for all single-source and the top 20 multiple-source physician-administered drugs. Federal reimbursement for covered outpatient drugs administered by a physician is not available to States that do not comply with Federal requirements for capturing data to bill and collect rebates.

Missouri did not collect the NDCs (from claims submitted by providers) that were required for it to invoice manufacturers for rebates associated with about \$34.8 million in physician-administered drugs. In addition, Missouri did not capture the utilization and coding data necessary to collect rebates for all physician-administered drugs. Without the NDCs, we were unable to determine whether Missouri improperly claimed Federal reimbursement for an additional \$13.2 million for other physician-administered drug claims.

Missouri did not concur with our recommendations, which were to:

- refund \$34.8 million for drug claims that were ineligible for Federal reimbursement;
- work with CMS to determine the portion of the \$13.2 million for other outpatient physician-administered drug claims that were ineligible for Federal reimbursement and refund that amount;
- work with CMS to determine and refund the unallowable Federal reimbursement for physician-administered drugs claimed without NDCs and not billed for rebates after December 31, 2011; and
- update its system edits to require NDCs for payment on all drug claims to ensure that all drugs eligible for drug rebates are invoiced. DSS did not concur with any of our recommendations.

■ *Iowa Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs (A-07-14-06049 <http://oig.hhs.gov/oas/reports/region7/71406049.pdf>) July 2015*

Iowa did not always comply with Federal Medicaid requirements for invoicing drug manufacturers for rebates for physician-administered drugs. To collect these rebates, States submit to the manufacturers the NDCs for all single-source and the top 20 multiple-source physician-administered drugs. Federal reimbursement for covered outpatient drugs administered by a physician is not available to States that do not comply with Federal requirements for capturing data to invoice and collect rebates.

Iowa did not submit utilization data to manufacturers for rebates associated with \$174,000 in physician-administered drugs. We were unable to determine whether Iowa improperly claimed Federal reimbursement for an additional \$111,000 for other physician-administered drug claims that were not for single-source drugs or top-20 multiple-source drugs.

Iowa concurred with our recommendations to:

- refund \$174,000 for claims for physician-administered drugs that were ineligible for Federal reimbursement;

- work with CMS to determine the unallowable portion of the \$111,000 for other claims for outpatient physician-administered drugs that were ineligible for Federal reimbursement and refund that amount;
 - work with CMS to determine and refund the unallowable Federal reimbursement for physician-administered drugs that were not invoiced for rebates after December 31, 2012; and
 - strengthen the State's internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.
- *New Jersey Claimed Medicaid Hospice Services That Were Not in Compliance With Federal and State Requirements (A-02-11-01014 <http://oig.hhs.gov/oas/reports/region2/21101014.pdf>) April 2015*

New Jersey claimed Federal Medicaid reimbursement for some hospice services that did not comply with Federal and State requirements. Of the 150 beneficiary-months in our random sample, 108 complied with Federal and State requirements, but 42 did not. We estimated that New Jersey improperly claimed at least \$8.4 million in Federal Medicaid reimbursement for hospice services that did not meet Federal and State requirements.

The deficiencies occurred because New Jersey did not monitor hospices for compliance with certain Federal and State requirements until after our audit period, when the State implemented a postpayment review process for hospice services.

New Jersey did not comment on our recommendations that it:

- refund \$8.4 million and
 - continue to monitor hospices to ensure that they comply with Federal and State requirements.
- *Texas Paid Millions for Unallowable Medicaid Orthodontic Services (A-06-11-00048 <http://oig.hhs.gov/oas/reports/region6/61100048.pdf>) June 2015*

Texas did not ensure that requests for prior authorization of Medicaid orthodontic services were approved in accordance with State Medicaid guidelines. We estimated that Texas paid at least \$133.4 million (Federal share) for unallowable orthodontic services. Of 106 sampled orthodontic prior-authorization requests, 17 were approved in accordance with State Medicaid guidelines and 89 were not. Of the 89 improperly approved prior authorizations, 78 did not qualify for orthodontic services and 11 did not have sufficient documentation to determine whether they qualified.

Texas provided information on actions that it had taken or planned to take to address our recommendations, which were to:

- refund \$133.4 million;
 - determine and refund the Federal share of any additional amounts related to orthodontic prior authorizations that Texas improperly claimed after our audit period; and
 - monitor the orthodontic program to ensure that it is in compliance with State Medicaid guidelines.
- *Connecticut Claimed Unallowable Medicaid Payments for Targeted Case Management Services Provided to Individuals With Chronic Mental Illness (A-01-14-00001 <http://oig.hhs.gov/oas/reports/region6/61100048.pdf>) August 2015*

Connecticut did not always claim Federal Medicaid reimbursement for targeted case management (TCM) services in accordance with Federal and State requirements. The monthly payment rates that Connecticut calculated included costs that (1) had already been accounted for in a different service cost base and, therefore, should not have been included in the payment rate calculation or (2) were overstated. Connecticut also included potentially unallowable costs in its payment rate calculations, which may have overstated its claims for Federal Medicaid reimbursement.

Connecticut concurred with our recommendations that it:

- refund \$958,000 to the Federal Government,
- adjust future payment rates for targeted case management services and work with CMS to determine the unallowable Medicaid payments that should be refunded,
- establish controls to ensure that the payment rate methodology used to claim Medicaid reimbursement for targeted case management services is in accordance with Federal and State requirements, and
- improve controls used to detect and prevent duplicate payments.

Connecticut did not concur with our recommendations that it:

- provide additional documentation to CMS that shows how much of the \$43 million in potentially unallowable costs is allowable or refund \$23 million.

- *Missouri Claimed Unallowable and Unsupported Medicaid Payments for Group Home Habilitation Services (A-07-14-03201 <http://oig.hhs.gov/oas/reports/region6/61100048.pdf>) August 2015*

Missouri's Medicaid payment rates for group home habilitation services provided and paid for during State FYs 2011 through 2013 were not always in accordance with Federal requirements. Specifically, Missouri included room-and-board costs in some of its payment rates for group home habilitation services. Because this practice is prohibited under Federal requirements, the associated payments were unallowable. In addition, the State agency could not provide supporting documentation for some of its payment rates, and as a result we could not determine whether those payment rates included room-and-board costs.

Missouri agreed with our recommendations that it:

- follow Federal requirements by ensuring that room-and-board costs are excluded when determining the payment rates for group home habilitation services and
- follow Federal requirements by maintaining supporting documentation to show how payment rates for group home habilitation services are calculated.

Missouri disagreed with our recommendations that it:

- refund \$3 million to the Federal Government;
- obtain supporting documentation from the group home providers for the unsupported Medicaid payments of \$39.1 million; and
- recalculate any payment rates that include room-and-board costs, apply any recalculated payment rates to actual claims, and refund any additional unallowable amount.

- *Some of New Jersey's Claims for Personal Care Services Did Not Comply With Federal and State Requirements (A-02-13-01022 <http://oig.hhs.gov/oas/reports/region6/61100048.pdf>) August 2015*

New Jersey claimed at least \$32.2 million in unallowable Medicaid reimbursement for personal care services during the period August 1, 2008, through December 31, 2011, that did not meet Federal and State requirements. Of the 100 claims in our random sample, 83 claims complied with Federal and State requirements, but 17 claims did not.

New Jersey partially concurred with our recommendation that it:

- refund \$32.2 million to the Federal Government.

New Jersey described actions it had taken to address our recommendation that it:

- issue guidance to the provider community regarding Federal and State requirements for claiming Medicaid reimbursement for personal care services.

- *North Carolina Received Millions in Unallowable Bonus Payments (A-04-14-08035 <http://oig.hhs.gov/oas/reports/region4/41408035.pdf>) July 2015*

Congress appropriated \$3.225 billion for qualifying States to receive performance bonus payments for FYs 2009 through 2013 to offset the costs of increased enrollment of children in Medicaid.

Most of the bonus payments that North Carolina received for the audit period were not allowable in accordance with Federal requirements. Most of the data used in North Carolina's bonus payment calculations were in accordance with Federal requirements. However, North Carolina overstated its FYs 2011 through 2013 current enrollment in its bonus requests to CMS because it included individuals who did not qualify. As a result, CMS overpaid North Carolina \$34.8 million in bonus payments.

North Carolina disagreed with our recommendation that it refund \$34.8 million.

- *Texas Made Incorrect Medicaid Electronic Health Record Incentive Payments (A-06-13-00047 <http://oig.hhs.gov/oas/reports/region6/61300047.pdf>) August 2015*

Texas made incorrect electronic health record (EHR) incentive payments to 38 hospitals totaling \$15.3 million. Texas overpaid 26 hospitals a total of \$13.9 million and underpaid 12 hospitals a total of \$1.4 million, for a net overpayment of \$12.5 million. Because the hospital calculation is computed once and then paid out over 3 years, payments made after December 31, 2014, will also be incorrect. The adjustments to these payments total \$163,000.

Texas did not agree or disagree with our recommendations that it:

- refund \$12.5 million in net overpayments made to the 38 hospitals and adjust the 38 hospitals' remaining incentive payments to account for the incorrect calculations (which will result in future cost savings of \$163,000);
- review the calculations for the hospitals we did not review to determine whether payment adjustments are needed and refund any overpayments;
- review supporting documentation for the numbers provided in the cost reports and ensure that the correct cost report periods are used; and
- provide guidance to the hospitals about what costs and services should be included and excluded.

Texas provided information on corrective actions taken and actions to be implemented. Although we did not verify that Texas took these actions, it is our opinion that the actions described could address our findings and recommendations.

- *South Carolina Claimed Some Unallowable Room-and-Board Costs Under the Intellectual and Related Disabilities Waiver for State Fiscal Year 2010 (A-04-14-04019* <http://oig.hhs.gov/oas/reports/region4/41404019.pdf>) April 2015

South Carolina claimed Federal Medicaid reimbursement of \$1.6 million during State FY 2010 for unallowable room-and-board costs under the Intellectual and Developmental Disabilities waiver program and did not reduce its Federal reimbursement by \$7.9 million for an overpayment settlement.

South Carolina claimed unallowable room-and-board costs because it (1) did not have adequate controls to ensure that it followed either applicable Federal law and guidance or its own guidance and (2) did not detect errors or misstatements on the cost reports.

South Carolina agreed with our recommendations to:

- refund to the Federal Government \$1.6 million;
- ensure that the State removes room-and-board-related administrative costs from the cost reports;
- implement the use of a uniform cost reporting process;
- strengthen its cost report review processes to detect errors and to ensure compliance with Federal regulations;
- report as a credit the overpayment of \$7.9 million that South Carolina identified in July 2010; and
- develop and implement controls to ensure that, after being notified of an overpayment, the State reports the overpayment as a credit in a timely manner.

- *Massachusetts Made Claim Adjustments in Accordance With Federal Time Limit Regulations (A-01-15-00001* <http://oig.hhs.gov/oas/reports/region1/11500001.pdf>) June 2015

Massachusetts reported 209,167 claim adjustments, totaling \$9.1 million, in accordance with Federal regulations pertaining to the time limit to claim payment for expenditures. Accordingly, this report contains no recommendations.

Medicaid payments, policies, and practices

- *Questionable Billing for Medicaid Pediatric Dental Services in California (OEI-02-14-00480* <http://oig.hhs.gov/oei/reports/oei-02-14-00480.pdf>) May 2015

We identified 329 general dentists and 6 orthodontists in California with questionable billing. Medicaid paid these providers \$117.5 million for pediatric dental services in 2012. These 335 dental providers—representing 8 percent of California general dentists and orthodontists we reviewed—provided a large number of services or provided certain services to an extremely large number of children. Half of the dental providers with questionable billing worked for dental chains. The California Department of Health Care Services concurred with all of our recommendations, which were for the State to:

- increase its monitoring of dental providers to identify patterns of questionable billing;

- closely monitor billing by providers in dental chains;
- review its payment processes for orthodontic services; and
- take appropriate action against the dental providers identified as having questionable billing.

■ *Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin (OEI-03-13-00650 <http://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf>) April 2015*

We found that total rebates under Medicaid were substantially higher than total rebates under Medicare Part D. Also, Medicaid's net unit costs (i.e., the pharmacy reimbursement amounts minus rebates) were much lower than net unit costs under Part D in 2012 for the 200 selected brand-name drugs. Further, more than half of Medicaid rebates owed by manufacturers for selected brand-name drugs were attributed to the inflation-based add-on rebates. This report did not contain any recommendations.

■ *States' Collection of Rebates for Drugs Paid Through Medicaid Managed Care Organizations Has Improved (OEI-05-14-00431 <http://oig.hhs.gov/oei/reports/oei-05-14-00431.pdf>) September 2015*

Nearly all States that pay for drugs through Medicaid managed care organizations (MCOs) collected rebates for these drugs between July 1, 2013, and June 30, 2014, as required by ACA. This finding represents a significant improvement from previous OIG findings. However, some States are not collecting all eligible MCO rebates, which results in States and the Federal government failing to realize all of the savings they are owed under the Medicaid Drug Rebate Program. CMS should continue to work to ensure that all States are invoicing and collecting all eligible MCO rebates.

■ *New York Did Not Have Evidence Available in Readily Reviewable Form to Support That It Reimbursed Medicaid Diabetic Testing Supply Rebates to the Federal Government (A-02-13-01002 <http://oig.hhs.gov/oas/reports/region2/21301002.asp>) June 2015*

New York officials informed us that New York reported \$65.1 million in recorded rebates from diabetic testing supply manufacturers for the 8 quarters on Line 49 (Other Care Services) of Form CMS-64 but did not provide documentation to support that this amount related to diabetic testing supply rebates.

According to New York officials, New York did not have support for the \$65.1 million in rebate collections that it reported because of limited staff resources available during those quarters to effectively track and report on rebates as they were being collected.

New York agreed with our recommendation that it:

- ensure that the Federal share of all Medicaid diabetic testing supply rebates collected after June 30, 2012, are reported on Form CMS-64, and
- have supporting documentation compiled in readily reviewable form when the State files these claims.

■ *Maryland Claimed Unallowable Medicaid Costs for Residential Habilitation Add-on Services Under Its Community Pathways Waiver Program (A-03-13-00202 <http://oig.hhs.gov/oas/reports/region3/31300202.asp>) June 2015*

Maryland did not always comply with Federal requirements when it claimed Medicaid costs for add-on services under its Community Pathways waiver program (waiver). Maryland did not implement its waiver as approved by CMS. Rather, Maryland claimed \$34 million for provider claims for add-on services for beneficiaries who did not meet the waiver's level-of-need requirement for those services.

The waiver allowed add-on services for beneficiaries who met three requirements, including a level of need of “5” on Maryland’s Individual Indicator Rating Scale. However, Maryland did not consider the beneficiary’s level-of-need score when approving add-on services.

Maryland did not concur with our recommendations, which were to:

- refund to the Federal Government \$34 million and
 - claim add-on service costs only for beneficiaries who meet waiver requirements.
- *Providers Did Not Always Reconcile Patient Records With Credit Balances and Report and Return the Associated Medicaid Overpayments to State Agencies (A-04-14-04029 <http://oig.hhs.gov/oas/reports/region4/41404029.pdf>) August 2015*

We reviewed Medicaid credit balances in eight States and eight providers in each State. Providers (i.e., acute care hospitals, nursing facilities, or certain non-institutional providers) did not always reconcile patient records with credit balances and report and return the associated Medicaid overpayments to the State agencies. Of the 1,102 patient records with credit balances that we reviewed in 8 States, 538 did not contain Medicaid overpayments; however, 564 contained Medicaid overpayments totaling \$264,000 (\$170,000 Federal share). We estimated that the eight States in our review could realize an additional recovery of \$25 million (\$16.8 million Federal share) from our audit period and could obtain future savings if they enhanced their efforts to recover overpayments in provider accounts.

CMS concurred with our recommendation that it:

- issue Medicaid regulations to clarify the requirements of the ACA that parallel its proposed Medicare rules and require that States ensure that providers exercise reasonable diligence to identify, report, and return overpayments.

Medicaid quality of care and beneficiary access

- *Providers Terminated From One State Medicaid Program Continued Participating in Other States (OEI-06-12-00030 <http://oig.hhs.gov/oei/reports/oei-06-12-00030.pdf>) August 2015*

ACA requires States to terminate providers who were already terminated for cause in another State, yet States face challenges complying with this mandate. OIG noted (1) continued participation from providers terminated in one State in other States’ Medicaid programs and (2) about one-third received payments for services provided to Medicaid beneficiaries after the providers’ terminations for cause. Continued participation of providers after their terminations for cause presents a vulnerability to Medicaid and raises concern that these providers could continue to treat Medicaid beneficiaries. This report built on previous work that found weaknesses in the CMS process for sharing termination information among the States. OIG found that not all State Medicaid agencies were reporting to the database and that not all submitted records met the definition of a “for cause” termination.

