

Office of
Inspector
General

Semiannual Report to Congress

April 2013 – September 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 1,500 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 September 30, 2013.



*Daniel R. Levinson
Inspector General*

OIG is committed to driving positive change through work that is relevant, innovative, customer-focused, and high impact. During this reporting period, we continued to advance our core mission of protecting HHS programs and the people they serve.

Our partnership with other Federal, State, and local law enforcement entities as part of the Health Care Fraud Prevention and Action Team (HEAT) continues to yield impressive results. During fiscal year 2013, HEAT Strike Force efforts resulted in the filing of charges against 274 individuals or entities, 251 criminal actions, and \$333 million in investigative receivables. 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 and hold wrongdoers accountable.

We also identified opportunities to reduce waste in Medicare. For example, Medicare could have saved close to a billion dollars in 1 year if it had reimbursed for laboratory tests at the lower rates paid by the Federal Employees Health Benefits Program plans or State Medicaid programs. Also, Medicare could save up to hundreds of millions of dollars each year by implementing a payment policy for early discharges from hospitals to hospice care that is consistent with Medicare payment policies for such discharges from hospitals to other clinical settings, such as nursing facilities. OIG continued its audits of acute care hospital claims for services at risk of improper billing and identified questioned costs.

For this reporting period, OIG included significant contributions toward its oversight of public health and human services programs, including an examination of hospitals' use and sourcing of compounded drugs and the steps they take to ensure the quality of such drugs. This work was particularly important following the meningitis outbreak resulting from contaminated injections of compounded drugs.

During the same period, our investigations also resulted in resolutions with drug manufacturers whose alleged violations put patients and HHS programs at risk. The public health section of this report describes a manufacturer that resolved allegations that it had falsified records and data submitted to gain Food and Drug Administration (FDA) approval to sell drugs that were substandard. The section also describes two

manufacturers that resolved allegations of unlawful marketing of drugs for uses that were not approved by FDA.

Going forward, HHS faces significant challenges as it works to implement the Affordable Care Act and its signature element, the Health Insurance Marketplaces. OIG will be focusing on core risk areas associated with the Marketplaces, such as eligibility systems, payment accuracy, IT security, and contracting.

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 HHS 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 second half of fiscal year (FY) 2013 (April - September) and summarizes key accomplishments during the period and for the year.

Fiscal year 2013 accomplishments

For FY 2013, we reported expected recoveries of over \$5.8 billion consisting of nearly \$850 million in audit receivables and about \$5 billion in investigative receivables, which include about \$1 billion in non-HHS investigative receivables resulting from our work in areas such as the States' shares of Medicaid restitution. We also identified about \$19.4 billion in savings estimated for FY 2013 on the basis of prior-period legislative, regulatory, or administrative actions that were supported by OIG recommendations. Such estimates generally reflect third-party projections (such as those by the Congressional Budget Office or HHS actuaries) made at the time the action was taken. Actual savings may be higher or lower.

We reported FY 2013 exclusions of 3,214 individuals and entities from participation in Federal health care programs; 960 criminal actions against individuals or entities that engaged in crimes against HHS programs; and 472 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.

Medicare Fraud Strike Force accomplishments

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 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 FY 2013, Strike Force efforts resulted in the filing of charges against 274 individuals or entities, 251 criminal actions, and \$333 million in investigative receivables. The effectiveness of the Strike Force model is enhanced by interagency collaboration. For example, we refer credible allegations of fraud to the Centers for Medicare & Medicaid Services (CMS) so that it can suspend payments to the suspected perpetrators, thereby immediately preventing losses from claims submitted by Strike Force targets.

Nationwide Takedown. In May 2013, a nationwide takedown by Medicare Fraud Strike Force operations in eight cities resulted in charges against 89 individuals, including doctors, nurses, and other licensed medical professionals, for their alleged participation in Medicare fraud schemes involving approximately \$223 million in false billings. The defendants charged were accused of various health-care-fraud-related crimes, including conspiracy to commit health care fraud, violations of the anti-kickback statutes, and money laundering. The charges were based on a multitude of alleged fraud schemes involving various medical treatments and services, primarily home health care, but also mental health services, psychotherapy, physical and occupational therapy, medical equipment and supplies, and ambulance services. This coordinated operation was the sixth national Medicare fraud takedown in Strike Force history.

Strike Force Case Example—Home Health Services. Manuel Sanz was sentenced to 14 years of imprisonment and ordered to pay \$30 million in restitution after pleading guilty to charges of conspiracy to commit health care fraud and conspiracy to pay health care kickbacks. As co-owner of Ideal Home Health, Inc., a company that purportedly provided skilled nursing services and home health aides to Medicare beneficiaries, Sanz offered and paid kickbacks and bribes to recruiters and employees in exchange for recruiting Medicare beneficiaries to Ideal Home Health. Sanz then instructed nurses at Ideal Home Health to falsify patient medical records to make it appear that Medicare beneficiaries qualified for and received home health services when, in fact, the services were not medically necessary and were not provided.

Prescription drug issues

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, and flawed reimbursement methodologies.

Prescription Drug Fraud Scheme—Michigan. Babubhai Patel and 6 other defendants were sentenced and 19 others have been convicted for their roles in a widespread scheme. Patel was a licensed pharmacist who owned or controlled 26 pharmacies in Michigan. Patel offered and paid kickbacks, bribes, and other inducements to providers in exchange for their writing fraudulent prescriptions for patients with Medicare, Medicaid, and private insurance and directing the patients to fill their prescriptions at one of Patel's pharmacies. Patel's pharmacies falsely billed Medicare and Medicaid approximately \$57.8 million for medications purportedly provided to beneficiaries over the course of the scheme.

