

Office of  
Inspector  
General

Semiannual  
**Report**  
to **Congress**

October 2012 – March 2013



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**

## OIG Organization

The Department of Health and Human Services (HHS) Office of Inspector General (OIG) employs about 1,700 professional staff members who are deployed throughout the Nation in regional and field offices and in Washington, DC, headquarters. We collaborate with HHS and its operating and staff divisions, the Department of Justice (DOJ) and other executive branch agencies, Congress, and States to bring about systemic changes, successful prosecutions, negotiated settlements, and recovery of funds. Following are descriptions of our mission-based components. The components are supported by the Immediate Office of the Inspector General and the Office of Management and Policy.

OAS

**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 and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

OEI

**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 and promoting economy, efficiency, and effectiveness in HHS programs. OEI reports also present practical recommendations for improving program operations.

OI

**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 almost every State and the District of Columbia, OI actively coordinates with DOJ and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, or CMPs.

OCIG

**THE OFFICE OF COUNSEL TO THE INSPECTOR GENERAL (OCIG)** provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, 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 concerning the antikickback statute and other OIG enforcement authorities.

## 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), for the 6-month period that ended March 31, 2013.



*Daniel R. Levinson  
Inspector General*

During this reporting period, OIG continued to generate important work that significantly contributed toward our core mission of protecting HHS programs and beneficiaries. Much of what we accomplished in the first quarter of 2013 was the result of effective partnerships. OIG continuously looks for ways to enhance the relevance and impact of our work by engaging and working with our internal and external stakeholders.

Many of our cooperative activities have generated successful results. The Health Care Fraud Prevention and Enforcement Action Team (HEAT), the OIG Portfolio, and our series of audits examining the Centers for Disease Control and Prevention's (CDC) oversight of the President's Emergency Plan for AIDS Relief (PEPFAR) grants exemplify our successful efforts. These partnerships have demonstrated, or show great potential to produce, significant results and maximum utility of OIG resources.

Our partnership with other Federal, State, and local law enforcement entities as part of HEAT continues to yield impressive results. HEAT's strike force teams use sophisticated data analysis, combined with field intelligence and traditional law enforcement techniques, to quickly identify fraud schemes and trends. Strike Force teams mine voluminous amounts of data to pinpoint hot spots and target criminal behavior as it occurs. Since 2007, through the end of the semiannual period that ended March 31, 2013, Strike Force efforts have resulted in over \$887 million in investigative receivables and over 800 criminal actions. These significant results would not have been possible without our government partners.

OIG auditors, evaluators, investigators, and legal professionals joined forces to produce the first-ever OIG Portfolio, which synthesizes OIG's work examining vulnerabilities in Medicaid personal care services (PCS) and offers recommendations for improvement. Over the past 6 years, OIG has issued over 20 reports on the topic of PCS and conducted numerous investigations involving PCS fraud. This new product, which draws on all of OIG's professionals and disciplines, offers great potential for affecting positive change in programs shown to present serious vulnerabilities to program integrity.

HHS is the largest Federal grantmaker and the third largest Federal contracting agency. During this audit period, OIG produced three reports examining CDC's oversight of PEPFAR grants in South Africa, Namibia, and the Republic of Namibia. In planning for these audits, OIG coordinated closely with CDC to understand the program and its operations and to identify areas that posed the greatest risk for PEPFAR integrity. We developed a joint work planning process with the U.S. Agency for International Development, coordinated with other OIG offices conducting PEPFAR work, and sought input from domestic and international organizations to examine grants and controls related to PEPFAR.

Thus far, OIG's efforts have uncovered several opportunities to strengthen grant compliance practices, but showed no widespread problems overseas. Going forward, OIG will continue to benefit from the strong communication and coordination it has cultivated with its PEPFAR partners.

Since its 1976 establishment, OIG has worked diligently with its partners to fight waste, fraud, and abuse in Medicare and more than 300 other HHS programs. I would once again like to express my appreciation to Congress and to the Department for their sustained commitment toward improving the efficiency and effectiveness of HHS programs.



Daniel R. Levinson  
Inspector General

## Highlights

The Department of Health and Human Services (HHS) Office of Inspector General (OIG) *Semiannual Report to Congress* (Semiannual Report) describes significant problems, abuses, deficiencies, and investigative outcomes relating to the administration of HHS programs and operations that were disclosed during the reporting period. This edition addresses work completed during the first half of fiscal year (FY) 2013 (October - March) and provides summary data on key accomplishments during the period and for the year.

## Summary of Accomplishments

For the first half of FY 2013, we reported expected recoveries of about \$3.8 billion consisting of over \$521 million in audit receivables and about \$3.28 billion in investigative receivables, which includes \$642.3 million in non-HHS investigative receivables resulting from our work in areas such as the States' shares of Medicaid restitution.

We reported exclusions of 1,661 individuals and entities from participation in Federal health care programs; 484 criminal actions against individuals or entities that engaged in crimes against HHS programs; and 240 civil actions, which include false claims and unjust-enrichment lawsuits filed in Federal district court, civil monetary penalties (CMP) settlements, and administrative recoveries related to provider self-disclosure matters.

Following are highlights of some of the significant problems, abuses, deficiencies, activities, and investigative outcomes that are included in the Semiannual Report for the first half of FY 2013.

## Health Care Fraud Prevention and Enforcement Action Team

The Health Care Fraud Prevention and Enforcement Action Team (HEAT) was started in 2009 by HHS and the Department of Justice (DOJ) to strengthen programs and invest in new resources and technologies to prevent and combat health care fraud, waste, and abuse. HEAT has continued with increasing momentum to identify and hold accountable those who seek to defraud Medicare and Medicaid.

### Medicare Strike Force Teams

Medicare Fraud Strike Force teams coordinate law enforcement operations conducted jointly by Federal, State, and local law enforcement entities. The teams, now a key component of HEAT, have a record of successfully analyzing data to quickly identify and prosecute fraud. The Strike Force began in March 2007 and is operating in nine major cities.

**Strike Force Accomplishments**—During the first half of FY 2013, Strike Force efforts resulted in the filing of charges against 148 individuals or entities, 139 criminal actions, and \$193.7 million in investigative receivables.

**Nationwide Takedown**—In October 2012, Medicare Fraud Strike Force operations in 7 cities led to charges against 91 individuals, including doctors, nurses, and other licensed medical professionals, for their alleged participation in Medicare fraud schemes involving approximately \$429.2 million in false billing. HHS also suspended or took other administrative action against 30 health care providers based upon credible allegations of fraud.

**Strike Force Case**—15 defendants were sentenced to a combined 183 Years in Prison for their roles in a \$205 million Medicare fraud scheme. According to the indictment, the American Therapeutic Corporation (ATC) and the American Sleep Institute (ASI) submitted false and fraudulent claims to Medicare for services that were medically unnecessary, were not eligible for Medicare reimbursement, or were never provided. ATC paid up to approximately \$500,000 monthly in kickbacks in exchange for the recruitment of Medicare beneficiaries for purported mental health therapy and sleep study services at ATC and ASI. The 15 defendants were also ordered to pay \$87 million in restitution, joint and several, as well as \$37,000 in fines.

## Prescription Drugs

Medicare and Medicaid are major payers for prescription drugs. Our investigations and reviews find vulnerabilities at many levels, including pharmaceutical manufacturer noncompliance, retail pharmacy and prescriber schemes, drug diversion, and flawed reimbursement methodologies.

## Chemotherapy-Related Reports

The following reports describe pricing policy and improper billing associated with three types of drugs: prostate cancer drugs; Herceptin, used in treating breast cancer; and Emend, used to help reduce nausea and vomiting in chemotherapy patients.

**OEI-12-12-00210** **Prostate Cancer Drugs**—We found that Medicare spending for certain prostate cancer drugs is higher in the absence of least costly alternative (LCA) policies for clinically comparable drugs. If such policies had not been rescinded, Medicare expenditures would have been reduced by \$33.3 million over 1 year. There was concern that rescinding LCA policies may have created an unintentional incentive for physicians to administer costlier drugs, causing Medicare to pay more when less costly clinically comparable drugs were available. (*Least Costly Alternative Policies: Impact on Prostate Cancer Drugs Covered Under Medicare Part B.*)  
November 2012

**A-05-11-00114** **Herceptin (Trastuzumab)**—Herceptin is a Medicare-covered drug used to treat breast cancer that has spread to other parts of the body. In six reviews, we found that 75 to 89 percent of payments for selected line items were incorrect, resulting in overpayments by Medicare. Providers incorrectly billed units of service equivalent to the dosage of entire multi-use vials when only partial vials were administered, billed for unallowable services, incorrectly coded claims, and did not provide supporting documentation.  
A-09-12-02069  
A-06-12-00001  
A-04-12-06146  
A-04-12-03070  
A-05-12-00017  
Various Dates

**A-07-11-04181** **Emend (Aprepitant)**—For the oral form of Emend, one of three drugs in a regimen of oral anti-emetic drugs that are prescribed to help reduce nausea and vomiting in chemotherapy patients, we found that about 91 percent of selected line items that were billed by five selected providers during calendar year 2010 were incorrect, resulting in overpayments by Medicare. *(Providers Did Not Correctly Bill Medicare Part B for the Oral Form of the Drug Emend.)*  
December 2012

## Drug-Related Settlements and Criminal Actions

**Abbott Laboratories Agrees To Pay \$1.5 Billion (Virginia)**—Abbott Laboratories' (Abbott) also entered into a 5-year Corporate Integrity Agreement (CIA) in a global criminal, civil, and administrative settlement to resolve allegations that it violated the False Claims Act by improperly marketing and promoting the drug Depakote for uses not approved by the Food and Drug Administration (FDA), including the treatment of aggression and agitation in elderly dementia patients and the treatment of schizophrenia. Abbott allegedly offered and paid illegal remuneration to induce health care professionals and long-term care-pharmacies to prescribe Depakote.

**Amgen, Inc., Agrees To Pay \$762 Million (New York)**—After pleading guilty to violations of the Federal Food, Drug, and Cosmetic Act, pharmaceutical manufacturer Amgen, Inc. (Amgen), agreed to pay about \$762 million plus interest to resolve its criminal and civil liability arising from its sale and promotion of certain drugs, including Aranesp (used in treating anemia) and two other drugs that it manufactured. Amgen promoted uses and/or dosing regimens that were not approved by FDA; offered illegal kickbacks to influence health care providers to select and use its products, regardless of whether administered, reimbursable, or medically necessary; and engaged in false price-reporting practices. As part of the global settlement, Amgen also agreed to pay a criminal fine and forfeiture amount of \$150 million. Amgen entered into a CIA to increase accountability transparency, and to strengthen compliance.

**Clinic President Sentenced for Illegally Distributing Oxycodone and Other Schedule II Narcotics (Virginia)**—Paul Boccone treated patients and prescribed narcotics by directing medical practitioners to endorse prescriptions that he wrote. According to the indictment, though Boccone was the president of a pain management clinic, he lacked any medical education, qualifications, or licensing. He also hired medical professionals with no background or specialized training in pain management. In addition to being sentenced to 15 years imprisonment, Boccone was ordered to pay \$275,154 in restitution.

## Medicare Part A and Part B

Medicare Part A and Part B together are generally referred to as “traditional Medicare.” Part A helps cover certain inpatient services such as in hospitals and skilled nursing facilities and some home health services. Part B helps cover designated other medical services, equipment, supplies, and drugs that Part A does not cover.

## Hospitals

Certain indicators on hospitals' claims to Medicare identify conditions as being present on admission (POA). Centers for Medicare & Medicaid Services (CMS) officials have expressed continued interest in the accuracy of POA indicators because they provide an opportunity for monitoring hospital quality of care.

- OEI-06-09-00310** **Hospital claims-coding staff misreported POA indicators.** We found at least one incorrect indicator on 18 percent of claims we reviewed. Hospitals do not receive increased Medicare reimbursement for certain conditions (referred to as "hospital-acquired conditions") when such conditions develop during the hospital stay and are not present at the time of admission. *(Assessment of Hospital Reporting of Present on Admission Indicators on Medicare Claims.)*  
November 2012

## Skilled Nursing Facilities

Skilled nursing facilities (SNFs) provide skilled care to Medicare patients, such as nursing care, therapy, and other services. We found that many SNFs were not developing proper plans of care; were not providing adequate care; or were doing too much by providing unnecessary services that could actually cause harm, e.g., by providing intense therapy to terminal patients who did not want it.

- OEI-02-09-00201** **Poor Care and Discharge Planning at SNFs—**Medicare paid approximately \$5.1 billion for stays in which SNFs did not meet planning and discharge requirements. We also found poor quality care related to wound care, medication management, and therapy. These findings raise concerns about what Medicare is paying for. They also demonstrate that SNF oversight needs to be strengthened. *(Skilled Nursing Facilities Often Fail To Meet Care Planning and Discharge Planning Requirements.)*  
February 2013

- OEI-02-09-00200** **SNFs Misreported Information When Billing Medicare—**We found that SNFs billed one-quarter of claims in error in 2009, resulting in about \$1.5 billion in inappropriate Medicare payments. For 47 percent of claims, SNFs misreported information on the Minimum Data Set, the system used to classify beneficiaries into resource utilization groups (RUG) for payment. Some SNFs incorrectly reported items such as therapy and activities of daily living, thereby placing beneficiaries into higher paying RUGs. *(Inappropriate Payments to Skilled Nursing Facilities Cost Medicare More Than \$1 Billion in 2009.)*  
November 2012

## Ineligible Beneficiaries—Unlawfully Present or Incarcerated

Medicare does not make payments for care rendered to patients unlawfully present in the United States and generally does not pay for care rendered to incarcerated patients. We found that when CMS received untimely information indicating that a beneficiary's unlawful presence overlapped with the dates of service on previously paid Medicare claims, CMS did not notify Medicare's contractors of this updated information. In the absence of such notification, the contractors did not detect and recoup improper payments. Also, when CMS's data systems did not indicate until after a claim had been processed that a beneficiary

was incarcerated, CMS's controls were not adequate to detect and recoup the improper payments.

**A-07-12-01116** **Unlawfully Present Beneficiaries**—We identified \$91.6 million in improper Payments. (Medicare Improperly Paid Providers Millions of Dollars for Unlawfully Present Beneficiaries Who Received Services During 2009 Through 2011.)  
January 2013

**A-07-12-01113** **Incarcerated Beneficiaries**—We identified \$33.6 million in improper Payments. (Medicare Improperly Paid Providers Millions of Dollars for Incarcerated Beneficiaries Who Received Services During 2009 Through 2011.)  
January 2013

## Medicare Contractors' Activities To Detect and Deter Fraud

CMS contracts with several entities, including Program Safeguard Contractors, Medicare Drug Integrity Contractors, Recovery Audit Contractors, and Zone Program Integrity Contractors (ZPICs), to perform many Medicare integrity functions.

**OEI-04-11-00220** **Home Health Agencies**—The two CMS Medicare Administrative Contractors we reviewed prevented \$275 million in home health agency (HHA) improper payments and referred several instances of potential fraud, but the four ZPICs we reviewed, which served fraud-prone geographic areas, did not identify any HHA-specific vulnerabilities and varied substantially in their efforts to detect and deter fraud. (OEI-04-11-00220—Home Health Agencies—CMS and Contractor Oversight of Home Health Agencies.)  
December 2012

**OEI-04-11-00101** **Community Mental Health Centers**—Only one of nine payment contractors we reviewed performed activities to detect and deter community mental health center (CMHC) fraud in 2010, and most were part of a CMS-led special project. Activities to detect and deter CMHC fraud varied substantially among ZPICs in 2010; one ZPIC performed almost all such activities, most of which were part of the same CMS-led special project. The other contractors performed only minimal activities to detect and deter fraudulent CMHC billing, despite having jurisdiction over fraud-prone areas. (Vulnerabilities in CMS's and Contractors' Activities To Detect and Deter Fraud in Community Mental Health Centers.)  
January 2013

## Implementation of Surety Bonds for Medical Equipment Suppliers

**OEI-03-11-00350** **Medical Equipment Suppliers**—Two years after the surety bond requirement for medical equipment suppliers was implemented, CMS did not have accurate surety bond information for all suppliers. Information for thousands of bonded suppliers and surety bond amounts were not consistently maintained. Further, CMS can only collect up to \$50,000 per bonded supplier, so it is unlikely going to be able to reconcile surety bond collections with the tens of millions of dollars in overpayments owed by medical equipment suppliers. (Surety Bonds Remain an Underutilized Tool To Protect Medicare From Supplier Overpayments.)  
March 2013

## Fraudulent Billing by Clinic Owner and Optometrist

**Clinic Owner Sentenced to 12 Years and 7 Months for Engaging in Elaborate Medicare Fraud Scheme (Florida)**—Arbilio Yanes was sentenced to 12 years and 7 months of incarceration and ordered to pay \$11 million in restitution after pleading guilty to charges related to health care fraud. Yanes, the president and one of two owners of the purported medical clinic, paid more than \$2.3 million to third parties to recruit Medicare beneficiaries as purported patients for cash in return. The clinic then billed Medicare for alleged services, even though they either were not provided or were not medically necessary.

**Optometrist Sentenced to 3 Years in Prison for Submitting Claims for False Diagnoses (Idaho)**—Christopher Card was ordered to pay \$1 million in restitution and a \$100,000 fine after pleading guilty to charges. Card was a licensed optometrist who, according to the plea agreement, fraudulently billed Medicaid, Medicare, and other health care benefit programs for false diagnoses, including glaucoma, acquired color deficiency (color blindness), tension headaches, macular degeneration, treatment of eye injuries, and removal of foreign objects from the eye. Card also billed for testing that did not actually occur and for testing results that were falsified or altered.

## Medicare Part C and Part D

Medicare Part C, known as the Medicare Advantage (MA) program, provides covered services to qualified Medicare beneficiaries through State-licensed risk-bearing entities operating under contract with CMS. Medicare Part D is an optional outpatient drug benefit available to Medicare beneficiaries.

**OEI-03-11-00310** **Ability To Identify and Investigate Fraud**—Our review of the one Medicare Drug Integrity Contractor (MEDIC) responsible for detecting and preventing fraud, waste, and abuse in Medicare Parts C and D nationwide revealed that its Part C investigations and case referrals represented only a small percentage of its benefit integrity activities. We identified several problems hindering the MEDIC's ability to identify and investigate fraud and abuse in Part C and Part D. The two programs involved \$190 billion in expenditures in 2011 and 33 million beneficiaries in 2012. (MEDIC Benefit Integrity Activities in Medicare Parts C and D.)  
January 2013

**OEI-05-10-00450** **Part D Pharmacy and Therapeutics Committees**—Part D sponsors' pharmacy and therapeutics committees, whose decisions affect beneficiaries' access to specific prescription drugs and the cost of drugs to beneficiaries and the Federal Government, have limited definitions of conflicts of interest, which could hinder them from identifying conflicts. (Medicare Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions.)  
March 2013

## Medicaid Program

States have considerable flexibility in designing and operating their Medicaid programs; however, to receive a Federal share of Medicaid costs, applicable State and Federal requirements must be met.

- OIG-12-12-01**  
November 2012  
**Spotlight Article**  
**OIG Portfolio: Personal Care Services**—In the past 6 years, Medicaid costs for personal care services increased by 35 percent, totaling approximately \$12.7 billion in 2011. OIG has issued 23 reports on personal care services and conducted numerous investigations involving related fraud. This OIG Portfolio synthesizes our body of work and offers new and comprehensive recommendations to address vulnerabilities. (*Personal Care Services: Trends, Vulnerabilities, and Recommendations for Improvement.*)
- A-02-09-01017**  
November 2012  
**Disproportionate Share Hospital Payments**—New Jersey claimed payments of about \$50 million Federal share for five hospitals that did not meet Federal requirements during our audit period. States are required to make special payments, known as disproportionate share payments, to hospitals that serve a disproportionate share of low-income and/or uninsured patients. (*The New Jersey Department of Human Services Claimed Medicaid Disproportionate Share Hospital Payments to Five Hospitals That Did Not Meet Federal Eligibility Requirements.*)
- A-05-11-00071**  
February 2013  
**Collection of Sustained Overpayments**—As of December 2012, CMS reported collecting \$987.5 million of the \$1.2 billion in Medicaid overpayments that it had sustained in the 147 audit reports covered by our review. However, CMS had not collected the remaining \$225.6 million. The uncollected amount related to overpayments that OIG had identified in 10 audit reports that the States had not agreed to refund. In addition, CMS could not document that \$7.2 million that it reported as collected had been collected. (*The Centers for Medicare & Medicaid Services Collected the Majority of Medicaid Overpayments but Millions Remain Uncollected.*)
- OEI-03-11-00650**  
October 2012  
**Federal Upper Limit for Medicaid Drug Reimbursements**—For our review period, we found that Federal Upper Limit (FUL) amounts based on published prices were more than four times greater than sampled pharmacy acquisition costs. Medicaid FUL amounts based on average manufacturer prices (AMP) were 61 percent lower than FUL amounts based on published prices at the median, and AMP-based FULs exceeded sampled pharmacy acquisition costs by 43 percent in the aggregate. The findings support the implementation of the AMP-based FUL amounts for drug reimbursements. (*Analyzing Changes to Medicaid Federal Upper Limit Amounts.*)

## Public Health and Other HHS-Related Reviews

Public health activities and programs represent the country's primary defense against acute and chronic diseases and disabilities and generally promote and enhance health. Other HHS reviews address various human services and administrative issues.

### Global HIV/AIDS Program

Through its Global HIV/AIDS Program, the Centers for Disease Control and Prevention (CDC) implemented the President's Emergency Plan for AIDS Relief (PEPFAR), working with

ministries of health and other in-country partners to combat HIV/AIDS by strengthening health systems and building sustainable HIV/AIDS programs in more than 75 countries. CDC's offices in host countries are responsible for PEPFAR funds awarded to government agencies and for-profit and nonprofit organizations (recipients). Three reports indicate better guidance and oversight are needed.

- A-04-12-04022** **CDC South Africa**—We found insufficiencies in documentation and evidence of monitoring and assurances of use of funds. *(The Centers for Disease Control and Prevention's South Africa Office Did Not Always Properly Monitor Recipients' Use of the President's Emergency Plan for AIDS Relief Funds.)*  
February 2013
- A-04-12-04020** **CDC Namibia**— We found insufficiencies in documentation and evidence of monitoring. *(The Centers for Disease Control and Prevention's Namibia Office Did Not Always Properly Monitor Recipients' Use of the President's Emergency Plan for AIDS Relief Funds.)*  
November 2012
- A-04-12-04019** **Republic of Namibia**—We found Unallowable and potentially unallowable expenditures, reporting accomplishments not related to the cooperative agreement, and other deficiencies. *(The Republic of Namibia, Ministry of Health and Social Services, Did Not Always Manage the President's Emergency Plan for AIDS Relief Funds or Meet Program Goals in Accordance With Award Requirements.)*  
January 2013

## Food Safety—Dietary Supplements

Two reports related to dietary supplements addressed the extent to which FDA is able to effectively locate manufacturers through its Food Facility Registry and determined whether manufacturers' structure/function claims made on the labels of dietary supplements are truthful and not misleading.

- OEI-01-11-00211** **Locating Dietary Supplement Manufacturers in Emergencies**—Of the dietary supplement manufacturers we contacted for review, 28 percent failed to register with the FDA Food Facility Registry. Of the companies that did register, 72 percent failed to provide the complete and accurate information required by law. *(Dietary Supplements—Companies May Be Difficult To Locate in an Emergency)*  
October 2012
- OEI-01-11-00210** **Truthfulness of Claims on Dietary Supplement Labels**—For dietary supplements that were marketed for weight loss or immune system support, we found that manufacturers' substantiations for structure/function claims were inconsistent with FDA's guidance for evidence. Also, manufacturers did not always meet related notification and disclaimer requirements. *(Dietary Supplements—Structure/Function Claims Fail To Meet Federal Requirements.)*  
October 2012

## Deployment of HHS Resources in Emergencies

Within HHS, the Assistant Secretary for Preparedness and Response organizes HHS's resources and its response as the Coordinator and Primary Agency responsible for

Emergency Support Function-8 (ESF-8), Public Health and Medical Services. HHS also has responsibilities as a support agency for nine additional ESFs.