CMS concurred with our recommendations from both reports to:

- Require each State Medicaid agency to report all providers terminated for cause;
- Ensure that the shared information contains only records that meet CMS’s criteria for terminated for cause;

- Work with States to develop uniform terminology to clearly denote terminations for cause;
- Require that State Medicaid programs enroll all providers participating in Medicaid managed care; and
- Furnish guidance to State Medicaid agencies that termination is not contingent on the provider's active licensure status.

- *CMS's Reliance on New Jersey Qualification Requirements Could Not Ensure the Quality of Care Provided to Medicaid Beneficiaries Receiving Home Health Services (A-02-11-01019 <http://oig.hhs.gov/oas/reports/region2/21101019.pdf>) June 2015*

CMS could not rely on New Jersey's qualification requirements to ensure that quality of care and adequate protection was provided to Medicaid beneficiaries receiving home health services.

Of the 150 claims in our sample, HHA workers associated with 112 claims met Federal and State qualification requirements; however, workers associated with the remaining 38 claims did not. We estimated that home health workers did not meet qualification requirements for 73,260 of the 289,185 claims covered by our review and that the Federal Government reimbursed New Jersey \$4 million for these services during our audit period (January 1, 2007, through July 31, 2008).

New Jersey declined to comment, but CMS concurred with our recommendations that the agency:

- work with New Jersey to reinforce guidance to HHAs on worker qualification requirements and
 - direct New Jersey to improve its monitoring of HHAs to ensure compliance with worker qualification requirements.
- *Review of Intermediate Care Facilities in New York With High Rates of Emergency Room Visits by Intellectually Disabled Medicaid Beneficiaries (A-02-14-01011 <http://oig.hhs.gov/oas/reports/region2/21401011.pdf>) September 2015*

Intermediate Care Facilities in New York with high rates of emergency room (ER) visits by intellectually disabled Medicaid beneficiaries under their care reported on these visits, as required, and potential neglect or abuse was reported and investigated by the Office for People With Developmental Disabilities or the New York State Justice Center for the Protection of People with Special Needs. However, the vast majority of ER visits we reviewed resulted from circumstances associated with the Medicaid beneficiaries' underlying medical conditions—not from neglect or abuse. Accordingly, this report contained no recommendations.

We initiated this review in response to a congressional request to review the care of intellectually disabled Medicaid beneficiaries in group homes.

Medicaid managed care – Encounter data

- *Not All States Reported Medicaid Managed Care Encounter Data as Required (OEI-07-13-00120 <http://oig.hhs.gov/oei/reports/oei-07-13-00120.pdf>) July 2015*

We found that 8 of the 38 States we reviewed did not report encounter data from any managed care entities by the required deadline; an additional 11 States did not report encounter data for all managed

care entities. Our findings raise concerns about CMS enforcement of the requirement that States submit encounter data. CMS concurred with both of our recommendations, which were to:

- use CMS authority to withhold appropriate Federal funds from States that fail to submit encounter data until those States report encounter data as required and
- monitor encounter data to ensure they are reported for all managed care entities.

Legal and investigative activities related to Medicare and Medicaid

OIG investigates allegations of fraud, waste, and abuse in all of the Department's 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 services more extensive than those actually provided; 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;
- HHAs 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 dollars from Medicare, Medicaid, and other Federal health care programs. OIG investigators are seeing an increase in 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 operating divisions, including the Indian Health Service, Administration for Children and Families, Health Resources and Services Administration, and Administration for Community Living. OIG also investigates potential misuse of grants and contracts funds awarded by the National Institutes of Health, Centers for Disease Control and Prevention, Substance Abuse and Mental Health Services Administration, and other HHS agencies (HHS is the largest grantmaking organization and one of the largest contracting agencies in the Federal Government). 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 or the Civil Monetary Penalties Law. 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, 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 in Appendix D of this report and on our Web site at: <http://oig.hhs.gov/fraud/enforcement/cmp/>.

For all OIG investigations, the charges contained in an indictment or other charging document are merely accusations. A defendant is presumed innocent unless and until proven guilty.

For April 1 to September 30, 2015, we reported 378 criminal and 347 civil actions against individuals or entities that engaged in health care-related offenses. We also reported over \$756.9 million in investigative receivables due to HHS and over \$139.4 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.¹

Below are recently completed actions and settlements organized by allegation or subject type:

Patient harm

Michigan – Oncologist Farid Fata was sentenced to 45 years in prison and ordered to forfeit more than \$17 million after he pleaded guilty to charges of health care fraud, conspiracy to pay or receive kickbacks, and money laundering. Fata owned and operated the cancer treatment clinic Michigan Hematology Oncology, P.C., which had several locations in Michigan. Fata admitted that he prescribed and administered aggressive chemotherapy, cancer treatments, intravenous iron, and other infusion therapies to 553 individual patients who did not need these therapies, in order to increase his billings to Medicare and other insurance companies. He then submitted fraudulent claims to Medicare and other insurers for these unnecessary treatments. In total, Fata submitted about \$34 million in fraudulent claims to Medicare and private insurance companies. Fata also admitted to soliciting kickbacks from Guardian Angel Hospice and Guardian Angel Home Health Care in exchange for his referral of patients to those facilities.

Virginia – Gina Bradley and Melissa Forester were each sentenced to 4 months of home confinement and ordered to perform 100 hours of community service after pleading guilty to making false statements related to health care matters. Bradley was the director of nursing for the Brian Center Health and Rehabilitation Center (Brian Center), an SNF in Weber City, Virginia. The investigation revealed that, due largely to a lack of staffing and funding from the corporate owner, a number of Brian Center residents suffered from neglect and failure of care, causing patients to develop unnecessary pressure sores and

¹ The accomplishments reported in the *Semiannual Report to Congress: April 1 – September 30, 2014*, under “Legal and investigative activities related to Medicare and Medicaid,” represents accomplishments related to all programs. The correct information as it relates to healthcare only is as follows: For April 1 to September 30, 2014, we reported 440 criminal and 263 civil actions against individuals or entities that engaged in health-care-related offenses. We also reported over \$958.4 million in investigative receivables due to HSS and over \$294.5 million in non-HHS investigative receivables, including civil and administrative settlements or civil judgments related to Medicare, Medicaid, and other Federal, State, and private health care programs.

forcing many residents to live in unsanitary conditions. Bradley supervised the nursing staff's care and treatment of residents, including Medicare patients who developed pressure ulcers; she caused nursing staff to neglect the pressure ulcers and minimize the seriousness of the pressure ulcers in medical records. One patient was transported to an emergency room with a wound dressing that was found to be "full of feces," and the wound itself was severely infected. The patient later died. Forester was the Brian Center's wound care nurse under Bradley's supervision. Forester made multiple false entries on treatment administration records, indicating that she provided essential resident care that was not actually rendered, and that she provided resident care on days when she was not working. Brian Center closed in August 2012 after failing multiple special focus facility surveys and after CMS cancelled its Medicare Provider Agreement. Brian Center's Corporate Owner Avi Klein, Regional Vice President Alicia Dietrich, and Administrator Vickie Cox all pleaded guilty to racketeering charges. Cox was sentenced to 6 months in prison, while Klein and Dietrich were each sentenced to 4 months of home confinement and 400 hours of community service. Klein also must pay about \$1.6 million in restitution and fines. In addition, Klein agreed to be excluded from participating in all Federal health care programs for 50 years.

Quality of care

California – Country Villa Service Corp, d/b/a Country Villa Health Services, and the ARBA Group, Inc., CF Watsonville East, LLC and CF Watsonville West, LLC entered into separate settlement agreements worth a combined \$3.8 million to resolve allegations of false claims for materially substandard or worthless services. The United States alleged that employees at Country Villa Watsonville East Nursing Center and Country Villa Watsonville West Nursing Center persistently overmedicated elderly and vulnerable residents of their facilities, causing infection, sepsis, malnutrition, dehydration, falls, fractures, pressure ulcers, and for some beneficiaries, premature death. In addition to the settlements, the CF Watsonville companies entered into a 5-year corporate integrity agreement (CIA) with OIG, under which they will retain a quality monitor chosen by OIG to perform quarterly reviews of the facilities' quality and compliance systems.

Prescription drugs

New York – Kevin Lowe was convicted of conspiracy to distribute and possess with intent to distribute oxycodone and was convicted of conspiracy to distribute and possess with intent to distribute oxycodone. The charge carries a maximum sentence of 20 years in prison. Lowe owned and operated Astramed, a series of purported medical clinics with multiple locations in the Bronx, New York. Astramed doctors were paid cash in exchange for writing tens of thousands of medically unnecessary prescriptions for large quantities of oxycodone. These prescriptions were then filled at pharmacies by co-conspirators who, in turn, resold and distributed the drugs at vastly inflated rates. Patient recruiters would bring beneficiaries to the clinic, where they would receive a "doctor visit" that typically lasted just a minute or two and involved no actual physical examination, and consistently resulted in a prescription for a large dose of oxycodone. Crowds of up to 100 people gathered daily outside the clinics, waiting to see one of the doctors and receive a prescription for oxycodone. The "patient" would often be escorted by a patient recruiter, or crew member, to a pharmacy to fill the prescription. The crew member would then pay the patient and take possession of and ultimately sell the oxycodone on the street. Astramed also provided oxycodone prescriptions to drug addicts and dealers for a fee, typically in excess of \$1,000 in cash. In total, Astramed issued approximately 31,500 medically unnecessary prescriptions for

oxycodone, comprising nearly 5.5 million tablets with a street value of up to \$164 million. More than 20 defendants – including doctors, clinic employees, and drug traffickers – have previously pleaded guilty to their participation in the scheme.

Michigan – Jamall Gibson was sentenced to 12 years and 7 months in jail, and ordered to pay \$10,100 in restitution and fines—after pleading guilty to conspiracy to distribute and possess with intent to distribute controlled substances. Sierra Walker was sentenced to 1 year and 1 month in jail, and ordered to pay \$400,000 in joint and several restitution after pleading guilty to conspiracy to pay health care kickbacks. According to the investigation, Gibson and his co-conspirators obtained OxyContin pills and other controlled substances in Detroit, Michigan, for distribution to Portsmouth, Ohio, and elsewhere. Gibson and his co-conspirators also had Medicare patients attend "patient parties" to obtain prescriptions for OxyContin pills and other medically unnecessary controlled drugs, which were then diverted for illegal street sales. Walker and her co-conspirators acted as patient recruiters, recruiting and paying Medicare beneficiaries and subjecting them to physician visits. Their action resulted in fraudulent billings to Medicare for medically unnecessary health care visits and prescriptions for controlled and non-controlled substances, which were subsequently billed to Medicare.

California – Artak Ovsepien was sentenced to 15 years in prison and ordered to pay \$9.1 million in joint and several restitution after being convicted on charges of conspiracy to commit health care fraud, aggravated identity theft, conspiracy to misbrand pharmaceutical drugs, false statements to the Federal Government, and conspiracy to use other persons' identification documents in furtherance of fraud. Ovsepien and his co-conspirators operated Manor Medical Imaging, Inc., located in Glendale, California, where they employed an unlicensed medical practitioner to write bogus prescriptions using a physician's name and license number. They also had close relationships with pharmacies and a fraudulent drug wholesale company, which were used to funnel prescription drugs back to the pharmacies participating in the scheme. As such, patient recruiters brought beneficiaries to Manor Medical in exchange for cash or other inducements. The patients received prescriptions for antipsychotic medications, and sometimes other drugs. This occurred even though either they were not evaluated by a physician or there was no medical need for the medications. The patients were then driven to a pharmacy where, under the supervision of the driver, they filled their prescriptions and then gave the drugs to the driver. The drugs were eventually sold on the black market or redistributed to pharmacies, where they could be rebilled to Medicare and Medi-Cal as "new" bottles of drugs. In addition to recruiting beneficiaries, Ovsepien and his co-conspirators also stole the identities of beneficiaries. They used their information to generate fraudulent prescriptions. Ten of Ovsepien's co-conspirators were previously sentenced to a combined 28 years and 3 months in prison.

Identity theft

Florida – Adam Parrish was sentenced to 6 years in prison and ordered to pay \$351,358 in joint and several restitution after pleading guilty to conspiracy to commit health care fraud, aggravated identity theft, and obtaining a controlled substance with another person's Drug Enforcement Agency (DEA) registration number. Parrish admitted that he and his co-conspirators, including Delmer Parrish, submitted claims for reimbursement from Medicare, Medicaid, and TRICARE for prescriptions that were neither filled nor provided to beneficiaries or recipients, including prescriptions for patients that had not been written or authorized by a licensed physician. Specifically, Parrish and his co-conspirators wrote prescriptions for beneficiaries and recipients who were deceased, wrote prescriptions using the identification of individuals enrolled in Federal health care programs without their knowledge or

consent, and forged the initials and used the DEA registration number of a physician without his knowledge or consent. Parrish and others used Sunshine Pharmacy and Sunshine Solutions in Naples, Florida, to further their unlawful scheme to defraud the Government. Delmer Parrish, who was a licensed pharmacist and owner of Sunshine Pharmacy, previously pleaded guilty to conspiracy to commit health care fraud and was sentenced to 2 years in prison.

Florida – Gladys and Mario Fuertes were sentenced to a combined 30 years and 9 months of incarceration, and ordered to pay over \$1.2 million in joint and several restitution and forfeiture—after being convicted of conspiracy to commit health care fraud, health care fraud, and obstructing a health care fraud investigation. Gladys Fuertes was also convicted on aggravated identity theft. Evidence at trial showed that Gladys and her husband, Mario, established and operated a sham clinic, Gables Medical and Therapy Center. They also employed unlicensed medical professionals to bill Medicare for HIV services that were never rendered. The clinic used billing numbers of other medical professionals without their knowledge to submit the fraudulent claims. The couple also paid co-conspirators to recruit Medicare beneficiaries to obtain their Medicare identification numbers, instructing the beneficiaries to enroll into a targeted Medicare Part C & D plan. Co-conspirators also assisted in filling fraudulent prescriptions for controlled substances, such as oxycodone, which were billed and reimbursed by Medicare. They then purchased the pills from the Gables patients, later selling them on the street. In addition, the investigation found that the couple instructed Gables patients to lie to law enforcement agents, and they altered Medicare billing documentation after learning that their clinic was under investigation.

Home health

Florida – Felix Gonzalez was sentenced to 9 years and 5 months of imprisonment and ordered to pay \$21 million in restitution after pleading guilty to conspiracy to commit health care fraud. Gonzalez owned and operated AA Advanced Care, Inc., a Florida business that purportedly provided home health care and physical therapy services to Medicare beneficiaries who were not eligible for those services. According to the investigation, Gonzalez and his co-conspirators paid patient recruiters to place beneficiaries at AA Advanced. The recruiters then sent the beneficiaries to doctors to obtain prescriptions for home health services that were not medically necessary and were not provided. Gonzalez and his co-conspirators caused patient documentation to be falsified to bill Medicare about \$32 million for the fraudulent services. From about January 2006 to March 2009, AA Advanced submitted claims to Medicare for home health services purportedly provided to about 900 beneficiaries. Gonzalez was an OIG Most Wanted Fugitive—until he returned to the United States in September 2014 and was arrested.

Physicians

New York – Mahesh Kuthuru was sentenced to a year-and-a-half of imprisonment and ordered to pay \$84,265 in restitution after pleading guilty to charges of healthcare fraud and unlawful distribution of controlled substances. Kuthuru was a physician who owned and operated Upstate Pain Management, which had two offices in New York, as well as Desert Pain Management in Las Vegas, Nevada. Kuthuru admitted that, between January 2010 and September 2011, he submitted claims to Medicare that falsely reflected that he personally provided or directly supervised other licensed medical professionals to provide treatment or services to patients in the New York offices. In actuality, during these times

Kuthuru either was practicing at his Las Vegas office or was out of the country. In addition, clerical staff at the Upstate Pain Management offices partially filled out prescription forms and then sent the forms to Kuthuru in Las Vegas to sign and return. Staff then dated and provided the prescription to patients, even though the patients did not see a medical professional on these particular visits. This health care fraud scheme was discovered in the early stages thanks to a joint effort with the Federal Bureau of Investigation (FBI), DEA, and State and local law enforcement.

Personal care services

Illinois – Alicia Davis and her mother, Patricia Davis, were each sentenced to 3 years of probation and ordered to pay \$49,146 in joint and several restitution after pleading guilty to health care fraud. According to the investigation, Patricia and Alicia Davis, along with Patricia's other daughter, Michelle Calhoun, submitted Illinois Department of Human Resources Home Services time sheets that falsely represented dates, times, and hours for providing personal care services to Calhoun's husband, a Medicaid recipient. Calhoun pleaded guilty to participating in the scheme and is awaiting sentencing.