High-Prescribing Physicians. Some Part D high-prescribing physicians have questionable billing patterns. We identified over 700 general-care physicians with questionable prescribing patterns, including many who prescribed extremely high numbers of drugs per beneficiary, which may indicate that some of the prescriptions were not medically unnecessary. More than half of the providers we identified with questionable prescribing patterns prescribed extremely high percentages of Schedule II or III drugs, which have potential for addiction and abuse. ([OEI-02-09-00603.](#))

Anemia Management Drugs. Medicare payment adjustments could yield savings. Almost all people with end-stage renal disease (ESRD) have anemia. We estimated that Medicare and its beneficiaries could have saved \$510 million during CY 2011 if the ESRD base rate had been

adjusted to reflect the current utilization of Epogen and Aranesp and \$19 million if the base rate had been adjusted to reflect current utilization of Venofer and Ferrlecit. ([A-01-12-00522](#).)

Manufacturer Rebates. Medicare could collect billions if pharmaceutical manufacturers were required to pay rebates for Part B drugs. Medicaid recouped a substantial percentage of the \$28 billion it spent on prescription drugs in 2011 because of statutorily mandated rebates from manufacturers; however, no similar rebate authority exists for Part B to reduce its costs of drugs. Medicare Part B expenditures for prescription drugs exceeded \$16 billion in 2011. ([OEI-12-12-00260](#).)

Medicaid Pricing of Generic Drugs. Using more aggressive State pricing formulas and inclusion criteria could help States control Medicaid's generic drug costs. We identified the State with the most aggressive pricing model (Wyoming) and calculated the potential national savings had all States used that program. We found that 39 of 45 States could have achieved \$483 million in savings during the first half of calendar year 2011 had they used the Wyoming model. ([OEI-03-11-00640](#).)

Other Medicare and Medicaid reviews

Medicare Part A helps cover certain inpatient services, such as those provided in hospitals and skilled nursing facilities and some home health services. Part B helps cover certain other medical services, equipment, supplies, and drugs that Part A does not cover. Health care providers and suppliers bill Medicare. The claims are processed by Medicare contractors.

For the Medicaid program, States have considerable flexibility in designing and operating their programs; however, to receive a Federal share of Medicaid costs, applicable State and Federal requirements must be met. Health care providers and suppliers are paid by the States. The States then report the amounts to CMS to receive the Federal share.

Physical Therapy Fraud—Texas. An OIG Most Wanted Fugitive, Godwin Nzeocha, was captured and sentenced to 9 years and 1 month of incarceration and ordered to pay more than \$26 million in restitution, joint and several, after pleading guilty to charges of conspiracy to commit health care fraud and money laundering. Nzeocha was not licensed, trained, or otherwise qualified to provide physical therapy to patients. According to court documents, Nzeocha signed his name on patient files as the provider of physical therapy services and signed blank treatment data forms, progress notes, and daily physical therapy records. He also signed documents that were prefilled with units of physical therapy treatment that he knew had not been provided and that he was not qualified to provide.

Management of Provider Data. Medicare provider enumeration and enrollment data are often inaccurate, are occasionally incomplete, and are generally inconsistent between Medicare's two primary provider databases, hindering oversight and placing health care programs at risk of fraud and abuse. We reported that provider data were inconsistent between the two primary databases for 97 percent of records. ([OEI-07-09-00440](#).)

Laboratory Tests—Inefficient Methodology. We estimated that Medicare could have saved \$910 million in 2011 (38 percent) on selected high-volume and/or high-expenditure lab tests if it had paid providers at the lowest established rate under Medicaid or the Federal Employees

Health Benefits (FEHB) Program in each geographic area. Medicare is the largest payer of clinical laboratory services in the Nation. However, most State Medicaid programs and FEHB plans pay less than Medicare pays for many lab tests. ([OEI-07-11-00010](#).)

Hospitals—Early Discharges to Hospice Care. If Medicare Part A had implemented a hospital transfer payment policy for early discharges from hospitals to hospice care in 2009 and 2010, it could have saved over \$600 million. Generally, Medicare’s transfer payment policies assume that hospitals should not receive full payments for beneficiaries discharged early and then admitted for additional care in certain other clinical settings. Instead of making full payments, Medicare pays the discharging hospitals a per diem rate for early discharges. However, there is no similar policy for transfers to hospice care. ([A-01-12-00507](#).)

Critical Access Hospitals (CAHs). If CMS had decertified CAHs that were 15 or fewer miles from the nearest hospitals in 2011 and paid them at the applicable non-CAH rates, Medicare and beneficiaries would have saved \$449 million. Hospitals can be certified as CAHs if, for example, they are located at least a certain driving distance from other hospitals (including other CAHs) and are located in rural areas. Medicare pays more for care in CAH-certified hospitals but most CAHs would not meet the location requirements if required to re-enroll in Medicare. ([OEI-05-12-00080](#).)

Hospital Inpatient and Outpatient Claims in Risk Areas. Hospitals that appear to be at risk of submitting significant noncompliant claims to Medicare are subject to OIG review; risk areas are identified through data mining and analysis. Audits of seven hospitals with questioned costs are described in the "Medicare" section of this *Semiannual Report*. ([A-04-12-07033](#), [A-01-12-00523](#), [A-04-12-00083](#), [A-01-12-00527](#), [A-09-12-02071](#), [A-09-12-02048](#), and [A-04-12-03071](#).)

Medicare Hospital Outpatient Stays. Hospital practices with regard to care in outpatient observation stays instead of inpatient stays may limit some beneficiaries’ ability to access skilled nursing facility care (SNF) upon discharge. Only inpatient stays can be used to qualify for Medicare payment of SNF care. SNF care can cost tens of thousands of dollars. Hospital physicians decide whether to admit beneficiaries as inpatients or to extend outpatient stays. The potential financial burden of not meeting the inpatient stay requirement could discourage some beneficiaries from accessing the SNF care they need. ([OEI-02-12-00040](#).)