**OEI-04-11-00260** **HHS Emergency Support Function**—We found that HHS deployed resources in response to 28 emergency incidents in 2010 and 2011. Of the 28 incidents, we reviewed 3, which affected 17 States. HHS demonstrated its ability to effectively fulfill its emergency support function (ESF) responsibilities for the three selected incidents. We found that the other ESF coordinators and primary agencies did not always report having a clear understanding of HHS's support agency role and its available resources during incident response. (*HHS Public Health and Medical Services Emergency Support Preparedness.*)

November 2012

## OIG Participation in Congressional Hearings

**3-19-2013** Daniel R. Levinson, Inspector General, testified before the House Appropriations Committee, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, about HHS's top management challenges. [Testimony](#). [Video](#).



*Daniel R. Levinson  
Inspector General*

<http://oig.hhs.gov>

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<http://oig.hhs.gov>

## Medicare Program Reviews

Medicare Part A and Part B together are generally referred to as “traditional Medicare.” Part A helps cover certain inpatient services such as in hospitals and skilled nursing facilities and some home health services. Part B helps cover designated other medical services, equipment, supplies, and drugs that Part A does not cover.

Medicare Part C, known as the Medicare Advantage (MA) program, provides covered services to qualified Medicare beneficiaries through State-licensed risk-bearing entities operating under contract with CMS. Medicare Part D is an optional outpatient drug benefit available to Medicare beneficiaries.

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### Improper Payments and Other Wasteful Spending

Wasteful spending occurs when Medicare’s laws, policies, and methodologies fail to ensure that program costs are reasonable and appropriate or fail to reflect Medicare’s role as a high-volume, prudent insurer/payer in the health care marketplace. Medicare’s policies and methodologies may also cause waste when unintended loopholes or other inherent problems invite exploitation or hinder consistent payment determinations. Medicare’s supporting systems and practices sometimes cause waste by hindering timely and appropriate payment adjustments.

Improper payments, some of which are fraudulent, are a form of wasteful spending. For Part A and Part B, improper payments generally occur when Medicare does not effectively identify and reduce erroneous, inappropriate, and fraudulent billing by providers and suppliers.

Office of Inspector General (OIG) audits and evaluations do not routinely project the annual cost savings that could be realized at the program level from implementing the recommendations in our reports. However, the reports are indicative of the extent to which policies and methodologies may be less than effective and may be in need of correction.

### Ineligible Beneficiaries—Unlawfully Present or Incarcerated

We audited Medicare payments made for patients who were not lawfully present in the United States or were incarcerated. A lawfully present Medicare patient is an immigrant living in the United States legally. Unlawful presence occurs when a non-U.S. citizen remains in the United States longer than the time authorized by U.S. immigration agencies. Incarcerated patients are people who are under arrest, are imprisoned, reside in a halfway house, or are required to live under home detention. Medicare does not make payments for the care of unlawfully present patients and generally does not pay for incarcerated patients.

The Centers for Medicare and Medicaid Services (CMS) identifies these people in collaboration with the Social Security Administration (SSA), which obtains information from prison systems and other Federal agencies. SSA uses data systems to identify unlawfully present and incarcerated patients, then transmits the names to CMS via computer link. CMS does not always receive this information promptly. In such instances, inappropriate claims

are paid. CMS does not have policies and procedures to go back and detect and recover the money.

√ *Improper Payments*<sup>1</sup> *Medicare Improperly Paid Providers Millions of Dollars for Unlawfully Present Beneficiaries Who Received Services During 2009 Through 2011*

A-07-12-01116  
January 2013

CMS's controls were not adequate to ensure that all improper payments for services to unlawfully present beneficiaries were detected and recouped. We found that when CMS received untimely information indicating that the unlawful presence overlapped with the dates of service on previously paid Medicare claims, CMS did not notify Medicare's contractors of this updated information. In the absence of such notification, the contractors did not detect and recoup improper payments.

Recommendations—CMS should ensure that Medicare contractors recoup the \$91.6 million in improper payments we identified, identify improper payments made on behalf of unlawfully present beneficiaries after our audit period but before implementation of new policies and procedures, and ensure that Medicare contractors recoup those payments. We also recommend that CMS implement administrative policies and procedures to detect and recoup improper payments made for Medicare services when information relating to the unlawful presence is received on previously paid Medicare claims.

√ *Improper Payments* *Medicare Improperly Paid Providers Millions of Dollars for Incarcerated Beneficiaries Who Received Services During 2009 Through 2011*

A-07-12-01113  
January 2013

CMS's controls were not adequate to ensure that all improper payments for services to incarcerated beneficiaries were detected and recouped. With certain exceptions, prisons (instead of Medicare) pay for the health care of incarcerated people who are otherwise eligible for Medicare (incarcerated beneficiaries). CMS does not always receive timely updates regarding incarceration information before Medicare contractors pay providers on behalf of incarcerated beneficiaries. We found that when CMS's data systems did not indicate until after a claim had been processed that a beneficiary was incarcerated, CMS's controls were not adequate to detect and recoup the improper payments.

Recommendations—CMS should ensure that Medicare contractors recoup the \$33.6 million in improper payments we identified; identify improper payments made on behalf of incarcerated beneficiaries after our audit period but before implementation of policies and procedures and ensure that Medicare contractors recoup those payments; work with other entities, including SSA (which is CMS's primary source of information about incarcerated beneficiaries), to improve the timeliness of information; and work with the Medicare contractors to ensure that all claims with exception codes are processed consistently and pursuant to Federal requirements. We also recommend that CMS implement administrative policies and procedures to detect and recoup improper payments when incarceration information is received on previously paid Medicare claims.

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<sup>1</sup> To the left of each report title, we have flagged with a checkmark the management challenge(s) associated with the review's findings and recommendations, e.g., √ Improper Payments, √ Wasteful Spending, √ Quality of Care, etc. Implementing a report's recommendations would help curb negative outcomes associated with the designated management challenges.

## Long-Term Care Hospitals—Co-Location With Other Facilities

Long-term-care hospitals (LTCHs) generally treat patients who have been discharged from acute care hospitals but have complex medical conditions that require prolonged hospital-level care. An LTCH can be freestanding or co-located with another hospital-level provider (e.g., an acute care hospital) or a skilled nursing facility. A co-located LTCH is in the same building or in a separate building on the same campus as another provider. Co-located LTCHs must notify their Medicare claims processing contractors about the providers with which they are co-located and indicate whether there are any changes in co-located status. Because co-location creates incentives for providers to make decisions about admitting and discharging patients on the basis of maximizing Medicare payments, CMS developed payment policies that reduce payments to co-located LTCHs when certain thresholds are exceeded.

√ *Improper Payments*    *Co-Located Long-Term Care Hospitals Remain Unidentified, Resulting in Potential Overpayments*

[OEI-04-12-00491](#)  
March 2013 Medicare overpayments can result when LTCHs provide inaccurate data on their co-location status and the LTCHs exceed the threshold for Medicare's pertinent payment policies. Our preliminary data analysis shows that 67 percent of LTCHs we identified were co-located. At least 46 percent had not notified their claims processing contractors of their co-located status, according to contractor responses. The report does not contain recommendations.

## Inpatient Rehabilitation Facilities—Documentation Requirements

Inpatient rehabilitation facilities (IRFs) provide rehabilitation for patients who require hospital-level care to improve their ability to function. Effective for discharges on or after January 1, 2010, documentation requirements specified in regulations must be met to ensure that the IRF care is reasonable and necessary under the Social Security Act. If not, the claims are not allowable.

√ *Improper Payments*    *Norwalk Hospital Did Not Comply With Medicare Inpatient Rehabilitation Facility Documentation Requirements*

[A-01-11-00531](#)  
February 2013 Because procedures at one selected hospital did not ensure that IRF services were documented according to Medicare requirements, Medicare made improper payments. The hospital's medical records did not sufficiently support that it met requirements that a comprehensive preadmission screening occurred within the 48 hours immediately preceding the admission; that a rehabilitation physician performed a postadmission evaluation within the first 24 hours of the IRF admission; that a rehabilitation physician developed and documented an individualized overall plan of care within 4 days of the IRF admission; and that interdisciplinary team meetings met all Federal requirements.

Recommendations—The hospital should refund to the Medicare program \$2.7 million for claims in our sample that did not comply with requirements; work with CMS to resolve the claims that were not included in our sample, with potential overpayments estimated at \$5.2 million; identify IRF claims in subsequent years that did not meet documentation requirements and refund any associated overpayments; and develop and



the SNFs we identified as having billed in error.

## Medical Equipment and Supplies—Prosthetics, Custom Fabricated Orthotics, and Back Orthoses

The following reviews examine compliance with practitioner and supplier qualifications to bill for prosthetics and custom fabricated orthotics and compare acquisition costs and reimbursements for back orthoses.

**Prosthetics and Custom Fabricated Orthotics**—The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), § 427(a), prohibits Medicare payments for prosthetics and custom fabricated orthotics unless the items are furnished by a qualified practitioner and fabricated by either a qualified practitioner or a qualified supplier. The BIPA required the promulgation of regulations to implement the requirements. After more than a decade, CMS has not done so. Medicare suppliers are also required to maintain documentation supporting that prosthetics and custom fabricated orthotics were delivered to beneficiaries.

√ *Wasteful Spending*    *CMS Has Not Promulgated Regulations To Establish Payment Requirements for Prosthetics and Custom-Fabricated Orthotics*

**OEI-07-10-00410**    We found that 12 percent of nearly 1,000 claims allowed in 2010 did not  
October 2012    meet Federal requirements for delivery documentation. These claims were either missing all documentation of delivery or lacked a beneficiary signature on the documentation provided.

Recommendations—CMS should promulgate regulations to implement the statutory payment requirements, ensure that suppliers maintain delivery documentation that meets Federal requirements, and take appropriate action to address the inappropriately allowed claims we identified in our sample.

**Back Orthoses**—The following report provides information on supplier acquisition costs for certain back orthoses. Back orthoses provide back support, reduce back pain, and facilitate healing of the spine. To obtain payment for covered equipment, suppliers submit claims using procedure codes. Suppliers may bill Medicare for a variety of back orthosis products using the L0631 code we selected for review, and the suppliers' acquisition cost for each product may vary according to the manufacturer and model provided. However, Medicare does not collect information on the supplier acquisition costs or the models of back orthoses provided to beneficiaries.

√ *Wasteful Spending*    *Medicare Supplier Acquisition Costs for L0631 Back Orthoses*

**OEI-03-11-00600**    We found that Medicare payment amounts were more than four times  
December 2012    greater than supplier acquisition costs for back orthoses billed using code L0631. Consequently, Medicare and its beneficiaries paid approximately \$37 million more for L0631 back orthoses than suppliers paid to acquire them. Beneficiary copayments alone would have almost covered suppliers' L0631 acquisition costs. For 93 percent of the claims we reviewed, suppliers did not provide any additional services related to L0631 back orthoses other than general instructions.

Recommendations—CMS should lower the fee schedule amount for L0631

back orthoses by including them in the Competitive Bidding Program or by using CMS's inherent reasonableness authority.

## Medical Equipment and Supplies—Mail Order Diabetes Testing Supplies

Part B covers diabetic testing supplies, such as blood-testing strips (test strips), lancets, glucose control solutions, and spring-powered lancet devices for patients for whom the glucose monitor is covered. We identified inappropriate supplier billing and activities related to mail order and non-mail order test strips provided in competitive bidding areas. We also determined whether two mail order suppliers' billing of supplies as non-mail order was correct.

**Incentives for Improper Billing in Competitive Bidding Areas**—At the time of our review, the term “mail order” specified delivery by a common carrier, such as the U.S. Postal Service or FedEx. In competitive bidding areas, non-mail order test strips (e.g., those purchased at walk-in stores) are reimbursed at a rate more than double that for mail order test strips. The payment difference provides a financial incentive for suppliers to improperly bill Medicare items delivered by common carrier to beneficiaries as if they were higher paying non-mail order items. A supplier that knowingly presents to the Federal Government a false or fraudulent claim for payment faces liability under the Federal False Claims Act. The report below responds to a request from CMS to determine whether the increase in claims for non-mail order diabetes test strips between 2010 and 2011 may be associated with improper billing and other abusive practices.

√ *Improper Supplier Billing for Diabetes Test Strips and Inappropriate Supplier Activities Payments in Competitive Bidding Areas*

OEI-04-11-00760  
November 2012

We concluded that improper billing and other abusive practices contributed to a 33-percent increase in supplier claims for higher paying non-mail order test strips in 2011. For 20 percent of beneficiaries in our review, suppliers improperly billed Medicare for higher paying non-mail order test strips while beneficiaries reported having instead received them through mail order. Also, supplier claims for lower paying mail order test strips decreased by 71 percent in the same period. Twenty-three percent of beneficiaries reported other supplier activities that we determined to be inappropriate, i.e., routinely waiving coinsurance and sending unsolicited test strips to the beneficiaries. The report did not contain recommendations.

**Deliveries in Supplier-Owned Vehicles Billed as Non-Mail Order**—Pursuant to Medicare requirements in effect until CMS implements its revised definition of “mail order,” supplies delivered by company-owned vehicles are not considered mail order items and can be billed at higher rates that generally apply to walk-in purchases. To curb wasteful spending by Medicare, the revised definition of “mail order” includes any item “shipped or delivered to the beneficiary’s home, *regardless of the method of delivery.*” [Emphasis added.] The revised definition is targeted to become effective in July 2013.

√ *Wasteful Spending Neighborhood Diabetes, Inc., Submitted Claims for Diabetic Testing Supplies Without the KL Modifier in Accordance With Medicare Billing Requirements*

A-09-11-02073  
January 2013

We reviewed selected line items that one mail order supplier submitted to

Medicare as being *non-mail order*. Of the 100 line items we reviewed, 99 were properly claimed as *non-mail order* under the then-current definition because the supplies were delivered to the beneficiaries in company-owned vehicles instead of by common carrier. We limited our review to determining the supplier's compliance with use of a certain modifier code on the claims that identifies mail order supplies. The claims were correct in not including the mail order modifier code and could be paid at higher non-mail order rates.

The supplier, which serves more than 60,000 customers in the northeastern and southeastern United States, mails diabetic testing supplies or delivers them to customers' homes using company-owned vehicles. The supplier established its home delivery department in November 2008 to prepare for home delivery services beginning in January 2009, when Medicare reduced the reimbursement amount for supplies delivered by mail. The report did not contain recommendations.

√ *Wasteful Spending*    *Advanced Diabetes Supply Submitted Claims for Diabetic Testing Supplies Without the KL Modifier in Accordance With Medicare Billing Requirements*

A-09-12-02035  
March 2013

Similar to the preceding report, a review of a second mail order supplier revealed that almost all the supplies it claimed as being *non-mail order* were payable as claimed because the supplier used company-owned vehicles instead of common carriers to deliver diabetic testing supplies to Medicare beneficiaries at their homes or to warehouse stores for beneficiaries to pick up. This supplier, based in Carlsbad, California, uses company-owned vehicles to deliver supplies to customers who reside in the competitive bidding area or to deliver the supplies to warehouse club stores for pickup by customers. The supplier pays a fixed fee to the membership warehouse club for its general and administrative expenses related to providing the supplies to customers. The report did not contain recommendations.

## Medical Equipment Suppliers—Surety Bond Requirements

Surety bonds, which can discourage enrollment of fraudulent suppliers and aid the recovery of debts owed to Medicare, are issued by entities (sureties) guaranteeing to pay CMS the amount of any monetary obligations that are incurred during the term of the bond and for which the supplier is responsible, up to the surety's maximum obligation. We determined the extent to which CMS maintains complete and accurate surety bond data and the amount of supplier debt that could have been recovered through surety bonds.

√ *Wasteful Spending*    *Surety Bonds Remain an Underutilized Tool To Protect Medicare From*  
√ *Preventing Fraud*    *Supplier Overpayments*

OEI-03-11-00350  
March 2013

Two years after the surety bond requirement for medical equipment suppliers was implemented, CMS did not have accurate surety bond information for all suppliers. Information for thousands of bonded suppliers was missing, and surety bond amounts were not consistently maintained by supplier location. CMS can only collect \$50,000 per bonded supplier, so it is unlikely going to be able to reconcile surety bond collections with the tens of millions of dollars in overpayments owed by suppliers.

Recommendations—CMS should improve oversight of supplier data to ensure accurate and consistent information, immediately begin using the surety bond requirement to recover outstanding overpayments from suppliers' surety bonds, consider using the legislative authority given by the Patient Protection and Affordable Care Act of 2010 to require increased surety bond amounts for suppliers that receive high overall Medicare payments, and revise collection guidelines to state that collection of debts through surety bonds is based on dates of service.

## Part B Drugs Price Substitution Option

When Congress established average sales prices (ASPs) as the primary basis for Medicare Part B drug reimbursement, it also mandated that OIG compare ASPs with average manufacturer prices (AMPs). If the ASP for a particular drug exceeds the drug's AMP by a threshold of 5 percent, the Secretary of Health and Human Services may disregard the ASP for the drug when setting reimbursement and shall substitute the payment amount with the lesser of either the widely available market price or 103 percent of the AMP. OIG has issued about 30 reports comparing ASPs to AMPs since the ASP reimbursement methodology was implemented in January 2005.

As of February 2013 when the report was issued, CMS had yet to make any changes to Part B drug reimbursement as a result of OIG's reviews; however, the agency published a final rule in November 2012 that specifies the circumstances under which AMP-based price substitutions will occur. Under this rule, price substitutions apply to only certain codes that meet the 5-percent threshold using complete AMP data.

√ *Wasteful Spending*    *Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2011*

[OEI-03-12-00670](#)  
February 2013 Medicare failed to optimally exercise a statutory option to reduce payments for Part B-covered drugs under specified conditions. Medicare could have saved an estimated \$14.4 million over 1 year if CMS had lowered reimbursement for 58 drug codes that exceeded the threshold on the basis of complete AMP data in 2011. Under CMS's price substitution policy, reimbursement amounts for over 40 percent of these drugs would have been reduced, saving an estimated \$7 million over 1 year.

Recommendations—CMS should finalize the price substitution policy in the proposed rule and lower Medicare reimbursement amounts for drugs that exceed the 5-percent threshold, consider expanding the price substitution policy to include all drug codes with complete AMP data, consider expanding the price substitution policy to include certain drug codes with partial AMP data, and consider seeking a legislative change to require manufacturers of Part B-covered drugs to submit both ASPs and AMPs.

√ *Wasteful Spending*    *Comparison of First-Quarter 2012 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2012*

[OEI-03-12-00730](#)  
December 2012 In the first quarter of 2012, ASPs for 28 drug codes exceeded AMPs by at least 5 percent. Of these, 22 had complete AMP data. If reimbursement amounts for all 22 codes had been based on 103 percent of the AMPs in the third quarter of 2012, Medicare would have saved an estimated \$739,000

in that quarter alone.

√ *Wasteful Spending* *Comparison of Second-Quarter 2012 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2012*

**OEI-03-13-00100**  
December 2012 In the second quarter of 2012, ASPs for 29 drug codes exceeded AMPs by at least 5 percent. Of these, 19 had complete AMP data. If reimbursement for all 19 drug codes had been based on 103 percent of the drugs' AMPs in the fourth quarter of 2012, Medicare would have saved an estimated \$553,000 in that quarter alone.

## Part B Chemotherapy-Related Drugs

This section describes billing and pricing issues for three types of drugs: prostate cancer drugs; Herceptin, used in treating breast cancer; and Emend, used to help reduce nausea and vomiting in chemotherapy patients. Implementing the related recommendations would recover the identified overpayments and avoid the wasteful spending associated with improper billing for the drugs.

**Prostate Cancer Drugs**—Between 1995 and 2010, certain prostate cancer drugs covered under Medicare Part B (i.e., luteinizing hormone-releasing hormone (LHRH) agonists) were subject to least costly alternative (LCA) policies, which based the payment amount for a group of clinically comparable products on that of the least costly one. However, in April 2010, LCA policies for Part B drugs were discontinued in response to a court ruling stating that the use of an LCA policy was not authorized under Medicare law. There has been concern that the withdrawal of LCA policies for prostate cancer drugs may have created an unintentional incentive for physicians to administer costlier drugs.

√ *Wasteful Spending* *Least Costly Alternative Policies: Impact on Prostate Cancer Drugs Covered Under Medicare Part B*

**OEI-12-12-00210**  
November 2012 Medicare spending for LHRH agonists is higher in the absence of LCA policies for clinically comparable drugs. If LCA policies for LHRH agonists had not been rescinded, Medicare expenditures would have been reduced by \$33.3 million over 1 year, from \$264.6 million to \$231.3 million. After LCA policies were removed, utilization patterns shifted dramatically in favor of certain costlier products. However, the overall use of LHRH agonists to treat prostate cancer has been decreasing, a trend that began at least 1 year before elimination of LCA policies and continued for more than a year after.

Recommendation—CMS should consider seeking legislative authority to implement LCA policies for Part B drugs under appropriate circumstances.

**Herceptin (Trastuzumab)**—Herceptin is a Medicare-covered drug used to treat breast cancer that has spread to other parts of the body. The incorrect line items we found included that providers reported incorrect units of service on line items with unit counts that represented full multiuse vials, did not provide supporting documentation, billed for unallowable services, and reported a combination of incorrect units of service and incorrectly coded claims. The providers attributed the incorrect payments to clerical errors and to billing systems that could not prevent or detect the incorrect billing of units of service and other types of billing errors. The Medicare contractors made these incorrect payments because

neither the Fiscal Intermediary Standard System nor the Common Working File had sufficient edits in place during our audit period to prevent or detect the overpayments.

In this semiannual period, we reported the results of six reviews. We recommend that the responsible Medicare contractors recover the identified overpayments, implement or update system edits that identify for review multiuse-vial drugs that are billed with units of service equivalent to the dosage on an entire vial(s), and use the results of the audits in provider education activities.

- √ *Improper Payments* *Herceptin—The Medicare Contractor's Payments in 26 States From the WPS Legacy Workload for Full Vials of Herceptin Were Often Incorrect*
- [A-05-11-00114](#)  
February 2013 WPS Legacy Workload: 89 percent of payments made to providers from the Wisconsin Physician Services Insurance Corporation (WPS) Legacy Workload for selected line items for full vials of Herceptin were incorrect. Before Medicare contracting reform, WPS processed claims for hospitals and other institutional providers from all 15 jurisdictions. This workload, referred to as the "WPS Legacy Workload," will eventually transition to the appropriate Medicare contractors. (Recover \$3 million in identified overpayments.)
- √ *Improper Payments* *Herceptin—Medicare Contractors' Payments in Jurisdiction 1 for Full Vials of Herceptin Were Often Incorrect*
- [A-09-12-02069](#)  
February 2013 Medicare Jurisdiction 1: 75 percent of Medicare payments that Medicare contractors made to providers in Jurisdiction 1 of the selected line items for full vials of Herceptin were incorrect. (Recover \$1.7 million in identified overpayments.)
- √ *Improper Payments* *Herceptin—Medicare Contractors' Payments Made to Providers Currently Assigned to Jurisdiction 4 for Full Vials of Herceptin Were Often Incorrect*
- [A-06-12-00001](#)  
December 2012 Medicare Jurisdiction 4: 79 percent of the selected line items for full vials of Herceptin were incorrect. (Recover \$1.8 million in identified overpayments.)
- √ *Improper Payments* *Herceptin—The Medicare Contractor's Payments to Providers in Jurisdiction 9 for Full Vials of Herceptin Were Often Incorrect*
- [A-04-12-06146](#)  
January 2013 Medicare Jurisdiction 9: 78 percent of the selected line items for full vials of Herceptin were incorrect. (Recover \$1.3 million in identified overpayments.)
- √ *Improper Payments* *Herceptin—The Medicare Contractors' Payments in Jurisdiction 10 for Full Vials of Herceptin Were Often Incorrect*
- [A-04-12-03070](#)  
January 2013 Medicare Jurisdiction 10: 80 percent of the selected line items for full vials of Herceptin were incorrect. (Recover \$1.5 million in identified overpayments.)
- √ *Improper Payments* *Herceptin—Medicare Contractors' Payments in Jurisdiction 15 to Providers for Full Vials of Herceptin Were Often Incorrect*
- [A-05-12-00017](#)  
December 2012 Medicare Jurisdiction 15: 85 percent of the selected line items for full vials of Herceptin were incorrect. (Recover \$1.2 million in identified overpayments.)