Pennsylvania – Dawn Smith was sentenced to 1 year and 9 months in jail and ordered to pay \$103,402 in restitution after pleading guilty to conspiracy to commit false claims and false statements relating to health care. Smith was enrolled with the Medicaid Attendant Care Waiver program as a personal care attendant. The investigation related that Smith submitted time sheets to the Medicaid program for attendant care services that she did not provide. Smith also submitted attendant care time sheets to the Medicaid program for care purportedly provided by her associates. However, those Medicaid services were also not provided.

Electronic health records

Texas – Joe Dell White was sentenced to 1 year and 11 months in jail, and ordered to pay \$4.4 million in restitution after pleading guilty to making a false statement. White was the chief financial officer at Shelby Regional Medical Center, where he oversaw the implementation of electronic health records (EHRs) for the hospital. He was responsible for certifying that the hospital's EHR platform met meaningful use requirements to qualify for incentive payments under Medicare's EHR Incentive Program. However, during FY 2012, Shelby Regional did not meaningfully use the EHR platform, despite an attestation from White that it did. Instead, with White's knowledge, the hospital staff only minimally used the EHR platform and continued using paper records and charts as well as older, uncertified technology. In an effort to meet the required thresholds for meaningful use and to obtain EHR incentive payments from CMS, White directed others to manually input data from paper records and other sources into Shelby Regional's EHR system, often times many months after the patients were discharged from the hospital. White also created a user ID for a hospital representative, without the representative's knowledge or approval, and used that ID to falsely attest to CMS that the information provided about its EHR usage was true, accurate, and complete. White falsely certified to CMS that Shelby Regional met the meaningful use requirements, even though he was fully aware that Shelby Regional used the EHR system sparingly and did not meet the criteria for incentives. As a result of White's conduct, Shelby Regional received a \$785,655 EHR incentive payment from CMS in FY 2012.

Kickbacks

California – NuVasive Inc., agreed to pay \$13.5 million to resolve allegations that the company promoted its CoRoent System for surgical uses that were not approved or cleared by the Food and Drug Administration (FDA) and paid kickbacks to induce physicians to use its CoRoent System. The United States alleged that, between 2008 and 2013, NuVasive promoted its CoRoent System for certain surgical uses, including for use in treating two complex spine deformities: severe scoliosis and severe spondylolisthesis. Because these specific uses were not approved or cleared by the FDA, the claims submitted to Medicare and Medicaid from physicians and hospitals for these spine surgeries were not eligible for reimbursement. Brought to market in 2005, CoRoent implants are used mainly in minimally invasive spinal operations. As originally indicated, the devices were to be used for intervertebral body fusion or as partial vertebral body replacement devices. The United States also alleged that NuVasive knowingly offered and paid illegal remuneration to certain physicians to induce them to use the CoRoent System in spine fusion surgeries, in violation of the Federal anti-kickback statute. The alleged illegal remuneration consisted of promotional speaker fees, honoraria, and expenses for physicians' attendance at events sponsored by a group that was allegedly created, funded, and operated by NuVasive.

Pharmacies

Wisconsin and Rhode Island – PharMerica Corporation entered into two settlements for a total of \$31.5 million to resolve claims that it violated the False Claims Act and the Controlled Substances Act. PharMerica is a long-term care pharmacy that dispenses medications to residents of long-term care facilities, including nursing homes and skilled nursing facilities. It operates about 95 pharmacies in the United States. PharMerica allegedly dispensed and billed Medicare for Schedule II controlled substances without a valid prescription. The prescriptions were allegedly invalid because they did not have a prescriber's signature, or in the case of emergency dispenses, the prescriptions were not based on an oral prescription from the prescriber—followed by a written prescription with the prescriber's signature within 7 days. In addition to the settlement amount, PharMerica entered into a CIA with OIG that includes PharMerica's board retaining a compliance expert for 2 years. It also includes retaining an independent review organization to perform a prescription review to ensure that all claims submitted to Medicare Part D plans for controlled substances are based on valid prescriptions and comply with Controlled Substances Act requirements.

Laboratories

New Jersey – Three physicians were sentenced, during this reporting period, after pleading guilty to charges related to a test-referral kickback scheme. According to the investigation, Biodiagnostic Laboratory Services Inc. (BLS) solicited and paid bribes to physicians in exchange for referring patient blood specimens to the laboratory. As part of the kickback scheme, BLS entered into sham consulting agreements, sham rental and service agreements, and offered cash and other inducements, such as third-party businesses, credit card payments, and valuable items (cars and electronics). BLS used the patient blood specimens to submit more than \$100 million in claims to Medicare and private insurers. During this reporting period, physicians Eugene Desimone, Franz Goyzueta, and Anthony Deluca admitted to accepting about \$1,500 or more a month in return for referring patient blood specimens. The three were sentenced to a combined 7 years and 2 months in jail, and ordered to pay a combined

\$434,300 in restitution. BLS owner David Nicoll pleaded guilty to conspiracy to commit bribery and money laundering, and is awaiting sentencing.

Pharmaceutical companies

Pennsylvania – Shire Pharmaceuticals LLC agreed to pay \$56 million to resolve allegations that it promoted Adderall XP as clinically superior to other attention deficit hyperactivity disorder drugs based on its mechanism of action and its ability to “normalize” patients. This occurred despite a lack of clinical data to support the claims. Shire Pharmaceuticals allegedly suggested to doctors that treatment with Adderall XP would help prevent certain issues linked to this disorder, such as poor academic performance, loss of employment, criminal behavior, traffic accidents, and sexually transmitted disease. Shire also promoted the drug for the treatment of conduct disorder, an indication for use which was not FDA- approved, was not a medically accepted indication, and was not covered by State Medicaid programs. Shire allegedly made promotional claims and marketed other drugs (Vyvanse, Daytrana, Lialda, Pentasa) when there was insufficient clinical data to support the claims. In addition, certain Shire sales representatives knowingly and improperly made phone calls and drafted letters to Medicaid to assist physicians with the prior authorization process for Shire drug prescriptions. These prior authorization services were conducted to induce physicians to prescribe Shire drugs that were paid for by Medicaid.

Hospitals

Georgia – The Medical Center of Central Georgia, Inc. entered into a \$20 million settlement agreement with the United States to resolve allegations under the False Claims Act. The Medical Center is located in Macon, Georgia, and is the second largest hospital in the State. From January 2004 through August 2008, the Medical Center allegedly submitted false claims to Medicare for medically unnecessary inpatient admissions, including zero-day stays, one-day stays, cardiac stays with a procedure, and cardiac stays without a procedure. Specifically, these services should have been billed as outpatient or observation services due to the absence of medical necessity for inpatient services. In addition to the settlement agreement, the Medical Center entered into a 5-year CIA with OIG that requires this hospital to retain an independent review organization to conduct two reviews: (1) a claims review of a population of paid claims determined by OIG in its sole discretion each year, and (2) an inpatient medical necessity and appropriateness review of inpatient admissions during the third, fourth, and fifth reporting periods.

Psychiatric and psychological services

Arkansas – Health Management Associates, Inc. and 14 hospitals formerly owned and operated by Health Management entered into a \$15 million settlement agreement with the United States to resolve allegations under the False Claims Act. The United States alleged that the HMA hospitals, located in seven states, individually contracted with Allegiance Health Management to provide outpatient group psychotherapy to Medicare patients in exchange for paying Allegiance a percentage of the amounts reimbursed by Medicare. Allegiance is a post-acute healthcare management company based in Louisiana. From January 1, 2005, through December 31, 2013, the Health Management hospitals

allegedly submitted claims to Medicare for intensive outpatient psychotherapy services that Allegiance provided to patients where the services did not qualify for Medicare reimbursement because (1) the patient's condition did not qualify for intensive outpatient psychotherapy; (2) the patient's treatments were not provided pursuant to an individualized treatment plan designed to help the patient address specific mental health needs and reach achievable goals; (3) the patient's progress was not being adequately tracked or documented; (4) the patient received an inappropriate level of treatment; or (5) the therapy provided was primarily recreational or diversional in nature, and was not therapeutic.

Community mental health center

Florida – Ruben Busquets was sentenced to 4 years in prison and ordered to pay \$13.6 million in joint and several restitution after pleading guilty to conspiracy to commit health care fraud. Busquets was a licensed mental health counselor who worked as a therapist for Health Care Solutions Network, Inc., in Florida. Busquets admitted that he provided intensive therapy to mental health patients who were ineligible to receive the therapy or could not benefit from partial hospitalization program (PHP) services, including patients suffering from dementia, mental retardation, and Alzheimer's disease. During his employment, Busquets was aware that patient medical records were created weeks or months after the patients were admitted to Health Care Solutions for purported PHP treatment; these records were used to support false billings to Medicare and Medicaid. Busquets signed fabricated PHP therapy notes and other medical records, used to support the false claims. During his employment, Busquets and his co-conspirators submitted about \$31 million in false claims to the Medicare and Florida Medicaid programs.

Durable medical equipment

California – Adeline Ekwebelem was sentenced to 6 years and 6 months in prison and ordered to pay \$3.4 million in joint and several restitution after being convicted of conspiracy to commit health care fraud, health care fraud, and illegal remunerations for health care referrals. According to the investigation, Ekwebelem paid marketers to solicit beneficiaries for his company, Adelco Medical Distributors, Inc., a durable medical equipment (DME) supplier located in Gardena, California. Ekwebelem and his co-conspirators then offered the beneficiaries medically unnecessary power wheelchairs, hospital beds, orthotics, and other DME for free. The beneficiaries would be taken to see physicians who would create fraudulent patient files. These files included DME prescriptions and false statements in face-to-face examination forms, purporting to support the medical need for the DME, even though the physicians did not examine the beneficiaries. The physicians would then direct the beneficiaries back to Adelco to fill the prescriptions for the DME. Both Ekwebelem and the physicians would bill Medicare for DME, office visits, or diagnostic tests that were either medically unnecessary or were not provided. One of the physicians, Charles Okoye, was previously sentenced to 2 years in prison and ordered to pay over \$930,000 in restitution.

California – Olufunke Fadojutimi was sentenced to 4 years in prison and ordered to pay \$4.3 million in joint and several restitution after being convicted of conspiracy to commit health care fraud, health care fraud, and laundering of monetary instruments. Fadojutimi was a registered nurse who owned and operated Lutemi Medical Supplies, a DME company located in Carson, California. According to the investigation, Fadojutimi and her co-conspirators used cash and checks to pay illegal kickbacks to recruit Medicare beneficiaries for power wheelchairs and other DME, to which the beneficiaries did not have a legitimate medical need. Fadojutimi and her co-conspirators also paid illegal kickbacks to a physician in

exchange for writing false prescriptions and documents for the DME, which were then used to fraudulently bill Medicare.

International health care fraud scheme

Miami – Mirna Blanco was sentenced to 2 years in prison and ordered to pay \$16 million in joint and several restitution after pleading guilty to conspiracy to commit health care fraud and wire fraud. Blanco was employed by Florida Healthcare Plus, Inc. as well as by Axis Le Professional Medical Group Corp. and Rodney Montoya Corp. Florida Healthcare was a health maintenance organization in Florida, while Axis Le and Rodney Montoya contracted with Florida Healthcare and other organizations as a medical services provider. According to the investigation, Blanco, manager of social services at Florida Healthcare, submitted fraudulent Medicare and Medicaid enrollment applications for beneficiaries that claimed that the beneficiaries resided in Florida. However, these applicants actually resided in Nicaragua and the Dominican Republic. Blanco and her co-conspirators used nonresidential addresses, addresses belonging to the relatives and friends of these foreign residents, and addresses associated with the defendants—to falsely represent that the foreign residents lived in Florida. In addition to Blanco, five defendants connected to this health care fraud scheme were sentenced to a combined 10 years and 3 months in prison and ordered to pay \$16 million in restitution, joint and several.

Health care fraud prevention and enforcement

On May 20, 2009, former HHS Secretary Kathleen Sebelius and 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 HHS and the Justice Department who are strengthening programs, as well as investing in new resources and technologies, to prevent and combat fraud, waste, and abuse.

HEAT provider compliance training

OIG provides free training on our Web site 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 HEAT provider compliance training resources can be accessed at http://oig.hhs.gov/newsroom/video/2011/heat_modules.asp.

Medicare Fraud Strike Force

Medicare 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 Strike Force teams are partnerships among OIG and HHS, Department of Justice (DOJ), U.S. Attorneys' Offices, the FBI, and State and local law enforcement with a common goal: to 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;

southern Texas; Brooklyn, New York; southern Louisiana; Tampa, Florida; Chicago, Illinois; and Dallas, Texas.

Examples of Medicare Fraud Strike Force cases are shown below.

Southern Texas Strike Force – Earnest Gibson III, Earnest Gibson IV, Mohammad Kahn, and Regina Askew were sentenced to a combined 117 years of incarceration; they were also ordered to pay more than \$46 million in joint and several restitution after being convicted of conspiracy to commit health care fraud and conspiracy to pay and receive kickbacks. Gibson III and Gibson IV were also convicted of conspiracy to commit money laundering. The scheme involved the submission of more than \$158 million in false claims to Medicare for PHP services that were medically unnecessary, not eligible for reimbursement, and were not provided. To facilitate the scheme, the defendants offered and paid kickbacks, including cash, cigarettes, and food, to patient recruiters, group home owners, and assisted living facility owners in exchange for sending Medicare beneficiaries to Riverside General Hospital and its satellite facilities, where the patients watched television, played games, and engaged in other non-PHP activities—rather than receive the PHP services for which the hospital billed Medicare.

Detroit Strike Force – Three defendants were sentenced to a combined 20 years and 8 months in jail, and they were ordered to pay more than \$22 million in joint and several restitution after being convicted of conspiracy to commit health care fraud and other charges. Abdul Al-Jumail and Mohammed Sadiq jointly operated several HHAs in Michigan, while Abdul's daughter Jamella co-operated a HHA. According to the investigation, the three defendants, along with their co-conspirators, paid kickbacks and bribes to recruiters and others for beneficiary information that would be used to falsely bill Medicare millions for home health services that were medically unnecessary and not performed. The conspirators fabricated patient files and medical documents to give the false impression that medical services billed to Medicare were legitimate. After learning of her father's arrest, Jamella directed and participated in the burning of patient charts and records to cover her false billings to Medicare. Firas Alky, who jointly operated several of the home health care facilities, was indicted in September 2012, but investigators believe that he fled the country. Alky is one of OIG's Most Wanted Fugitives.

Miami Strike Force – Alexander Lara was sentenced to 10 years in prison and ordered to pay \$13 million in joint and several restitution after pleading guilty to conspiracy to commit health care fraud. Lara owned Longcare Home Health Corporation, a Miami-based business that purportedly provided home health and therapy services to Medicare beneficiaries. Lara admitted that he and his co-conspirators billed Medicare for, among other things, expensive physical therapy and home health care services that were not medically necessary or were not provided. Lara's primary role was to manage and supervise patient recruiters and other personnel and to coordinate, plan, organize, and oversee the submission of false claims to Medicare. Lara and his co-conspirators also paid kickbacks and bribes to co-conspirators in doctors' offices and clinics in exchange for providing home health and therapy prescriptions. From about January 2009 to November 2014, Longcare submitted more than \$13 million in claims to Medicare for home health services that were not necessary or were not provided. Eight defendants who participated in the fraud scheme were previously sentenced to a combined 53 years and 7 months in jail.

Other criminal and civil enforcement activities

Special Assistant U.S. Attorney Program

During this reporting period, OIG and DOJ continued their participation in a program in which OIG attorneys, some of whom are Special Agents, serve as Special Assistant U.S. Attorneys. OIG attorneys are detailed full time to DOJ's Criminal Division, Fraud Section, for temporary assignments, including assignments to the Medicare 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 on the fraudulent billing of medical equipment and supplies, infusion therapy, and physical therapy as well as on other types of Medicare and Medicaid fraud.

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. Examples of these CIAs are included in the case narrative section.

A related case example follows:

Illinois – LifeWatch Services, Inc., a durable medical equipment supplier, agreed to pay \$737,572 to settle allegations that it knowingly submitted false claims to Medicare from February 21, 2013 through June 30, 2014 for cardiac monitoring services. Specifically, OIG alleged that LifeWatch submitted claims to Medicare for ambulatory cardiac telemetry services for which the medical record documentation did not support that the physician had ordered these telemetry services. The settlement resolves a reportable event submitted by LifeWatch as required under its CIA. LifeWatch entered into the CIA in March 2012 as part of an \$18.5 million civil settlement with the United States, resolving allegations that, among other things, the supplier submitted claims to Medicare for cardiac monitoring services that were not medically necessary, and encouraged the use of more expensive cardiac monitoring devices when a less expensive device was sufficient to meet the patient's needs.