Recovery Audit Contractors (RAC)—Output and Effectiveness. The RACs’ mission is to protect Medicare by identifying improper payments and referring potential fraud to CMS. Prior OIG and Government Accountability Office work has identified problems with CMS’s interactions and oversight of RAC contractors. RACs identified improper payments totaling \$1.3 billion in 2010 and 2011. Although CMS took actions to correct the majority of vulnerabilities identified, it lacks metrics to evaluate the effectiveness of these corrections. Additionally, CMS did not take action to address the six referrals of potential fraud it received from RACs. ([OEI-04-11-00680](#).)

Medicaid—Diabetes Test Strips. The following reports estimated that selected States could reduce their Medicaid costs for blood glucose test strips: New York—savings of about \$5.9 million ([A-02-11-01042](#)); New Jersey—fee-for-service savings up to \$2.7 million and managed care savings up to \$4.5 million ([A-02-12-01010](#)); and Illinois—savings of about \$8.5 million ([A-05-12-00009](#)).

Medicaid—Traumatic Brain Injury (TBI) Waiver. We estimated that New York improperly claimed at least \$54 million in Federal Medicaid reimbursement for TBI waiver program services

that were unallowable. Beneficiary eligibility assessments were not conducted according to requirements, and providers did not ensure that they claimed reimbursement only for allowable, supported services. ([A-02-10-01043](#).)

Medicaid—Home Health Services. For a 2-year audit period, New York State improperly claimed almost \$31.5 million in Federal Medicaid reimbursement. Physicians did not review plans of care as required; other deficiencies were found. ([A-02-11-01008](#).)

Medicaid—Transformed Medicaid Statistical Information System (T-MSIS). Evidence from our early review of T-MSIS implementation indicated continued problems with completeness, accuracy, and other issues, and raised concerns about States' abilities to submit complete and accurate data. The T-MSIS is Medicaid's only nationwide Medicaid eligibility and claims database. Medicaid's national MSIS eligibility and claims database is used in analytical research, program integrity, planning, budgeting, and policy analyses associated with Medicaid. The T-MSIS initiative is intended to correct longstanding data deficiencies in MSIS. ([OEI-05-12-00610](#).)

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-related reviews include human services programs and administrative functions.

President's Emergency Plan for AIDS Relief (PEPFAR). The Centers for Disease Control and Prevention (CDC) implemented 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). During this semiannual period we reported the results of several reviews of CDC and host country performance with regard to PEPFAR funds. We variously questioned certain operating procedures, potentially unallowable value-added taxes, interest income, unallowable expenses, and reporting deficiencies. ([A-04-12-04023](#), [A-05-12-00021](#), [A-05-12-00022](#), [A-05-12-00023](#), [A-05-12-00024](#), [A-06-11-00056](#), and [A-06-11-00057](#).)

Generic Drug Manufacturer Settled Quality, Other Issues—Maryland. Ranbaxy Laboratories Limited (Ranbaxy) agreed to pay \$350 million plus interest to resolve allegations that it falsified records and other data to obtain Food and Drug Administration (FDA) approval to sell generic drugs in the United States and submitted false data to gain approval for substandard generic antiretroviral drugs that were purchased through the PEPFAR program. Ranbaxy entered into a consent decree with FDA that includes extensive auditing, monitoring, and review of Ranbaxy's current practices and data integrity program.

Unlawful Marketing of Drug for Unapproved Uses—Oklahoma. Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer, Inc., agreed to pay \$490 million to resolve criminal and civil liability arising from its unlawful marketing of Rapamune, an immunosuppressive drug that prevents the body's immune system from rejecting a transplanted organ. Wyeth received FDA approval in 1999 for Rapamune for use in treating renal (kidney) transplant patients. However, Wyeth also allegedly

trained its sales force to promote Rapamune use in treating nonrenal patients. Wyeth allegedly offered financial incentives to its sales staff to target all transplant patient populations in an effort to increase sales of Rapamune.

Use of High-Risk Compounded Sterile Preparations (CSPs). Pharmaceutical compounding is the creation of a prescription drug tailored to meet the needs of an individual patient. This work was particularly important following the meningitis outbreak resulting from contaminated injections of compounded drugs. Our survey revealed that the use of CSPs is widespread in hospitals, although the use of the highest risk products is limited to about one-quarter of hospitals, most commonly larger facilities. Hospitals took limited steps to ensure the quality of outsourced CSPs, but had few identified problems with the quality of CSPs from outside pharmacies. ([OEI-01-13-00150](#).)

License-Exempt Child Care Providers in the Child Care and Development Fund Program (CCDF). Gaps in health and safety requirements and gaps in monitoring represent vulnerabilities that could lead to harm for children in care. Some child care providers, such as family home providers, are legally exempt from regulation (license exempt). Not all States require license-exempt child care providers to meet Federal health and safety requirements, and States with health and safety requirements for license-exempt providers commonly allow providers to self-report compliance. States do not always monitor license-exempt providers. ([OEI-07-10-00231](#).)

CCDF Program in Connecticut. CCDF-funded providers did not always comply with applicable State licensing requirements to ensure the health and safety of children. Connecticut's onsite monitoring did not ensure that providers that received CCDF funds complied with State licensing requirements related to the health and safety of children. We determined that all 20 of the providers that we reviewed failed to comply with 1 or more State licensing requirements to ensure the health and safety of children. Two of the providers voluntarily surrendered their licenses after our review. ([A-01-12-02504](#).)