**Emend (Aprepitant)**—Emend is one of three drugs in a regimen of oral anti-emetic drugs that are prescribed to help reduce nausea and vomiting in chemotherapy patients. For the oral form of Emend to be payable as an outpatient service under Medicare Part B, providers must administer or prescribe a three-drug oral regimen (consisting of Emend, a 5-HT<sub>3</sub> antagonist, and dexamethasone), along with at least one of nine specified anticancer chemotherapeutic agents. The drugs should be billed on the same claim form.

√ *Improper Payments*    *Providers Did Not Correctly Bill Medicare Part B for the Oral Form of the Drug Emend*

**A-07-11-04181**  
December 12    For the oral form of Emend, we found that about 91 percent of selected line items that were billed by 5 selected providers during calendar year (CY) 2010 were incorrect.

**Recommendations**—CMS should verify that about \$531,000 in identified overpayments has been refunded to the Federal Government; direct the selected providers to review the remaining CY 2010 line items on claims for the oral form of Emend that were not reviewed as part of this audit, as well as all subsequent claims, and refund any overpayments; develop and implement system edits to prevent payments for the oral form of Emend when providers do not bill for all of the required drugs in the regimen on the same claim; and use the results of this audit to educate providers.

## Part B Infusion Drugs

Medicare pays 106 percent of the ASP for most drugs covered under Part B. However, payment amounts for infusion drugs administered in conjunction with durable medical equipment (DME) are instead set at 95 percent of the drugs' average wholesale prices (AWPs) that were in effect on October 1, 2003. Numerous OIG reports have shown that AWP greatly exceed drug acquisition costs. Basing payments for DME infusion drugs on AWP set almost a decade ago raises concerns about whether Medicare payment levels are appropriate.

√ *Wasteful Spending*    *Part B Payments for Drugs Infused Through Durable Medical Equipment*

**OEI-12-12-00310**  
February 2013    Overall, Medicare payment amounts for DME infusion drugs exceeded ASPs by 54 to 122 percent annually. Most individual drugs had Medicare payment amounts that exceeded ASPs, many by more than two times, in each year. However, for as many as one-third of DME infusion drugs in each year, the payment amounts were below their ASPs, meaning that Medicare may be underpaying providers for these drugs. Medicare spending on DME infusion drugs would have been reduced by 44 percent (\$334 million) between 2005 and 2011 had payment been based on ASPs.

**Recommendations**—CMS should either seek a legislative change requiring DME infusion drugs to be paid using the ASP methodology or include DME infusion drugs in the next round of the competitive bidding program.

## Appeals of Claims-Related Decisions

Administrative law judges (ALJs) in the Office of Medicare Hearings and Appeals (OMHA) decide appeals at the third level of the Medicare appeals system. OMHA reports directly to

the Secretary of Health and Human Services. In 2005, among other changes, ALJs were required to follow new regulations addressing how to apply Medicare policy, when to accept new evidence, and how CMS participates in appeals. Medicare providers and beneficiaries may appeal certain decisions related to claims for health care services and items.

√ *Wasteful Spending*    *Improvements Are Needed at the Administrative Law Judge Level of Medicare Appeals*

OEI-02-10-00340  
November 2012

Wasteful spending may occur when payment decisions are inappropriately reversed on appeal because guidance to ALJs and quality assurance controls are insufficient or ineffective. We found that for 56 percent of appeals, ALJs reversed the prior-level decisions made by Qualified Independent Contractors (QICs) and decided in favor of appellants. However, when CMS participated in the appeals, ALJ decisions were less likely to be favorable to appellants. QICs are retained by CMS to make second-level decisions on appeals. We found that the reversal rate varied substantially across Medicare program areas; the variations were due to different interpretations of Medicare policies and other factors.

Recommendations—CMS should continue to increase its participation in ALJ appeals. We also recommend that CMS and OMHA seek statutory authority to postpone appeals with fraud involvement when necessary; revise regulations to provide more guidance to ALJs regarding the acceptance of new evidence; and implement administrative actions pertaining to training, policy clarifications, and electronic case files. We also recommend that OMHA seek statutory authority to establish a filing fee, implement administrative actions concerning quality assurance reviews of ALJ decisions, assess specialization among ALJs, and develop policies to handle suspicions of fraud and train staff accordingly.

## Preventing and Detecting Medicare Fraud

CMS contracts with several entities, including Program Safeguard Contractors, Medicare Drug Integrity Contractors, Recovery Audit Contractors, and Zone Program Integrity Contractors (ZPICs), to perform many Medicare integrity functions. OIG reviews have found vulnerabilities in Medicare contractors' efforts to identify and investigate potential fraud and abuse, as well as limitations in CMS's oversight of these contractors.

### Home Health Agencies—Fraud Detection

In 2010, Medicare paid \$19.5 billion to 11,203 home health agencies (HHAs) for services provided to 3.4 million beneficiaries. HHAs are considered to be particularly vulnerable to fraud, waste, and abuse. CMS designated newly enrolling HHAs as high-risk providers in March 2011, citing their record of fraud, waste, and abuse. A 2012 OIG report also found that one in four HHAs had questionable billing, which was concentrated in certain geographic areas where Federal investigators and analysts have focused their efforts to combat fraud, waste, and abuse.

√ *Detecting Fraud*    *Home Health Agencies—CMS and Contractor Oversight of Home Health Agencies*

- [OEI-04-11-00220](#)  
December 2012  
[Podcast](#)
- We found issues with CMS's and its contractors' ability to identify and respond to potential fraud. The two CMS Medicare Administrative Contractors (MACs) we reviewed prevented \$275 million in HHA improper payments and referred several instances of potential fraud, but the four ZPICs we reviewed did not identify any HHA-specific vulnerabilities and varied substantially in their efforts to detect and deter fraud. Two of the four ZPICs recommended administrative actions and referred law enforcement cases for approximately eight times the number of HHAs as the other two ZPICs. All four ZPICs served fraud-prone geographic areas.
- We also found that in 2011, Medicare inappropriately paid five HHAs with suspended or revoked billing privileges. Further, because CMS did not promptly act on five revocation recommendations it directly received from a contractor, potentially inappropriate payments resulted.
- Recommendations—CMS should establish additional contractor performance standards for high-risk providers in fraud-prone areas (including newly enrolled HHAs). CMS should also develop a system to track revocation recommendations and respond to them in a timely manner and follow up on and prevent inappropriate payments to HHAs with suspended or revoked billing privileges.

## Community Mental Health Centers—Fraud Detection

During 2010, 206 community mental health centers (CMHCs) received an estimated \$218.6 million for providing partial hospitalization program services to approximately 25,000 Medicare beneficiaries. Arrests by Medicare Fraud Strike Forces indicate that some parts of the country have a higher prevalence of CMHC fraud, including areas in Florida, Louisiana, and Texas. A recent OIG review found that approximately half of CMHCs exhibited questionable billing in 2010. Most of the centers were in Florida, Louisiana, and Texas. Other OIG reviews have found problems with CMS's oversight of its contractors.

√ *Detecting Fraud*    *Vulnerabilities in CMS's and Contractors' Activities To Detect and Deter Fraud in Community Mental Health Centers*

- [OEI-04-11-00101](#)  
January 2013  
[Podcast](#)
- One of nine MACs we reviewed performed activities to detect and deter CMHC fraud in 2010, and most of the activities were part of a CMS-led special project. Activities to detect and deter CMHC fraud varied substantially among ZPICs in 2010; one ZPIC performed almost all such activities, most of which were part of the same CMS-led special project. Other MACs and ZPICs performed minimal activities to detect and deter fraudulent CMHC billing, despite having jurisdiction over fraud-prone areas. Also, Medicare paid CMHCs that did not comply with its requirements after their revocations were effective and while their revocations were being approved. Medicare could have prevented payments to potentially fraudulent CMHCs by consistently applying an autodenial edit across Florida CMHCs.

Recommendations—CMS should implement additional CMHC fraud mitigation activities in all fraud-prone areas, develop a system to track revocation recommendations and improve revocation communication with contractors (e.g., coordinate activities to deter CMHC fraud in Florida), and follow up on payments made to CMHCs after the effective dates of their

billing privilege revocations.

## Medical Equipment and Supplies—Supplier Solicitation of Physicians

The Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program is an important new initiative for controlling costs and reducing fraud, waste, and abuse in Medicare's medical equipment benefit program. The Round 1 Rebid of the program began in nine competitive bidding areas on January 1, 2011, and made significant changes to the amount that Medicare pays for items included in the program and to the suppliers that Medicare will pay to furnish these items. Although a prescription change in the product brand or mode of delivery would not typically result in a different Medicare payment amount, we examined the extent to which suppliers might solicit physicians to make changes in their prescribing.

√ *Potential for Abuse*    *Limited Supplier Solicitation of Prescribing Physicians Under Medicare DMEPOS Competitive Bidding Program*

[OEI-06-11-00081](#)  
12/21/2012    To curb potential abuses, Congress statutorily required OIG to review supplier solicitation of physicians in the competitive bidding environment. We found that most physicians in our sample were not solicited by suppliers to change the prescribed brand or mode of delivery for competitive-bid items. Many physicians did not prescribe the brand or mode of delivery for any competitive-bid items and, therefore, had no reason to be solicited by suppliers. Further, most physicians who prescribed a specific brand or mode of delivery received no solicitation from suppliers for changes. Within our sample, most physicians who received requests from suppliers described such requests as rare or occasional and typically approved the changes. Physicians reported that supplier reasons for change requests included the supplier's belief that a different brand or mode of delivery would better meet patient needs, the supplier's not carrying the prescribed brand, and requests from patients. Finally, none of the nearly 37,000 hotline calls related to the Medicare DMEPOS Competitive Bidding Program involved concerns about supplier solicitation of physicians regarding brand or mode of delivery. The report did not contain recommendations.

## Identity Theft—CMS Response to Known Breaches

CMS maintains the protected health information of millions of Medicare beneficiaries. If a breach occurs and the security or privacy of this information is compromised, CMS is required by the American Recovery and Reinvestment Act of 2009 to notify the affected beneficiaries. Such breaches can lead to medical identity theft, i.e., the appropriation or misuse of a patient's or a provider's medical identifying information (such as a Medicare identification number) to fraudulently obtain or bill for medical care. Identity theft can create patient safety risks and impose financial burdens on those affected, leading to significant financial losses for the Medicare Trust Funds and taxpayers.

√ *Preventing Fraud*    *CMS Response to Breaches and Medical Identity Theft*

[OEI-02-10-00040](#)  
October 2012    Our review of CMS's response to known breaches of protected health information and to medical identity theft involving Medicare identification

numbers revealed opportunities for improvement. Although CMS notified Medicare beneficiaries affected by known breaches, we found that several requirements were not met. CMS has made progress in responding to medical identity theft by developing a compromised number database for contractors, but the database's usefulness could be improved. Further, Medicare's contractors do not consistently develop edits to stop payments on compromised numbers.

Recommendations—CMS should pursue the following administrative actions: ensure that breach notifications meet statutory requirements, improve the compromised number database, provide guidance to contractors about using database information and implementing edits, develop a method for ensuring that beneficiaries who are victims of medical identity theft retain access to needed services, and develop a method for reissuing identification numbers to beneficiaries affected by medical identity theft.

## Savings and Return on Investment From Fraud Prevention Technologies

Pursuant to the Small Business Jobs Act of 2010, which requires the Department of Health and Human Services (HHS) to implement predictive analytics technologies, CMS developed a Fraud Prevention System, which reviews claims processed in all 50 States, the District of Columbia, and the territories. The system detects patterns and aberrancies (referred to as "leads") that CMS provides to its benefit integrity contractors for investigation. Investigations can result in administrative actions, including payment suspensions, provider and supplier revocations, and referrals to law enforcement. Investigations can also result in the introduction of payment edits that screen claims automatically for specific problems.

OIG is required to certify the actual and projected improper payments recovered and avoided and the return on investment related to HHS's use of predictive analytics technologies in the Medicare fee-for-service program. OIG must also recommend whether the HHS should continue, expand, or modify its use of predictive analytics technologies.

√ *Detecting Fraud*    *The Department of Health and Human Services Has Implemented Predictive Analytics Technologies But Can Improve Its Reporting on Related Savings and Return on Investment*

[A-17-12-53000](#)  
December 2012    We found that in the first year of implementation, HHS did not fully meet the requirements for reporting actual and projected improper payments recovered and avoided in the Medicare fee-for-service program and reporting HHS's return on investment related to its use of such technologies. HHS did not report some of the amounts required and had inconsistencies in its data; in addition, its methodology for calculating other reported amounts included some invalid assumptions that may have affected the accuracy of those amounts.

Recommendations—HHS should require contractors to track recoveries that result from Fraud Prevention System leads; coordinate with law enforcement to enhance reporting of investigative and prosecutorial outcomes in cases predicated on referrals from the system; revise the methodology used to calculate projected savings with respect to improper payments avoided; revise the methodology used to calculate costs avoided from edits and payment suspensions, including verifying that the information in the Department's records is consistent with that maintained

by the benefit integrity contractors; and include all costs associated with the system, including reporting costs, indirect costs, and projected costs, in its return on investment calculation.

## Other Part A- and Part B-Related Oversight

### Electronic Health Records—Incentive Payment Program

The following review is an early assessment of CMS's oversight of the Medicare electronic health record (EHR) incentive program, for which CMS estimates it will pay \$6.6 billion in incentive payments between 2011 and 2016. To qualify for Medicare EHR incentive payments, professionals and hospitals must possess certified EHR technology and meaningfully use that certified EHR technology in accordance with requirements defined by CMS. Professionals and hospitals self-report data to demonstrate that they meet program requirements.

√ *Other Oversight* *Early Assessment Finds That CMS Faces Obstacles in Overseeing the Medicare Electronic Health Record Incentive Program*

OEI-05-11-00250  
November 2012

CMS does not verify the accuracy of professionals' and hospitals' self-reported information prior to payment because data necessary for verifications are not readily available. CMS also does not direct high-risk professionals and hospitals to submit supporting documentation for prepayment review. CMS's ability to safeguard incentive payments after they have been made is also limited. CMS's planned postpayment audits may not conclusively verify the accuracy of professionals' and hospitals' self-reported information because supporting documentation may not be available.

Recommendations—CMS should obtain and review supporting documentation from selected professionals and hospitals before payment to verify the accuracy of their self-reported information and issue guidance with specific examples of documentation that professionals and hospitals should maintain to support their compliance. The report also includes recommendations for the Office of the National Coordinator for Health Information Technology that define EHR technology certification requirements in Federal regulations.

### Information Security—Compliance With Statutory Requirements

Federal law requires that each Medicare contractor have its information security program evaluated annually by an independent entity. These evaluations must address the eight major requirements enumerated in the Federal Information Security Management Act of 2002 (FISMA). The FISMA also requires evaluations of the information security controls for a subset of systems. OIG must submit to Congress annual reports on the results of these evaluations, including assessments of their scope and sufficiency. This report fulfills that responsibility for fiscal year (FY) 2010.

√ *Other Oversight* *Review of Medicare Contractor Information Security Program Evaluations for Fiscal Year 2010*

A-18-12-30100  
January 2013

We found that evaluations of the contractor information security programs were adequate in scope and were sufficient. Assessments for one of the two enterprise data centers tested were adequate in scope and were sufficient. However, at the other enterprise data center, we could not determine whether the scope and sufficiency of the review were adequate because of issues with the working papers, such as lack of evidence that all testing procedures had been completed and that all identified weaknesses were adequately supported.

Recommendation—CMS should ensure that its enterprise data center technical assessments are adequately supported.

## Hospital Quality of Care—Conditions Present on Admission

The report below provides national estimates for the extent to which hospital coding staff misreported indicators that identified conditions as present on admission (POA). Hospitals do not receive increased Medicare reimbursement for certain conditions (referred to as “hospital-acquired conditions”) when they develop during the hospital stay and are not present at the time of admission. CMS officials have expressed continued interest in the accuracy of POA indicators because they provide an opportunity for monitoring hospital quality of care and are critical to CMS's efforts to link payment to quality; the coding must be accurate to serve these purposes.

√ *Other Oversight* *Assessment of Hospital Reporting of Present on Admission Indicators on Medicare Claims*

OEI-06-09-00310  
November 2012

We found that hospital coders incorrectly reported 3 percent of the 5,491 POA indicators reviewed, resulting in the presence of at least one incorrect indicator on 18 percent of claims.

We did not make formal recommendations; however, encouraging hospitals to assess POA reporting practices related to developing conditions and exemption codes and to retrain staff as needed could improve accuracy.

## Medicare Part C and Part D

### Part C Risk Adjustment Data Validation

CMS categorizes patient diagnoses, which are submitted by Medicare Advantage (MA) organizations, into groups of clinically related diseases called Hierarchical Condition Categories and uses the categories and demographic characteristics to calculate a risk score for each beneficiary. CMS then uses the risk scores to adjust the monthly capitated payments to MA organizations for the next payment period. The two examples below demonstrate the impact of unsupported diagnosis data on risk ratings and adjustments to capitated payments.

Recommendations—We recommend that the two MA organizations refund to the Federal Government the overpayments identified for the sampled beneficiaries; work with CMS to determine the correct contract-level adjustment for the estimated overpayments; implement written policies and procedures for obtaining, processing, and submitting valid risk adjustment data; and improve current practices to ensure compliance with Federal requirements.

√ *Improper Part C Payments* *Risk Adjustment Data Validation of Payments Made to PacifiCare of California for Calendar Year 2007 (Contract Number H0543)*

[A-09-09-00045](#)  
November 2012

On the basis of our sample results, we estimated that PacifiCare was overpaid approximately \$423.7 million in calendar year (CY) 2007. The risk scores for 45 of 100 selected beneficiaries were invalid because the diagnoses PacifiCare provided were not supported. (Refund to the Federal Government \$224,388 in overpayments identified for the sampled beneficiaries.)

√ *Improper Part C Payments* *Risk Adjustment Data Validation of Payments Made to Excellus Health Plan, Inc., for Calendar Year 2007 (Contract Number H3351)*

[A-02-09-01014](#)  
October 2012

On the basis of our sample results, we estimated that Excellus was overpaid approximately \$41.6 million in CY 2007. The risk scores of 45 of 98 selected beneficiaries were invalid because the diagnoses Excellus submitted were not supported. (Refund to the Federal Government \$157,777 in overpayments identified for the sampled beneficiaries.)

## Parts C and Part D Benefit Integrity Activities

This report focuses on the one Medicare Drug Integrity Contractor (MEDIC) responsible for detecting and preventing fraud, waste, and abuse in Medicare Parts C and D nationwide. The report provides an update on MEDIC identification of potential Part D fraud and abuse and is the first review of MEDIC antifraud (benefit integrity) activities for Part C.

√ *Fraud and Abuse* *Benefit Integrity Contractors—MEDIC Benefit Integrity Activities in Medicare Parts C and D*

[OEI-03-11-00310](#)  
January 2013

Our review of the MEDIC that has responsibility for both Medicare Part C and Part D revealed that its Part C investigations and case referrals represented only a small percentage of its benefit integrity activities. We identified several problems hindering the MEDIC's ability to identify and investigate fraud and abuse in Part C and Part D. The two programs involved \$190 billion in expenditures in 2011 and 33 million beneficiaries in 2012.

Recommendations—CMS should amend its regulations to require Part C and Part D plan sponsors to refer potential fraud and abuse incidents to the MEDIC and authorize the MEDIC to directly obtain information from entities such as pharmacies, physicians, and pharmacy benefit managers. We also recommend the following administrative improvements: provide the MEDIC with centralized Part C data, clarify policy and instruct the MEDIC about the circumstances under which the MEDIC may share specific information with other entities, explore methods to develop and implement a mechanism to recover payments from Part C and Part D plan sponsors when law enforcement agencies do not accept for further action

cases involving inappropriate services, and enhance the MEDIC's monthly workload reporting requirements.

## Part D Pharmacy and Therapeutics Committees—Conflicts of Interest

Part D Sponsors' Pharmacy and Therapeutics (P&T) committees make prescription drug coverage decisions on the basis of scientific evidence and standards of practice. Such decisions affect beneficiaries' access to specific prescription drugs and the cost of drugs to beneficiaries and the Federal Government. To comply with the law, sponsors' P&T committees must prevent conflicts of interest from influencing members to give preference to certain drugs. In addition, sponsors' P&T committees must comply with Federal law and regulations requiring that at least one physician and at least one pharmacist on each committee be independent and free of conflict relative to the sponsor and pharmaceutical manufacturers.

√ *Ethics*    *Medicare Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions*

[OEI-05-10-00450](#)  
March 2013  
[Podcast](#)

Sponsors' P&T committees have limited oversight of their members' conflicts of interest, thereby compromising sponsors' ability to prevent financial interests from influencing decisions about drug coverage. The majority of sponsors' P&T committees have limited definitions of conflicts of interest, which could hinder them from identifying conflicts. Also, many sponsors' P&T committees allow their members to determine and manage their own conflicts. Additionally, CMS does not adequately oversee sponsors' compliance with the requirement that at least two members on each P&T committee be independent and free of conflict relative to the sponsor and pharmaceutical manufacturers.

**Recommendations**—CMS should define pharmacy benefit managers as entities that could benefit from drug coverage decisions, direct sponsors to ensure that safeguards exist to mitigate improprieties related to employment by the entity managing the P&T committee, and ensure that an objective process is used to determine and manage conflicts. CMS should also oversee sponsors' compliance with the requirement that at least two committee members be independent and free of conflicts.

<http://oig.hhs.gov>

## Medicaid Program Reviews

States have considerable flexibility in designing and operating their Medicaid programs; however, to receive a Federal share of Medicaid costs, applicable State and Federal requirements must be met. The Federal Government pays its share of a State's medical assistance expenditures under Medicaid based on the Federal medical assistance percentage, which varies depending on a State's relative per capita income.

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### Improper State Claims for Federal Reimbursement

Improper payments are those that should not have been made or that were made in incorrect amounts, i.e., overpayments or underpayments. This section focuses on Federal overpayments (a form of wasteful spending) that resulted from improper State claims for Federal reimbursement. For example, States do not always effectively identify and reduce their erroneous and inappropriate payments for provider and supplier billings before submitting the amounts for reimbursement of the Federal share. Provider billings may be inappropriate for several reasons: the items or services billed are not supported by the documentation in the providers' medical files or are not medically necessary for the patient's condition, the billings have administrative or policy errors, or other Federal and State requirements are not met.

States' own administrative errors or misinterpretations may also result in unallowable claims for the Federal share of Medicaid.

### Disproportionate Share Hospital Payments (New Jersey)

Under the Medicaid disproportionate share hospital (DSH) program, a State is required to make special payments, known as DSH payments, to hospitals that serve a disproportionate share of low-income and/or uninsured patients. For a hospital to receive DSH payments, the State must classify the hospital as a DSH. A State may not define or deem a hospital as a DSH unless the hospital has a Medicaid inpatient utilization rate (MIUR) of not less than 1 percent. A hospital's MIUR, expressed as a percentage, is the number of inpatient days attributable to patients who were Medicaid eligible, divided by the total of the hospital's inpatient days in a particular year.

✓ *Improper Claims for Federal Share*<sup>2</sup>    *The New Jersey Department of Human Services Claimed Medicaid Disproportionate Share Hospital Payments to Five Hospitals That Did Not Meet Federal Eligibility Requirements*

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<sup>2</sup> To the left of each report title, we have flagged with a checkmark the management challenge(s) associated with the review's findings and recommendations, e.g., ✓ Improper Claims for the Federal Share, ✓ Other Wasteful Medicaid Spending, ✓ Quality of Care, etc. Implementing a report's recommendations would help curb negative outcomes associated with the designated management challenges.

[A-02-09-01017](#) New Jersey claimed DSH payments of about \$100 million (\$50 million Federal share) for five hospitals that did not meet Federal requirements for DSH payments during our audit period. Specifically, for the five hospitals, New Jersey calculated a MIUR of less than 1 percent during one or more State fiscal years but claimed DSH payments for the hospitals because it misinterpreted Federal regulations on DSH eligibility.

November 2012

Recommendations—New Jersey should refund \$50 million to the Federal Government and ensure that all hospitals designated as DSHs meet Federal eligibility requirements for DSH payments.