OIG's Most Wanted Fugitives

Garnering national and international attention, the OIG Most Wanted Fugitives Web site has greatly assisted our efforts to capture fugitives charged with defrauding Federal health care programs and stealing millions of taxpayer dollars. The Most Wanted Fugitives Web site is continuously 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 <http://oig.hhs.gov/fraud/fugitives>.

One of the OIG's Most Wanted Fugitives is Armando "Ana" Zamora, who was indicted in July 2004 on charges of health care fraud conspiracy and health care fraud. Investigators believe that Zamora and her co-conspirators received about \$550,000 in reimbursement from Medicare for the cost of DME and other related items and services that were either medically unnecessary or were never provided. Zamora and Aurora Estevez established Health South Medical Supply Corporation, a DME company in Miami-Dade County, Florida. According to the indictment, Zamora, Estevez, and their co-conspirators acquired Medicare beneficiary information, which Health South allegedly used to prepare fraudulent Medicare claims. The defendants also acquired the identification numbers of doctors to help further the fraud. Zamora, Estevez, and their co-conspirators falsely represented that doctors had treated patients; that doctors had prescribed DME, including custom-fitted orthotics, and other related items and services for patients; and that such DME had been delivered to Medicare beneficiaries. Estevez pleaded guilty and was sentenced in January 2005 to 2 years in jail and ordered to pay \$505,704 in restitution, joint and several. Zamora fled the United States and is believed to be residing in Central or South America. She remains a fugitive at large.

Because of the success of OIG's Most Wanted Fugitives Web site, OIG launched its Child Support Enforcement webpage. Updated frequently, this page includes information on OIG's role in investigating parents who fail to pay court-ordered child support and information on OIG's Most Wanted Deadbeat parents. These parents put an unnecessary strain on the children and their custodial parents as well as on agencies that enforce these matters. Examples are provided in the "Human Services Reviews" section of this *Semiannual Report*.

OIG Hotline Operations

The mission of OIG Hotline Operations is to assist OIG in protecting the integrity of all HHS programs and agencies. Strategically placed within the Office of Investigations (OI), OIG Hotline Operations serves as the "public face" of OIG through the analysis and processing of complaints and of information received through various available hotlines and numbers, including, but not limited to, OIG's Fraud, Waste and Abuse Hotline; OIG's Fugitive Hotline; and the CDC's Select Agent and Import Permit Hotlines. Constantly working to improve outcomes and results, OIG Hotline Operations uses state-of-the-art approaches and current technology to best address all matters received.

OIG Hotline Activity

Contacts Received: 04/01/15 – 09/30/15

Total Calls Received	57,636
(Total Operator-Assisted Calls: 10,784)	
<u>Total Non-Call Matters Received</u>	<u>6,736</u>
<i>Total Contacts</i> ²	64,372
Total Complaints Evaluated	17,816

² A contact is the total number of instances in which a person contacts OIG Hotline Operations, regardless of the nature of the contact, and receives service through automated or manual means.

State Medicaid Fraud Control Units

IG oversight of State Medicaid Fraud Control Units

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 an MFCU; the States contribute the remaining 25 percent. MFCUs investigate and prosecute Medicaid provider fraud and Medicaid patient abuse and neglect in health care facilities or board and care facilities. MFCU accomplishment data and onsite reviews for FY 2015 will be reported in OIG's spring 2016 *Semiannual Report*.

IG onsite reviews of MFCUs

OIG has developed 12 performance standards for use in assessing the operations of MFCUs. A copy of the MFCU performance standards, most recently revised in June 2012, may be found on the OIG Web site. Periodically—about every 5 years—OIG conducts an in-depth onsite review of each MFCU's operations as related to these 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. The full reports are available on our Web site.

- *Rhode Island State Medicaid Fraud Control Unit: 2014 Onsite Review (OEI-02-14-00580*
<http://oig.hhs.gov/oei/reports/oei-02-14-00580.asp>) *September 2015*
- *Alabama State Medicaid Fraud Control Unit: 2014 Onsite Review (OEI-06-13-00660*
<http://oig.hhs.gov/oei/reports/oei-06-13-00660.pdf>) *April 2015*
- *Maine State Medicaid Fraud Control Unit: 2015 Onsite Review (OEI-07-15-00140*
<http://oig.hhs.gov/oei/reports/oei-07-15-00140.pdf>) *September 2015*
- *Ohio State Medicaid Fraud Control Unit: 2014 Onsite Review (OEI-07-14-00290*
<http://oig.hhs.gov/oei/reports/oei-07-14-00290.asp>) *April 2015*
- *Hawaii State Medicaid Fraud Control Unit: 2014 Onsite Review (OEI-09-14-00540*
<http://oig.hhs.gov/oei/reports/oei-09-14-00540.asp>) *September 2015*
- *Georgia State Medicaid Fraud Control Unit: 2015 Onsite Review (OEI-07-15-00090*
<http://oig.hhs.gov/oei/reports/oei-07-15-00090.asp>) *September 2015*
- *District of Columbia State Medicaid Fraud Control Unit: 2015 Onsite Review (OEI-07-14-00660*
<http://oig.hhs.gov/oei/reports/oei-07-14-00660.pdf>) *September 2015*

Examples of joint efforts with MFCUs:

Texas – William Owuama was sentenced to 5 years of incarceration, and ordered to pay \$3.9 million in joint and several restitution after pleading guilty to conspiracy to commit healthcare fraud and violate

the anti-kickback statute. Owuama owned and directed Wilmar Healthcare Systems. Florida Holiday Island, a co-conspirator, worked at Wilmar and was paid for recruiting Medicare beneficiaries and transporting them to Wilmar, where they were paid cash for each visit they made to the office. Owuama admitted that Wilmar typically billed Medicare and Medicaid for a battery of diagnostic vestibular tests three times a week for months, and in some cases, years. These tests, however, were either not actually performed, not medically necessary, or were not directly overseen by a physician. Wilmar used a former licensed physician to bill for the tests, although the physician was incarcerated on tax-related charges at the time he was supposedly seeing the patients and ordering the tests. Island also pleaded guilty to conspiracy to commit healthcare fraud and violate the anti-kickback statute, and was sentenced to 13 months of home confinement and ordered to pay \$1.9 million in joint and several restitution. This case was worked jointly with the FBI and the Texas MFCU.

Massachusetts – Punyamurtula Kishore was sentenced to 1 year in jail, and ordered to pay \$9.3 million in joint and several restitution after pleading guilty to Medicaid kickbacks, Medicaid false claims, and larceny. Kishore also agreed to surrender his medical license. Kishore owned and managed Preventive Medicine Associates, Inc., a network of 29 medical branches and laboratories throughout Massachusetts. According to the investigation, Kishore induced owners of sober houses with bribes and kickbacks to send their residents' urine drug screening business to his laboratories for testing. Sober houses, also known as half-way houses, are alcohol- and drug-free living environments for people in recovery. Residents at these sober houses were typically screened three times per week. Kishore then fraudulently billed Medicare and Medicaid millions of dollars for these urine drug screening tests, even though the patients were never treated by providers at Preventative Medicine. Thomas Leonard and John Coughlin, two owners of sober houses who provided screening tests to this entity in return for payments, were each sentenced to 2 years in prison. This case was worked jointly with the Massachusetts Attorney General's Office, Medicaid Fraud Division.

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. Developed in consultation with DOJ, advisory opinions are issued to requesting parties on the interpretation and applicability of certain statutes relating to Federal health care programs. The Health Insurance Portability and Accountability Act of 1996, § 205, allows OIG to provide case-specific formal guidance on the application of the anti-kickback statute and safe harbor provisions and on other OIG health care fraud and abuse sanctions. From April 1, 2015, to September 30, 2015, OIG received 21 requests for advisory opinions and issued 8 opinions.

Sanction authorities and other administrative actions

Various Federal laws provide the authority to impose administrative sanctions for fraud and abuse as well as on 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 civil monetary penalties (CMPs) for submitting false 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 2,437 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 Web site at <http://oig.hhs.gov/fraud/enforcement/cmp>.

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 to Federal district and appellate courts regarding the basis for and the length of the exclusion.

Exclusions case examples follow:

Massachusetts – Michael Galatis was excluded for a minimum period of 38 years based on his conviction for conspiracy to commit health care fraud, health care fraud, and money laundering. Galatis owned the home health agency MJG Management, d/b/a At Home VNA. According to the investigation, Galatis recruited patients to his facility and trained his nurses to complete forms to make it appear as if the recruited patients were homebound and in need of skilled nursing services. However, in actuality, the patients were not homebound and did not need skilled nursing services. Galatis submitted false claims to Medicare for the purported home health and other related services. He also diverted the proceeds from the fraud for his own personal use and benefit. As a result of his conviction, Galatis was sentenced to 7 years and 8 months in prison and ordered to pay about \$7 million in restitution.

Michigan – Pharmacist Waleed Yaghmour was excluded for a minimum period of 18 years based on his conviction for conspiracy to distribute and possess with intent to distribute controlled substances and monetary transactions in property derived from specified unlawful activity. Yaghmour owned and operated Sav-Mart Pharmacy in Detroit, Michigan. He conspired with other individuals to bring him fraudulent prescriptions, to which he dispensed controlled substances with no legitimate medical purpose. Yaghmour then received cash payments for illegally dispensing the controlled substances. He was sentenced to 6 years of incarceration.

Indiana – Lance Anglin was excluded for a minimum period of 20 years based on his conviction for criminal deviate conduct. While working in a group home, Anglin instructed a mentally retarded patient to perform oral sex on him in the group home’s living room. As a result of his conviction, Anglin was sentenced to 10 years of incarceration.

Florida – Sircy Sacerio was excluded for a minimum period of 15 years based on his conviction for conspiracy to commit mail fraud and mail fraud. Sacerio worked as a receptionist/office assistant/registered chiropractic assistant for a chiropractic center that submitted fraudulent claims for chiropractic and massage treatments for individuals who participated in staged automobile accidents. Sacerio helped recruit individuals to participate in staged automobile accidents, instruct those recruited on how to participate in the accident and on how to collect police reports, and told them what clinics they should go to for treatment (even though treatment was not needed). In addition, Sacerio prepared fraudulent insurance documentation for chiropractic and massage therapy treatments for those involved in the staged accidents, knowing that the treatments were not medically necessary or received. The false claims were then submitted to various automobile insurance companies. As a result of his conviction, Sacerio was sentenced to 4 years in prison and ordered to pay about \$1.1 million in restitution.

Suspensions and debarments

Suspensions and debarments are administrative tools used by HHS and other Federal agencies to protect the Government from individuals and entities that have engaged in contract fraud, that have misused grant funds, or that are otherwise not presently responsible. Because these are Government-wide sanctions, an individual or entity that has been suspended or debarred by HHS or any other agency is ineligible 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.

Two debarment examples follow:

Missouri – Cheryl A. White, former chief executive officer of Southeast Missouri Health Network, was debarred for a 5-year period based on her conviction for criminal conspiracy. Southeast Missouri Health is a nonprofit, federally qualified health center that provides health services in six counties in southeast Missouri. Between 2004 and 2009, White submitted false statements to the Government in order to obtain Federal grant funds on Southeast Missouri Health’s behalf from the Health Resources and Services Administration. Once the funds were secured, White further abused her position of trust by personally using and allowing her employees to use this nonprofit health center’s funds to purchase personal items and services, such as household furniture, clothing, and a designer wallet. Moreover, White took various measures to obstruct auditors from discovering her improper business practices. Based on her scheme, White was sentenced to 2 years and 9 months of incarceration, and ordered to pay over \$103,000 in restitution.

Indiana – Christina Lynn-Wright, director of fiscal operations for the Indiana Association for Child Care Resource and Referral, was debarred for a 3-year period based on her criminal theft conviction. Indiana Association is an indirect recipient of Federal grant funds from the Administration for Children and Families, and its mission is to perform advocacy services for local families to ensure the availability of high-quality and affordable child care. Lynn-Wright used her position of trust to write 88 association checks totaling over \$160,000 to herself for her own personal use and benefit. She was sentenced to 2 years of home detention and ordered to pay \$161,477 in restitution.

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 \$31.9 million in CMPs and assessments.

The following are case examples:

New Jersey – Sandoz, Inc. agreed to pay \$12.6 million to settle allegations that it misrepresented drug pricing data to the Medicare Program. Sandoz, a division of Novartis Pharmaceuticals and one of the world's largest generic drug manufacturers, markets hundreds of generic medications in the United States. Under Federal law, drug makers must report both accurate and timely average sales price information to CMS. CMS uses this information to set payment amounts for most drugs covered under Medicare Part B. OIG alleged that Sandoz failed to submit accurate average sales price data to CMS for each quarter from January 2010 through March 2012. OIG previously pursued CMPs against Sandoz for late reporting of drug pricing information to CMS. That case was settled in December 2011 with Sandoz agreeing to a \$230,000 settlement. The 2015 Sandoz settlement is the largest ever under OIG's drug price reporting CMP authority.

Florida – Timothy Fennell, a licensed mental health counselor, agreed to pay \$120,000 to settle allegations that he submitted false claims to Medicare for psychotherapy and other services rendered at his former company, Lakemont Clinic. OIG alleged that Fennell used the provider information of an Orlando-area physician to enroll in Medicare and submit claims for services that were neither rendered nor supervised by a physician. Fennell also agreed to be excluded for 12 years.

Iowa – Accurate Home Care, LLC agreed to pay \$334,651 for allegedly violating the CMPL. OIG contended that from October 12, 2010, through June 25, 2013, Accurate billed for items and services provided by an excluded nurse. As part of the settlement, Accurate certified that it has in place policies and procedures to prevent the hiring of, or contracting with, any excluded individual or entity.

Patient Dumping

Some of the CMPL cases that OIG resolved between April 1, 2015, and September 30, 2015, 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.

A case example follows:

Kansas – Newton Healthcare Corporation d/b/a Newton Medical Center (NMC) agreed to pay \$45,000 to resolve its liability under EMTALA. OIG alleged that NMC failed to provide an adequate medical screening examination for a patient who arrived at its emergency department 38 weeks pregnant and complaining of abdominal and lower back pain. OIG contended that NMC did not record the patient’s medical history, take any vitals, conduct fetal monitoring, test for fetal movement, or perform any exam on the patient. Instead, OIG alleged that NMC instructed the patient to leave and see her personal physician. The patient left NMC by private vehicle and arrived at the emergency department of another hospital, where she was admitted and delivered a stillborn baby.

Provider self-disclosure protocol

OIG is committed to assisting health care providers and suppliers in detecting and preventing fraud and abuse. Since 1998, we have made available comprehensive guidelines describing the protocol for providers to voluntarily submit to OIG self-disclosures of fraud, waste, or abuse. The provider self-disclosure protocol gives providers an opportunity to minimize the potential costs and disruption that a full-scale OIG audit or investigation might entail if fraud were uncovered. The self-disclosure also allows the provider to negotiate a fair monetary settlement and potentially avoid being excluded from participating in Federal health care programs.

The protocol guides providers and suppliers through the process of structuring a disclosure to OIG about matters that constitute potential violations of Federal laws. After making an initial disclosure, the provider or supplier is expected to thoroughly investigate the nature and cause of the matters uncovered and to make a reliable assessment as to their economic impact. OIG evaluates the reported results of each internal investigation to determine the appropriate course of action. The self-disclosure guidelines are available on the OIG Web site at <https://oig.hhs.gov/compliance/self-disclosure-info/index.asp>.

During this semiannual reporting period, self-disclosure cases resulted in over \$46.8 million in HHS receivables.

These are examples of provider self-disclosure settlements:

Georgia – Theratech, Inc., self-disclosed to OIG that it submitted claims to Medicare for transcutaneous electrical nerve stimulators (TENS) units and related supplies without adequate documentation. Specifically, Theratech, a durable medical equipment supplier, disclosed that from July 1, 2008, through March 31, 2014, it submitted claims for TENS units without a detailed physician order and without adequate clinical documentation from the patient’s medical record to support medical necessity and coverage. Theratech agreed to pay \$6,646,911 to resolve its liability under the CMPL.

Alabama – Vantage Oncology, LLC, Radiation Oncology Services of America, Inc. (ROSA), ROSA of Southern Alabama, LLC, and ROSA of Eastern Shore, LLC (collectively, “Vantage”) and Gulf Coast Cancer Center, Monroeville Radiation-Oncology, P.C., South Alabama Radiation Oncology, P.C., Eastern Shore Radiation Oncology, P.C., and William Hixon, M.D. (collectively, “Gulf Coast”) concurrently disclosed to OIG that they submitted claims to various Federal health care programs for radiation oncology services at five different radiation oncology centers in southern Alabama that were not provided as claimed. Specifically, Vantage and Gulf Coast disclosed that, between December 13, 2007, and December 13, 2013, they filed claims to Medicare, Medicaid, and other Federal health care programs for radiation

oncology and related services—without appropriate physician supervision or timely physician review, or both. Vantage and Gulf Coast agreed to pay \$9,561,998 and \$2,557,824, respectively, to resolve their liability under the CMPL.