Child Support Enforcement—New York. An OIG "Most Wanted Deadbeat Parent," Robert Sand, was sentenced to 2 years and 7 months of incarceration and ordered to pay \$903,789 in restitution after pleading guilty to charges of failure to pay child support for his two children. Sand was arrested after accruing more than \$1 million in unpaid child support obligations, penalties, and interest. According to court documents, Sand admitted that he initially relocated from New York to Florida and then fled the United States in order to evade his child support obligations following the issuance of arrest warrants in both State and Federal court in 2000 and 2002. While overseas, Sand operated a business in Thailand, but was arrested upon entering the Philippines without proper identification documents. In December 2012, he was returned to the United States, where he was taken into custody and arraigned.

OIG participation in congressional hearings

9-11-2013 **Kay Daly**, Assistant Inspector General for Audit Services, testified before the House Committee on Homeland Security, Subcommittee on Cybersecurity, about infrastructure protection and security technologies, threats to Americans' personal information, and the security and reliability of the Health Exchange Data Hub. [Testimony](#).



Kay Daly, Assistant Inspector General for Audit Services

6-24-2013 **Stuart Wright**, Deputy Inspector General for Evaluation and Inspections, and **Gary Cantrell**, Deputy Inspector General for Investigations, testified before the Senate Committee on Homeland Security and Governmental Affairs on curbing prescription drug abuse in Medicare. [Testimony](#).



Stuart Wright, Deputy Inspector General for Evaluation and Inspections and Gary Cantrell, Deputy Inspector General for Investigations

<http://oig.hhs.gov>

Semiannual Report to Congress Fall 2013

Medicare Part A and Part B Reviews-----1

Address wasteful policies and practices ----- 1

Significant problems, abuses, and deficiencies: ----- 2

- 01 Hospitals—Early Discharges to Hospice Care.** Medicare pays hospitals more for early discharges to hospice care than it pays for early discharges to certain other care settings; a hospice-specific hospital transfer payment policy is needed. ----- 2
- 02 Critical Access Hospitals (CAHs).** Medicare and its beneficiaries pay more for care in CAH-certified hospitals, but most CAHs would not meet the location requirements if required to re-enroll in Medicare. ----- 2
- 03 Laboratory Tests.** Medicare paid more for lab tests than did the State Medicaid programs and Federal Employee Health Benefit (FEHB) plans we reviewed; better aligning payments with Medicaid and FEHB could yield substantial savings. ----- 3
- 04 Medical Equipment/Supplies—Continuous Positive Airway Pressure (CPAP) Therapy.** Medicare’s replacement schedule for CPAP supplies has remained largely the same for the past 20 years and may not align with current payers and professional recommendations. ----- 4
- 05 Part B Prescription Drugs.** Medicare could recoup billions on Part B drug costs if pharmaceutical manufacturers were required to pay rebates as they do for Medicaid drugs. - 4
- 06 Dialysis—Anemia Management Drugs.** Utilization of anemia management drugs in dialysis treatments in 2011 was generally significantly less than the utilization reflected in the base rate calculation; adjustments could yield savings for Medicare. ----- 5
- 07 Claims Processing—G Modifiers.** Medicare contractors fail to consider billing codes that flag claims as being unallowable for payment; practice and procedure adjustments are needed. -- 6

Prevent, deter, and address abusive billing-----6

Significant problems, abuses, and deficiencies: ----- 7

- 01 Hospital Postacute Discharges and Transfers.** Medicare overpaid millions to hospitals for claims subject to the postacute care transfer policy reduced rate. ----- 7
- 02 Hospital Claims for Mechanical Ventilation.** Medicare overpaid millions to hospitals that used the incorrect procedure code for mechanical ventilation. ----- 8
- 03 Hospital Claims for Canceled Elective Surgeries.** Medicare overpaid millions to hospitals for canceled elective surgeries. ----- 8
- 04 Hospital Inpatient and Outpatient Claims in Risk Areas.** Hospitals that appear to be at risk of submitting significant noncompliant claims to Medicare are subject to OIG review; risk areas are identified through data mining and analysis. ----- 9
- 05 Outpatient Therapy Services—**An outpatient therapy supplier improperly billed most of its claims to Medicare; the supplier did not have a thorough understanding of Medicare’s

requirements and did not have adequate policies and procedures in place to ensure correct billing. -----10

06 Medical Equipment/Supplies—Diabetes Test Strips. Billing abuses continue in non-competitive-bidding areas and for non-mail-order purchases. -----11

07 Medical Equipment/Supplies—Diabetic Testing Supplies. One provider’s CY 2011 claims billed at the higher non-mail-order rate illustrate the effect of prior payment policy, now revised. -----11

08 Medical Equipment/Supplies—Lower Limb Prosthetics. Medicare overpaid lower limb prosthetics claims that did not meet local coverage determinations; the contractor lacked effective edits.-----12

09 Part B Drugs—Herceptin. Medicare overpays for the cancer drug Herceptin; incorrect units of service billed and supporting documentation are inadequate. -----13

10 Part B Ambulance Services—Increased Utilization. Increases in the utilization of ambulance transports are disproportionate in relation to increases in the population of Medicare fee-for-service beneficiaries. -----13

11 Management of Provider Data. Medicare provider enumeration and enrollment data are often inaccurate, are occasionally incomplete, and are generally inconsistent between Medicare’s two primary provider databases, hindering oversight and placing health care programs at risk of fraud and abuse. -----14

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Significant problems, abuses, and deficiencies: ----- 15

01 Overpayment Recoveries. Inaccurate provider types and contact information and other data gaps delay or prevent overpayment demand letters from reaching providers; not all overpayments are recovered. -----15

02 CMS Recovery Audit Contractors (RACs)—Output and Effectiveness. Despite active identification of improper payments, high amounts of such payments continue; evaluation methods are lacking.-----16

Promote quality, safety, and value ----- 17

Significant problems, abuses, and deficiencies: ----- 17

01 Hospital Outpatient Stays. Hospital practices with regard to outpatient observation stays may limit beneficiaries’ ability to access skilled nursing facility (SNF) care upon discharge. ---17