## Inpatient Psychiatric Hospitals (Indiana)

For States to claim Federal reimbursement for their Medicaid inpatient psychiatric service payments to a psychiatric hospital, the hospital's inpatient services must meet the Federal definitions of such services. The definitions require the provider to demonstrate compliance with the basic Medicare Conditions of Participation (CoPs) generally applicable to all hospitals and two special Medicare CoPs applicable to psychiatric hospitals.

√ *Improper Claims for Federal Share,* *Indiana Improperly Claimed Federal Reimbursement for All Reviewed Medicaid Inpatient Psychiatric Hospital Service Payments to Logansport State Hospital*  
√ *Quality of Care*

[A-05-12-00042](#) Indiana claimed Federal reimbursement for Medicaid inpatient psychiatric service payments made to Logansport State Hospital (Logansport) that were not in accordance with Federal requirements for inpatient psychiatric hospital services. Logansport did not demonstrate compliance with the special Medicare CoP at any time during the audit period. Therefore, none of the Federal reimbursement for Medicaid inpatient psychiatric service payments made to Logansport for claims with dates of service during the audit period was allowable.

February 2013

Recommendations—Indiana should refund \$5.8 million to the Federal Government, identify and refund the Federal share of any additional payments made to Logansport for claims with dates of service after the audit period if neither the State agency nor Logansport can demonstrate Logansport's compliance with Federal requirements for inpatient psychiatric hospital services, and ensure that Federal reimbursement for Medicaid inpatient psychiatric service payments to psychiatric hospitals is claimed only if those hospitals can demonstrate compliance with the special Medicare CoP.

## Personal Care Services—An OIG Portfolio

Eligible beneficiaries can receive personal care services (PCS) under Medicaid State plan options or waivers. States providing PCS through demonstration or waiver authorities must adhere to the terms approved by CMS. PCS must be provided at home or another approved location and follow a specific plan of care and are typically performed by care attendants—a career field that is expected to grow substantially over the next few years, along with the costs to Medicaid for personal care services. In the past 6 years, Medicaid costs for such services increased by 35 percent, totaling approximately \$12.7 billion in 2011. In the same

period, the Office of Inspector General (OIG) issued 23 reports on personal care services and conducted numerous investigations involving related fraud. Our latest product, the OIG Portfolio below, synthesizes this body of work and offers new and comprehensive recommendations to address vulnerabilities.

√ Potentially Improper Claims,  
√ Quality of Care  
√ Fraud and Abuse

*Personal Care Services: Trends, Vulnerabilities, and Recommendations for Improvement*

OIG-12-12-01  
November 2012  
Spotlight  
Article

Our audit and evaluation work has revealed a pattern of improper PCS payments linked to lack of compliance with State policies and requirements and found that existing controls designed to prevent improper payments are ineffective. PCS fraud (including many cases in which the care attendants and the beneficiaries act as conspirators to scam the Medicaid system) is on the rise, representing more cases investigated by State Medicaid Fraud Control Units than any other type of Medicaid fraud.

Recommendations—CMS should take action to address the concerns in our prior reports. We further recommend that CMS make qualification standards for care attendants more consistent; require care attendants to be enrolled or registered with the State; require dates, times, and attendants' identities to be listed on claims submitted to Medicaid; and expand Federal requirements and guidance to reduce variation in requirements for claims documentation, beneficiary assessments, plans of care, and supervision of attendants across States. OIG also recommends that CMS issue guidance to States regarding adequate prepayment controls and provide States with the data they need to identify overpayments occurring when beneficiaries are receiving institutionalized care. Finally, CMS should consider whether additional program controls are needed.

## HCBS-Covered Assisted Living Facilities in Seven States

CMS may waive certain requirements to allow State Medicaid programs to cover home and community-based services (HCBS) for beneficiaries. However, States must implement their waivers as specified in their CMS-approved applications, including any additional requirements related to plans of care. Little information exists about the HCBS furnished to beneficiaries in assisted living facilities (ALFs), the costs of those HCBS, or the extent to which those HCBS are furnished in compliance with Federal and State requirements. The review cited below revealed that in 2009, 35 Medicaid programs reported that they covered various HCBS for beneficiaries in ALFs under waivers at an annual cost of \$1.7 billion. Each State had federally mandated provider standards; however, ALFs in seven States we selected for further review did not always comply with them, and required plans of care did not always meet Federal requirements.

√ Potentially Improper Claims,  
√ Quality of Care

*Home and Community-Based Services in Assisted Living Facilities*

OEI-09-08-00360  
December 2012

In seven selected States, we found that 77 percent of beneficiaries received HCBS in ALFs that were cited for a deficiency with regard to at least one State licensure or certification requirement. Nine percent of beneficiaries'

records did not include plans of care required by the States. Forty-two percent of the federally required plans of care did not include the frequency of HCBS furnished, as required. Five of the seven States required that plans of care specify the beneficiaries' goals and the interventions to meet them, but 69 of 105 plans of care for selected beneficiaries did not meet that requirement. Two of the seven States also required that plans of care be signed by beneficiaries or their representatives. In the 2 States, 12 of 25 plans of care for beneficiaries receiving HCBS in ALFs did not meet that requirement.

Recommendation—CMS should issue guidance to State Medicaid programs emphasizing the need to comply with Federal requirements for covering HCBS under the 1915(c) waiver.

## Home Health Services (New York)

Certified Home Health Agencies (CHHAs) in New York City provide preventive, therapeutic, and/or rehabilitative services to Medicaid beneficiaries. Pursuant to Federal regulations, home health services are provided to a beneficiary at the beneficiary's place of residence and on his or her physician's orders as part of a written plan of care that the physician reviews every 60 days.

√ *Improper Claims for Federal Share, Quality of Care*     *New York Improperly Claimed Medicaid Reimbursement for Some Home Health Services Claims Submitted by Certified Home Health Agencies in New York City*

[A-02-10-01022](#)     New York claimed Federal Medicaid reimbursement for some home health services claims submitted by CHHAs in New York City that were not in accordance with Federal and State requirements. Specifically, for 17 claims, the plan of care was not reviewed every 60 days, and for 1 claim, the provider was unable to document that the service was provided. On the basis of our sample results, we estimated that the State improperly claimed \$69.1 million in Federal Medicaid reimbursement during our January 1, 2007, through December 31, 2009, audit period.

Recommendations—New York should refund \$69.1 million to the Federal Government and issue guidance to CHHAs in New York City on Federal and State requirements for physicians' orders and plans of care.

## Family-Based Treatment Rehabilitation Services (New York)

Family-based treatment (FBT) rehabilitation services include training and assistance with daily living skills, medication management, socialization, counseling, family support, and health services.

√ *Improper Claims for Federal Share*     *New York Improperly Claimed Medicaid Reimbursement for Family-Based Treatment Rehabilitation Services*

[A-02-10-01024](#)     New York improperly claimed a Federal share of FBT rehabilitation services that did not meet Federal and State requirements. Of the 100 claims in our random sample, 84 did not comply and 58 contained more than 1 deficiency. These deficiencies occurred because providers did not fully comply with State regulations, authorizing physicians were not

familiar with applicable State regulations and program requirements, and the State did not adequately monitor the program.

Recommendations—New York should refund \$27.5 million to the Federal Government. If the State does not close the FBT program by a date it has set as a deadline, we further recommend that it provide guidance to the provider community on State regulations, provide guidance to physicians on State regulations and program requirements, and improve its monitoring and oversight to ensure compliance.

## Family Planning (Arkansas and California)

The Federal Government pays its share of a State's medical assistance expenditures under Medicaid on the basis of the Federal medical assistance percentage, which varies depending on the State's relative per capita income. Family planning services are reimbursed at an enhanced 90-percent rate. Family planning services are those that prevent or delay pregnancy or otherwise control family size. Following are the results of family planning services reviews in Arkansas and California.

√ *Improper Claims for Federal Share*    *Arkansas Inappropriately Received Medicaid Family Planning Funding for Federal Fiscal Years 2006 Through 2010*

[A-06-11-00022](#)  
January 2013

Arkansas improperly claimed expenditures that did not qualify for the 90-percent rate for family planning. The expenditures exceeded limits specified in the State's infant delivery allocation methodology and resulted from errors in compiling the family planning expenditures and from errors in the computer programming used to identify infant delivery costs. Other questionable expenditures were set aside for further analysis.

Recommendations—Arkansas should refund to the Federal Government \$1.9 million in family planning Federal share, work with CMS to determine the allowable portion of \$929,000 in family planning Federal share that it received for allocated sterilization costs, review the claim-level data of quarters that we did not analyze, identify infant delivery costs incorrectly classified, and refund overpayments to the Federal Government. We also recommend that the State review its pertinent computer programming; submit documentation to CMS supporting the reasonableness of the percentages used in allocations; and establish review procedures to ensure that expenditures are correctly compiled, assigned, and claimed.

√ *Improper Claims for Federal Share*    *California Improperly Claimed Enhanced Federal Reimbursement for Medicaid Family Planning Services Provided in San Diego County*

[A-09-11-02040](#)  
December 2012

California did not always comply with certain Federal and State requirements when claiming Federal reimbursement at the 90-percent rate for family planning services. The rate was unallowable because the primary purpose of the visits was not family planning, the visits were for followup properly reimbursed at the regular rate, or the supporting documentation was insufficient. We also found claims that contained either no procedure code or a procedure code that was not approved by CMS for reimbursement at the 90-percent rate.

Recommendations—California should refund \$5.7 million to the Federal Government, establish billing procedures to ensure that only services

whose primary purpose is family planning are claimed for reimbursement at the 90-percent enhanced rate, and establish Medicaid Management Information System edits to ensure that family planning claims meet Federal and State requirements for reimbursement at the 90-percent enhanced rate and at the regular rate for followup visits.

## Medicaid School-Based Transportation Services (New Hampshire)

Medicaid payments are allowed for medical services provided to children under the Individuals with Disabilities Education Act through a child's individualized education plan. Covered services may include, but are not limited to, physical therapy, occupational therapy, speech pathology/therapy services, psychological counseling, nursing, and transportation services.

√ *Improper Claims for Federal Share*    *Transportation Services—New Hampshire Did Not Always Correctly Claim Medicaid Payments for School-Based Transportation Services*

**A-01-11-00008**    New Hampshire did not always claim Federal Medicaid reimbursement for school-based transportation services submitted by schools in accordance with Federal and State requirements during calendar years (CYs) 2006 through 2009. Of the 115 items in a random sample, 78 items had 1 or more transportation services that were not reimbursable. The deficiencies occurred because New Hampshire issued incorrect guidance to the school administrative units (SAUs) on the basis of its misunderstanding of Federal requirements. In addition, the State did not adequately monitor the claims for Medicaid school-based transportation services submitted by SAUs.

October 2012

Recommendations—New Hampshire should refund an estimated \$2.7 million to the Federal Government, work with CMS to review Medicaid payments made to SAUs after our audit period and refund any overpayments, strengthen its oversight of the New Hampshire Medicaid to Schools program to ensure that claims for school-based transportation services comply with Federal and State requirements, and issue new guidance on school-based transportation that is consistent with Federal requirements.

## Medicaid School-Based Services Administrative Costs (Arizona)

Federal law provides for States to be reimbursed for administrative activities that directly support identifying and enrolling potentially eligible children in Medicaid. The Federal reimbursement is 50 percent of allowable administrative expenses. According to Federal regulations, random moment sampling (RMS), which uses random moment timestudies (RMTS), is one of the federally acceptable methods for allocating costs to Federal awards when employees work on multiple activities not allocable to a single Federal award. CMS guidance clarifies the regulations by providing information on the sample universe, sampling plan methodology, treatment of the summer period, RMTS documentation, training for RMTS participants, and the monitoring process.

√ *Improper Claims for Federal Share*    *Administrative Costs—Arizona Improperly Claimed Federal Reimbursement for Medicaid School-Based Administrative Costs*

**A-09-11-02020**    Arizona did not always maintain required documentation to support the

January 2013 RMTS methodology used to allocate school-based administrative costs to Medicaid, and the RMTS methodology was not fully consistent with Federal requirements. Also, the 2004 State guide included incorrect guidance that allowed its contractor to discard sample items.

Recommendations—Arizona should refund to the Federal Government \$11.7 million for unallowable school-based administrative costs, work with CMS to determine the allowability of \$18.8 million that we set aside for further analysis, and refund to the Federal Government any amount determined to be unallowable. We also recommend that Arizona strengthen controls to ensure that all required documentation to support the RMTS methodology is maintained and the RMTS methodology is consistent with Federal requirements. Arizona should also review periods after our audit period and make appropriate financial adjustments for any unallowable school-based administrative costs claimed.

### Administrative Costs Unallowable or Indeterminable (Florida)

Florida's Agency for Persons With Disabilities (APD) serves individuals with developmental disabilities and their families. Because APD performed certain services required under the State plan on behalf of individuals with developmental disabilities, the allowable portion of its administrative costs allocable to Medicaid was eligible for Federal reimbursement. On the quarterly Form CMS-64, Florida claimed a 50-percent Federal share for APD's Medicaid administrative costs, including costs allocated on the basis of APD's quarterly RMS...

√ *Improper Claims for Federal Share* Florida Claimed Some Medicaid Administrative Costs That Did Not Comply With Program Requirements

[A-04-10-00076](#) A portion of the administrative costs Florida's APD allocated to Medicaid during our review period did not comply with Federal requirements and therefore was unallowable for Federal financial participation. Also, we could not determine whether the remaining amount we reviewed was allowable because we could not quantify the effect of vulnerabilities identified in the statistical sampling methods used.

March 2013

Recommendations—Florida should refund \$2.2 million to the Federal Government; ensure that APD follows pertinent procedures defined in its cost allocation plan; work with CMS to determine what portion of the remaining \$40 million (\$20 million Federal share) in costs allocated to Medicaid on the basis of RMS was allowable under Federal requirements; and require APD to amend its cost allocation plan to ensure that APD's RMS gives appropriate consideration to all hours worked by employees, properly accounts for invalid responses and nonresponses, and requires observation forms to include the sampled position numbers.

### Administrative Costs for Housing Program (Pennsylvania)

The Social Security Act permits States to claim Federal reimbursement for Medicaid administrative costs. Such costs must be "for the proper and efficient administration of the State plan." CMS guidance clarifies that allowable claims must be "directly related to the administration of the Medicaid program." The Federal share of most Medicaid administrative costs is reimbursed at the 50-percent rate.

√ *Improper Claims for Federal Share*    *Pennsylvania Claimed Unallowable Medicaid Administrative Costs for the Regional Housing Coordinator Initiative*

A-03-11-00210  
December 2012

Pennsylvania did not comply with Federal requirements when it claimed a Federal share of Medicaid administrative costs for the Pennsylvania Regional Housing Coordinator Initiative (Initiative) costs. The claimed costs represented indirect services, such as information, referrals, training, and technical assistance, to support Pennsylvania's housing programs, including programs that provided housing services to Medicaid beneficiaries transitioning to waiver programs. These indirect services were not directly related to the administration of the Medicaid program. Accordingly, Pennsylvania's claims for the Initiative's costs from July 2008 through December 2011 were unallowable.

Recommendations—Pennsylvania should refund \$2 million in Federal funds for unallowable Initiative costs, refund the Federal share of unallowable Initiative costs claimed after our audit period, and discontinue all future claims for Initiative costs.

## Other Sources of Wasteful Medicaid Spending

### Federal Upper Limits on Drug Payments

The Medicaid Federal upper limit (FUL) program limits Medicaid reimbursement for certain multiple-source drugs and seeks to ensure that the Federal Government acts as a prudent buyer by taking advantage of market prices for these drugs. Prior OIG work consistently found that the published prices used to set Medicaid's FUL amounts often greatly exceeded prices available in the marketplace. CMS has taken steps to implement FUL amounts based on average manufacturer prices (AMPs), but wasteful spending has occurred because FULs continue to be based on published prices.

√ *Other Wasteful Medicaid Spending*    *Drug Pricing—Analyzing Changes to Medicaid Federal Upper Limit Amounts*

OEI-03-11-00650  
October 2012

For our review period, we found that Medicaid FUL amounts based on AMPs were 61 percent lower than FUL amounts based on published prices at the median and AMP-based FULs exceeded sampled pharmacy acquisition costs by 43 percent in the aggregate. FUL amounts based on published prices were more than four times greater than sampled pharmacy acquisition costs.

Recommendation—CMS should complete the implementation of the AMP-based FUL amounts for drug reimbursements.

### Overpayments To Be Collected, Adjusted

Failure to recoup overpayments perpetuates waste. Our objective was to determine the extent to which CMS had collected sustained overpayments identified in selected OIG Medicaid audit reports. When CMS concurs with a recommendation to collect overpayments, it may sustain either the entire amount or a different amount. If the State

agrees in writing with OIG or CMS to refund the overpayment, the State should refund it to the Federal Government. If the State does not agree, CMS follows different procedures to resolve the OIG recommendations. In 147 OIG audit reports issued between fiscal years (FYs) 2000 and 2009, OIG recommended that States refund Medicaid overpayments, and CMS agreed to sustain \$1.2 billion.

√ *Other Wasteful Medicaid Spending*    *Uncollected Overpayments—The Centers for Medicare & Medicaid Services Collected the Majority of Medicaid Overpayments but Millions Remain Uncollected*

**A-05-11-00071**    As of December 2012, CMS reported collecting \$987.5 million of the February 2013    \$1.2 billion in Medicaid overpayments that it had sustained in the 147 audit reports covered by our review. However, CMS had not collected the remaining \$225.6 million. The uncollected amount related to overpayments that OIG had identified in 10 audit reports that the States had not agreed to refund. In addition, CMS could not document that \$7.2 million that it reported as collected had been collected.

Recommendations—CMS should collect the remaining \$225.6 million that is due the Federal Government, review and address delays in resolving OIG audit recommendations and promptly pursue corrective actions, maintain adequate documentation to support the collection of overpayments in accordance with requirements, and educate the States about their responsibility to report overpayments on the correct line of the Form CMS-64 and to improve oversight of the reporting process.

## Federal Share of Collected Overpayments Not Returned (Florida)

√ *Other Wasteful Medicaid Spending*    *Florida Medicaid: Millions in Overpayments Not Refunded*

**A-04-11-08007**    Florida did not return to CMS the Federal share of Medicaid overpayments 3-27-2013    the State identified or collected in our audit period (July 1, 2007, through June 30, 2010). The State also collected overpayments during the 2 years that followed our audit period and did not return the Federal share.

Recommendations—Florida should repay \$1.4 million (Federal share) of overpayments collected during our audit period, repay \$852,000 (Federal share) of overpayment collections during the 2 State fiscal years after our audit period, improve internal coordination to report State-identified Medicaid overpayments and collections, and work with CMS to determine whether the State must repay \$10.8 million (Federal share) of recipient overpayments identified but not collected.

## Third Party Liability

Medicaid is intended to be the payer of last resort. Millions of Medicaid beneficiaries have additional health insurance through third-party sources, such as Medicare, TRICARE, or other payers. If beneficiaries have another source of payment, that source should pay before Medicaid does, up to the extent of its liability. Medicaid has provisions designed to enhance States' ability to identify and recover payments from liable third parties. Cost avoidance is the method that States use to avoid payment when other insurance resources

are available to the beneficiary. In contrast, the pay-and-chase method occurs when States pay providers for submitted claims and then attempt to recover payments from liable third parties.

√ *Other Wasteful Medicaid Spending*    *Third Party Liability—Medicaid Third-Party Liability Savings Increased, But Challenges Remain*

**OEI-05-11-00130**  
January 2013    States reported increased Medicaid savings from third-party liability cost avoidance and recoveries. States reported that improvements to their processes facilitated savings. Despite these improvements, States reported longstanding challenges with third parties when trying to identify insurance coverage and recover payments. In addition, States reported challenges—caused, they say, by laws and regulations—that hinder the recovery of payments. We found \$4 billion in third-party liability overpayments that remain at risk of not being recovered.

Recommendations—CMS should work with States to address longstanding challenges related to identification of insurance coverage and recovery of payments, address States' challenges with 1-year timely filing limits for Medicare and TRICARE, and work to strengthen enforcement mechanisms designed to deal with uncooperative third parties.

## Overpayments Associated With Credit Balances (North Carolina)

North Carolina's Billing Guide requires providers to submit a quarterly report showing all identified Medicaid overpayments recorded as credit balances in the providers' accounting systems as of the last day of each calendar quarter. Credit balances may occur when a provider's reimbursement for services it provides exceeds the allowable amount or when the reimbursement is for unallowable costs, resulting in an overpayment. Credit balances also may occur when a provider receives payments from Medicaid and a third-party payer for the same services. The audit objectives were to determine whether the providers reconciled invoice records with credit balances and reported the associated Medicaid overpayments to the State agency, as required.

√ *Other Wasteful Medicaid Spending*    *Unreported Overpayments—Noninstitutional Providers in North Carolina Did Not Reconcile Invoice Records With Credit Balances and Report the Associated Medicaid Overpayments to the State Agency*

**A-04-11-04016**  
November 2012    The noninstitutional providers we reviewed did not identify and report Medicaid overpayments because North Carolina did not require them to exercise reasonable diligence in reconciling invoice records with credit balances to determine whether overpayments existed. Of the 185 invoice records with both Medicaid payments and credit balances in our sample, 112 contained Medicaid overpayments, but 73 did not.

Recommendations—North Carolina should refund \$7,000 (Federal share) to the Federal Government for overpayments paid to the selected providers. The State should also enhance its efforts to recover additional overpayments estimated at \$1.26 million (\$902,000 Federal share) from our audit period and realize future savings by requiring providers to exercise reasonable diligence in reconciling invoice records with credit balances and reporting the associated Medicaid overpayments.

## Preventing and Detecting Medicaid Fraud

### OIG Oversight of State Medicaid Fraud Control Units

Medicaid Fraud Control Units (MFCU) are key partners in the fight against fraud, waste, and abuse in State Medicaid programs. OIG is responsible for overseeing MFCUs' activities. As part of this oversight, OIG conducts periodic reviews of all Units and prepares public reports based on these reviews. The reviews describe the Units' caseloads; assess performance in accordance with the 12 MFCU performance standards; identify any opportunities for improvement; and identify any instances of noncompliance with laws, regulations, or policy transmittals.

√ *Fraud and Abuse* *New Hampshire State Medicaid Fraud Control Unit: 2012 Onsite Review*

[OEI-02-12-00180](#)  
October 2012 From FYs 2009 to 2011, the New Hampshire Unit reported recoveries of \$14 million, filed criminal charges against 25 defendants, and obtained 15 convictions. The overall number of cases opened and closed by the Unit decreased. This was due to a decrease in patient abuse and neglect cases. The Unit attributed the overall decrease primarily to staffing limitations; for all 3 years, the Unit's staffing levels were below the number of staff that the Unit requested and OIG approved. Additionally, although the Unit reported that its best source of fraud referrals was the State's Surveillance and Utilization Review Subsystem (SURS), the Unit noted that the number of referrals from SURS was low.

Recommendations—The New Hampshire Unit should seek to expand staff sizes to reflect the number of staff approved in the Unit's budget, ensure that it maintains an adequate workload through referrals from SURS, ensure that case files contain documented supervisory reviews, and establish annual training plans for each professional discipline.

√ *Fraud and Abuse* *Louisiana State Medicaid Fraud Control Unit: 2012 Onsite Review*

[OEI-09-12-00010](#)  
December 2012 From FYs 2009 through 2011 (our period of review), the Unit reported recoveries of \$95 million, obtained 192 convictions and 86 civil judgments or settlements, and received 1,043 referrals. Provider fraud referrals to the Unit increased, and the Unit received patient abuse and neglect referrals from a variety of sources. Findings, which are addressed below, included that the Unit had not updated its memorandum of understanding (MOU) with the Louisiana Department of Health and Hospitals (DHH) to reflect current law and practice. Except for not reporting all of its program income, we found no evidence of Unit noncompliance with applicable laws, regulations, and policy transmittals.

Recommendations—The Louisiana Unit should revise its policies and procedures to ensure that periodic supervisory reviews are documented in Unit case files, ensure that letters referring providers for exclusion from Federal health care programs are submitted to OIG within the appropriate timeframe, revise its MOU with DHH to reflect current law and practice, and ensure that all program income is reported properly on its Federal Financial Status Reports.