Texas – Wael Asi, M.D., P.A., d/b/a Respiratory and Sleep Disorder Specialists (RSDS), self-disclosed that it submitted claims to Medicare for services performed at a joint venture facility that does not participate in the Medicare program. Specifically, RSDS disclosed that, between June 2013 and September 2014, it treated 202 Medicare patients at the nonparticipating joint venture sleep lab and billed those services to Medicare under RSDS's National Provider Identifier (NPI) number as though the services had been performed at a Medicare participating facility. RSDS agreed to pay \$152,821 to resolve its liability under the CMPL.

New Jersey – Premier Urology Associates, LLC self-disclosed that it improperly submitted claims to Medicare, Medicaid, and TRICARE. Specifically, Premier disclosed that it (1) submitted claims where the services were provided by a physician assistant and failed to meet “incident to” physician supervision requirements; (2) submitted claims using Modifier 25 for evaluation and management (E&M) services, where medical record documentation did not support the separate E&M service charge; and (3) submitted separate claims for services, when the services were already covered by global surgical package claims submitted by Premier. Premier agreed to pay \$266,882 to resolve its liability under the CMPL.

Public health agencies and enforcement activities

Public health agencies

Food and Drug Administration

- *FDA Has Made Progress on Oversight and Inspections of Manufacturers of Generic Drugs (OEI-01-13-00600 <http://oig.hhs.gov/oei/reports/oei-01-13-00600.pdf>) May 2015*

We found that the FDA has increased preapproval inspections for manufacturers of generic drugs and has made progress toward other inspection-based performance goals. However, FDA did not conduct all requested preapproval inspections and has not yet used its authority to request records in lieu or in advance of an inspection. These findings highlight areas where FDA can improve oversight over manufacturers of generic drugs. FDA concurred with all three of our recommendations, which were to:

- conduct outstanding preapproval inspections of manufacturers of generic drugs;
- ensure compliance with the requirement for manufacturers of generic drugs to register with FDA; and
- use its authority to request records in lieu of or in advance of an inspection.

Health Resources and Services Administration

- *Information Security at the Health Resources and Services Administration Needs Improvement Because Controls Were Not Fully Implemented and Monitored (A-18-14-30430 <http://oig.hhs.gov/oas/reports/region1/181430430.pdf>) April 2015*

We assessed the adequacy of Health Resources and Services Administration (HRSA) information security controls. Specifically, we reviewed controls over inventory management, patch management, antivirus management, event management, logical access, encryption, configuration management, Web vulnerability management, and Universal Serial Bus port control management.

We found that HRSA had not fully implemented or monitored some information security controls. This report summarized our recommendations because of the sensitive nature of the information discussed. We provided more detailed recommendations to HRSA.

HRSA concurred or partially concurred with all 18 of our detailed recommendations.

Indian Health Service

- *OIG Site Visits to Indian Health Service Hospitals in the Billings, Montana Area (OEI-09-13-00280 <http://oig.hhs.gov/oei/reports/oei-09-13-00280.pdf>) August 2015*

During our onsite reviews, we observed that Blackfeet Community Hospital and Crow/Northern Cheyenne Hospital faced staffing and service limitations that impacted patient care. To address the challenges, Blackfeet Community contracted with individual providers to supplement the services provided directly by hospital staff; it used Purchased/Referred Care funds when patient-required services that could not be provided directly from hospital staff. Crow used short-term contracts to provide services in its emergency department; used Purchased/Referred Care funds, on a limited basis, to pay for patient services that were not available from IHS providers; and maintained transfer agreements with four other hospitals to link patients to the services they needed. Our observations highlight long-standing challenges in IHS facilities that affect IHS beneficiaries' access to care. Our report contains no recommendations.

National Institutes of Health

- *NIH Postaward Grant Administration and Oversight Could Be Improved (OEI-07-11-00190 <http://oig.hhs.gov/oei/reports/oei-07-11-00190.pdf>) August 2015*

We found that National Institutes of Health (NIH) grant files were largely complete, but weaknesses existed in the oversight of grantee progress. Specifically, we found weaknesses in NIH's review of progress reports. Effective oversight of grant funds is crucial to the success of programs designed to improve public health and well-being. NIH concurred with both of our recommendations, which were to:

- confirm that grants management staff ensure timely submission of required awardee reports and
- revise the NIH Policy Manual and Award Worksheet Report to require a brief narrative that documents awardee progress and whether any change in research goals may influence continued funding.

Substance Abuse and Mental Health Services Administration

- *SAMHSA Has Improved Outcome Reporting for the Substance Abuse Prevention and Treatment Block Grant (OEI-04-12-00160 <http://oig.hhs.gov/oei/reports/oei-04-12-00160.pdf>) June 2015*

We found that the Substance Abuse and Mental Health Services Administration's (SAMHSA) efforts to improve outcome measurement for the Substance Abuse Prevention and Treatment Block Grant program achieved nearly complete reporting compliance by the grantees in our review. We also found that SAMHSA conducted onsite reviews and provided technical assistance to program grantees, in part to improve the reporting of outcomes. This memorandum report does not contain recommendations.

Information Technology Infrastructure and Operations Office

- *The Information Technology Infrastructure and Operations Office Had Inadequate Information Security Controls (A-18-14-30420 <http://oig.hhs.gov/oas/reports/region1/181430420.pdf>) April 2015*

We assessed the adequacy of the Information Technology Infrastructure and Operations Office's (ITIO) information security controls at a selection of HHS's operating divisions that are managed by ITIO. Specifically, we reviewed controls over inventory management, patch management, antivirus management, event management, logical access, encryption, configuration management, Web vulnerability management, and Universal Serial Bus port control management. We found that ITIO had not fully implemented or monitored some information security controls. This report summarized our recommendations because of the sensitive nature of the information discussed. We provided more detailed recommendations to ITIO.

ITIO concurred with all our detailed recommendations.

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, the Health Resources and Services Administration (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.

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 of 2014 (Pub. L. 113-76). The transfer was completed on July 1, 2014.

HEAL Exclusions

During this semiannual reporting period, seven 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 debts are repaid and they may not appeal the exclusions.

After being excluded for nonpayment of their HEAL debts, a cumulative 2,596 individuals chose to enter into settlement agreements or completely repay their debts. That figure includes 26 individuals who entered into such settlement agreements or completely repaid their debts during this semiannual reporting period. More than \$205 million is being repaid through settlement agreements or through complete repayment. Of that amount, \$3.3 million is attributable to this semiannual reporting period.

Practitioners in two States entered into settlement agreements to repay the amounts indicated:

- Puerto Rico – Medical Doctor - \$28,423
- Florida – Chiropractor - \$19,777

Human services agencies and enforcement activities

Administration for Children and Families

Family child day care centers and State health and safety requirements

- *Some Pennsylvania Family Child Day Care Home Providers Did Not Always Comply With State Health and Safety Requirements (A-03-14-00250 <http://oig.hhs.gov/oas/reports/region3/31400250.pdf>) May 2015*

Pennsylvania did not always ensure that providers that received Child Care and Development Funds (Administration for Children and Families, or ACF) complied with applicable State requirements related to child health and safety. Three providers complied with the State requirements, but 17 did not comply with 1 or more of the State requirements. Sixteen providers did not comply with requirements related to the physical conditions of their facilities, 14 providers did not comply with administrative requirements, and 4 providers did not comply with requirements to obtain criminal history and child protection reports. In addition, one provider falsified the renewal application by certifying that there were no prohibited criminal charges pending. We determined that the provider had pending criminal charges including, but not limited to, corruption of minors and child endangerment. When we advised Pennsylvania of the pending charges, it immediately suspended this provider.

Pennsylvania concurred with our recommendations that it:

- correct the specific health and safety issues with the providers noted in this report;
- implement policies and practices to ensure that inspections of family child day care homes are conducted before children are placed into care and that at least one annual unannounced onsite visit is conducted in accordance with new Federal requirements;
- develop and implement State regulations to require that criminal background checks are conducted at least once every 5 years in accordance with new Federal requirements;
- ensure that providers obtain required criminal background checks and child protection reports; and
- ensure adequate oversight by reducing inspector caseloads.

- *Some Pennsylvania Child Day Care Centers Did Not Always Comply With State Health and Safety Licensing Requirements (A-03-14-00251 <http://oig.hhs.gov/oas/reports/region3/31400251.pdf>) September 2015*

States must perform an initial onsite monitoring visit and at least one annual unannounced onsite visit of providers that have received Child Care and Development Fund subsidies. States must also maintain an inspector-to-provider ratio sufficient to ensure timely inspections.

Pennsylvania conducted the required inspections at all three of the providers that we reviewed and ensured that they complied with the administrative and background check requirements. However, all three providers did not comply with requirements related to the physical conditions of their child day care centers. Pennsylvania lacked a sufficient number of inspectors to identify all areas of noncompliance. Pennsylvania's average inspector-to-provider ratio was 1:143, which far exceeds the 1:50 ratio recommended by Child Care Aware of America.

Pennsylvania concurred with our recommendations that it:

- Correct the specific health and safety issues with the providers noted in this report, and
- ensure more thorough onsite monitoring of provider compliance with health and safety requirements by reducing licensing inspectors' caseloads.

The Commonwealth of Puerto Rico did not ensure that providers that received Child Care and Development Fund subsidies complied with State plan requirements related to the health and safety of children. Although Puerto Rico conducted the required inspections at all three providers that we reviewed, we found potentially hazardous conditions at the locations of the three providers, and two of the providers did not comply with requirements to obtain background checks on workers.

- *Puerto Rico Child Day Care Centers Did Not Always Comply With Commonwealth Health and Safety Requirements (A-02-14-02001 <http://oig.hhs.gov/oas/reports/region2/21402001.pdf>) September 2015*

Puerto Rico concurred with our findings, which led to our recommendations that it:

- establish binding health and safety requirements for all CCDF providers in Puerto Rico law or regulation, in accordance with the State plan;
- have procedures in place to ensure that providers receive adequate training on health and safety requirements;
- develop a single comprehensive, specific checklist to aid in the monitoring of providers for compliance with health and safety requirements, and provide all centers with the checklist;
- correct the specific health and safety issues with the three providers noted in this report; and
- ensure that providers employ only individuals with proper background certification.

- *New York Improperly Claimed Some Child Care and Development Targeted Funds (A-02-12-02012 <http://oig.hhs.gov/oas/reports/region2/21202012.pdf>) July 2015*

New York did not comply with Federal requirements for the use of almost \$3.9 million in Child Care Development Fund targeted funds for FYs 2007 through 2009. New York improperly claimed \$2.3 million of inadequately supported targeted funds, and improperly obligated \$1.5 million of targeted funds after the obligation period had ended. These errors occurred because the State agency did not have adequate fiscal controls and accounting procedures in place to ensure that expenditures complied with Federal requirements.

New York generally disagreed with our recommendations, which were that it:

- refund \$3.9 million to the Federal Government and

- establish fiscal controls and accounting procedures to ensure that targeted funds are used in compliance with Federal requirements.

Child support enforcement activities

OIG investigations

OIG works to address referrals of egregious child support enforcement cases with appropriate investigative and prosecutorial action by collaborating with ACF's Office of Child Support Enforcement, DOJ, U.S. Attorneys' Offices, the U.S. Marshals Service, and Federal, State, and local partners. OIG investigations of child support enforcement cases nationwide resulted in 23 criminal actions and court-ordered restitution and settlements of over \$1.4 million during this semiannual reporting period.

Engaging the public in capturing deadbeat parents

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

The following are examples of child support enforcement cases:

New York – Scott Persson was sentenced to 5 years of probation and ordered to pay \$136,868 in restitution after pleading guilty to failure to pay past due child support obligation. Persson was originally ordered to pay child support in August 1999. However, according to the investigation, despite the fact that he owned and operated a successful catering service in the Los Angeles, California, area, he failed to make proper child support payments. Persson was arrested in June 2013 in Los Angeles. At the time of his arrest, he admitted that he worked "off the books" to hide his money from his ex-wife, to whom he owed court-ordered child support.

New York – Kurtiss Tomasovich entered into a deferred prosecution agreement in which he will pay \$189,938 in restitution, representing the amount owed in child support arrears for his three children. Tomasovich was arrested in May 2014 for willfully failing to pay child support, despite having sufficient assets to make the required child support payments. According to the investigation, Tomasovich and his second wife purchased and developed property in Florida, including constructing a pool and tennis court at their residence. Tomasovich also published two books titled "This Time Around" and "Knowledge and Passion - A Handbook for American Living," which included a writeup in which Tomasovich claims he "became a millionaire at 30 and floated above the streets instead of treading through them." He also started a website for people to pledge to "be good Americans" and stated that "I will hold myself personally accountable and to do the right things."

Alabama – Mark Sims was sentenced to 5 years of probation and ordered to pay \$120,451 in restitution after pleading guilty to failure to pay child support. Sims was ordered to pay child support in 2003 to the custodial parents of his two minor children. However, he had not made any payments in over 2 years.

IT infrastructure reviews

- *Public Summary Report: Penetration Test of the Administration for Children and Families' Computer Networks and External Web Applications (A-18-14-30330 <http://oig.hhs.gov/oas/reports/region1/181430330.pdf>) September 2015*

We assessed the ACF network's exposure to cyberattacks by performing penetration testing of its network and Internet-facing systems. Although we did not obtain unauthorized access to the ACF network, we identified issues that could lead to a cyber security incident involving ACF systems and data, given enough time and persistence by malicious computer hackers. We identified vulnerabilities in two primary areas: selected external Web applications and wireless networks. ACF's information technology investments include systems that support operations for grants management, child support enforcement, foster care and adoption programs, and Head Start programs.

This report summarized our recommendations because of the sensitive nature of the information discussed. We provided more detailed recommendations to ACF.

ACF concurred with all of our detailed recommendations.

Other HHS-related reviews

Grants and Contracts

HHS is the largest grantmaking organization in the United States and one of the largest Federal contracting agencies. In FY 2015, HHS awarded over \$400 billion in grants and over \$21 billion in contracts across all program areas. OIG's direct annual discretionary appropriation funding is used to conduct program integrity and enforcement activities on the over 100 public health and human services programs carried out by over 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 congressional appropriations increased OIG's discretionary funding for public health and human services oversight.

Improper payments and misuse of grant funds

- *U.S. Department of Health and Human Services Met Many Requirements of the Improper Payments Information Act of 2002 but Did Not Fully Comply for Fiscal Year 2014 (A-17-15-52000 <http://oig.hhs.gov/oas/reports/region1/171552000.pdf>) May 2015*

OIG is required to review and report on HHS's annual *Agency Financial Report and Other Accompanying Information* (AFR) to determine compliance with the Improper Payments Information Act of 2002 (IPIA) as amended by the Improper Payments Elimination and Recovery Act of 2010. ("IPIA" will refer to the Act as amended by the 2010 Act.) In addition, under the Disaster Relief Appropriations Act, all programs receiving related funds must report and calculate an improper payment estimate.

HHS followed the guidance, and in general, the methodologies used by HHS to estimate improper payments were reasonable and valid, resulting in reasonable estimates. HHS also reported information on its efforts to recapture improper payments and the results of those actions.

However, HHS did not fully comply with several IPIA requirements in that it did not perform some risk assessments of payments; did not publish an improper payment estimate for the Temporary Assistance for Needy Families (TANF) program; did not publish corrective action plans for TANF; did not meet improper payment rate reduction targets for four of the six programs for which it reported reduction targets in the FY 2013 AFR (Medicare Fee-for-Service [FFS], Medicaid, Foster Care, and Child Care Development Fund); and did not report an improper payment rate of less than 10 percent for one of the eight programs deemed susceptible to improper payments (Medicare FFS) and two of the seven programs deemed susceptible to improper payments under the Disaster Relief Appropriations Act (Administration for Children and Families Social Services Block Grants and Substance Abuse and Mental Health Services Administration Grants). In addition, HHS has not been in compliance with the IPIA for four consecutive FYs for TANF and three consecutive FYs for Medicare FFS.

HHS provided a status of actions it has taken in response to our recommendations, which were:

- to fully address all of our recommendations from prior years, including the need to provide an improper payment estimate for TANF, meet improper payment rate reduction targets, and reduce improper payment error rates to below 10 percent and
 - to address a new requirement under OMB's guidance, conduct risk assessments of payments to employees and charge card payments as part of its risk assessment process for 2015.
- *The Fraud Prevention System Increased Recovery and Prevention of Improper Medicare Payments, but Updated Procedures Would Improve Reported Savings (A-01-14-00503 <http://oig.hhs.gov/oas/reports/region1/11400503.asp>) June 2015*

IG must certify the actual and projected savings with respect to improper payments recovered and avoided and the return on investment related to HHS's use of the Fraud Prevention System (FPS) for each of its first three implementation years.