02 Survey and Certification of Home Health Agencies (HHAs). CMS’s lack of surveys for oversight of State agencies’ HHA survey performance could present a vulnerability to program effectiveness and quality of care for Medicare beneficiaries. -----18

03 Survey and Certification of Hospices. State recertification surveys of hospices are not sufficiently frequent to ensure compliance and quality of care.-----19

04 Hospices—Use of General Inpatient Care. Medicare hospices’ inconsistent use of general inpatient care raises questions about whether the hospices provide appropriate levels of care to beneficiaries. -----20

05 Part B Drugs—Vaccines. Some Medicare beneficiaries are being given pneumococcal vaccinations more often than recommended by the Centers for Disease Control and Prevention (CDC).-----20

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- 01 Part C Overpayments.** Diagnoses submitted by two Medicare Advantage (MA) organizations resulted in risk score calculation errors and Medicare overpayments; causes include service provider errors, ineffective policies and procedures, and inadequate documentation. -----21
- 02 Part D Investment Income.** Medicare loses potential cost savings because Federal requirements governing Medicare Part D do not limit the ability of Part D plans to retain investment income earned on Medicare funds. -----22
- 03 Part D Billing Patterns.** Some Part D high-prescribing physicians have questionable billing patterns. -----23
- 04 Part D Unauthorized Prescribers.** Medicare and Part D sponsors fail to detect many drugs, including controlled substances, that are being ordered by individuals without the authority to prescribe. -----23
- 05 Part D Dual Eligibles—Mandatory Review.** Prescription drug plans generally cover most drugs commonly used by individuals who are fully eligible for both Medicare Part D and Medicaid. -----24

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- 02 Prescription Drugs—Pricing Generics.** The use of more aggressive State Maximum Allowable Cost (MAC) pricing formulas and inclusion criteria could help States achieve additional cost-savings for generic drugs. -----28

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- 01 Hospital Inpatient Care—High-Dollar Payments.** Wisconsin and Indiana improperly claimed Federal reimbursement for unallowable high-dollar payments they made to hospitals for inpatient services; the hospitals had submitted incorrect charges, which they attributed to data entry errors. -----29
- 02 Hospital Inpatient Care—Psychiatric Services and Disproportionate Share Hospital Payments.** Missouri and Indiana improperly claimed Federal reimbursement for certain payments to psychiatric hospitals that could not demonstrate compliance with Medicare Conditions of Participation (CoP). -----30
- 03 Intermediate Care Facilities (ICFs)—Services to Individuals With Intellectual and Developmental Disabilities.** Missouri’s internal controls and procedures were inadequate to prevent it from improperly claiming Federal reimbursement for duplicate or unsupported payments. -----31

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<http://oig.hhs.gov>

Medicare Part A and Part B Reviews

This segment of the Department of Health and Human Services (HHS) Office of Inspector General's (OIG) *Semiannual Report to Congress (Semiannual Report)* pertains to Medicare Part A and Medicare Part B. Medicare Part A and Part B together are generally referred to as "traditional Medicare" or "original Medicare," respectively. Medicare Part C (Medicare Advantage) and Part D (Medicare Prescription Drug Benefit) are further additions to the program.

Medicare Part A helps cover certain inpatient services in hospitals and skilled nursing facilities (SNFs) and some home health services. Medicare Part B helps cover designated practitioners' services; outpatient care; and certain other medical services, equipment, supplies, and drugs that Part A does not cover.

As required by the Inspector General Act of 1978, as amended, the *Semiannual Report* identifies and describes significant problems, abuses, deficiencies (i.e., issues), and recommendations for corrective action. For Medicare Part A and Part B, the issues fall into the following broad operational categories:

- addressing wasteful policies and practices.
- preventing, deterring, and addressing abusive billing.
- maximizing recovery of public funds.
- promoting quality, safety, and value.

The Table of Contents lists the issues reported for each category. The body of the document provides corresponding background information and savings potential and identifies recommendations that would address each issue.

Address wasteful policies and practices

The recommendations in this subsection address the wasteful spending that arises from shortcomings in current Medicare policies or practices. "Waste" is a broad term that applies to situations in which Medicare pays more than it should. Policies or practices sometimes result in waste when unintended loopholes or other inherent problems invite exploitation or hinder consistent payment determinations. Medicare's supporting systems and practices sometimes result in waste by hindering timely and appropriate payment adjustments. Later subsections address abusive billing and failure to recover public funds, which are related forms and sources of wasteful spending.

OIG's audit and evaluation reports do not routinely project the annual program-level cost savings that could be realized from implementing the recommendations. Instead, the reports indicate within the scope of each review the extent to which policies or practices may be ineffective and describe the corrective actions that OIG recommends. We describe the monetary findings of each report (which may result in receivables or funds made available better use) under the subheading "Savings Potential."

Significant problems, abuses, and deficiencies:

01 Hospitals—Early Discharges to Hospice Care. Medicare pays hospitals more for early discharges to hospice care than it pays for early discharges to certain other care settings; a hospice-specific hospital transfer payment policy is needed.

Generally, Medicare’s transfer payment policies assume that hospitals should not receive full payments when beneficiaries are discharged early and then admitted for additional care in certain other clinical settings. Instead of making full payments, Medicare pays the discharging hospitals a reduced rate for early discharges. There is no similar policy for transfers to hospice care.

We found that about 30 percent of all hospital discharges to hospice care were early discharges that, under a transfer payment policy, would have resulted in payment to the hospitals of a reduced rate instead of full payments. Medicare beneficiaries’ discharges from acute-care hospitals to hospice care increased about 66 percent from calendar year (CY) 2007 to CY 2010, and Part A payments increased about 80 percent (i.e., payments increased from \$1.5 billion to \$2.7 billion).