√ *Fraud and Abuse* *South Carolina State Medicaid Fraud Control Unit: 2012 Onsite Review*

[OEI-09-11-00610](#) Our analysis of collected data from FYs 2008 through 2010 shows that the

October 2012 Unit's caseload increased by 65 percent and that the amount of funds the Unit recovered nearly doubled, from \$15.3 million in FY 2008 to \$30.3 million in FY 2010. Our findings, which are addressed by the recommendations below, included that although the Unit maintained proper fiscal control of its resources, it did not report program income properly in FY 2010.

Recommendations—The South Carolina Unit should ensure that periodic supervisory reviews are documented in Unit case files, complete revisions to its policies and procedures manual to reflect Unit operations and revise its MOU with South Carolina's State Medicaid agency to reflect current law and practice, and ensure that program income is reported properly.

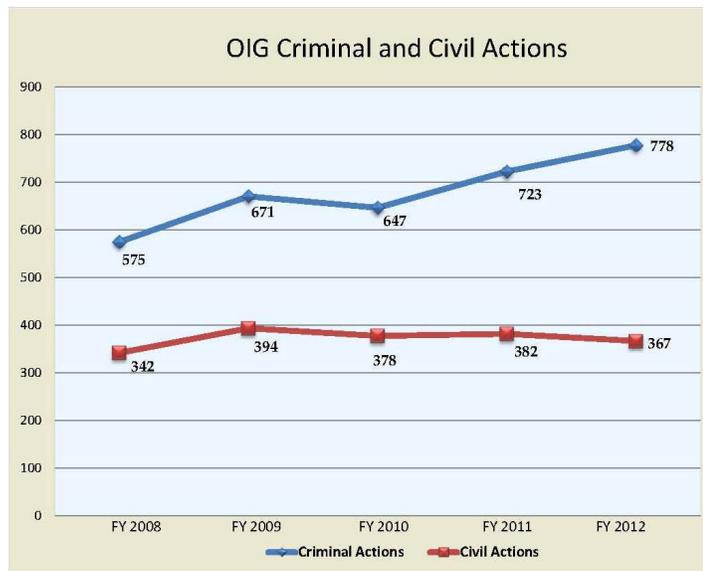
## Legal and Investigative Activities Related to Medicare and Medicaid

For this semiannual period, we reported 436 criminal and 232 civil actions against individuals or entities that engaged in health-care-related offenses. We also reported \$2.64 billion in investigative receivables due the U.S. Department of Health and Human Services (HHS) and \$640 million in non-HHS investigative receivables, including civil and administrative settlements or civil judgments related to Medicare; Medicaid; and other Federal, State, and private health care programs.

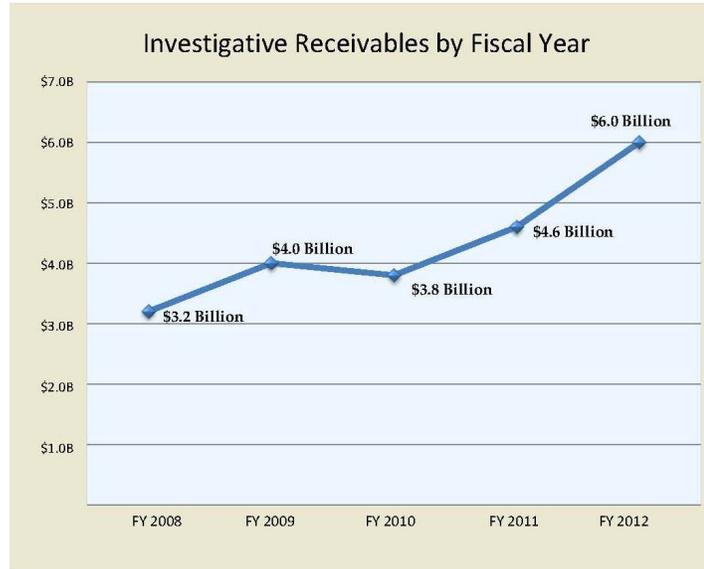
The Office of Inspector General’s (OIG) investigations often involve the combined efforts and resources of our office and other Federal and State law enforcement agencies. One of the most common types of fraud perpetrated against Medicare, Medicaid, and other Federal health care programs involves filing false claims for reimbursement. False claims may be pursued under Federal and State criminal statutes and, in appropriate cases, under the False Claims Act Amendments of 1986 (FCA), as further amended in 2009.

Depending on the types of fraud or other violations involved, OIG investigations may culminate in criminal or civil court judgments and decisions, administrative sanctions and decisions, and/or negotiated settlement agreements. Investigative outcomes take many forms, including incarceration, restitution, fines, penalties, forfeitures, assessments, and exclusion of individuals or entities from participation in all Federal health care programs. Frequently used exclusion and penalty authorities are described in Appendix D of this *Semiannual Report to Congress* (Semiannual Report) and on our Web site at: <http://www.oig.hhs.gov/fraud/enforcement/cmp/index.asp>.

Chart 1- Actions: All HHS Programs



**Chart 2 – Receivables: All HHS Programs**



(Includes non-HHS receivables, e.g., States' share of Medicaid restitution.)

## Advisory Opinions and Other Industry Guidance

As part of OIG's continuing efforts to promote the highest level of ethical and lawful conduct by the health care industry, we issue advisory opinions and other guidance to educate industry and other stakeholders on how to avoid fraud, waste, and abuse. Advisory opinions, which are developed in consultation with the Department of Justice (DOJ), are issued to requesting parties regarding the interpretation and applicability of certain statutes relating to Federal health care programs. The Health Insurance Portability and Accountability Act of 1996, § 205, allows OIG to provide case-specific formal guidance on the application of the anti-kickback statute and safe harbor provisions and other OIG health care fraud and abuse sanctions. From October 1 through March 31, 2013, OIG received 31 requests for advisory opinions and issued 10 opinions. OIG also issued one modification of an earlier opinion.

## HEAT—Health Care Fraud Prevention and Enforcement Action Team

On May 20, 2009, 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 DOJ and HHS 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. Following are links to OIG's provider compliance training resources:

[http://oig.hhs.gov/newsroom/video/2011/heat\\_modules.asp](http://oig.hhs.gov/newsroom/video/2011/heat_modules.asp)

[http://oig.hhs.gov/newsroom/video/2011/heat\\_modules.asp#modules](http://oig.hhs.gov/newsroom/video/2011/heat_modules.asp#modules)

<http://oig.hhs.gov/compliance/provider-compliance-training/index.asp#materials>

## Medicare Fraud Strike Force Activities

The Medicare Fraud Strike Force (Strike Force) is a key component of HEAT. The Strike Force was established in March 2007 and is operating in nine cities—Miami, Florida; Los Angeles, California; Detroit, Michigan; Houston, Texas; Brooklyn, New York; Baton Rouge, Louisiana; Tampa, Florida; Chicago, Illinois; and Dallas, Texas. Strike Force teams coordinate joint law enforcement operations conducted by Federal, State, and local law enforcement entities. These teams have a proven record of success in analyzing data to quickly identify fraud and bring prosecutions. During this reporting period, Strike Force efforts resulted in the filing of charges against 148 individuals or entities, 139 criminal actions, and \$193.7 million in investigative receivables.

## Strike Force Takedown Led to Charges Against 91 Individuals

In October 2012, Medicare Fraud Strike Force operations in 7 cities led to charges against 91 individuals, including doctors, nurses, and other licensed medical professionals, for their alleged participation in Medicare fraud schemes involving approximately \$429.2 million in false billing. The coordinated nationwide takedown encompassed indictments charging more than \$230 million in home health care fraud, more than \$100 million in mental health care fraud, more than \$49 million in ambulance transportation fraud, and millions more in other types of fraud. HHS also suspended or took other administrative actions against 30 health care providers following credible allegations of fraud.

## Additional Examples of Strike Force Efforts

**Florida**—Twenty-four defendants have been charged and 15 sentenced in a \$205 million Medicare fraud scheme perpetrated by Lawrence Duran and his co-conspirators. Duran owned and operated American Therapeutic Corporation (ATC), an umbrella organization that managed seven community mental health centers. According to the indictment, ATC and the American Sleep Institute (ASI), another company owned by Duran, submitted more than \$205 million in false and fraudulent claims for services that were medically unnecessary, were not eligible for Medicare reimbursement, or were never provided.

Duran and his co-conspirators created a massive criminal operation, in which ATC paid up to approximately \$500,000 in cash each month in kickbacks to a network of patient recruiters, assisted living facilities, and halfway houses in exchange for Medicare

beneficiaries who received purported mental health therapy and sleep study services at ATC and ASI. The defendants created fictitious identities, set up various corporations, and used multiple individuals to launder money. The corporate officers of the companies, and other individuals who received personal checks, deposited the checks, withdrew cash, and returned it to Duran to pay the kickbacks. Evidence at trial revealed that ATC medical directors signed patient files without reading them; did not see patients; and changed, removed, or placed patients on psychotropic medications without medical evaluation, all in an effort to conceal from Medicare the fact that many ATC patients did not qualify for reimbursement.

Duran was sentenced to 50 years in prison and ordered to pay \$87 million in restitution, joint and several. To date, 14 other defendants have been sentenced to a combined 133 years in prison and ordered to pay \$87 million in restitution, joint and several, as well as more than \$30,000 in fines.

**New York**—Boris Sachakov was sentenced to 2 years and 6 months in prison and ordered to pay \$1.1 million in restitution and forfeit \$1.1 million after being convicted on health care fraud charges. Evidence at trial showed that from January 2008 to January 2010, Sachakov defrauded Medicare and private insurers by billing for surgeries and services that he never provided. Sachakov owned and operated Colon and Rectal Care of New York, P.C., a clinic that purportedly provided proctological services, including examinations and hemorrhoidectomies. According to the indictment, Sachakov submitted and caused the submission of more than \$22 million in false and fraudulent claims to Medicare and private insurers for services that were not performed. Sachakov also billed for multiple office visits, examinations, and hemorrhoidectomies as if he were treating distinct, unrelated conditions. However, to the extent any of these services were performed, Sachakov merely provided followup services related to the initial procedure.

**Florida**—Eulises Escalona was sentenced to 10 years in prison and ordered to pay \$26 million in restitution, joint and several, after pleading guilty to charges of conspiracy to commit health care fraud. Escalona was owner and operator of Willsand Home Health Services, Inc. (Willsand), which purportedly provided home health care and physical therapy services to Medicare beneficiaries. According to court documents, Escalona paid kickbacks to patient recruiters for enrolling Medicare beneficiaries to be placed at Willsand and signed false documents stating that they received home health care services. Escalona also paid kickbacks to physicians in return for signing false prescriptions for these patients. From about January 2006 through November 2009, Willsand submitted more than \$40 million in claims to Medicare for home health services it purportedly provided to beneficiaries when, in fact, the patients were not homebound and/or had no medical need for the services.

**Texas**—Michelle Turner was sentenced to 2 years in prison and ordered to pay \$295,000 in restitution, joint and several, after being found guilty on charges of conspiracy to commit health care fraud and conspiracy to defraud the United States and to receive health care kickbacks. The investigation revealed that Turner ran a "boiler room" operation in which she employed teenagers to call Medicare beneficiaries and try to persuade them to accept "arthritis kits," which consisted of a box of neoprene braces for various body parts. Family DME, the Houston company with which she contracted, billed Medicare for several high-quality rigid braces. Turner's company would often find physicians who would sign off on the bogus orders when the patients' primary care physicians refused. Turner is the fifth and final defendant to be sentenced in this case.

## Other Criminal and Civil Enforcement Activities

### Special Assistant U.S. Attorney Program

During this reporting period, DOJ and OIG continued their participation in a program in which OIG attorneys, some of whom are Special Agents, serve as Special Assistant U.S. Attorneys. 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 relating to fraud pertaining to medical equipment and supplies, infusion therapy, and physical therapy and other types of Medicare and Medicaid fraud.

### Most Wanted Fugitives Listed on OIG's Website

The OIG Most Wanted Fugitives Web site continues to garner national and international attention and greatly assists in helping to capture fugitives charged with defrauding Federal health care programs and stealing millions of taxpayer dollars. The Most Wanted Fugitives Web site is periodically updated and features a profile and statistics for each fugitive, as well as an online tip form and a hotline number for individuals to report fugitive-related information to OIG, in English or Spanish, 24 hours a day, 365 days a year. The Most Wanted Fugitives list can be accessed at <https://oig.hhs.gov/fraud/fugitives>.

The Web site features recently captured fugitives, including Elisabet Martinez, who was arrested in December 2012 after she arrived at Miami International Airport. In 2012, Martinez was indicted on charges of health care fraud and conspiracy to commit health care fraud. Investigators believe that, through her company, Your Neighbor Pharmacy, LLC, Martinez submitted false and fraudulent claims to Medicare for prescription drugs that were medically unnecessary, were not prescribed by a doctor, or were not provided to Medicare beneficiaries.

Because of the success of OIG's Most Wanted Fugitives Web site, OIG also launched its Most Wanted Deadbeat Parents Web site at: <https://oig.hhs.gov/fraud/child-support-enforcement/index.asp>. The site highlights parents who fail to pay court-ordered child support for their children and put an unnecessary strain on the custodial parents and the children, as well as on agencies that enforce these matters. Examples are provided in the "Human Services Reviews" section of this Semiannual Report.

## Recently Completed Actions and Settlements

Following are summaries of various civil and criminal actions from this semiannual period. The summaries are organized by the sector of the health care industry involved or by the nature of the offense.

## Home Health Providers

**Florida**—Seventeen defendants have been sentenced in a home health care fraud scheme. According to the indictment, employees at Superstar Home Health Care, Inc., a provider in Miami, Florida, allegedly offered and paid thousands of dollars in kickbacks and bribes to patient recruiters and Medicare beneficiaries. In exchange, the beneficiaries acted as patients for the health agency. Beneficiaries involved in the scheme received prescriptions and health-related services from Superstar, even though there was no medical need. Superstar used beneficiary information to submit \$1.5 million in claims to Medicare for home health services that either were medically unnecessary or were not provided. During this reporting period, Jesus Cabanes-Hernandez, Vivian Augustine, Yuria Perez-Rivero, Olga Martinez, Joel Loyola, Marianela Terrero, Daymi Fuentes-Gil, Victor Escalante, Marisela Sherwood, Pablo Orama, Nancy Diaz, Jose Abreu, Carlos Herrera, Marlene Garcia, Jose Orelvis-Ortega, Ivon Perez, and Elba Caicedo were sentenced to a combined 17 years of incarceration and ordered to pay \$742,742 in restitution, joint and several.

**Florida**—Kelvin Soto and Odalys Fernandez were sentenced after being found guilty on charges of conspiracy to commit health care fraud and health care fraud. According to evidence at trial, Soto and Fernandez were registered nurses employed by Ideal Home Health, Inc., a company that allegedly submitted approximately \$40 million in false claims to Medicare. Soto and Fernandez falsified and caused Medicare beneficiaries to falsify Weekly Visits and/or Time Records sheets, which indicated that they provided skilled nursing services to Medicare beneficiaries. From about August 2007 through March 2009, Soto and Fernandez caused Medicare to make approximately \$1.3 million in payments to Ideal Home Health. Soto was sentenced to 6 years of imprisonment and ordered to pay \$727,418 in restitution. Fernandez was sentenced to 3 years and 5 months of imprisonment and ordered to pay \$240,369 in restitution.

**Texas**—Home health agency Kai Heart, Inc., also known as Kai Heart Home Health Care (Kai Heart), agreed to pay \$778,093 to resolve FCA allegations. The Government alleged that from July 2006 through June 2007, Kai Heart falsified Outcome and Assessment Information Set (OASIS) certifications in support of improper claims submitted to Medicare for home health services. Specifically, the Government alleged that Kai Heart knowingly altered the OASIS forms by upcoding the severity of patients' conditions in order to receive additional Medicare reimbursement. Kai Heart also agreed to enter into a 5-year corporate integrity agreement (CIA) with OIG.

## Pharmaceutical Companies

**Virginia**—Abbott Laboratories (Abbott) agreed to pay \$1.5 billion and enter into a 5 year CIA in a global criminal, civil, and administrative settlement to resolve allegations that it violated the FCA by improperly marketing and promoting the drug Depakote. As part of the settlement, Abbott agreed to pay \$800 million in a civil settlement; plead guilty to a misdemeanor violation of the Federal Food, Drug, and Cosmetic Act; and pay a criminal fine and forfeiture of \$700 million. Between 1998 and 2008, Abbott promoted Depakote for uses not approved by the Food and Drug Administration (FDA), including the treatment of aggression and agitation in elderly dementia patients and the treatment of schizophrenia. Abbott also allegedly offered and paid illegal remuneration to induce health care professionals and long-term care pharmacies to prescribe Depakote. The CIA requires

Abbott to maintain a centralized system to identify and mitigate risks associated with the sale, marketing, and promotion of drugs.

**New York**—Pharmaceutical manufacturer Amgen, Inc. (Amgen), agreed to pay approximately \$762 million plus interest to resolve its criminal and civil liability arising from its sale and promotion of certain drugs, including Aranesp, an erythropoiesis-stimulating agent approved by FDA at specific doses for particular patient populations suffering from anemia. The Federal civil settlement agreement resolved allegations that Amgen promoted Aranesp and two other drugs that it manufactured, Enbrel and Neulasta, for off-label uses and/or dosing regimens that were not approved by FDA; offered illegal kickbacks to a wide range of entities in an effort to influence health care providers to select and use several of its products, regardless of whether they were administered, reimbursable by Federal health care programs, or medically necessary; and engaged in false price-reporting practices involving several of its drugs. As part of the global settlement, Amgen agreed to plead guilty to a misdemeanor violation of the Federal Food, Drug, and Cosmetic Act and pay a criminal fine and forfeiture of \$150 million. Amgen also agreed to enter into a CIA that includes provisions designed to increase accountability of individuals and board members, to increase transparency, and to strengthen Amgen's compliance program.

In a separate New York civil settlement, International Nephrology Network (INN), renamed Integrated Nephrology Network, an AmerisourceBergen Corporation subsidiary, agreed to pay \$15 million plus interest to resolve its civil liability arising from its role in the marketing of Aranesp. INN allegedly offered illegal kickbacks to physicians, pharmacists, and physician organizations to influence their selection of Aranesp for treating kidney disease and chronic renal failure. These kickbacks came in the form of, among other things, meals, travel, hotels, consulting fees, education and research grants, and improper discounts.

**Massachusetts**—Sanofi-Aventis U.S., Inc., and Sanofi-Aventis U.S. LLC, subsidiaries of international drug manufacturer Sanofi (collectively, Sanofi), agreed to pay \$109 million to resolve allegations that it violated the FCA. Sanofi allegedly provided physicians with free units of Hyalgan, a knee injection, in violation of the anti-kickback statute, to induce them to purchase and prescribe the product. The settlement also resolved allegations that Sanofi submitted false average sales price (ASP) reports for Hyalgan that failed to account for the free units distributed contingent on Hyalgan purchases. The Government alleged that the false ASP reports, which were used to set reimbursement rates, caused Government programs to pay more than they should have for Hyalgan.

**Maryland**—Boehringer Ingelheim Pharmaceutical, Inc. (BIPI), agreed to pay \$95 million to resolve FCA allegations involving the promotion of its stroke-prevention drug Aggrenox, chronic obstructive pulmonary disease (COPD) drugs Atrovent and Combivent, and hypertension drug Micardis. The Government alleged that between 2001 and 2008, BIPI promoted the four drugs for uses that were not approved by FDA. Specifically, BIPI promoted Aggrenox for certain cardiovascular events, such as myocardial infarction and peripheral vascular disease; marketed Combivent for use prior to another bronchodilator in treating COPD; and marketed Micardis for treating early diabetic kidney disease. In addition, BIPI allegedly promoted the sale and use of Combivent and Atrovent at doses that exceeded those covered by Federal health care programs, made unsubstantiated claims about the efficacy of Aggrenox, and paid kickbacks to health care professionals to induce them to prescribe all four drugs. In addition to agreeing to the monetary settlement, BIPI agreed to enter into a comprehensive 5-year CIA with OIG.

**Massachusetts**—Pfizer, Inc., agreed to pay \$55 million plus interest to resolve allegations that one of its subsidiaries, Wyeth LLC, illegally misbranded and promoted its drug Protonix, a proton pump inhibitor (PPI) used to treat various forms of gastro-esophageal reflux disease (GERD). Protonix was approved by FDA for short-term treatment of erosive esophagitis, a condition associated with GERD that can be diagnosed only with invasive endoscopy. According to published reports, Wyeth allegedly promoted Protonix for all forms of GERD, including symptomatic GERD, which was far more common and could be diagnosed without endoscopy. Wyeth allegedly trained its sales force to promote Protonix for all forms of GERD, beyond its limited erosive esophagitis indication, and its sales representatives frequently promoted Protonix to physicians for unapproved uses, such as treatment of symptomatic GERD. In addition, Wyeth allegedly promoted Protonix as the “best PPI for nighttime heartburn,” even though there was never any clinical evidence that Protonix was more effective than any other PPI for that condition. Finally, Wyeth allegedly used continuing medical education programs to promote Protonix for unapproved uses.

**New York**—RxAmerica, LLC, agreed to a \$5.25 million settlement to resolve FCA allegations. From January 2007 to December 2008, RxAmerica allegedly submitted false drug prices for certain generic prescription drugs to CMS in order to induce Medicare Part D beneficiaries to enroll in RxAmerica’s Advantage Freedom Plan. As a result, RxAmerica allegedly received Medicare Part D payments for these drugs at prices that, in some cases, were significantly higher than the prices that RxAmerica submitted to CMS. As a result, some Medicare Part D beneficiaries who were enrolled with RxAmerica entered the Medicare Part D coverage gap or “donut hole” earlier than they otherwise would have. This is the first FCA settlement with a Medicare Part D plan.

## Physicians

**Illinois**—Bahir Khalil was sentenced to 10 years in prison and ordered to pay \$2.9 million in restitution after being convicted on charges of health care fraud and fraud regarding visas, permits, or other documents. Khalil was manager and co-owner of House Call Physicians, LLC, a home health care provider. According to court documents, through Khalil’s direction, House Call Physicians billed Medicare for services that were not medically necessary, including uncomfortable nerve conduction tests; services purportedly provided by physicians when, in fact, they were performed by physician assistants; and services purportedly performed by a licensed podiatrist when, in fact, they were performed by a podiatrist whose license had been suspended. Khalil also directed the false certification of patients as eligible for home health services when they were not homebound, as required by Medicare. Two other defendants, including Khalil’s business partner, Mohammed Rashed, and the suspended podiatrist, Paschal Oparah, were also sentenced to 6 months and 1 year and 6 months of incarceration, respectively. Rashed was also fined \$20,000, while Oparah was ordered to pay \$791,095 in restitution. After completing his sentence, Khalil, a Canadian citizen who was not authorized to work in the United States, faces possible deportation.

**Michigan**—Jonathan Agbebiyi was sentenced to 5 years of incarceration and ordered to pay \$2.9 million in restitution, joint and several, after being convicted on charges of conspiracy to commit health care fraud and health care fraud. An obstetrician/gynecologist, Agbebiyi served as a general practitioner for three clinics: Blessed Medical Clinic, Alpha and Omega Medical Clinic, and Manuel Medical Clinic. According to evidence presented at trial, Agbebiyi joined a conspiracy to bill Medicare for medically unnecessary neurological tests,

some of which involved sending electrical current through the arms and legs of patients. Clinic employees, who lacked any meaningful training, administered the diagnostic tests. The patients never received any followup treatment by neurologists. Evidence at trial also showed that the patients were neither referred to the clinics by their primary care physicians nor referred for any legitimate purpose. Rather, they were recruited with prescriptions for controlled substances, cash payments, and fast food. The three clinics then billed Medicare for diagnostic tests that were medically unnecessary.

## Kickbacks

**Florida**—Hassan Collins was sentenced to 4 years and 3 months of imprisonment and ordered to pay \$2.4 million in restitution, joint and several, after pleading guilty to charges of conspiracy to receive and pay health care kickbacks. Collins was owner and operator of a halfway house, New Way Recovery, Inc. According to court documents, Collins, in exchange for kickbacks, sent Medicare beneficiaries who resided at New Way to American Therapeutic Corporation (ATC) for partial hospitalization services. Investigators believe that the services were not medically necessary and were not provided at ATC. ATC billed Medicare for the services.