In the third implementation year, HHS complied with the statutory requirements. We certified \$133.2 million of actual and projected savings and a return on investment of \$2.84 for every dollar spent on the FPS. We also certified the \$454 million in unadjusted savings that the FPS identified.

HHS conducted an evaluation of the cost-effectiveness and feasibility of applying predictive analytics technology to Medicaid and the Children's Health Insurance Program (CHIP) and determined that it is not cost-effective and feasible, at this time, to systematically expand the FPS to Medicaid and CHIP in all States. Although HHS has made significant progress to address the challenges of measuring actual and projected savings, HHS's written directives to its contractors were not sufficient to ensure that the contractors could identify and report the most accurate estimate of FPS savings.

CMS concurred with our recommendation to:

- provide its contractors with improved written instructions on how to attribute the FPS savings accurately and better document the contribution of the FPS leads toward achieving administrative actions.
- *HHS Oversight of Grantees Could Be Improved Through Better Information-Sharing (OEI-07-12-00110 <http://oig.hhs.gov/oei/reports/oei-07-12-00110.pdf>) September 2015*

Awarding agencies' grant officials use various sources of information and communication to mitigate grantee risks. However, grant officials noted limitations in some instances. Our findings raise concerns about whether awarding agencies' grant officials have all available information to assess and mitigate risks relating to poor performance and misuse of grant funds. The HHS Assistant Secretary for Financial Resources concurred with all three of our recommendations, which included:

- analyzing whether to implement the use of integrated databases that contain adverse information on grantees' past performance;
- establishing a departmentwide source of adverse information from audits of grantees; and
- facilitating departmentwide information-sharing about grantees that have past performance issues.

Misuse of grant funds case examples

Puerto Rico – Elba Bonilla-Bayon was sentenced to 5 years of probation, 600 hours of unpaid community service, and ordered to pay \$754,248 in restitution and assessment after pleading guilty to theft of government property. Bonilla-Bayon was the president of Programa Avance En Puerto Rico, a delegated agency/grantee of ACF and USDA grant funds. Bonilla-Bayon admitted that she stole and/or converted for her personal use over \$750,000 in Federal funds from Head Start/Early Head Start (HHS), Child Care Development Fund (HHS), Child and Adult Care Food (USDA), and the American Recovery and Reinvestment Act (HHS) programs. The investigation revealed that Bonilla-Bayon unlawfully negotiated and/or converted at least 93 checks for her own personal use.

Mississippi – Linda Harvey-Irvin was sentenced to 7 years and 1 month in jail and ordered to pay \$531,236 in joint and several restitution after pleading guilty to theft or bribery concerning programs receiving Federal funding. Harvey-Irvin was the deputy director of the non-profit organization Mississippi Gulf Coast Community Action Agency, a Head Start and American Recovery and Reinvestment Act grantee. According to the investigation, Harvey-Irvin embezzled Gulf Coast funds by entering into consulting work contracts on behalf of GCCAA with Markuntala Croom, the owner of Croom Management Services. Croom, who was paid \$750 per day for every day she was under contract with Gulf Coast, would in turn pay a portion of the proceeds received from this community action agency to Harvey-Irvin. Much of the work purportedly conducted by Croom was, in fact, fictitious or not actually performed. Croom received more than \$500,000 for the purported consulting work. She paid Harvey-Irvin close to \$70,000 as a reward for hiring her. In addition to her arrangement with Croom, Harvey-Irvin also rigged the bidding process for construction work paid for by Gulf Coast to ensure that Donald Walton, owner of Walton Construction, would be awarded virtually all the contracts he bid on. Walton Construction received over \$130,000 from Gulf Coast, and in turn, Walton paid Harvey-Irvin about \$31,000 as a reward for winning the bids. Both Croom and Walton pleaded guilty to theft or bribery concerning programs receiving Federal funding and were sentenced to 4 years and 9 months and 3 years and 1 month in jail, respectively.

Montana – Three members of the Rocky Boy Health Board Clinic in Box Elder, Montana, were sentenced to a combined 3 years in prison and ordered to pay a combined \$131,948 in restitution after being convicted on different embezzlement schemes. Rocky Boy is a health facility for the Chippewa Cree Tribe community and receives funds from the Indian Health Service. According to the investigations, Rocky Boy Finance Manager Theodora Morsette regularly accessed tribal coffers for payments over and above her salary and supplemental compensation package. Rocky Boy director Fawn Ann Tadios expended tribal travel funds from the health clinic to purportedly make “site visits” to the Yankton Indian Health Service facility in South Dakota when, in actuality, she was visiting her incarcerated husband. Wilford Sunchild, the director for Rocky Boy’s Wellness Center, deposited tribal funds in an account over which he had control and then withdrew the funds for his own personal use. The investigations were conducted as part of Operation Smoke and Mirrors, a joint operation among OIG’s Office of Investigations, Office of Audit, and Office of Evaluation and Inspections.

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 to it related to fraud, waste, or abuse in the Small Business Innovative Research/Small Business Technology Transfer (SBIR/STTR) programs well as on the action(s)

taken in each case, the justification for not taking action on a case, and an accounting of funds used to address program waste, fraud, and abuse. In our November 2014 report delivered to the three Congressional oversight committees, we reported that OIG spent about \$236,860 in salaries on oversight related to the SBIR/STTR program. HHS referred 13 new SBIR/STTR cases to OIG in FY 2014. OIG will include the 2015 report information in our spring 2016 Semiannual Report.

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.

OIG did not discontinue or decline to conduct any Recovery Act whistleblower retaliation complaint investigations during this reporting period.

Hurricane Sandy

- *Medical Reserve Corps Volunteers in New York and New Jersey During Superstorm Sandy.* (OEI-04-13-00350 <http://oig.hhs.gov/oei/reports/oei-04-13-00350.pdf>) May 2015

We found that Medical Reserve Corps (MRC) stakeholders reported challenges and successes during Superstorm Sandy that were most frequently associated with communication, shelter staffing, and shelter operations. Although our review was limited to the MRC response in New York and New Jersey, these reported challenges highlight issues that other States may encounter while using MRC volunteers during future incident responses. Conversely, the successes that MRC stakeholders identified may highlight practices for States, including New York and New Jersey, to improve their future responses. The HHS Assistant Secretary for Preparedness and Response concurred with our three recommendations to work with States and localities to strengthen plans for:

- volunteer communication;
- shelter staffing; and
- shelter operations.

Office for Civil Rights

- *OCR Should Strengthen Its Oversight of Covered Entities' Compliance with the HIPAA Privacy Standards* (OEI-09-10-00510 <http://oig.hhs.gov/oei/reports/oei-09-10-00510.pdf>) September 2015

The Office for Civil Rights (OCR) should strengthen its oversight of covered entity compliance with Health Insurance Portability and Accountability Act (HIPAA) Privacy standards. OCR primarily investigates possible noncompliance in response to complaints and has not fully implemented an audit program to proactively identify noncompliance. In addition, OCR did not include complete documentation of

corrective actions in 26 percent of cases, and 29 percent of staff reported rarely or never checking whether covered entities had been previously investigated. Finally, OCR's case-tracking system had limited search functionality. These findings highlight the need for OCR to strengthen its oversight of covered entities' safeguarding of health information. OCR concurred with all five of our recommendations, which include:

- fully implement a permanent audit program;
- maintain complete documentation of corrective action in OCR's case-tracking system;
- develop an efficient method in OCR's case-tracking system to search for and track covered entities' histories of being investigated;
- develop a policy requiring OCR staff to check whether covered entities have been previously investigated; and
- continue to expand outreach and education efforts to covered entities.

■ *OCR Should Strengthen Its Followup of Breaches of Patient Health Information Reported by Covered Entities (OEI-09-10-00511 <http://oig.hhs.gov/oei/reports/oei-09-10-00511.pdf>) September 2015*

OCR should strengthen its followup of breaches of protected health information (PHI) that covered entities report to OCR. OCR had incomplete documentation of corrective action in 23 percent of cases, did not record small-breach information in its case-tracking system, and did not investigate small breaches during the period of our review from September 23, 2009, to March 31, 2011. Further, 39 percent of OCR staff reported rarely or never checking whether covered entities reported prior breaches during breach investigations. These findings raise questions about whether OCR is identifying systemic weaknesses resulting in breaches and whether covered entities are addressing the problems that led to the breaches. OCR concurred with all five of our recommendations, which include:

- maintain complete documentation of corrective action in OCR's case-tracking system;
- enter small-breach information into OCR's case-tracking system or a searchable database linked to it;
- develop an efficient method in OCR's case-tracking system to search for covered entities that reported prior breaches;
- develop a policy requiring OCR staff to check for prior breaches; and
- continue to expand outreach and education efforts to covered entities.

Contract audits

Pursuant to the National Defense Authorization Act for Fiscal Year 2008, § 845, OIGs appointed under the Inspector General Act of 1978 are required to submit, as part of their Semiannual Report(s) to Congress information on final, completed contract audit reports issued to the contracting activity. This information must contain significant audit findings issued during the period covered by the semiannual report. This requirement is pursuant to Section 5 of such Act.

OIG did not issue 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 694 reports covering \$2 trillion in audited costs. Federal dollars covered by these audits totaled \$624.5 billion, of which about \$285 billion were HHS funds.

Office of Management and Budget Circular A-133 establishes audit requirements for State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards. Under this circular, 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. This oversight also identifies any significant internal control weakness, noncompliance, and questioned costs for resolution or follow-up.

We identify entities for high-risk monitoring, alert program officials to any trends that could indicate problems in HHS programs, and profile non-Federal audit findings of a particular program or activity over time to identify systemic problems. We also provide training and technical assistance to grantees and members of the auditing profession.

OIG maintains a process to assess the quality of the non-Federal reports received and the audit work that supports the selected reports. OIG’s reports on non-Federal audits reviewed during this reporting period are categorized in the table below.

Non-Federal Audits
April 1, 2015, through September 30, 2015

	Number
Not requiring changes or having minor changes	635
Requiring major changes	55
Having significant technical inadequacies	4
Total	694

The 694 reports included 1,836 recommendations for improving management operations. In addition, these audit reports provided information for 14 OIG special memorandums that identified concerns for increased monitoring by management.

- *Public Summary Report: The Centers for Medicare & Medicaid Services' Implementation of Security Controls Over the Multidimensional Insurance Data Analytics System Needs Improvement* (A-06-14-00067 <http://oig.hhs.gov/oas/reports/region6/61400067.pdf>) September 2015

Although CMS had implemented controls to secure the Multidimensional Insurance Data Analytics System (MIDAS) and consumer PII data in the systems and databases we reviewed, we identified areas for improvement in MIDAS's information security controls. The MIDAS is a central repository for insurance-related data intended to provide reporting and performance metrics to HHS for various initiatives mandated by the Affordable Care Act. At the time of our fieldwork, CMS had neither disabled unnecessary generic accounts in its test environment, encrypted user sessions, conducted automated vulnerability assessments that simulate known attacks, nor used a shared read-only account for access to the database that contained the PII.

In addition to the information security control vulnerabilities mentioned above, our database vulnerability scans identified 22 high, 62 medium, and 51 low vulnerabilities. We made recommendations relevant to the issues we identified.

CMS concurred with all of our recommendations. CMS reported that it remediated all vulnerabilities and addressed all findings we identified before we issued our final report. We have since reviewed the supporting documentation and verified CMS's remediation.

- *Public Summary Report: Penetration Test of the Administration for Children and Families' Computer Networks and External Web Applications (A-18-14-30330*
<http://oig.hhs.gov/oas/reports/region1/181430330.pdf>) September 2015

We assessed the ACF network's exposure to cyberattacks by performing penetration testing of its network and Internet-facing systems. Although we did not obtain unauthorized access to the ACF network, we identified issues that could lead to a cyber security incident involving ACF systems and data, given enough time and persistence by malicious computer hackers. We identified vulnerabilities in two primary areas: selected external Web applications and wireless networks. ACF's information technology investments include systems that support operations for grants management, child support enforcement, foster care and adoption programs, and Head Start programs.

This report summarized our recommendations because of the sensitive nature of the information discussed. We provided more detailed recommendations to ACF.

ACF concurred with all of our detailed recommendations.

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*
<http://oig.hhs.gov/oas/reports/region4/41406175.pdf>) 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 on HHS's programs and operations and to make recommendations concerning their impact on program economy and efficiency or the prevention and detection of fraud, waste, 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. (<http://oig.hhs.gov/reports-and-publications/semiannual/index.asp>)
- Our *Compendium of Priority Recommendations* describes priority findings and recommendations from past periods that remain to be implemented. (<http://oig.hhs.gov/reports-and-publications/compendium/index.asp>)
- Our annual *Work Plan*, published at the start of each fiscal year, provides citations to laws and regulations that are the subject of ongoing or future reviews. (<http://oig.hhs.gov/reports-and-publications/workplan/index.asp>)

We also review proposed legislation and regulations related to HHS programs and operations. HHS routinely involves us and its operating and 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.

Affordable Care Act implementation

OIG continues to review programs implemented pursuant to the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (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 the Government Accountability Office and other Federal and State oversight agencies.

Examples of our recent ACA reviews follow.

Marketplaces

- *Early Alert: Without Clearer Guidance, Marketplaces Might Use Federal Funding Assistance for Operational Costs When Prohibited by Law (A-01-14-02509* <http://oig.hhs.gov/oas/reports/region1/11402509.pdf>) April 2015

The ACA establishes a clear prohibition that private health insurance marketplaces cannot use grant funds to support ongoing operations after January 1, 2015. We have concerns that, without more detailed guidance from CMS, State-based marketplaces (state marketplaces) might have used, and might continue to use, establishment grant funds for operating expenses after January 1, 2015, contrary to law. Some state marketplaces face uncertain operating revenues in 2015 and in future years. Thus, there a risk that state marketplaces might use establishment grant funds to cover operational costs.

We encouraged CMS to:

- consider developing and publishing clear guidance on what constitutes (1) operational costs and (2) design, development, and implementation costs;

- review state marketplace plans for using establishment grant funds to ensure that the guidance addresses real-world examples; and
- monitor state marketplaces' use or potential use of establishment grant funds for operational costs and take appropriate action.

■ *CMS's Internal Controls Did Not Effectively Ensure the Accuracy of Aggregate Financial Assistance Payments Made to Qualified Health Plan Issuers Under the Affordable Care Act (A-02-14-02006 <http://oig.hhs.gov/oas/reports/region2/21402006.pdf>) June 2015*

CMS's internal controls did not effectively ensure the accuracy of nearly \$2.8 billion in aggregate financial assistance payments made to insurance companies under the ACA during the first 4 months that these payments were made. CMS's reliance on issuer attestations did not ensure that advance cost-sharing reduction (CSR) payment rates identified as outliers were appropriate. Moreover, CMS did not have systems in place to ensure that financial assistance payments were made on behalf of confirmed enrollees and in the correct amounts and that State marketplaces could submit enrollee eligibility data for financial assistance payments. Furthermore, CMS did not always follow its guidance for calculating advance CSR payments and does not plan to perform a timely reconciliation of these payments.

CMS concurred or generally concurred with all our recommendations that it:

- correct these internal control deficiencies by requiring its Office of the Actuary to review and validate qualified health plan (QHP) issuers' actuarial support for index rates that CMS identifies as outliers;
- implement computerized systems to maintain confirmed enrollee and payment information so that CMS does not have to rely on QHP issuers' attestations in calculating payments;
- implement a computerized system so State marketplaces can submit enrollee eligibility data;
- follow CMS guidance for calculating estimated advance CSR payments; and
- develop interim reconciliation procedures to address potentially inappropriate CSR payments.

■ *Not All Internal Controls Implemented by the New York Marketplace Were Effective in Ensuring That Individuals Were Enrolled in Qualified Health Plans According to Federal Requirements (A-02-14-02020 <http://oig.hhs.gov/oas/reports/region2/21402020.pdf>) September 2015*

Not all of the New York health insurance exchange's (marketplace) internal controls were effective in ensuring that individuals were enrolled in QHPs according to Federal requirements. QHPs are private health insurance plans that each marketplace recognizes and certifies as meeting certain participation standards and covering a core set of benefits.

In CY 2014, certain internal controls were effective, such as the controls for verifying the applicant's Social Security number through the Social Security Administration. However, the internal controls were not always effective for verifying annual household income, resolving inconsistencies in eligibility data, and verifying eligibility for minimum essential coverage through employer-sponsored insurance (ESI) and ensuring that insurance affordability programs were authorized only for individuals who do not have ESI.