Savings Potential—If Medicare Part A had implemented a hospital transfer payment policy for early discharges from hospitals to hospice care in 2009 and 2010, it could have saved over \$600 million.

We recommend that the Centers for Medicare & Medicaid Services (CMS)

- change its regulations or pursue a legislative change if necessary to establish a hospital transfer payment policy for early discharges to hospice care.

2013 MAY Medicare Could Save Millions by Implementing a Hospital Transfer Payment Policy for Early Discharges to Hospice Care. [A-01-12-00507](#).

02 Critical Access Hospitals (CAHs). Medicare and its beneficiaries pay more for care in CAH-certified hospitals, but most CAHs would not meet the location requirements if required to re-enroll in Medicare.

Our August 2013 report revealed that nearly two-thirds of CAHs would not meet the location requirements if required to re-enroll and the vast majority would not meet the distance requirement. Also, CMS does not have the authority to decertify most of these CAHs because they are designated as “necessary providers” that are permanently exempt from meeting the distance requirement.

CMS pays CAHs under a system different from that for paying most other hospitals. Medicare reimburses CAHs at 101 percent of their reasonable costs, rather than at the rates set by prospective payment systems or fee schedules. Currently, hospitals can be certified as CAHs if

they meet a variety of regulatory requirements, including being located at least a certain driving distance from other hospitals (including other CAHs) and being located in rural areas.

Savings Potential—If CMS had decertified CAHs that were 15 or fewer miles from their nearest hospitals in 2011 and had paid them at the applicable non-CAH rates, Medicare and beneficiaries would have saved \$449 million.

We recommend that CMS

- seek legislative authority to remove the permanent exemption from the distance requirement for “necessary provider” CAHs, thus allowing CMS to reassess the CAHs’ eligibility; seek legislative authority to revise the CAH Conditions of Participation to include alternative location-related requirements; ensure that it periodically reassesses CAHs for compliance with all location-related requirements; and ensure that it applies its uniform definition of “mountainous terrain” to all CAHs.

2013 AUG Most Critical Access Hospitals Would Not Meet the Location Requirements if Required To Re-enroll in Medicare. [OEI-05-12-00080](#).

03 Laboratory Tests. Medicare paid more for lab tests than did the State Medicaid programs and Federal Employee Health Benefit (FEHB) plans we reviewed; better aligning payments with Medicaid and FEHB could yield substantial savings.

Medicare is the largest payer of clinical laboratory (lab) services in the Nation. It paid approximately \$8.2 billion for lab tests in 2010, which accounted for 3 percent of all Medicare Part B payments. Our June 2013 report revealed that in 2011, Medicare paid between 18 and 30 percent more than other insurers for 20 high-volume and/or high-expenditure lab tests.

State Medicaid programs and 83 percent of FEHB plans use the Medicare Clinical Laboratory Fee Schedule as a basis for establishing their own fee schedules and payment rates, although most pay less. Some State Medicaid programs and FEHB plans required copayments for lab tests, which, in effect, lowered the costs of lab tests for the insurer. Unlike Medicare, FEHB programs incorporate factors such as competitor information, changes in technology used in performing lab tests, and provider requests in their payment rates.

Savings Potential—Medicare could have saved \$910 million in 2011 (38 percent) on selected high-volume and/or high-expenditure lab tests if it had paid providers at the lowest established Medicaid or FEHB rate in each geographic area.

We recommend that CMS

- seek legislation that would allow it to establish lower payment rates for lab tests and to institute copayments and deductibles for lab tests.

2013 JUN Comparing Laboratory Test Payment Rates: Medicare Could Achieve Substantial Savings. [OEI-07-11-00010](#).

04 Medical Equipment/Supplies—Continuous Positive Airway Pressure (CPAP) Therapy. Medicare’s replacement schedule for CPAP supplies has remained largely the same for the past 20 years and may not align with current payers and professional recommendations.

Positive airway pressure, commonly administered by a CPAP machine, is the most widely used method for treating obstructive sleep apnea (OSA). Individuals diagnosed with OSA experience physical blockages or obstructions in the airway during sleep. Supplies—such as masks, tubing, chinstraps, and filters—must occasionally be replaced, thus resulting in recurring expenses.

We found that for most State Medicaid programs, frequency schedules for replacing CPAP supplies equaled or were less frequent than Medicare’s. CPAP supplies are included in one product category of CMS’s competitive-bidding process. However, competitive bidding does not address replacement schedules.

Savings Potential—Providing supplies more frequently than necessary leads to wasteful spending. For example, we estimated that if Medicare reduced the frequency of mask replacement from one per 3 months to one per 6 months, expenditures would decrease by more than \$14 million (about 14 percent).

We recommend that CMS

- review the CPAP supply replacement schedule and revise the national coverage determination for CPAP therapy for obstructive sleep apnea or request that the Durable Medical Equipment Medicare Administrative Contractors (MACs) revise their local coverage determinations as appropriate.

2013 JUN Replacement Schedules for Medicare Continuous Positive Airway Pressure Supplies. [OEI-07-12-00250](#).

05 Part B Prescription Drugs. Medicare could recoup billions on Part B drug costs if pharmaceutical manufacturers were required to pay rebates as they do for Medicaid drugs.

Medicaid recouped a substantial percentage of the \$28 billion it spent on prescription drugs in 2011 because of statutorily mandated rebates from manufacturers. That same year, Medicare Part B expenditures exceeded \$16 billion on prescription drugs; however, no similar rebate authority exists for Part B to reduce the costs of drugs to the program.

In response to a congressional request, OIG estimated in 2011 that if pharmaceutical manufacturers had been required to pay rebates similar to those under Medicaid for 20 high-expenditure Part B brand-name drugs, Medicare could have collected up to \$2.4 billion in rebates, representing as much as 26 percent of expenditures for those drugs in 2010.