**California**—Drug manufacturer Victory Pharma, Inc. (Victory), agreed to pay \$12.2 million to resolve allegations under the FCA. The Government contended that Victory engaged in a kickback scheme to induce prescriptions for its pain medication Naprelan and three other drugs. The alleged kickbacks primarily took the form of meals, gifts; entertainment; event tickets; recreational activities; speaker fees; and preceptorships, under which Victory sales representatives “shadowed” doctors while they saw their patients and paid the doctors a stipend in return. Preceptorships are typically not in violation of Federal regulations if the purpose is to educate sales representative about the doctor and/or the medical practice. However, investigators believe that Victory used preceptorships to pay doctors to influence them to prescribe its drugs.

## Durable Medical Equipment

**Florida**—Ramon Miguel Llanes was sentenced to 11 years and 3 months of incarceration and ordered to pay \$1.7 million in restitution, joint and several, after pleading guilty to charges of conspiracy to commit health care fraud. Llanes co-owned MA Medical Supply, Inc., which purportedly provided durable medical equipment (DME) to Medicare beneficiaries. Investigators believe that Llanes and employees at MA Medical Supply paid beneficiaries for allowing them to use their information to create false and fraudulent prescriptions for DME and medical services that either were not rendered or were unnecessary. From January 2006 through July 2011, MA Medical Supply submitted \$4 million in false and fraudulent claims to Medicare. In addition, Ramon and his co-conspirators caused the submission of false and fraudulent claims and prescriptions to Medicare through several pharmacies. From approximately April 2009 through January 2012, Medicare paid more than \$16 million to these pharmacies on the basis of claims for medical benefits, primarily prescription drugs, which, in turn, were never actually received by the beneficiaries.

**Massachusetts**—Orthofix International NV agreed to pay \$30 million to resolve allegations that its subsidiary, Blackstone Medical, Inc., paid illegal kickbacks to physicians to induce the use of its products. Orthofix is an orthopedic products company that offers a line of surgical and nonsurgical products. In 2006, Orthofix acquired Blackstone Medical, which

manufactures, markets, and sells spinal implants and spinal surgery products. The Government contended that from October 2000 through September 2007, Blackstone offered and paid physicians through fraudulent Medical Advisory Board memberships and agreements in a manner intended to induce the promotion, use, and/or purchase of its products. The kickbacks allegedly came in the form of company stock options, royalty fees for Blackstone products, expensive meals, gifts, entertainment and sporting event tickets, travel, unrestricted grants, and charitable donations, all in violation of the Federal anti-kickback statute. Orthofix also entered into a 5-year CIA with OIG.

**New York**—Husband and wife Armando and Maria Montiel were sentenced for their roles to defraud Medicare. Armando and Maria, who resided in Florida, owned Care Plus Medical Equipment, a medical equipment company based in Puerto Rico. Care Plus allegedly submitted \$1.5 million in false claims to Medicare for wound care, prosthetics, orthotics, and power wheelchairs that were not medically necessary and/or were never provided. Investigators found that a high percentage of beneficiaries for whom Care Plus billed lived in the Miami area while the referring physicians all practiced in Puerto Rico. Interviews with these referring physicians revealed that they never treated the beneficiaries and never ordered any DME for them. Armando was sentenced to 3 years and 6 months of imprisonment, while Maria was sentenced to 3 years of probation. Both were ordered to pay \$262,687 in restitution, joint and several.

## Clinics

**Florida**—Arbilio Yanes was sentenced to 12 years and 7 months of incarceration and ordered to pay \$11 million in restitution after pleading guilty to charges of conspiracy to commit health care fraud and to pay health care kickbacks, health care fraud, payment of health care kickbacks, and money laundering. Yanes was the president and one of two owners of Research Center of Florida, Inc., a purported medical clinic. According to court documents, Yanes paid more than \$2.3 million to fraudulent companies controlled by outside patient recruiters to recruit Medicare beneficiaries who were willing to attend Research Center as purported patients for cash. Between October 2003 and November 2004, Research Center submitted claims to Medicare for nearly \$21 million, almost exclusively for the purported treatment of HIV-positive Medicare beneficiaries and for the administration of prescription drugs. On the basis of these claims, Medicare paid Research Center more than \$11 million for medications that either were not provided or were not medically necessary.

**Virginia**—Paul Boccone was sentenced to 15 years of incarceration and ordered to pay \$275,154 in restitution after being convicted on charges related to illegally distributing oxycodone and other Schedule II narcotics. Boccone was president of Chantilly Specialists, a pain management clinic in Chantilly, Virginia. According to the indictment, Boccone lacked any medical education, qualifications, or licensing and he hired medical professionals with no background or specialized training in pain management. However, he treated patients and prescribed narcotics by directing medical practitioners to endorse prescriptions that he wrote. According to court records, Boccone charged customers approximately \$200 in cash per routine visit and he misinformed customers that Federal and State law required that they return to the clinic every 28 days to receive prescriptions. Customers would then receive only cursory examinations before being prescribed Schedule II narcotic pain medications.

Court records showed that Charles Brown, Jr., the lead nurse practitioner at Chantilly Specialists, provided 600 customers, including known drug addicts, with more than 800,000

oxycodone-based pills over 1 year. One addict received more than 14,000 oxycodone-based pills. Brown, who at Buccone's direction altered one of the patient's files after Chantilly Specialists learned of the patient's death, was sentenced to 5 years of incarceration after being convicted at trial.

**California**—Ramanathan Prakash was sentenced to 10 years of incarceration and ordered to pay \$607,456 in restitution, joint and several, and a \$75,000 fine after being convicted on charges of conspiracy to commit health care fraud and health care fraud. Prakash served as a physician for the Sacramento Clinic. Evidence at trial showed that the clinic and two associated clinics recruited Medicare patients, almost all of whom were elderly and did not speak English, who were transported to the clinics by individuals who were paid according to the number of patients they brought to the facilities. Rather than being charged a co-payment, the patients were paid for their time and the use of their Medicare eligibility, generally \$100 per visit. According to court records, patient charts were created that falsely stated each patient received comprehensive exams and/or diagnostic tests. However, only a few of the tests were performed, none were based on any medical need, and clinic employees filled out other portions of the charts using preprinted templates. The patient files were used to bill Medicare for treatments and services that were unnecessary and/or were never performed. Several other defendants associated with the scheme were also convicted and sentenced or are awaiting sentencing.

## Mental and Social Services

**Indiana**—Carol Woodard was sentenced to 6 years and 8 months of incarceration and ordered to pay more than \$1.9 million in restitution after pleading guilty to health care fraud. Woodard owned Gideon's Gate, which purportedly provided tutoring and day care services to indigent and school-age children. Woodard admitted that she executed a scheme to defraud Indiana Medicaid by filing more than 2,400 illegitimate reimbursement claims for psychological services that she never performed. Woodard conspired with a previously convicted defendant, who provided Medicaid recipients' personal identifiers to Woodward, which she then used in false billings.

**New York**—Westchester County Health Care Corporation (WCHCC) agreed to pay \$7 million to resolve allegations that it violated the FCA. WCHCC operates the freestanding mental health facility Westchester Behavioral Health Center (BHC). From August 2001 through June 2010, WCHCC allegedly submitted false certifications to Medicaid stating that claims for services at BHC complied with applicable regulations. However, WCHCC allegedly knew or should have known that many of the claims lacked the required supporting documentation and that many of the services either did not meet the minimum duration requirements and/or were provided by staff who lacked proper certification. Specifically, WCHCC allegedly billed for professional services by uncredentialed nurse practitioners; billed for services rendered without required progress notes, physician signatures, or other supporting records; billed for hospital stays without the required certification or recertification of medical necessity; routinely failed to collect copayments from psychiatric inpatients to induce use of services; and offered potential kickbacks to private-practice physicians in return for patient referrals. The investigation also revealed that BHC allegedly billed Medicaid for psychiatric services without creating or maintaining treatment plans and progress notes.

## Hospitals

**Tennessee**—Hospital Corporation of America (HCA) agreed to pay \$16.5 million plus interest to resolve allegations under the Federal Stark Law and anti-kickback statute. HCA, through subsidiaries Parkridge Medical Center, Inc., and HCA Physician Services, allegedly paid remuneration to Diagnostic Associates of Chattanooga (DAC) and provided other financial benefits intended to induce physician members to refer patients to HCA facilities. HCA Physician Services also purchased DAC, hired many of its physicians, and leased office space from DAC at a rental rate much higher than fair market value to meet the mortgage obligations of the DAC members. These financial arrangements were in violation of the Stark Law and anti-kickback statute.

**Kentucky**—American Sleep Medicine, LLC (ASM), agreed to pay \$15 million to resolve allegations that it violated the FCA. ASM is headquartered in Jacksonville, Florida, and operates 19 sleep diagnostic centers throughout the United States. ASM allegedly submitted claims to Medicare and other Federal health care programs for sleep diagnostic services that were not eligible for payment because the diagnostic tests were performed by individuals who lacked the required license, certification, or credentials. Between January 2004 and December 2011, ASM submitted nearly 20,000 claims for reimbursement. In addition to entering into the monetary agreement, ASM entered into a CIA with OIG.

**Missouri**—Freeman Health System (Freeman) agreed to pay \$9.3 million to resolve allegations under the FCA. Freeman provides comprehensive health care and behavioral health services at multiple hospitals and other provider facilities. Freeman self-disclosed through the U.S. Attorney's Office that between January 1999 and December 2009, it compensated certain employed physicians on the basis of a formula that improperly took into account the volume and value of revenue generated by the physicians' referrals for certain diagnostic tests and other procedures that constituted "designated health services" under the Physician Self-Referral Law, also known as the Stark Law.

## Medicaid Fraud

**Texas**—Juanita Leyva, Arlene Rodriguez, Edward Devally, Leticia Orosco, Michelle Aguilar, Patricia Cortez, and Loretta Cortez all were sentenced during this semiannual period on charges related to a scheme to defraud Texas Medicaid's Medical Transportation Program (MTP) of more than \$200,000. The investigation revealed that MTP employees obtained the Medicaid numbers and personally identifiable information of Medicaid recipients, including friends and family members, to submit false MTP claims for transportation services that were never provided or were unnecessary. According to the indictment, the defendants fraudulently obtained reimbursement checks, cashed the checks, and either kept the money or divided it among the co-conspirators. Several other defendants were previously sentenced in this case. In total, 19 defendants were sentenced to a combined 6 years of incarceration and ordered to pay more than \$247,542 in restitution and fines. As a result of the investigation, a new MTP director was appointed, the program was restructured, and new policies were put in place.

**District of Columbia**—Jacqueline Wheeler was sentenced to 6 years and 3 months of incarceration and ordered to pay \$3.1 million in restitution after being convicted of charges related to health care fraud. According to the indictment, Wheeler was part-owner and chief executive officer of the Health Advocacy Center, Inc. (HAC), in Washington, DC, which purportedly was an advocate for improving health care delivery to the community. About

October 2002, HAC entered into an agreement with D.C. Medicaid to provide health care services to DC Medicaid beneficiaries.

Wheeler owned two apartments that were rented by HAC patients who had alcohol and/or drug addictions. Wheeler's employees transported many of the patients to HAC, where they often slept, watched television, and occasionally received drug and alcohol counseling. From these visits, Wheeler submitted more than \$6 million in claims to D.C. Medicaid for manual therapy services. Wheeler did not maintain required progress notes and related documentation for the purported manual therapy and other services, she frequently billed for services for which HAC lacked medical equipment, and she frequently billed for more than 24 hours of services for a single patient in a given day.

## Medicaid Fraud Control Units

### Funding and Accomplishments

Medicaid Fraud Control Units (MFCU) are key partners in the fight against fraud, waste, and abuse in State Medicaid programs. In fiscal year (FY) 2012, HHS awarded \$162.9 million in Federal grant funds to 50 MFCUs (including 1 in Washington, DC), which employed 1,901 individuals. Collectively, in FY 2012, MFCUs reported 15,531 investigations, of which 11,660 were related to Medicaid fraud and 3,871 were related to patient abuse and neglect, including misappropriation of patients' private funds. The cases resulted in criminal charges against or indictments of 1,359 individuals, including 995 for fraud and 364 for patient abuse and neglect, including patient funds cases. In total, 1,337 criminal actions were reported in FY 2012, of which 982 were related to Medicaid fraud and 355 were related to patient abuse and neglect, including patient funds cases. Civil judgments and settlements for FY 2012 totaled 823.

### Joint Investigations

The following are examples of joint investigations with MFCUs.

**Idaho**—Christopher Card was sentenced to 3 years in prison and ordered to pay \$1 million in restitution and a \$100,000 fine after pleading guilty to charges of executing a scheme to defraud health care benefit programs. Card was a licensed optometrist who owned, managed, and provided care at Total Vision, P.A. According to the plea agreement, Card fraudulently billed Medicaid, Medicare, and other health care benefit programs for false diagnoses, including glaucoma, acquired color deficiency (color blindness), tension headaches, macular degeneration, treatment of eye injuries, and removal of foreign objects from the eye. Card also billed for testing that did not occur and for testing results that were falsified or altered. According to the plea agreement, 18 patients identified in the original indictment were diagnosed by Card as having glaucoma or glaucoma-related conditions. All were subsequently examined by other doctors, and only one patient was found to have glaucoma or glaucoma-related diseases. The patients named in the original indictment represented only a fraction of those for whom Card falsely billed health insurance companies. This was a joint investigation with the Federal Bureau of Investigation (FBI), the Idaho Medicaid Fraud and Program Integrity Unit, and the Railroad Retirement Board OIG.

**California**—Dr. Kenneth Thaler was sentenced to 1 year and 1 day in prison and ordered to pay \$11 million in restitution after pleading guilty to conspiracy to receive kickbacks. According to court documents, Tustin Hospital paid marketers to recruit "skid row" patients and transport them to the facility. Thaler admitted the patients; then he and the hospital billed Medicare for inpatient services, even if the services were not medically necessary. Thaler admitted that many of the recruited patients had been coached to recite false symptoms and that he falsified medical records to justify the admissions of some patients. On average, Thaler admitted approximately 60 patients per month to the hospital. This was a joint investigation with the Internal Revenue Service, the FBI, and the Bureau of Medi-Cal Fraud and Elder Abuse.

## Sanction Authorities and Related Administrative Actions

Various Federal laws provide authorities to impose administrative sanctions for fraud and abuse, as well as other activities that pose a risk to Federal health care programs and their beneficiaries. (See Appendix D for a summary of frequently used sanction authorities.)

Sanctions include the exclusion of individuals and entities from Federal health care programs and the imposition of civil monetary penalties (CMPs) for submitting false and fraudulent claims to a Federal health care program or for violating the anti-kickback statute; the Stark Law; or the Emergency Medical Treatment and Labor Act of 1986 (EMTALA), also known as the anti-patient-dumping law.

During this semiannual reporting period, OIG imposed 1,712 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://www.oig.hhs.gov/fraud/enforcement/cmp/index.asp>.

### Program Exclusions

During this semiannual reporting period, OIG excluded 1,661 individuals and entities from Medicare, Medicaid, and other Federal health care programs. Most of the exclusions resulted from convictions for crimes relating to Medicare or Medicaid, for patient abuse or neglect, or as a result of license revocation. OIG is also responsible for reinstating providers who apply and have met the requirements of their exclusions. For a list of excluded individuals and entities, see <https://exclusions.oig.hhs.gov/>.

Examples are as follows:

**Florida**—Juan De Dios Gomez, owner and operator of a pain clinic, was excluded for a minimum of 50 years on the basis of his convictions for conspiracy to possess with intent to distribute oxycodone and oxymorphone, attempt to possess with intent to distribute oxycodone, and conspiracy to commit health care fraud. From November 2007 to about September 2011, Gomez owned and operated the pain clinic for the purpose of obtaining false prescriptions for oxycodone and oxymorphone for beneficiaries of the Medicare, Medicaid, and private health care prescription drug insurance plans. These drugs were medically unnecessary. Gomez would also offer kickbacks, bribes, and inducements to beneficiary recruiters so they would bring beneficiaries to his pain clinic. The court

sentenced Gomez to more than 16 years of incarceration and ordered him to pay \$15 million in restitution.

**Massachusetts**—Leo Lawless, a pharmacist, was excluded for an indefinite period. The Massachusetts Board of Pharmacy found that Lawless was involved in multiple patient safety adverse events, including verifying the wrong quantity of a drug that was prescribed for a patient, verifying a prescription for insulin NPH (neutral protamine Hagedorn) that was filled partially with another pharmaceutical, and verifying and dispensing a drug that was intended for another patient. On the basis of these charges, the Board revoked the license of Lawless to practice as a pharmacist.

**Pennsylvania**—Christopher Vassalluzzo, an osteopath, was excluded for a minimum of 20 years on the basis of his drug trafficking conviction. Between September 2000 and March 2010, Vassalluzzo and others distributed controlled substance prescription diet drugs outside professional practice. This included more than 1.5 million doses of a substance that contained phendimetrazine and more than 2.5 million doses of a substance that contained phentermine. Vassalluzzo made it appear as though he maintained a professional medical practice when, in fact, he was running the practice as a “pill mill” for the prescribing of diet drugs. The court sentenced Vassalluzzo to 2 years and 10 months of incarceration. The Pennsylvania State Board of Osteopathic Medicine revoked his license to practice as an osteopath.

**Kansas**—Wendy Parmenter, a licensed practical nurse, was excluded for a minimum of 10 years on the basis of her conviction on charges of consumer product tampering and adulteration of a drug. Parmenter would steal morphine from a particular patient at the facility where she worked. To conceal her behavior, she added tap water to the patient’s medication bottle and then placed the bottle back on the medication cart to dispense to the patient. The court sentenced Parmenter to 3 years of incarceration. The Kansas State Board of Nursing permanently revoked her license to practice nursing.

## 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. OIG may impose penalties on entities that fail to comply with the requirements of their CIAs. More information on CIAs is available on our Web site.

## 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 \$10.8 million in CMPs and assessments. Following are examples of CMP actions resolved during this reporting period:

**South Carolina**—Heritage Medical Partners agreed to pay \$170,260 to resolve allegations that from April 2008 through December 2008, Heritage violated the CMPL by requesting that its 5,474 patients who were Medicare beneficiaries pay a \$50 administrative fee. Heritage told these Medicare beneficiaries that “the Federal Government (Medicare) continue[s] to increase the amount of paperwork we’re required to fill out to assure you receive the benefits to which you’re entitled” and that Heritage instituted the fee as partial compensation for the time the “physician and staff spend assuring [patients] receive prescription renewals quickly [and] maximum benefits from Medicare.” OIG alleged that a portion of the \$50 constituted payment for Medicare services that are covered and reimbursed by Medicare and constituted a request for payment other than copayments or coinsurance, which violated Medicare assignment regulations. Heritage agreed to return the money it collected to patients and pay a penalty to OIG.

**Illinois**—ForTec Medical, Inc.; ForTec Litho, LLC; ForTec Litho Florida, LLC; ForTec Litho Central, LLC; and ForTec Litho NY, LLC (collectively, ForTec), agreed to pay \$126,249 to resolve their liability under the CMPL for offering remuneration in exchange for referrals. From 2006 through 2011, ForTec allegedly provided customers, including physicians, with all-expense paid trips to the Masters Golf Tournament in Augusta, Georgia. Invitations to these trips were extended to physicians on the basis of their use of ForTec’s products and services and the potential for additional business from those physicians.

## Patient Dumping

Some of the CMPL cases that OIG resolved between October 1, 2012, and March 31, 2013, were pursued under EMTALA, a statute designed to prevent hospitals from denying emergency care to patients and to ensure patient access to appropriate emergency medical services. Following are examples of settlements under this statute:

**New Mexico**—University of New Mexico Hospital (UNMH) agreed to pay \$30,000 to resolve its liability under the anti-patient-dumping statute. UNMH allegedly failed to provide an adequate medical screening examination and failed to stabilize a suicidal patient when it did not prevent the patient from hanging himself in the hospital. The patient came to the emergency room experiencing suicidal thoughts and was placed in an observation room, but he was not medically screened for 7 hours. During that time, he used his shoelaces to hang himself from an air vent. After the patient was found still alive by a security employee, the hospital treated and admitted him. UNMH self-reported the incident to the State.

**Michigan**—Hackley Hospital agreed to pay \$90,000 to resolve its liability for CMPs under the patient-dumping statute. Hackley allegedly failed to provide stabilizing treatment within its capabilities to a woman in labor and her unborn child before transferring her to another hospital for treatment.

**Illinois**—University of Chicago Medical Center (UCMC) agreed to pay \$50,000 to resolve its liability under the anti-patient-dumping statute. UCMC allegedly failed to provide appropriate medical screening and stabilizing treatment within its capabilities to a patient who arrived at its emergency department complaining of severe jaw pain after an assault. The results of a CT scan taken by UCMC revealed injuries that needed corrective surgery. However, UCMC did not provide further treatment and discharged the patient with instructions to go to another hospital for further care.

## 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 process 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 is uncovered. The self-disclosure also allows the provider to negotiate a fair monetary settlement and potentially avoid being excluded from participation 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 make a reliable assessment of 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 <http://www.oig.hhs.gov/fraud/selfdisclosure.asp>.

During this reporting period, self-disclosure cases resulted in \$20.5 million in HHS receivables. Following are examples:

**Alaska**—Bartlett Regional Hospital agreed to pay more than \$1.4 million to resolve its liability under the CMPL. Bartlett self-disclosed that from May 2006 to April 2012, when a patient was seen by a physician who was not enrolled with Medicare B or who had not completed an assignment of revenue to the hospital, Bartlett instructed billing staff to submit claims under the name of a physician who was enrolled with Medicare Part B and had completed the assignment, even if that physician did not perform the service.

**Arizona**—Maryvale Hospital agreed to pay \$361,041 to resolve its liability under the CMPL. Maryvale self-disclosed that from December 2002 through July 2009, it employed a cardiovascular pulmonary technician who was excluded from participation in the Federal health care programs.

**New York**—Woodmark Services, Inc., agreed to pay \$311,193 to resolve its liability under the CMPL. Woodmark self-disclosed that from September 2002 through October 2010, KABA Health, a medical equipment company and a subsidiary of Woodmark, submitted claims for Medicare patients who were not properly qualified by an independent testing facility to receive those services, as required by Medicare.

<http://oig.hhs.gov>

## Public Health Reviews

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### Centers for Disease Control and Prevention

#### Global HIV/AIDS Program

The Centers for Disease Control and Prevention (CDC) implemented the President's Emergency Plan for AIDS Relief (PEPFAR) through the Global HIV/AIDS Program, working with ministries of health and other in-country partners to combat HIV/AIDS by strengthening health systems and building sustainable HIV/AIDS programs in more than 75 countries. CDC's offices in host countries are responsible for PEPFAR funds awarded to government agencies and for-profit and nonprofit organizations (recipients). (See also the Office of Inspector General's (OIG) [Spotlight](#) article on grants management and oversight.)

√ *Grants Management*<sup>3</sup> *CDC South Africa—The Centers for Disease Control and Prevention's South Africa Office Did Not Always Properly Monitor Recipients' Use of the President's Emergency Plan for AIDS Relief Funds*

[A-04-12-04022](#) February 2013 CDC South Africa did not always monitor recipients' use of PEPFAR funds in accordance with Department of Health and Human Services (HHS) and other Federal requirements. Most of the recipient cooperative agreement files did not include required documentation or evidence of required monitoring. CDC South Africa did not have written policies and procedures for monitoring and did not have assurance that PEPFAR funds were used as intended by law. Recommendation—CDC South Africa should implement standard operating procedures for monitoring recipients' use of PEPFAR funds.

√ *Grants Management* *CDC Namibia—The Centers for Disease Control and Prevention's Namibia Office Did Not Always Properly Monitor Recipients' Use of the President's Emergency Plan for AIDS Relief Funds*

[A-04-12-04020](#) November 2012 Most of CDC Namibia's recipient cooperative agreement files did not include required documents or evidence that CDC Namibia had monitored all cooperative agreements, as required. Recommendation—CDC Namibia should implement standard operating procedures for monitoring recipients' use of PEPFAR funds.

√ *Grants Management* *The Republic of Namibia, Ministry of Health and Social Services, Did Not Always Manage the President's Emergency Plan for AIDS Relief Funds or Meet Program Goals in Accordance With Award Requirements*

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<sup>3</sup> To the left of each report title, we have flagged with a checkmark the management challenge(s) associated with the review's findings and recommendations, e.g., √ Grants Management, √ Food Safety, √ Financial Statements, or the name of a specific program. Implementing a report's recommendations would help curb negative outcomes associated with the designated management challenges.