New York concurred with all of our recommendations to:

- modify its eligibility and enrollment system to always verify annual household income properly;
- use existing system functionality to resolve inconsistencies in eligibility data;

- ensure that the State follows requirements to verify applicants' eligibility for minimum essential coverage through ESI and that applicants who are eligible for minimum essential coverage through ESI are not determined eligible for advance premium tax credits and cost-sharing reductions; and
- redetermine, if necessary, the eligibility of the sample applicants for whom we determined that verifications were not performed according to Federal requirements.

■ *CMS Did Not Always Manage and Oversee Contractor Performance for the Federal Marketplace as Required by Federal Requirements and Contract Terms (A-03-14-03001 <http://oig.hhs.gov/oas/reports/region3/31403001.pdf>) September 2015*

We reviewed 20 of 62 contracts that CMS identified as awarded for the development, implementation, and operation of the Federal marketplace to determine the contract requirements for monitoring and overseeing contractor performance. Contracting officers and contracting officer's representatives did not always manage and oversee contractor performance as required by Federal requirements and contract terms. CMS did not always comply with Federal regulations regarding designation and certification requirements for contracting officer's representatives. Also, contracting records did not always include all critical contract deliverables and other management and oversight documentation.

Because CMS did not always provide adequate contract management and oversight for Federal marketplace contracts, a number of issues ensued: contractor delays and performance issues were not always identified, a contractor incurred unauthorized costs that increased the cost of the contract, contracting officers in all Government agencies did not have access to contractor past-performance evaluations when making contract awards, and critical deliverables and management decisions were not properly documented.

CMS concurred with our recommendations that it:

- direct contracting officers and contracting officer's representatives to comply with Federal regulations and contract terms by ensuring that all contract deliverables are received and are used in their contract management and oversight;
- direct acquisition personnel not to authorize additional work on contracts until the work is approved by the contracting officer and properly funded;
- direct contracting officers to prepare and submit contractor past-performance evaluations at least annually and at the conclusion of the contract;
- direct contracting officers to designate and authorize contracting officer's representatives in writing and identify their specific duties, responsibilities, and limitations for each contract they manage and oversee; and
- require all acquisition personnel to disclose their past-employment relationships.

■ *CMS Did Not Identify All Federal Marketplace Contract Costs and Did Not Properly Validate the Amount to Withhold for Defect Resolution on the Principal Federal Marketplace Contract (A-03-14-03002 <http://oig.hhs.gov/oas/reports/region3/31403002.pdf>) September 2015*

CMS did not accurately identify all obligations and expenditures related to the Federal marketplace. We reviewed the 62 contracts that CMS identified as awarded for the development, implementation, and operation of the Federal marketplace to determine the contract requirements for the processing and payment of contractor invoices. For six of the contracts, CMS recorded \$24.3 million of obligations and \$22.9 million of expenditures; but it did not identify either as being related to the Federal marketplace.

Consequently, CMS is unable to accurately account for and report to interested stakeholders the amount spent on the development, implementation, and operation of the Federal marketplace.

Generally, contractors invoiced and CMS paid Federal marketplace contracts correctly. Although CMS withheld fixed fees that CGI Federal identified as being related to defect resolution and rework, CMS did not validate the accuracy of the amount (\$267,000). CGI Federal Inc. did not agree that the work was related to correcting defects or rework, and CMS had not made a final decision about the fixed-fee payment that it withheld. At the time of our review, CGI Federal had not filed a certified claim under the Contract Disputes Act.

CMS agreed with our recommendation that it:

- include all relevant contract costs when it identifies total obligations and expenditures related to the design, development, and operation of the Federal marketplace.

CMS did not agree with our recommendation that it review all charges submitted by CGI Federal for the federally facilitated marketplace contract and that it make a final determination on the appropriate amount to withhold for correcting defects by validating the \$267,000 withheld for the fixed fee.

Medicaid payment suspension

- *Ohio Did Not Always Comply With the Requirements of the Affordable Care Act in its Review of Cases of Credible Allegations of Medicaid Fraud (A-05-14-00008 <http://oig.hhs.gov/oas/reports/region5/51400008.asp>) March 2015*

Ohio did not always comply with the requirements of the ACA in its review of cases for which there were credible allegations of fraud between July 1, 2011, and June 30, 2013. Of the 401 cases for which Ohio found credible allegations of fraud by Medicaid providers, the State provided good cause to not suspend payments in 321 cases. For the remaining 80 cases, Ohio suspended payments to the Medicaid providers but continued to pay claims associated with 24 of the 80 cases and received Federal reimbursement totaling about \$97,000.

Ohio concurred with our recommendation, which was to:

- properly suspend all Medicaid payments to a provider when the State determines that there is a credible allegation of fraud in accordance with Federal requirements.

Information technology

- *California Implemented Security Controls Over the Web Site and Databases for Its Health Insurance Exchange but Could Improve Protection of Personally Identifiable Information (A-09-14-03005 <http://oig.hhs.gov/oas/reports/region9/91403005.pdf>) April 2015*

Covered California, California's health insurance exchange, implemented security controls over the Web site and databases for its health insurance exchange, but improvements are needed to fully comply with Federal requirements and to increase protection of PII.

We reviewed Covered California's information security controls in place as of June 2014. Covered California had implemented security controls, including policies and procedures, to protect PII on its Web site and databases. But the exchange had not performed a vulnerability scan in accordance with Federal requirements. Also, Covered California's security plan did not meet some of CMS's minimum requirements for protection of marketplace systems, and Covered California did not have secure settings for some user accounts.

Covered California concurred with all our detailed recommendations.

- *Public Summary Report: The Centers for Medicare & Medicaid Services' Implementation of Security Controls Over the Multidimensional Insurance Data Analytics System Needs Improvement (A-06-14-00067 <http://oig.hhs.gov/oas/reports/region6/61400067.pdf>)* September 2015

Although CMS had implemented controls to secure the Multidimensional Insurance Data Analytics System (MIDAS) and consumer PII data in the systems and databases we reviewed, we identified areas for improvement in the MIDAS information security controls. The MIDAS is a central repository for insurance-related data intended to provide reporting and performance metrics to HHS for various initiatives mandated by the ACA. At the time of our fieldwork, CMS had not disabled unnecessary generic accounts in its test environment, had not encrypted user sessions, had not conducted automated vulnerability assessments that simulate known attacks, or used a shared read-only account for access to the database that contained the PII.

In addition to the information security control vulnerabilities mentioned above, our database vulnerability scans identified 22 high, 62 medium, and 51 low vulnerabilities. We made related recommendations to address the issues we identified.

CMS concurred with all of our recommendations. CMS reported that it remediated all vulnerabilities and addressed all findings we identified before we issued our final report. We have since reviewed the supporting documentation and verified CMS's remediation.

Establishment grants

- *Maryland Misallocated Millions to Establishment Grants for a Health Insurance Marketplace (A-01-14-02503 <http://oig.hhs.gov/oas/reports/region1/11402503.pdf>)* March 2015

Maryland did not allocate costs to its establishment grants and Medicaid in accordance with Federal requirements, the terms and conditions of the establishment grants, and its Cost Allocation Plan. Maryland allocated a total of \$76.6 million to its establishment grants on the basis of a cost allocation methodology that (1) did not prospectively use updated or better data when available and (2) included a material defect. As a result, Maryland misallocated \$28.4 million in costs to the establishment grants instead of to Medicaid.

Maryland did not concur with our recommendations to:

- refund \$15.9 million that was misallocated to cooperative agreements;
- refund \$12.5 million that was misallocated to establishment grants; and
- immediately amend the Cost Allocation Plan and the Advance Planning Document for July 1 through December 31, 2014, so that allocated costs correspond to the relative benefits received.

- develop a written policy that explains how to calculate cost allocations and that emphasizes using updated and actual data and
- oversee operations to ensure the identification and correction of enrollment projection errors, the use of better or updated enrollment data, and the application of these data to allocate costs.

Community Health Center Fund

- *Lone Star Circle of Care Complied With Federal Requirements Related to Its Affordable Care Act-Funded Community Health Center Fund Grant (A-06-14-00058 <http://oig.hhs.gov/oas/reports/region6/61400058.pdf>) April 2015*
- *East Harlem Council for Human Services, Inc., Complied With Federal Requirements Related to Its Affordable Care Act-Funded Community Health Center Fund Grant (A-02-14-02021 <http://oig.hhs.gov/oas/reports/region2/21402021.pdf>) May 2015*
- *Chase Brexton Health Care Complied With the Requirements of a Community Health Center Grant Funded Under the Affordable Care Act (A-03-14-03303 <http://oig.hhs.gov/oas/reports/region3/31403303.pdf>) May 2015*
- *Community of Hope Generally Complied With the Requirements of a Capital Development Grant Funded Under the Affordable Care Act (A-03-14-03304 <http://oig.hhs.gov/oas/reports/region3/31403304.pdf>) August 2015*

We are conducting a series of reviews of certain grants for expansion and construction projects administered by HRSA and awarded under the ACA-funded Community Health Center Fund because of the risks associated with them. Lone Star Circle of Care, East Harlem Council for Human Services, Inc., and Chase Brexton Health Care had adequate financial management controls over capital development grant funds, followed procurement standards in accordance with Federal requirements, met reporting requirements in accordance with their individual grant's terms and conditions, and claimed allowable costs for construction. East Harlem and Chase Brexton also generally met grant-established project milestone dates. Although Lone Star did not meet its grant-established project milestone dates, it had reasonable justification for the delays that occurred. Accordingly, these reports contained no recommendations.

Community of Hope, in the District of Columbia, generally complied with applicable Federal requirements and the terms and conditions of the grant. However, Community of Hope did not request approval before making significant changes in its approved budget.

HRSA concurred with our recommendation that it work with Community of Hope to ensure compliance with grant terms and conditions, including approval for the re-budgeting of approved costs.

Eligibility

- *Not All of the Federally Facilitated Marketplace's Internal Controls Were Effective in Ensuring That Individuals Were Properly Determined Eligible for Qualified Health Plans and Insurance Affordability Programs (A-09-14-01011 <http://oig.hhs.gov/oas/reports/region9/91401011.pdf>) August 2015*

Certain Federal marketplace controls over eligibility for qualified health plans (QHPs) were effective, such as the controls for verifying applicants' incarceration status, but other controls were not. The Federal marketplace had deficiencies related to verifying applicants' eligibility and to resolving and expiring inconsistencies. ("Expiring" an inconsistency means making a determination about an applicant's eligibility generally on the basis of available data sources when a marketplace is unable to resolve the inconsistency.)

We also identified procedures related to resolving inconsistencies that could be improved. The Federal marketplace (1) resolved inconsistencies related to annual household income on the basis of applicants' responses to income discrepancy questions, using a higher threshold than the threshold used to initially verify income and (2) extended inconsistency periods indefinitely for the CY 2014 coverage period on the basis of applicants' good-faith efforts to obtain required documentation.

CMS concurred with all of our recommendations that it:

- take action to improve the Federal marketplace's internal controls related to verifying applicants' eligibility and to resolving and expiring inconsistencies addressing the specific deficiencies we identified;
- redetermine, if necessary, the eligibility of the sample applicants for whom we determined that the verification of eligibility and resolutions and the expiration of inconsistencies were not performed according to Federal requirements; and
- improve procedures related to resolving inconsistencies.

Consumer Operated and Oriented Plan

 *Actual Enrollment and Profitability Was Lower Than Projections Made by the Consumer Operated and Oriented Plans and Might Affect Their Ability to Repay Loans Provided Under the Affordable Care Act (A-05-14-00055 <http://oig.hhs.gov/oas/reports/region5/51400055.pdf>) July 2015*

The Affordable Care Act established the Consumer Operated and Oriented Plan (CO-OP) program and directed the Secretary of HHS to provide loans to help establish new consumer-governed, nonprofit health insurance issuers, or CO-OPs, in every State. Factors such as low enrollments and net losses could limit the ability of some CO-OPs to repay startup and solvency loans and to remain viable and sustainable.

Most of the 23 CO-OPs we reviewed had not met their initial program enrollment and profitability projections as of December 31, 2014. Member enrollment for 13 of the 23 CO-OPs that provided health insurance in 2014 was considerably lower than the CO-OP's initial projections, and 21 of the 23 CO-OPs had incurred net losses as of December 31, 2014. Although CMS recently placed four CO-OPs on enhanced oversight or corrective action plans and two CO-OPs on low-enrollment warning notifications, CMS had not established guidance or criteria to assess whether a CO-OP was viable or sustainable.

CMS concurred with our recommendations that it:

- continue to place underperforming CO-OPs on enhanced oversight or corrective action plans,
- work with State insurance regulators to identify and correct underperforming CO-OPs,

- provide guidance or establish criteria to determine when a CO-OP is no longer viable or sustainable, and
- pursue available remedies for recovery of funds from terminated CO-OPs.

Appendixes

- A Savings Decisions Supported by OIG Recommendations
- B Questioned Costs and Funds to Be Put to Better Use
- 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 Office of Inspector General (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 \$20.6 billion was attributed to FY 2015. 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)
<p>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.</p>	<p>Section 3201 of the Patient Protection and Affordable Care Act (ACA) reduced the Medicare Advantage (MA) benchmark percentages that are applied to Medicare fee-for-service, resulting in cost savings for Medicare Part C as compared to prior law. CBO estimated Part C savings through FY 2019, including \$16.7 billion for FY 2015. CBO produced its estimate in 2010, prior to two significant implementation decisions by HHS that affect the actual savings; however, neither CBO nor HHS has calculated a revised estimate.⁴</p>	<p>\$16,700</p>

⁴ One implementation decision related to a nationwide quality bonus payment demonstration, which GAO found would reduce MA savings. (See U.S. General Accountability Office, *Medicare Advantage: Quality Bonus Payment*

OIG Recommendations	Policy Decisions	Estimated Savings (millions)
<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>	<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.</p>	<p>\$799</p>
<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>	<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 \$300 million for FY 2015.</p>	<p>\$300</p>
<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>	<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 \$900 million attributed to FY 2015. (77 Fed. Reg. 67523, November 9, 2012.)</p>	<p>\$900</p>
<p>Medicaid Third-Party Liability. Determine whether legislation is needed to explicitly include pharmacy benefit management companies in the Medicaid definition</p>	<p>Section 6035 of the Deficit Reduction Act (DRA) made several changes to strengthen Medicaid’s third-party liability provisions, including clarification regarding pharmacy benefit managers. The section also</p>	<p>\$260</p>

Demonstration Undermined by High Estimated Costs and Design Shortcomings [GAO-12-409R <http://www.gao.gov/products/GAO-12-409R>.] The other was a change in policy about how HHS calculates the fee-for-service rate against which MA payments are benchmarked that would increase the savings associated with the reduced benchmark. (See CMS’s Medicare Advantage Rate Announcement from April 1, 2013.)