Whereas our original analysis was limited to 20 brand-name drugs, this current study provides a more thorough examination of the potential collections associated with Part B rebates, as well as implementation issues. However, several implementation issues related to claims and data would need to be addressed if such a rebate program were implemented.

Savings Potential—We estimated that Medicare could have collected \$3.1 billion if pharmaceutical manufacturers had been required in 2011 to pay rebates based on average manufacturer price for 60 high-expenditure Part B drugs, representing 22 percent of spending for those drugs. Requiring manufacturers to pay rebates based on average sales price for the same 60 drugs could have garnered Medicare \$2.7 billion in rebate payments, representing 20 percent of spending.

We recommend that CMS

- examine the additional potential impacts of establishing a prescription drug rebate program under Medicare Part B and, if appropriate, seek legislative change. As part of its consideration, CMS should address administrative issues that may hinder rebate collections.

2013 SEP Medicare Could Collect Billions If Pharmaceutical Manufacturers Were Required To Pay Rebates for Part B Drugs. [OEI-12-12-00260](#).

06 Dialysis—Anemia Management Drugs. Utilization of anemia management drugs in dialysis treatments in 2011 was generally significantly less than the utilization reflected in the base rate calculation; adjustments could yield savings for Medicare.

Medicare payment adjustments could yield savings. Almost all people with end-stage renal disease (ESRD) have anemia. We estimated that Medicare and its beneficiaries could have saved \$510 million during CY 2011 if the ESRD base rate had been adjusted to reflect the current utilization of erythropoiesis-stimulating agents (ESAs) Epogen and Aranesp and \$19 million if the ESRD base rate had been adjusted to reflect current utilization of iron supplements Venofer and Ferrlecit. Also, we identified limitations that CMS should consider when it relies on ESRD claims data for program oversight. These limitations include inaccuracies in the quantities of drugs claimed and the inability to determine the extent of drug waste or overfill usage.

To comply with statutory requirements, CMS used CY 2007 utilization and payment data for ESAs and iron supplements to calculate the base rate for the ESRD prospective payment system (PPS) payment bundle. In CY 2011, Medicare and beneficiaries paid approximately \$10 billion for dialysis services under a bundled ESRD prospective payment system (PPS) that went into effect on January 1, 2011. The anemia management drugs Epogen, Aranesp, Venofer, and Ferrlecit represent approximately 25 percent of the base rate payment made to dialysis facilities for each dialysis treatment furnished to a beneficiary.

Savings Potential—We estimated that Medicare and its beneficiaries could have saved \$510 million during CY 2011 if the ESRD base rate had been adjusted to reflect current utilization of Epogen and Aranesp and \$19 million if the ESRD base rate had been adjusted to reflect current utilization of Venofer and Ferrlecit.

We recommend that CMS

- adjust the bundled base rate to realize program savings associated with decreased utilization of ESAs and iron supplements; develop new policies, procedures, or other guidance for recording drug waste and overfill; and remind dialysis facilities of the importance of claims accuracy.

2013 MAY Medicare and Beneficiaries Could Save Millions If Dialysis Payments Were Adjusted for Anemia Management Drug Utilization. [A-01-12-00522](#).

07 Claims Processing—G Modifiers. Medicare contractors fail to consider billing codes that flag claims as being unallowable for payment; practice and procedure adjustments are needed.

When processing claims, Medicare’s contractors often do not consider the “G” service code modifiers that providers and suppliers use to indicate that they expect services or items to be denied as not reasonable and necessary. Contractors also do not always consider the G modifiers that providers and suppliers use to indicate that services or items are not covered by Medicare. Although contractors have checks that affect some of these claims, such as determining whether the services and items met Medicare frequency limitations, they do not specifically check for claims for which providers expect not to be paid.

Savings Potential—In 2011, Medicare paid nearly \$744 million for Part B claims with G modifiers.

OIG did not make formal recommendations to CMS but provided a number of options that would help address the problems we found. For example, CMS could

- ensure that all contractors are following instructions to automatically deny claims with GZ modifiers; instruct contractors to automatically deny claims with GY modifiers and ensure that contractors follow the instructions; decide whether to implement the GX modifier for Part B claims, since providers are already using it; and ensure that contractors do not pay for claims with inappropriate combinations of G modifiers.

2013 MAY Medicare Payments for Part B Claims with G Modifiers. [OEI-02-10-00160](#).

Prevent, deter, and address abusive billing

Medicare makes improper payments (a form of wasteful spending) when it does not effectively prevent, deter, identify or address inappropriate and abusive billing by providers and suppliers. Some, but not all, abusive billing is fraudulent.

Improper payments include both overpayments and underpayments. This section of the *Semiannual Report* focuses primarily on significant overpayment issues, although the suggested remedies may also prevent underpayments. Ultimately, the goal is for all payments to be correct and to comply with rules and requirements.

Abusive billing occurs when the items or services billed to Medicare are not supported by the documentation in the providers' or suppliers' medical files as required, are not medically necessary, are not covered by Medicare, or other requirements and conditions for payment are not met. Also, administrative errors on claims may be associated with the improper payments.

In addition to recovering improperly paid amounts, OIG's recommendations associated with erroneous or abusive billing may include that CMS and/or its contractors educate providers on proper claims submission, conduct prepayment and postpayment reviews of medical records (including third-party records, such as records of the providers who ordered the items or performed the services) as appropriate; conduct unannounced site visits of providers; implement system edits to detect and reject questionable entries on claims; develop data sets and other tools to assist in proper billing; track billing histories for capped items and services; establish risk-based levels for screening and reviewing providers; monitor provisions historically vulnerable to error, procedures, providers, benefit categories, and system codes; ensure effective guidance and communications among CMS, its payment contractors, and the public; collect overpayments; and impose sanctions, such as penalties, suspensions, and revocations on providers with serious deficiencies. Some of OIG's recommendations are made directly to the billing provider or supplier.