- [A-04-12-04019](#) Our review of the Republic of Namibia, Ministry of Health and Social Services (Ministry), revealed unallowable and potentially unallowable expenditures, the reporting of accomplishments that were not related to the cooperative agreement, and deficiencies in meeting various other requirements. Recommendation—The Ministry should refund to CDC \$243,000 of unallowable expenditures, work with CDC to resolve whether the \$565,000 of potentially unallowable value-added taxes was an allowable expenditure, file an amended financial report for the budget period we reviewed, develop and implement reconciliation and supporting documentation before submission, use correct exchange rates, develop policies and procedures for reporting goals and objectives related to the cooperative agreement, have an annual audit performed, and submit all required reports in a timely manner.
- January 2013

## Food and Drug Administration

### Food Safety—Dietary Supplements

Our final reports related to dietary supplements addressed the extent to which the Food and Drug Administration (FDA) is able to effectively locate manufacturers through its Food Facility Registry and determined whether manufacturers' structure/function claims made on the labels of dietary supplements are truthful and not misleading.

**Locating Dietary Supplement Manufacturers in Emergencies.** The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires certain dietary supplement companies to register with FDA. Registration in the Food Facility Registry (the registry) is intended to provide FDA with sufficient information to contact companies in an emergency. Previous OIG work identified problems with FDA's registry. Recent recalls of dietary supplements tainted with prescription drugs, synthetic steroids, and other potentially dangerous ingredients highlight the importance of registration and adverse event contact information so that FDA can trace the source of the product. These problems raised questions about FDA's ability to identify and contact manufacturers in a food emergency to protect public health.

√ FDA—Food Safety *Companies May Be Difficult To Locate in an Emergency*

- [OEI-01-11-00211](#) Of the dietary supplement manufacturers we contacted for review, 28 percent failed to register with the registry. Of the companies that did register, 72 percent failed to provide the complete and accurate information required by law. Twenty percent of dietary supplement labels we sampled did not provide the required telephone numbers or addresses.
- October 2012

Recommendations—FDA should seek statutory authority to impose civil monetary penalties on companies that do not comply with registration requirements, take administrative action to educate the dietary supplement industry about registration and labeling requirements, and improve the accuracy of information in the registry.

**Truthfulness of Claims on Dietary Supplement Labels.** Manufacturers use structure/function claims to promote the health benefits of their products. Stakeholders have urged FDA to

strengthen oversight of these claims because they are potentially misleading and may lack scientific support. FDA lacks authority to review or approve such claims before products enter the market. Manufacturers are supposed to have evidence of their claims but do not have to submit it to FDA, and FDA has only voluntary standards for it. Manufacturers must notify FDA when they use structure/function claims, and product labels must include disclaimers stating that FDA has not reviewed the claims and that the products are not intended to diagnose, treat, cure, or prevent any disease.

√ *FDA—Food Safety Structure/Function Claims Fail To Meet Federal Requirements*

[OEI-01-11-00210](#)  
October 2012 Our findings raised questions about whether some structure/function claims made on the labels of dietary supplements are truthful and not misleading. We selected for our review dietary supplements that were marketed for weight loss or immune system support. Overall, we found that manufacturers' substantiation for structure/function claims was inconsistent with FDA's guidance. Also, manufacturers did not always meet related notification and disclaimer requirements.

Recommendations—FDA should seek statutory authority to review manufacturers' evidence for structure/function claims and determine whether the claims are truthful and not misleading. We also recommend that FDA take administrative actions to improve the notification system for such claims to make it more organized, complete, and accurate and expand market surveillance to enforce manufacturers' use of required disclaimers.

## Drug Safety—Risk Evaluation and Mitigation Strategies

FDA requires drug manufacturers to submit structured plans, known as Risk Evaluation and Mitigation Strategies (REMS), for drugs associated with known or potential risks that may outweigh the drugs' benefits. If FDA does not properly monitor REMS' performance, it cannot ensure that the public is provided maximum protection from a drug's known or potential risks. However, FDA does not have the authority to require, but may request, drug manufacturers (i.e., sponsors) to submit specific information regarding REMS' effectiveness.

√ *FDA—Drug Safety FDA Lacks Comprehensive Data To Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety*

[OEI-04-11-00510](#)  
February 2013  
[Podcast](#) Nearly half of sponsor assessments for the 49 REMS we reviewed did not include all information requested in FDA assessment plans, and 10 were not submitted to FDA within required timeframes. FDA determined that 7 of the 49 REMS we reviewed met all of their goals. However, FDA has not identified reliable methods to assess the effectiveness of REMS. Finally, FDA's assessment review times exceeded its goal of 60 days for all but one sponsor assessment, which reduces sponsors' time to make suggested changes before submitting subsequent assessments.

Recommendations—FDA should seek legislative authority to make assessment plans enforceable. We also made seven administrative recommendations regarding FDA's evaluation and assessment of REMS and its review of sponsors' REMS assessments.

## Health Resources and Services Administration

### HIV Testing at Health Center Sites

Health center sites funded by the Health Resources and Services Administration (HRSA) provide primary health care to millions of patients each year and are critical to efforts to test patients for HIV and reduce its spread. Since 2006, CDC has recommended routine HIV testing—i.e., that patients be tested as a routine part of care and be told they will be tested unless they decline. This approach aims to expand testing to a wider patient population and increase testing rates. The review summarized below determines the extent to which HRSA-funded sites adopted practices that CDC recommended.

√ *HRSA Grants Management* *HIV Testing in HRSA-Funded Health Center Sites*

[OEI-06-10-00290](#)  
January 2013 Health center sites had not fully adopted certain practices recommended by CDC for routine HIV testing. Regarding whom to test, for which CDC's recommendation varies according to the circumstances of individual health care providers, 20 percent of sites reported testing all patients 13-64 years of age; 1 percent tested all adults, but not teens; and 55 percent targeted testing to high-risk patients. Regarding the other practices, 29 percent adopted the practice regarding prevention counseling; 27 percent adopted the practice regarding gaining patient consent for the HIV test; and 15 percent adopted the practice regarding providing HIV tests as standard, opt-out tests. Most sites had written HIV testing policies that were influenced by CDC's recommendations.

Recommendations—HRSA should require grantees to establish and report the prevalence of undiagnosed HIV among their patient populations and report HIV positivity (the proportion of patients who test positive among all those tested). We also recommend that HRSA continue to provide guidance and education to grantees and sites regarding the CDC-recommended practices and HIV testing.

### Health Center Program Section 330 Grants

The Health Center Program, administered by HRSA, provides grants to nonprofit private or public entities that serve designated medically underserved populations and areas, as well as vulnerable populations of migrant and seasonal farmworkers, the homeless, and residents of public housing. These grants are commonly referred to as "section 330 grants." Below is one example of our recent work in this area.

√ *HRSA—Grants Management* *Community Medical and Dental Care, Inc., Did Not Meet Select Financial Performance Measures and Claimed Unallowable Federal Grant Expenditures*

[A-02-11-02001](#)  
November 2012  
[Spotlight Article on Grants](#) We found that one grantee we reviewed did not meet select HRSA financial performance measures. In addition, the grantee claimed Federal grant expenditures totaling \$3 million that were not separately accounted for. Specifically, the grantee commingled expenditures in its accounting system with other operational payments and did not maintain personnel activity reports for employees who worked on HRSA grants. Therefore, we could

not determine whether these costs were allowable.

Recommendation—HRSA should either require the grantee to refund \$3 million to the Federal Government or work with the grantee to determine whether any of the costs that it claimed against these grants were allowable.

## Public-Health-Related Legal Actions and Investigations

### Health Education Assistance Loan Program

Under the Health Education Assistance Loan (HEAL) program, HRSA guarantees commercial loans to students seeking education in health-related fields. The students are allowed to defer repayment of the loans until after they graduate and begin to earn income. Although HHS's Program Support Center (PSC) takes steps to ensure repayment, some loan recipients do not resolve their indebtedness. After PSC has exhausted efforts to secure repayment of a debt, it declares an individual in default. Thereafter, the Social Security Act permits exclusion from Medicare, Medicaid, and all other Federal health care programs for nonpayment of these loans.

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

### HEAL Exclusions

During this semiannual reporting period, 21 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 2,480 individuals chose to enter into settlement agreements or completely repay their debts. That figure includes 31 individuals who entered into such settlement agreements or completely repaid their debts during this semiannual reporting period. The amount of money being repaid through settlement agreements or through complete repayment is \$190,889,720. Of that amount, \$3,219,958 is attributable to this semiannual reporting period.

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

- Virgin Islands podiatrist (\$295,297)
- Florida pharmacist (\$203,685)

- Washington medical doctor (\$147,349)
- Colorado chiropractor (\$98,912)
- Georgia pharmacist (\$86,128)

## Human Services Reviews

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### Title IV-E Foster Care and Adoption Assistance Programs

Federal financial participation for the Administration for Children and Families (ACF) Title IV-E foster care and adoption assistance programs allows intensive agency training sessions at an enhanced rate (75 percent) for salaries, fringe benefits, travel, and per diem for employees in initial inservice training of at least 1 week. An employee who accepts a new position at a Title IV-E agency may be considered a new employee for the purpose of training cost reimbursement. However, training cannot be considered intensive when an employee has a full caseload.

√ *ACF—Grants Management*    *Connecticut Title IV-E Training Costs Did Not Always Comply With Federal Requirements*

**A-01-12-02500**    Connecticut improperly claimed Title IV-E foster care and adoption assistance programs training costs at the enhanced rate (75 percent) that it should have claimed at the administrative rate (50 percent); thus a net overpayment resulted. This occurred because Connecticut did not have procedures in place to ensure that it claimed the enhanced rate only when training occurred during an employee's initial inservice period and was intensive.  
December 2012

Recommendation—Connecticut should refund the Federal share of \$1.3 million to the Federal Government and implement procedures to correlate training, human resources, and caseload data to help ensure that it claims training costs in accordance with Federal requirements.

### Child Support Enforcement

OIG investigates noncustodial parents who fail to pay court-ordered child support. OIG works with the Office of Child Support Enforcement (OCSE); the Department of Justice; U.S. Attorneys' Offices; the U.S. Marshals Service; and other Federal, State, and local partners to expedite the collection of child support in cases that meet prosecutorial guidelines.

## Child Support Investigative Outcomes

OIG investigations of child support cases nationwide resulted in 29 criminal actions and court-ordered restitution and settlements of \$1.49 million during this semiannual period. Examples of OIG's enforcement results for failure to pay child support included the following.

**Kansas**—David Fuller was sentenced to 5 years of probation and ordered to pay \$53,778 in restitution after being found guilty on charges of willful failure to pay child support. Fuller was ordered by the court in February 1994 to pay child support for his three children. However, court records showed that he did not make any payments toward his child support obligations. Fuller, who works as a musician in the Kansas City area using the stage name "Doc" Fuller, was indicted in July 2012, owing at the time more than \$54,000 in child support obligations.

**South Dakota**—Alton McEachern was sentenced to 5 years of probation and ordered to pay \$98,991 in restitution after pleading guilty to charges of failure to pay legal child support. McEachern was indicted in March 2011 on charges that, dating back to April 2009, he willfully and unlawfully failed to pay past due child support obligations for his two children, who are twins. McEachern moved out of State from his children and had been living in North Carolina.

## Engaging the Public in Capturing Deadbeat Parents

OIG's Most Wanted Deadbeat Parents Web site at:  
<https://oig.hhs.gov/fraud/child-support-enforcement/index.asp>.

The site highlights parents who fail to pay court-ordered child support for their children and put an unnecessary strain on the custodial parents and the children as well as on agencies that enforce these matters. The site is updated frequently and includes information on OIG's role in pursuing parents who fail to pay court-ordered child support. It has a link to report deadbeat parents.

One of OIG's most wanted deadbeat parents, Robert Sand, was arrested during this semiannual reporting period. Sand had a total delinquent support payment of more than \$1.2 million for his three children from two marriages. Sand had been ordered to pay child support since 1996, and arrest warrants were issued in 2000, 2002, and 2010 on charges of failure to comply with a court order and failure to pay child support. The investigation revealed that Sand made several attempts to elude his child support obligations, including underreporting his income and moving from New York to Florida and then to Thailand. Sand was arrested on December 17, 2012, at Los Angeles International Airport after being deported from the Philippines.

## Other HHS-Related Reviews and Investigations

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### HHS Preparedness and Support in Emergencies

In 2010, the Council of the Inspectors General on Integrity and Efficiency published *An IG's Guide for Assessing Federal Response Capabilities*, which recommended that Federal agencies assess their emergency preparedness. Within HHS, the Assistant Secretary for Preparedness and Response (ASPR) organizes HHS's resources and its response as the coordinator and primary agency responsible for Emergency Support Function-8 (ESF-8), Public Health and Medical Services.

HHS also has responsibilities as a support agency for nine additional ESFs.

√ *ASPR—Emergency Support Function*    *HHS Public Health and Medical Services Emergency Support Preparedness*

**OEI-04-11-00260**    We found that HHS deployed resources to 28 emergency incidents in 2010 and 2011. Of the 28 incidents, we reviewed 3 that affected 17 States. HHS demonstrated its ability to effectively fulfill its emergency support function (ESF) responsibilities for the three selected incidents. We found that the other ESF coordinators and primary agencies did not always report having a clear understanding of HHS's support agency role and its available resources during incident response. States reported receiving multiple requests from HHS for the same information, which was burdensome during incident response.

Recommendation—ASPR should continue to increase communication with the ESF coordinators and primary agencies for which HHS serves as a support agency and coordinate requests from HHS staff divisions and operating divisions to reduce the burden on States during incident response.

### HHS and CMS Financial Statement Audits

**Chief Financial Officers Act of 1990, as amended**—OIG (or an independent external auditor, as determined by OIG) is required to audit the HHS financial statements in accordance with applicable standards. To support this audit, OIG must also audit the Centers for Medicare & Medicaid Services (CMS) financial statements.

√ *Financial Statement Audits, (HHS)*    *Report on the Financial Statement Audit of the Department of Health and Human Services for Fiscal Year 2012*

**A-17-12-00001**    Independent external auditors provided an unqualified opinion on the November 2012    FY 2012 HHS financial statements, except for the Statement of Social

Insurance and the related Statement of Changes in Social Insurance Amounts, which are described below. This means that for the 14th consecutive year, the statements were reliable and were fairly presented. However, the report on internal controls noted one significant deficiency related to financial reporting systems, analyses, and oversight and one material weakness related to financial management information systems. In addition, the report on compliance with laws and other matters noted areas of noncompliance. HHS declared a violation to certain provisions of the Anti-Deficiency Act and OMB Circular A-11 and is not in full compliance with the Improper Payments Information Act of 2002 as amended by the Improper Payments Elimination and Recovery Act of 2010. HHS did not comply with the Federal Financial Management Improvement Act of 1996, which requires Federal agencies to have integrated financial management systems that provide effective and efficient interrelationships involving software, hardware, personnel, procedures, controls, and data in the systems and that are in compliance with the United States Standard General Ledger at the transaction level and applicable Federal accounting standards. HHS does not expect to be compliant with the Federal Financial Improvement Act of 1996 until FY 2015. Finally, noncompliance with other legislative provisions was noted.

**Financial Reporting Systems, Analyses, and Oversight**—In FY 2012, HHS made continued progress in its ability to report accurate and timely financial information. However, HHS does not have integrated financial management systems, which continues to impair its ability to support and analyze account balances reported. In addition, HHS did not perform sufficient analysis of certain accounts; as a result, HHS's ability to report timely financial information was impaired.

**Financial Management Information Systems**—In FY 2012, HHS made continued improvement in the controls that support information technology and the financial application systems. HHS and its Operating Divisions have made efforts to address the existing needs for processes and practices that protect the integrity of information systems that support financial reporting. However, despite improvements, longstanding deficiencies were not remediated to a level that supports reliance on controls that exist within these systems.

√ *Financial Report on the Financial Statement Audit of the Centers for Medicare & Medicaid Services for Fiscal Year 2012*  
*(CMS)*

**A-17-12-02012**  
November 2012

Independent external auditors provided an unqualified opinion on the fiscal year (FY) 2012 CMS consolidated balance sheets, the related consolidated statements of net costs, changes in net position, and the combined statement of budgetary resources. CMS management noted that the actual future costs for Medicare are likely to exceed those projections estimated under the Patient Protection and Affordable Care Act and other current law. As a result, the auditors were unable to express an opinion on the Statements of Social Insurance as of January 1, 2012, 2011, and 2010 and the Statements of Changes in Social Insurance Amounts for the periods ending January 1, 2012, 2011, and 2010.

In addition, the report on internal controls noted two significant deficiencies—in the financial reporting process and in information systems controls related to CMS's Medicare fee-for-service claims processing

systems.

**Financial Reporting Process**—In FY 2012, CMS took steps to improve its financial reporting process, but it can still be improved. CMS’s management and review control was not functioning as designed or intended and did not detect errors. Also, weaknesses in financial reporting oversight were identified.

**Information Systems Controls**—In continuing to provide affordable health care, monitoring, and validation activities, CMS has not kept pace with the increased volume of activity at the Medicare fee-for-service contractors and new Government mandates for enhanced information security processes. When combined with inadequately designed controls over monitoring and oversight, the factors may result in unauthorized system access; inconsistencies in access rights, which allow a potential lack of segregation of duties; and a lack of compliance with established policies. Additional focus is required to minimize the risk of current and unresolved prior-year deficiencies.”

## Improper Payment Reporting

**Improper Payments Elimination and Recovery Act of 2010 (IPERA)**—OIG is required to determine whether HHS has reported required improper payment information in its annual Agency Financial Report (AFR) of the most recent FY. Specifically, OIG must determine whether HHS conducted program-specific risk assessments to identify programs or activities that are susceptible to significant improper payments and whether it reported specific information on those programs in its AFR, including whether the rate of improper payments was less than 10 percent. OIG must also evaluate the accuracy and completeness of agency reporting and evaluate agency performance in reducing and recapturing improper payments.

√ *Improper Payment Reporting*    *U.S. Department of Health and Human Services Met Many Requirements of the Improper Payments Information Act of 2002 but Was Not Fully Compliant*

**A-17-13-52000**    Although HHS met many of the statutory requirements applicable to reporting on improper payments in its AFR, it did not fully comply with all criteria. Our report describes a number of findings that are addressed by the following recommendations.

March 2013

**Recommendations**—HHS should improve its compliance with requirements by assessing the need for additional actions to meet improper payment rate reduction targets, developing and reporting improper payment rate reduction targets and corrective action plans for the Children’s Health Insurance Program, ensuring that amounts used in the computations for reporting overpayments recaptured are accurate and complete, and ensuring that data are retained in accordance with program requirements.

## OIG Reviews of Non-Federal Audits

In this semiannual period, OIG's National External Audit Review Center reviewed 1,764 reports covering \$651 billion in audited costs. Federal dollars covered by these audits totaled \$160.5 billion, about \$62 billion of which was HHS money.

Office of Management and Budget (OMB) 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 and identifies any significant areas of internal control weakness, noncompliance, and questioned costs for resolution or followup.

We identify entities for high-risk monitoring, alert program officials to any trends that could indicate problems in HHS programs, and profile non-Federal audit findings of a particular program or activity over time to identify systemic problems. We also provide training and technical assistance to grantees and members of the auditing profession. OIG maintains a process to assess the quality of the non-Federal reports received and the audit work that supports the selected reports. OIG's reports on non-Federal audits reviewed during this reporting period are categorized in the following table.

### Non-Federal Audits, October 1, 2012, Through March 31, 2013

Number of Non-Federal Audits:	
➤ Not requiring changes or having minor changes	1,679
➤ Requiring major changes	83
➤ Having significant technical inadequacies	2
<b>Total</b>	<b>1,764</b>

The 1,764 reports included 3,242 recommendations for improving management operations. In addition, these audit reports provided information for 37 OIG special memorandums that identified concerns for increased monitoring by management.

## Grants and Contracts

HHS is the largest grantmaking organization in the Federal Government. Its funding of health and human services programs touches the lives of almost all Americans. Increased concerns by Congress and the Administration regarding transparency of and accountability for agency expenditures is creating heightened scrutiny over the administration of grant and contract dollars. (See also OIG's Spotlight article on grants management and oversight.)

## Misuse of Grant Funds

Following are examples of grant-related investigative outcomes in this semiannual period.

**South Dakota**—Nathan Janis, Tanya Walking Eagle, and Barbara Duysak (aka Barbara McCloskey) were all sentenced after pleading guilty to charges that included theft from an Indian tribal organization. Duysak was the former assistant director of the Rosebud Sioux Tribe's Child Care Services Program (CCSP). Janis was a childcare provider/vendor for CCSP, while Walking Eagle was receiving benefits from CCSP for the care of her children. According to court documents, between October 2009 and December 2010, the three defendants submitted false payment request forms to CCSP for falsified childcare hours. They then embezzled money meant for the program that they were not entitled to receive. Janis was sentenced to 6 months of incarceration and ordered to pay \$33,816 in restitution, joint and several; Walking Eagle was sentenced to 1 month of incarceration and ordered to pay \$30,304 in restitution, joint and several; and Duysak was sentenced to 2 months of incarceration and ordered to pay \$42,433 in restitution, a portion of which was joint and several.

**Pennsylvania**—Craig Grimes was sentenced to 3 years and 5 months of incarceration and ordered to pay \$640,660 in restitution after pleading guilty to charges of wire fraud, false statements, and money laundering. According to published reports, Grimes was a Penn State professor who owned the research company SentechBiomed. The company requested a nearly \$1.2 million grant from the National Institutes of Health (NIH) to perform research related to the measurement of gases in a patient's blood. Grimes was supposed to direct nearly half of the grant to the Hershey Medical Center to conduct clinical research on adult and infant subjects. However, he never paid the center to conduct the studies and trials. Instead, Grimes misspent the money for his own use.

## Significant Grant-Related Reviews

Brief descriptions of the following significant grant-related reports issued in this period are described in the "Public Health" and "Human Services" sections of this document:

√ *CDC – Global HIV/AIDS Program*    *CDC South Africa—The Centers for Disease Control and Prevention's South Africa Office Did Not Always Properly Monitor Recipients' Use of the President's Emergency Plan for AIDS Relief Funds.* [A-04-12-04022](#).

*CDC Namibia—The Centers for Disease Control and Prevention's Namibia Office Did Not Always Properly Monitor Recipients' Use of the President's Emergency Plan for AIDS Relief Funds.* [A-04-12-04020](#).

*The Republic of Namibia, Ministry of Health and Social Services, Did Not Always Manage the President's Emergency Plan for AIDS Relief Funds or Meet Program Goals in Accordance With Award Requirements.* [A-04-12-04019](#).

√ *HRSA – Health Center Program*    *Community Medical and Dental Care, Inc., Did Not Meet Select Financial Performance Measures and Claimed Unallowable Federal Grant Expenditures.* [A-02-11-02001](#).

√ *ACF –Foster Care and Adoption*    *Connecticut Title IV-E Training Costs Did Not Always Comply With Federal Requirements.* [A-01-12-02500](#).

## Small Business Innovative Research Program

**National Defense Authorization Act for Fiscal Year 2012, §5143**—Certain inspectors general are required to annually report on the number of cases referred to them related to fraud waste, or abuse related to Small Business Innovative Research (SBIR) program; the actions taken in each case; justification for not taking action on a case; and an accounting of funds used to address waste, fraud, and abuse in this program. Since its enactment in 1982, as part of the Small Business Innovation Development Act, SBIR has helped small businesses to compete for Federal research and development awards. In a November 2, 2012, report delivered to the three Congressional oversight committees, HHS OIG reported that it spent approximately \$133,595 in salaries on self-initiated oversight activities related to the SBIR program. HHS did not refer any SBIR cases to OIG in FY 2012.

## Contract Audits

**National Defense Authorization Act for FY 2008, § 845**—Inspectors General appointed under the Inspector General Act of 1978 are required to submit, as part of their *Semiannual Reports to Congress* pursuant to section 5 of such Act, information on final, completed contract audit reports issued during the period to the contracting activity containing significant audit findings. OIG did not issue final reports meeting § 845 criteria during this semiannual period.