OIG Recommendations	Policy Decisions	Estimated Savings (millions)
<p>of "third party," require third parties to match their eligibility files with Medicaid's eligibility files, and allow Medicaid up to 3 years to recover payments from liable third parties. The recommendations reflected findings in OIG report number OEI-03-00-00030.</p>	<p>requires States to ensure that health insurers provide requested coverage data; accept the State's right of recovery; and agree, conditionally, not to deny a claim solely on the basis of date of submission of the claim when the claim is submitted by the State within a 3-year period beginning on the date of service. CBO estimated savings of \$260 million for FY 2015.</p>	
<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 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>	<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 2015.</p>	<p>\$200</p>
<p>Capped Rental Durable Medical Equipment. Eliminate the semiannual maintenance payment allowed for capped rental equipment, pay only for repairs that are needed, eliminate the 15-month rental option, and convert rentals to purchases after the 13th month. The recommendations reflected findings in report number OEI-03-00-00410.</p>	<p>Section 5101 of the DRA revised the payment rules for capped rental equipment to require that ownership of the item transfer to the beneficiary after the 13th month and that Medicare pay for maintenance services on a cost-reimbursement basis. CBO estimated savings of \$300 million for FY 2015.</p>	<p>\$300</p>
<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>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 \$100 million for FY 2015.</p>	<p>\$100</p>

OIG Recommendations	Policy Decisions	Estimated Savings (millions)
<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>		
<p>Rebates for Physician-Administered Drugs. Encourage States to take action to collect rebates on physician-administered drugs, especially single-source drugs. States should either use National Drug Codes (NDC) instead of procedure codes or link procedure codes to NDCs for single-source drugs. The recommendations reflected findings in OIG report number OEI-03-02-00660</p>	<p>Section 6002 of the DRA requires States to provide for the collection and submission of utilization data needed to secure rebates for physician-administered drugs and provides that the utilization data for single source and specified multiple-source physician-administered drugs be submitted using NDC numbers (unless the Secretary specifies an alternative coding system). CBO estimated savings of \$20 million for FY 2015.</p>	<p>\$20</p>
<p>Medicare Payments for Vacuum Erection Systems. Seek legislative authority to include vacuum erection systems (VES) in the Competitive Bidding program and then implement a National Mail-Order Competitive Bidding program for VES. The recommendation reflected findings in OIG report number A-07-12-05024.</p>	<p>Section 203 of the Achieving a Better Life Experience Act of 2014 implements changes to treat VES prosthetic devices and related accessories as statutorily noncovered in the same manner that erectile dysfunction drugs are treated in Medicare Part D. CBO estimated savings of \$444 million over 10 years.</p>	<p>\$44.4</p>
<p>Payments for Prescription Drugs Provided to Incarcerated Beneficiaries. Work with prescription drug plan sponsors to identify and resolve improper Medicare Part D payments made for prescription drugs provided to incarcerated beneficiaries. The recommendation reflected findings in OIG report number A-07-12-06035.</p>	<p>CMS issued a final rule about the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug programs. The eligibility requirements to enroll in Medicare Advantage and Part D are outlined in Sections 1851(a)(3)(B) and 1860D-1(a)(3)(A) of the 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</p>	<p>\$73</p>

OIG Recommendations	Policy Decisions	Estimated Savings (millions)
	<p>incarcerated beneficiary still meets the eligibility requirements for Part A and Part B. In order to implement the exclusion from Medicare coverage for incarcerated individuals, CMS explicitly excluded facilities in which beneficiaries are incarcerated. CMS estimated savings of \$1.6 billion over 10 years with \$73 million attributed to FY 2015. (79 Fed. Reg. 100, 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 report number 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 \$850 million attributed to FY 2015.</p>	<p>\$850</p>

Administration for Children and Families programs

OIG Recommendations	Policy Decisions	Estimated Savings (millions)
<p>Triennial Reviews of Child Support Orders and Medical Support by Parents. Ensure that more periodic reviews are initiated and take action to increase medical support by parents. The recommendations reflected findings in OIG report number OEI-05-98-00100.</p>	<p>Section 7302 of the DRA required States to adjust child support orders of families enrolled in the Temporary Assistance for Needy Families program every 3 years. Section 7307 requires States to assess the ability of either or both parents to provide medical support for their children. CBO estimated savings (combined) of \$34 million for FY 2015.</p>	<p>\$34</p>

Appendix B: Monetary recommendations

The tables below summarize the Office of Inspector General's (OIG) monetary recommendations and the Department of Health and Human Services (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	226	\$514,720,000	\$23,745,000
Reports issued during the reporting period	66	<u>\$638,799,000</u>	<u>\$ 34,101,000</u>
Total Section 1	292	\$1,153,519,000	\$57,846,000
Section 2			
Reports for which management decisions were made during the reporting period ^{2,3}			
Disallowed costs	189	\$583,405,000*	\$9,637,000
Costs not disallowed	6	<u>\$50,648,000</u>	<u>\$1,385,000</u>
Total Section 2	195	\$634,053,000	\$11,022,000
*Audit receivables (expected recoveries).			
Section 3			
Reports for which no management decisions had been made by the end of the reporting period (Sec. 1 minus Sec. 2)	97	\$519,466,000	\$46,824,000
Section 4			
Reports for which no management decisions were made within 6 months of issuance ⁴	50	\$177,682,000	\$19,406,000

Audit Reports With Funds Recommended to Be Put to Better Use

The phrase “recommendations that funds be put to better use” means that funds could be used more efficiently if an action was taken 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	15	\$15,895,206,000
Reports issued during the reporting period	<u>7</u>	<u>\$68,068,000</u>
Total Section 1	22	\$15,963,274,000
Section 2		
Reports for which management decisions were made during the reporting period ²		
Value of recommendations agreed to by management		
Based on proposed management action	9	\$105,795,000
Based on proposed legislative action		
Value of recommendations not agreed to by management	<u>2</u>	<u>\$713,764,000</u>
Total Section 2	11	\$819,559,000
Section 3		
Reports for which no management decisions had been made by the end of the reporting period ³ (Sec. 1 minus Sec. 2)	11	\$15,143,715,000

End Notes—Table 1

¹The opening balance was adjusted upward by \$44.6 million because of a reevaluation of previously issued recommendations.

²Revisions to previously reported management decisions:

- A-01-08-00511 Review of Separately Billed Laboratory Tests Submitted by Spectra Laboratories for Medicare Beneficiaries with End-Stage Renal Disease Receiving Dialysis at Fresenius Medical Care North America's Facilities. Subsequent review by CMS determined that the provider was over paid. Unallowable cost totaling \$1,729,254 was refunded.
- A-04-01-00005 Audit of Medicaid Fee-for-Service Payments to Local Education Agencies in North Carolina for the Period July 1, 1999 to June 30, 2000. Upon further review of methodology and State's supporting documentation, CMS determined that the \$2,785,151 in questioned cost was allowable.
- A-09-09-00030 Review of Medicaid Personal Care Services Claimed by Washington State. Subsequent review of the State Agency's payment system by CMS reduced the disallowed cost by \$5,781,607.
- Not detailed are net reductions to previously disallowed management decisions totaling \$ 1.3 million.

³Included are management decisions to disallow \$32.5 million in questioned costs that were identified by non-Federal auditors in audits of State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards conducted in accordance with Office of Management and Budget Circular A-133. OIG is currently ensuring that work performed by these non-Federal auditors complies with Federal audit standards; accordingly, OIG tracks, resolves, and reports on recommendations in these audits.

⁴Because of administrative delays, some of which were beyond management control, resolution of the following 50 audits was not completed within 6 months of issuance of the reports. Agency management has informed us, however, 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-01-12-02507	REVIEW OF CONNECTICUT'S TITLE IV-E ADOPTION ASSISTANCE MAINTENANCE PAYMENTS, NOV 2013, \$17,499,083
CIN: A-06-13-00038	CHILD CARE DEVELOPMENT FUND: TARGETED FUNDS REVIEW IN TEXAS, AUG 2014, \$14,967,129
CIN: A-04-12-00085	ACCURACY OF MEDICAID COLLECTIONS REPORTED BY THE GEORGIA DEPARTMENT OF COMMUNITY HEALTH, APR 2014, \$10,915,180
CIN: A-03-12-00004	REVIEW OF HORIZON'S 2009 AND 2010 BONA FIDE SERVICE FEES, MAR 2013, \$4,344,417

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-07-12-03175	REVIEW OF CCDF TARGETED FUNDS IN NEBRASKA, APR 2013, \$2,965,913
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-01-12-01501	REVIEW OF SAMHSA COSTS CLAIMED AT LATIN AMERICAN HEALTH INSTITUTE, BOSTON, MA, APR 2013, \$1,261,328
CIN: A-03-13-00021	REVIEW OF FALLON COMMUNITY HEALTH PLAN'S 2009, 2010, AND 2011 BONA FIDE SERVICE FEES, JAN 2014, \$1,079,578
CIN: A-05-12-00089	THE COUNCIL ON RURAL SERVICE PROGRAMS, INC., CLAIMED UNALLOWABLE HEAD START COSTS, NOV 2013, \$1,074,352
CIN: A-03-13-00022	REVIEW OF MD CARE, INC.'S 2009, 2010, AND 2011 BONA FIDE SERVICE FEES, JAN 2014, \$1,040,501
CIN: A-03-13-00023	REVIEW OF NATIONAL RURAL ELECTRIC COOPERATIVE ASSOCIATION'S 2009, 2010, AND 2011 BONA FIDE SERVICE FEES, JAN 2014, \$957,921
CIN: A-02-11-02020	REVIEW OF ACTION FOR A BETTER COMMUNITY, INC. CSBG ARRA COSTS CLAIMED BY NEW YORK STATE, SEP 2013, \$795,608
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-07-12-06035	REVIEW OF MEDICARE PART D PAYMENTS FOR INCARCERATED BENEFICIARIES, JAN 2014, \$325,903
CIN: A-01-11-02510	REVIEW OF CT CSBG RECOVERY ACT COSTS CLAIMED, APR 2013, \$314,605
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-06-12-00057	CHILD CARE DEVELOPMENT FUND: TARGETED FUNDS REVIEW IN LOUISIANA, SEP 2013, \$221,578
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-02-10-01044	MEDICAID CLAIMS SUBMITTED BY NEW YORK STATE UNDER ITS DEVELOPMENTAL DISABILITIES WAIVER PROGRAM - REST OF STATE PROVIDERS, JAN 2015, \$79,328
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
CIN: A-07-13-03194	REVIEW OF CCDF TARGETED FUND IN COLORADO, DEC 2014, \$4,543

CIN: A-03-12-00250 AUDIT OF LANCASTER COUNTY COMMUNITY ACTION PROGRAM, NOV 2013,
\$2,813

TOTAL CINS: 50

TOTAL AMOUNT: \$177,682,000

End Notes—Table 2

¹The opening balance was adjusted upward by \$41,000 because of reevaluation of previously issued recommendations.

²Revisions to previously reported management decisions:

- A-09-12-02085 *Medicare Could Have Saved Millions if Organ Procurement Organizations Had Correctly Reported Procurement of Double Lungs As Two Organs.* Costs incurred by the OPO are passed on to the Certified Transplant Centers and hospitals. Subsequent review by CMS determined that revisions in policy and procedures would not result in cost savings totaling 8,900,900.

³Because of administrative delays, some of which were beyond management control, 5 of the 11 audits open at the 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, APR 2014, \$15,000,000,000

CIN: A-02-10-01044 MEDICAID CLAIMS SUBMITTED BY NEW YORK STATE UNDER ITS
DEVELOPMENTAL DISABILITIES WAIVER PROGRAM - REST OF STATE PROVIDERS,
JAN 2015, \$76,738,116

CIN: A-04-12-06154 REVIEW OF HOSPITAL OUTPATIENT PAYMENTS FOR ESTABLISHED PATIENTS,
MAR 2014, \$7,536,964

CIN: A-04-13-06168 REVIEW OF MEDICARE OUTPATIENT PAYMENTS FOR CLINIC VISITS OF
ESTABLISHED PATIENTS CY 2012, DEC 2014, \$4,555,929

CIN: A-05-06-00023 UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS - MN, SEP 2006, \$28,240

TOTAL CINS: 5

TOTAL AMOUNT: \$15,088,859,000

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 peer review results

During this semiannual reporting period, one review involving the Office of Audit Services (OAS) was completed.

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
	May 2012	HHS OIG, OAS	U.S. Environmental Protection Agency (EPA)

The system of quality control for the audit organization of EPA OIG in effect for the year ending September 30, 2011, has been suitably designed and complied with to provide EPA 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.” EPA OIG received a peer review rating of pass.

(Peer Review Results continued on next page)

Office of Investigations peer review results

During this semiannual reporting period, HHS OIG's Office of Investigations (OI) did not conduct a peer review of another OIG. A peer review of OI by the Department of Labor OIG was conducted during this reporting period. The final report from this peer review was not issued by the time this *Semiannual Report to Congress* was published.

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

Civil Monetary Penalties Law

The Civil Monetary Penalties Law (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 (FCA), as amended by the False Claims Amendments Act of 1986, (31 U.S.C. §§ 3729–3733), a person or an entity is liable for up to treble damages and a penalty between \$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	<i>OIG Compendium of Unimplemented Recommendations</i>
(a)(4)	Matters referred to prosecuting 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 Federal Information Security Modernization Act (FIMSA)	Reported annually in the spring <i>Semiannual Report to Congress</i> , "Other HHS-Related Issues" section

Section	Requirement	Location
(a)(14)-(16)	Results of peer reviews of HHS-OIG conducted by other OIGs or the date of the last peer review, outstanding recommendations from peer reviews, and peer reviews conducted by HHS-OIG of other OIGs	Appendix C

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 reporting period.	"Other HHS-Related Issues" section

Appendix F: Anti-kickback statute—Safe harbors

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

In crafting safe harbors for a criminal statute, it is incumbent upon 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 2015 annual solicitation, OIG received the following proposals related to safe harbors:

Proposal	OIG Response
A new safe harbor protecting gainsharing distributions within accountable care organizations and clinical integration networks or initiatives.	OIG is not adopting this suggestion at this time. Whether a safe harbor is appropriate and feasible to protect gainsharing distributions broadly for accountable care organizations and clinical integration networks or initiatives requires further study.
Modification of the employee safe harbor (42 C.F.R. § 1001.952(i)) to include non-employee contractual arrangements with physicians in accountable care organizations or other innovative healthcare delivery systems.	OIG is not adopting this suggestion. The employee safe harbor at 42 C.F.R. § 1001.952(i) is based upon a statutory exception to the anti-kickback statute (section 1128B(b)(3)(B) of the Act, 42 U.S.C. § 1320a-7b(b)(3)(B)), which is limited to bona fide employment relationships. A separate safe harbor at 42 C.F.R. § 1001.952(d) applies to personal services and management contracts. Whether an additional safe harbor is appropriate specifically for contractual arrangements with physicians in accountable care organizations or other innovative healthcare delivery systems requires further study.
A new safe harbor for on-line tools to enhance transparency and provider-selection so the public can view profiles and rankings of practitioners and providers, including hospital medical staff members willing to participate in the tool.	OIG is not adopting this suggestion. While the proposal states that there is no practical way for hospitals to fund an on-line tool to make such data readily available to patients without raising anti-kickback concerns, it is not clear why this should be so. 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 community benefit and patient safety initiatives which provide an incidental benefit to referral sources. Examples given are health fairs, immunization campaigns and sharps-disposal and removal.	OIG is not adopting this suggestion. The examples given do not necessarily implicate the anti-kickback statute. To the extent that a hospital or other entity is concerned that specific arrangements implicate the anti-kickback statute because of incidental benefit to providers, questions about its application should be addressed on a case-by-case basis, such as under the advisory opinion process.

Proposal	OIG Response
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 healthcare provider.	OIG is not adopting this suggestion at this time, as it requires further study.
Modification of the safe harbor applicable to price reductions offered to eligible managed care organizations (42 C.F.R. § 1001.952(t)) to protect payments involving Prescription Drug Plans (PDPs) serving the Medicare Part D program.	OIG is not adopting this suggestion. The risks associated with payments involving Medicare Part D PDPs differ from those involving managed care organizations. Whether a separate safe harbor protecting remuneration involving Medicare PDPs is appropriate requires further study.
New safe harbors for CMS-approved innovation initiatives regarding financing, payment, and service delivery in the Medicare and Medicaid programs.	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 section 1115A(d)(a)(1) of the Act. Whether safe harbors are appropriate for the types of arrangements involved in these demonstrations requires further study.
Modification of the group purchasing organization safe harbor (42 C.F.R. § 1001.952(j)) to amend the definition of group purchasing organization and to impose certain additional requirements to qualify for safe harbor protection.	OIG is not adopting this suggestion. The group purchasing organization safe harbor at 42 C.F.R. § 1001.952(j) is based on a statutory exception to the anti-kickback statute (section 1128B(b)(3)(C) of the Act, 42 U.S.C § 1320a—7b(b)(3)(C)). Whether the proposed modifications to the safe harbor are consistent with the statutory exception and otherwise appropriate requires further study.

Proposal	OIG Response
<p>A new safe harbor for remuneration that would provide the same protection under the anti-kickback statute as the protection offered by the exception to the civil monetary penalties law (CMPL) applicable to beneficiary inducements, for remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs. See Section 1128A(i)(6)(F) of the Act, 42 U.S.C § 1320a—7a(i)(6)(F).</p>	<p>On October 3, 2014, OIG issued a Notice of Proposed Rulemaking soliciting comments regarding the implementation of the referenced exception to the definition of remuneration for purposes of the CMPL. See 79 Fed. Reg. 59717. Comments were due by December 2, 2014 and are being considered at this time. 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>
<p>A new safe harbor to protect payments made under the terms of a risk-sharing contract, in which financial consequences are assigned to a party based on clinical or economic outcomes targets and whether they are achieved with the use of specified drugs, devices, equipment or medical supplies.</p>	<p>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.</p>
<p>Modification of the safe harbor for waiver of beneficiary coinsurance and deductible amounts (42 C.F.R. § 1001.952(k) to extend protection to reductions or waivers offered to American Indians and Alaskan Natives (AI/ANs) eligible for Indian Health Service services.</p>	<p>OIG is considering modifying this safe harbor or proposing a new safe harbor to address the concerns described in this proposal.</p>
<p>A new safe harbor or safe harbors protecting exchanges or transfers of value among Indian health care providers; transfers of value from an Indian health care provider to AI/ANs eligible for or receiving services from that provider; arrangements for the exchange, transfer, or sharing of medical care facilities and resources between an Indian health care provider and other health care providers; and certain transfers of goods, items, services, notations, or loans from an individual or entity to an Indian health care provider.</p>	<p>OIG is considering whether to promulgate a safe harbor that would address the concerns described in this proposal. 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>