## Other HHS-Related Matters

### Recovery Act Retaliation Complaints

**The American Recovery and Reinvestment Act of 2009 (Recovery Act), § 1553**—The Recovery Act 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 investigations of Recovery Act whistleblower retaliation complaints during this reporting period.

### Employee Misconduct

**North Carolina**—Jihan Cover was sentenced to 6 months of imprisonment and ordered to pay \$114,494 in restitution after pleading guilty to embezzlement charges. Cover worked as a purchasing agent for NIH's National Cancer Institute (NIH/NCI). From approximately June 2009 to December 2010, Cover used and caused to be used NIH/NCI purchase cards assigned to her to complete more than 250 unauthorized personal transactions, totaling \$114,494. These purchases included buying personal items at Amazon.com; using the cards to pay off balances she accrued from various cash advances and loan vendors; and making self-payments to her personal accounts, which were designed to appear as a legitimate vendor. When Cover was confronted by her supervisor regarding suspicious transactions,

she falsely claimed that she was the victim of identity theft and filed false dispute forms with the credit-card-issuing bank.

## Legislative and Regulatory Reviews

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

- Our *Semiannual Report to Congress* describes findings and recommendations from recently completed reviews, many of which focus on existing laws and regulations.
- Our *Compendium of Unimplemented Recommendations*, which is published annually, describes priority findings and recommendations from past periods that remain to be implemented, along with pertinent citations of existing laws and regulations.
- Our annual *Work Plan*, which is published at the start of each fiscal year, provides citations to laws and regulations that are the subject of ongoing or future reviews.

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

## Affordable Care Act—Implementation

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Affordable Care Act), created new programs and initiatives and expanded and modified a number of existing HHS programs. OIG has begun to issue reports of its reviews related to the implementation of the new programs. Two such reports issued during this semiannual period relate to the National Background Check program and the affordable insurance exchanges.

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## National Background Check Program

The Affordable Care Act mandates that OIG submit a report to Congress evaluating the Nationwide Program for National and State Background Checks on Direct Patient Access Employees of Long Term-Care Facilities and Providers. This report provides baseline information for the mandated report on the extent to which nurse aides with substantiated findings of abuse, neglect, and/or misappropriation of resident property had previous criminal convictions that could have been detected through background checks and the nature of those convictions.

√ *Affordable Care Act Implementation*    *Background Checks—Criminal Convictions for Nurse Aides With Substantiated Findings of Abuse, Neglect, and Misappropriation*

**OEI-07-10-00422**  
October 2012    Our review of nurse aides provided baseline information for a mandatory evaluation of the background check program. Our analysis of - criminal history records maintained by the Federal Bureau of Investigation revealed that 19 percent (300 of 1,611) of nurse aides who received substantiated findings of abuse, neglect, or misappropriation in 2010 had at least 1 conviction prior to their substantiated findings. This information will be used in an evaluation report mandated by the Affordable Care Act, § 6201. The report does not contain recommendations.

## Eligibility and Enrollment in State Health Subsidy Programs

The Affordable Care Act, § 1413, requires HHS and States to streamline eligibility and enrollment systems in State health subsidy programs, i.e., Medicaid, the Children's Health Insurance Program, and State exchanges. Implementation of affordable insurance exchanges affects information systems, application forms, and eligibility data sharing.

√ *Affordable Care Act Implementation*    *Health Subsidy Programs—Most States Anticipate Implementing Eligibility and Enrollment Requirements by 2014*

**OEI-07-10-00530**  
February 2013    We found that streamlining of eligibility and enrollment systems was on track, but States reported challenges. In response to a national survey, 35 of the 45 States that responded to our survey said they generally anticipate streamlining the systems by the January 1, 2014, target date. However, States reported challenges in upgrading outdated systems and resolving implementation-related funding issues. They reported needing more information and guidance from HHS on a number of topics. We concluded that CMS should continue to provide guidance to States as they implement the streamlined eligibility and enrollment systems. The report does not contain recommendations.

<http://oig.hhs.gov>

## List of Appendixes

Appendix A	Reporting Requirements
Appendix B	Questioned Costs and Funds To Be Put to Better Use
Appendix C	Peer Review Results
Appendix D	Summary of Sanction Authorities

<http://oig.hhs.gov>

## Appendix A

# Reporting Requirements

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
<b>Section 4</b>		
(a)(2)	Review of legislation and regulations	Other HHS-Related Issues.
<b>Section 5</b>		
(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>Compendium of Unimplemented Recommendations</i>
(a)(4)	Matters referred to prosecutive authorities	Legal and Investigative Activities
(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 B
(a)(9)	Statistical Table 2 – Funds Recommended To Be Put to Better Use	Appendix B
(a)(10)	Summary of previous audit reports without management decisions	Appendix B
(a)(11)	Description and explanation of revised management decisions	Appendix B
(a)(12)	Management decisions with which the Inspector General disagrees	None

Section	Requirement	Location
(a)(13)	Information required by the Federal Financial Management Improvement Act of 1996	Reported annually in the spring <i>Semiannual Report to Congress</i> , Other HHS-Related Issues.
(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

Requirement	Location
<b>Contract Audits</b> —Report to Congress on significant contract audits pursuant to criteria in the National Defense Authorization Act for Fiscal Year 2008, § 845.	Other HHS-Related Reviews
<b>Safe Harbors</b> —Solicit proposals annually via a <i>Federal Register</i> 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. Report annually to Congress on the status of the proposals received related to new or modified safe harbors. Health Insurance Portability and Accountability Act of 1996 (HIPAA).	Reported annually in the fall <i>Semiannual Report</i> , Other HHS-Related Reviews
<b>Recovery Act</b> —Report to Congress the retaliation complaint investigations OIG decided not to conduct or continue during the period. American Reinvestment and Recovery Act of 2010 (Recovery Act), § 1553.	Other HHS-Related Reviews
<b>Small Business Innovative Research (SBIR)</b> —Report on cases referred to OIG related to fraud waste, or abuse related to SBIR. National Defense Authorization Act for Fiscal Year 2012, §5143.	Other HHS-Related Reviews

Appendix B

## Questioned Costs and Funds Recommended To Be Put to Better Use

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

### Audit Reports With Questioned Costs

Questioned costs are those questioned by OIG audits because of an alleged violation of a provision of a law, regulation, contract, grant, or other agreement governing the expenditure of funds. Costs are questioned because the expenditure was not supported by adequate documentation or because the expenditure was unnecessary or unreasonable. OIG includes those questioned costs that HHS program officials, in a management decisions, have agreed should not be charged to the Federal Government, commonly referred to as disallowed costs, as part of the expected recoveries in the Accomplishment section at the beginning of the *Semiannual Report*. Superscripts indicate end notes.

Table 1 – Audit Reports With Questioned Costs

	Reports	Dollar Value Questioned	Dollar Value Unsupported
<b>Section 1</b>			
Reports for which no management decisions had been made by the beginning of the reporting period <sup>1</sup>	228	\$757,571,000	\$41,257,000
Reports issued during the reporting period	97	\$593,866,000	\$3,238,000
<b>Total Section 1</b>	<b>325</b>	<b>\$1,351,437,000</b>	<b>\$44,495,000</b>
<b>Section 2</b>			
Reports for which management decisions were made during the reporting period <sup>2,3</sup>			
Disallowed costs	203	\$521,231,000*	\$12,683,000
Costs not disallowed	11	\$52,218,000	\$4,813,000
<b>Total Section 2</b>	<b>214</b>	<b>\$573,449,000</b>	<b>\$17,496,000</b>

\*Audit receivables (expected recoveries).

	Reports	Dollar Value Questioned	Dollar Value Unsupported
<b>Section 3</b>			
Reports for which no management decisions had been made by the end of the reporting period (Sec. 1 minus Sec. 2)	111	\$777,988,000	\$26,999,000
<b>Section 4</b>			
Reports for which no management decisions were made within 6 months of issuance <sup>4</sup>	46	\$198,822,000	\$23,762,000

## Audit Reports With Funds Recommended To Be Put to Better Use

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

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

	Reports	Dollar Value
<b>Section 1</b>		
Reports for which no management decisions had been made by the beginning of the reporting period <sup>1</sup>	17	\$1,480,248,000
Reports issued during the reporting period	15	\$14,298,000
<b>Total Section 1</b>	<b>32</b>	<b>\$1,494,546,000</b>
<b>Section 2</b>		
Reports for which management decisions were made during the reporting period		
Value of recommendations agreed to by management		
Based on proposed management action	7	\$801,744,000
Based on proposed legislative action	0	0
Value of recommendations not agreed to by management	4	\$213,612,000
<b>Total Section 2</b>	<b>11</b>	<b>\$1,015,356,000</b>
<b>Section 3</b>		
Reports for which no management decisions had been made by the end of the reporting period <sup>2</sup> (Sec. 1 minus Sec. 2)	21	\$479,190,000

## End Notes

### Table 1 End Notes

<sup>1</sup> The opening balance was adjusted upward by \$107.6 million because of a reevaluation of previously issued recommendations.

<sup>2</sup> Revisions to previously reported management decisions:

- CMS determined that it could not recoup disallowances totaling \$517,355,025 associated with 21 audits because Federal regulations at 42 CFR 405.980(b) prevented it from reopening claims beyond 4 years after its initial determination.
- A-05-06-00045, *Review of Indiana Medicaid Hospital Disproportionate Share Eligibility – State FYs 2001-2003*. On the basis of additional information provided by the State, CMS determined that one of three psychiatric hospitals reviewed by OIG met specific conditions of participation and reduced its original disallowance of \$88,236,417 by \$34,008,371.
- A-09-07-88410, A-09-09-92146, and A-09-09-94256, *State of California*. CMS revised a finding involving duplicate Medicaid payments made to long-term care facilities and providers that was initially reported in the FY 2006 single audit and subsequently included in the FY 2007 and 2008 single audits. On the basis of information provided by the State auditor, CMS determined that the Federal share of duplicate payments was \$3,311,446 and reduced its original disallowances by \$14,524,773.
- A-05-10-95134, *State of Indiana*. CMS determined that prior to FY 2010, the State could charge allowable administrative expenses against the subsequent year's grant award and reversed its disallowance of \$14,017,440.
- A-05-07-88075, *State of Indiana*. On the basis of a review of an amended cost report for a State-owned facility that had the effect of reducing the amount of overpayment identified in the non-Federal audit of the State, CMS reduced its original disallowance of \$16,376,503 by \$9,103,881.
- A-09-07-00039, *Review of Medicaid Outpatient Drug Expenditures in California for FYs 2004 and 2005*. CMS reduced its original disallowance of \$24,082,193 by \$6,553,600 on the basis of OIG's revised estimate of unallowable drug expenditures.
- A-01-04-00525, *Review of Interrupted Stays at Inpatient Rehabilitation Facilities*. CMS contractors completed their review of claims and recovered \$3,994,014 in additional overpayments.
- A-05-01-65324, *State of Indiana*. On the basis of additional information from the State Board of Accounts regarding the reimbursement of medical supplies to Medicaid providers, CMS reduced its original disallowance of \$5,396,116 by \$2,557,019.

<sup>3</sup> Included are management decisions to disallow \$25.7 million in questioned costs that were identified by non-Federal auditors in audits of State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards conducted in accordance with Office of Management and Budget Circular A-133. By law, OIG is responsible for 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.

<sup>4</sup> Because of administrative delays, some of which were beyond management control, resolution of the following 46 audits was not completed within 6 months of issuance of the reports; however, agency management has informed us that the agency is working to resolve the outstanding recommendations before the end of the next semiannual reporting period:

A-09-06-00023	REVIEW OF LOS ANGELES COUNTY APPROVAL PROCESS OF RELATIVE FOSTER FAMILY HOMES, OCT 2009, \$45,520,603
A-05-08-00098	REVIEW OF OHIO DEPARTMENT OF JOB AND FAMILY SERVICES CLAIMS FOR COSTS REPORTED BY THE HAMILTON COUNTY DEPARTMENT OF JOB AND FAMILY SERVICES, JAN 2011, \$34,056,598
A-01-02-00006	REVIEW OF RATE SETTING METHODOLOGY FOR MEDICAID SCHOOL-BASED HEALTH SERVICES , CT, MAY 2003, \$32,780,146
A-01-10-00513	NATIONWIDE REVIEW OF PLACE OF SERVICE CODING FOR PHYSICIAN SERVICES PROCESSED BY PART B CONTRACTORS FOR CY 2008, SEP 2011, \$19,266,050
A-07-10-06004	REVIEW OF PART D DRUGS PRESCRIBED BY EXCLUDED PROVIDERS, DEC 2011, \$15,079,608
A-03-09-00019	REVIEW OF MEMBERHEALTH'S 2006 AND 2007 DIRECT AND INDIRECT REMUNERATION REPORTS, OCT 2010, \$9,339,013
A-01-11-00534	NATIONWIDE REVIEW OF INPATIENT REHABILITATION FACILITIES PATIENT ASSESSMENT INSTRUMENTS FOR CALENDAR YEARS 2009 AND 2010, SEP 2012, \$8,397,071
A-01-10-00508	REVIEW OF PAYMENTS TO HOSPITALS FOR NONPHYSICIAN OUTPATIENT SERVICES UNDER THE I/P PROSPECTIVE PAYMENT SYSTEM, JUN 2012, \$6,100,000
A-04-08-03521	AUDIT OF UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS IN TN FOR THE PERIOD OCTOBER 1, 1998 - DECEMBER 31, 2007, FEB 2009, \$5,768,243
A-01-11-02500	REVIEW OF MASSACHUSETTS' TITLE IV-E ADOPTION ASSISTANCE COSTS FOR FEDERAL FISCAL YEARS 2006 - 2008, AUG 2011, \$4,242,540
A-04-11-01095	ADMINISTRATIVE AND CLERICAL COSTS CHARGED TO FEDERAL GRANTS AND CONTRACTS, JUL 2012, \$2,977,548
A-03-11-00002	REVIEW OF NEW ENGLAND JOINT ENTERPRISE 2009 DIR REPORTS, APR 2012, \$2,710,732
A-07-11-03163	REVIEW OF CCDF TARGETED FUNDS IN IOWA, MAR 2012, \$2,654,238
A-04-11-08008	REVIEW OF CONCURRENTLY ENROLLED CHIP AND MEDICAID BENEFICIARIES IN AL, SEP 2012, \$1,699,959
A-02-11-02007	LONG ISLAND CHILD AND FAMILY DEVELOPMENT SERVICES, INC.'S FINANCIAL MANAGEMENT SYSTEM DID NOT ACCURATELY DISCLOSE HEAD START PROGRAM RESULTS, MAY 2012, \$1,489,093
A-06-11-00031	RCA OF THE CHILD DEVELOPMENT COUNCIL OF ACADIANA, INC., SEP 2012, \$1,173,276

A-02-10-01001	NEW JERSEY DID NOT ALWAYS CLAIM FEDERAL MEDICAID REIMBURSEMENT FOR PERSONAL CARE SERVICES MADE BY BAYADA NURSES, INC., IN ACCORDANCE WITH FEDERAL AND STATE REQUIREMENTS, SEP 2012, \$774,274
A-02-11-02005	LIMITED HEAD START REVIEW OF INCLUDED EDUCATIONAL SERVICES, JUL 2012, \$588,830
A-01-11-02506	CHILDCARE LEARNING CENTERS, HEAD START LIMITED SCOPE REVIEW, ALLOCATING OF COSTS – ARRA, MAY 2012, \$563,059
A-01-11-02505	NEON - HEAD START LIMITED SCOPE REVIEW – ALLOCATING OF COSTS – ARRA, JAN 2012, \$406,434
A-02-11-01004	REVIEW OF THE QUARTERLY MEDICAID STATEMENT OF EXPENDITURES FOR THE MEDICAL ASSISTANCE PROGRAM IN THE U.S. VIRGIN ISLANDS FOR THE QUARTER ENDED SEPTEMBER 30, 2009, APR 2012, \$393,316
A-06-11-00034	RCA OF THE ECONOMIC OPP. DEV. CORP. OF ATASCOSA, KARNES, WILSON COUNTIES, SEP 2012, \$372,081
A-01-10-02505	RESULTS OF LIMITED SCOPE REVIEW OF CTE, INC., MAY 2011, \$293,870
A-05-05-00033	UNDISTRIBUTED CHILD SUPPORT COLLECTIONS – MI, AUG 2006, \$257,859
A-01-11-02508	REVIEW OF VERMONT'S TITLE IV-E ADMINISTRATIVE AND TRAINING COSTS, FEB 2012, \$242,233
A-07-06-01035	AUDIT OF QUALITY IMPROVEMENT ORGANIZATION – IOWA, OCT 2007, \$208,974
A-05-09-00044	RISK ADJUSTMENT DATA VALIDATION OF PAYMENTS MADE TO PARAMOUNT CARE, INC., FOR CALENDAR YEAR 2007 (CONTRACT NUMBER H3653), SEP 2012, \$205,534
A-06-09-00012	RISK ADJUSTMENT DATA VALIDATION – PACIFICARE H4590, MAY 2012, \$183,247
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
A-04-11-03538	HEAD START HIGH RISK GRANTEE - MOBILE COMMUNITY ACTION AGENCY, INC., DEC 2011, \$147,587
A-09-09-01007	REVIEW OF IDAHO'S TITLE IV-E ADOPTION ASSISTANCE COSTS FOR FEDERAL FISCAL YEARS 2006 – 2008, JUL 2009, \$124,046
A-04-07-01045	COSTS CLAIMED FOR ESRD NETWORK 6 OPERATIONS, AUG 2009, \$116,728
A-06-11-00058	REVIEW OF CSBG ARRA COSTS CLAIMED BY CROWLEY'S RIDGE DEVELOPMENT COUNCIL, AUG 2012, \$115,420
A-09-11-02044	SOUTHERN CALIFORNIA RENAL DISEASE COUNCIL, INC., CONTRACT 500-2006-NW018C, YRS 07/2006 – 09/2010, MAY 2012, \$112,670
A-02-11-02000	REVIEW OF SELECT EXPENDITURES, SUNY AT ALBANY, OCT 2011, \$62,560
A-09-12-01000	REVIEW OF CSBG RECOVERY ACT ADMINISTRATIVE COSTS CLAIMED BY HI OFFICE OF COMMUNITY SERVICES, JUN 2012, \$34,861
A-04-06-00023	REVIEW OF QUALITY IMPROVEMENT ORGANIZATIONS - TENNESSEE, JUL 2008, \$30,654
A-09-11-02005	REVIEW OF INCURRED COSTS OF NETWORK COORDINATING CENTER CONTRACT, APR 2012, \$29,192
A-03-10-03110	TIGER TEAM – CONTRACT HHSN267-2007-00014C, OCT 2011, \$27,707
A-09-11-01014	REVIEW OF CSBG RECOVERY ACT COSTS CLAIMED BY HI FOR THE HAWAII COUNTY ECONOMIC OPPORTUNITY COUNCIL, JUL 2012, \$22,602

A-09-10-02045	REVIEW OF INCURRED COSTS OF ESRD NETWORK 18 CONTRACT, MAR 2012, \$19,996
A-02-11-02008	REVIEW OF SELECT EXPENDITURES, SUNY AT STONY BROOK, AUG 2012, \$18,254
A-05-11-00042	MEDICARE PART D MADE SOME INCORRECT PAYMENTS TO COMMUNITY INSURANCE INC FOR INSTITUTIONAL BENEFICIARIES IN 2008, AUG 2012, \$13,346
A-05-11-00053	THE COLUMBUS URBAN LEAGUE CLAIMED SOME UNALLOWABLE COSTS TO HEAD START, SEP 2012, \$13,102
A-05-06-00043	REVIEW OF OHIO KEPRO, INC., FEB 2008, \$11,874
A-01-12-02501	REVIEW OF CSBG RECOVERY ACT COSTS CLAIMED - CFC, FALL RIVER, MA, AUG 2012, \$10,769

TOTAL NUMBER OF REPORTS: 46  
TOTAL AMOUNT: \$198,821,592

## Table 2 End Notes

<sup>1</sup>The opening balance was adjusted downward by \$31.3 million because of reevaluation of previously issued recommendations.

<sup>2</sup> Because of administrative delays, some of which were beyond management control, resolution of the following five audits was not completed within 6 months of issuance of the report. OIG is working with management to reach resolution on these recommendations before the end of the next semiannual reporting period:

A-04-10-03059	REVIEW OF CMS MONETARY RECOVERIES MADE AS A RESULT OF OAS AUDIT REPORTS, MAY 2012, \$416,287,546
A-06-10-00059	REVIEW OF HOSPICE COVERED DRUGS NATIONWIDE, JUN 2012, \$33,638,137
A-05-05-00033	UNDISTRIBUTED CHILD SUPPORT COLLECTIONS - MI, AUG 2006, \$4,397,133
A-05-06-00023	UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS - MN, SEP 2006, \$28,240
A-09-09-01007	REVIEW OF IDAHO'S TITLE IV-E ADOPTION ASSISTANCE COSTS FOR FEDERAL FISCAL YEARS 2006 - 2008, JUL 2009, \$17,764

TOTAL NUMBER OF REPORTS: 5  
TOTAL AMOUNT: \$454,368,820

## Appendix C

# Peer Review Results

The Inspector General Act of 1978, as amended, requires Offices of Inspector General (OIGs) to report the results of peer reviews of their operations conducted by other OIGs, the date of the last peer review, and outstanding recommendations from peer reviews. OIGs also report peer reviews they conducted 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, OAS did not participate in any peer review process. Listed below is information concerning OAS's peer review activities during prior reporting periods.

OAS	Date	Reviewing Office	Office Reviewed
	June 2012	Department of Homeland Security	HHS OIG, OAS

The system of quality control for the audit organization of HHS OIG in effect for the year ending September 30, 2011, 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
		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.

## Office of Investigations Peer Review Results

During this semiannual reporting period, OI did not participate in any peer review process. Listed below is information concerning OI's peer review activities during prior reporting periods.

OI	Date	Reviewing Office	Office Reviewed
	August 2012	USPS-OIG	HHS-OIG, OI

The system of internal safeguards and management procedures for the investigative function of HHS-OIG in effect for the year ending September 30, 2012, were in full compliance with the quality standards established by CIGIE and the Attorney General's guidelines.

OI	Date	Reviewing Office	Office Reviewed
	July 2011	HHS-OIG, OI	Department of Defense (DoD)-OIG

The system of internal safeguards and management procedures for the investigative function of DoD-OIG in effect through July 2011 were in full compliance with the quality standards established by CIGIE and the Attorney General's guidelines.

OI	Date	Reviewing Office	Office Reviewed
	January 2011	HHS-OIG, OI	Department of Housing and Urban Development (HUD) OIG

The system of internal safeguards and management procedures for the investigative function of HUD-OIG in effect through February 2011 was in full compliance with the quality standards established by CIGIE and the Attorney General's guidelines.

## Appendix D

# Summary of Sanction Authorities

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

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## 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: Medicare or Medicaid fraud; patient abuse or neglect; felonies for other health care fraud; and felonies for illegal manufacture, distribution, prescription, or dispensing of controlled substances.

The Office of Inspector General (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 Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) 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 Department of Health and Human Services Departmental Appeals Board and 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 Affordable Care Act added more grounds for imposing civil monetary penalties (CMPs). These include, among other 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) for which the Affordable Care Act 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 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 purchasing, leasing, 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 of the 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)).

**False Claims Amendments Act of 1986**—Under the Federal False Claims Amendments Act of 1986 (FCA) (31 U.S.C. §§ 3729–3733), a person or an entity is liable for up to treble damages and a penalty between \$5,500 and \$11,000 for each false claim it knowingly submits, or causes to be submitted, to a Federal program. Similarly, a person or an entity is liable under the FCA if it knowingly makes or uses, or causes to be made or used, a false record or statement to have a false claim paid.

The FCA defines “knowing” to include not only the traditional definition but also instances in which the person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information. Under the FCA, no specific intent to defraud is required. Further, the FCA contains a qui tam, or whistleblower, provision that allows a private individual to file a lawsuit on behalf of the United States and entitles that whistleblower to a percentage of any fraud recoveries. The FCA was again amended in 2009 in response to recent Federal court decisions that narrowed the law's applicability. Among other things, these amendments clarify the reach of the FCA as extending to false claims submitted to contractors or grantees of the Federal Government.