Significant problems, abuses, and deficiencies:

01 Hospital Postacute Discharges and Transfers. Medicare overpaid millions to hospitals for claims subject to the postacute care transfer policy reduced rate.

Medicare makes full Medicare Severity Diagnosis-Related Group (MS-DRG) payments to hospitals that discharge inpatients to their homes. In contrast, for specified MS-DRGs, Medicare pays hospitals that transfer inpatients to certain postacute care settings, such as home health care and skilled nursing facilities, a reduced rate for each day of the stay, not to exceed the full MS-DRG payment for a discharge. Whether Medicare pays for a discharge or a transfer depends on the patient discharge status code indicated on the inpatient claim.

The hospitals we reviewed were overpaid by Medicare's contractor, Palmetto GBA, LLC, (Palmetto). The audited hospitals used incorrect patient discharge status codes on their claims, indicating that the patients were discharged to home rather than transferred to postacute care. Of the selected claims on which hospitals said patients were discharged to home, 97 percent were followed by claims for home health services. The hospitals should have been paid at reduced rates pursuant to postacute care transfer policy instead of at the full rates.

Savings Potential—Palmetto overpaid about \$10.8 million for 1,656 selected hospital claims subject to the postacute care transfer policy during CYs 2008 through 2011.

We recommend that Palmetto

- educate hospitals in its jurisdiction on the importance of reporting the correct patient discharge status codes on transfer claims, especially when home health services have been ordered; continue working with the pertinent data system maintenance contractor to ensure that it receives the system edits and alerts and associated information; and recover the overpayments we identified.

2013 MAY Palmetto GBA, LLC, Inappropriately Paid Hospitals' Medicare Claims Subject to the Postacute Care Transfer Policy in Jurisdiction 1. [A-09-12-02038](#).

02 Hospital Claims for Mechanical Ventilation. Medicare overpaid millions to hospitals that used the incorrect procedure code for mechanical ventilation.

With certain MS-DRGs, Medicare requires beneficiaries to receive 96 or more hours of mechanical ventilation—the use of a ventilator or respirator to take over active breathing for a patient. Hospitals indicate that beneficiaries meet this requirement by using procedure code 96.72 on claims.

If a beneficiary received fewer than 96 hours of mechanical ventilation, the claim is coded with a different procedure code and is assigned to an MS-DRG with a lower severity level, resulting in a lower payment. The hospitals incorrectly used procedure code 96.72 when the beneficiaries had not received 96 or more hours of mechanical ventilation, resulting in overpayments.

Savings Potential—Of the 377 selected claims, 363 were coded with the incorrect procedure code, resulting in overpayments of about \$7.7 million.

We recommend that CMS

- direct the Medicare contractors to review any claims for which procedure code 96.72 was used with a length of stay of 4 days or fewer, recover any overpayments after our audit period and before implementation of the length-of-stay edit, and ensure that the Medicare contractors recover the overpayments we identified.

2013 SEP Medicare Incorrectly Paid Hospitals for Beneficiaries Who Had Not Received 96 or More Hours of Mechanical Ventilation. [A-09-12-02066](#).

03 Hospital Claims for Canceled Elective Surgeries. Medicare overpaid millions to hospitals for canceled elective surgeries.

The Medicare Part A Trust Fund made payments that were not reasonable and necessary for short-stay inpatient hospital claims involving canceled elective surgeries. The payments occurred because the hospitals were unclear about the Medicare requirements for billing for canceled inpatient surgeries, particularly with regard to changing a beneficiary's status from inpatient to outpatient after discharge, and hospitals did not always have adequate utilization review controls to confirm whether admissions were reasonable and necessary after elective surgeries had been canceled.

Savings Potential—Medicare overpaid about \$38 million over a 2-year period. Hospitals may bill Medicare Part B for services related to the incorrectly billed Medicare Part A admissions. The estimated overpayments could be reduced if hospitals correctly rebill Part B and Part B pays for the services.

We recommend that CMS

- strengthen guidance to better explain the Medicare rule that a clinical condition requiring inpatient care must exist for hospitals to bill for Part A payments for elective surgeries that were canceled, instruct MACs to emphasize to hospitals the need for stronger utilization review controls for claims that include admissions for elective surgeries that did not occur, adjust the sampled claims representing overpayments of over \$345,000 to the extent allowed under the law, and work with OIG to resolve the remaining nonsampled claims and recover overpayments to the extent feasible and allowed under the law.

2013 AUG Medicare Could Save Millions by Strengthening Billing Requirements for Canceled Elective Surgeries. [A-01-12-00509](#).

04 Hospital Inpatient and Outpatient Claims in Risk Areas. Hospitals that appear to be at risk of submitting significant noncompliant claims to Medicare are subject to OIG review; risk areas are identified through data mining and analysis.

The reports listed below (examples for this semiannual period) are part of an ongoing series of reviews of selected inpatient and outpatient services claims submitted by acute care hospitals. Prior audits, investigations, and inspections identified certain types of payments to hospitals that are at risk for noncompliance with Medicare billing requirements. These types of payments (referred to here as “risk areas”) were identified by using computer matching, data mining, and data analysis techniques.

Because the reviews focus on selected risk areas, the findings do not represent overall assessments of all claims submitted by the hospitals. The objective is to determine whether hospitals complied with Medicare requirements when billing for services in the selected risk areas. The goals are to improve the hospitals’ internal controls, increase provider awareness and compliance with Medicare rules, and recommend recovery of overpayments. Acute care hospitals submit claims to Medicare under the Inpatient Prospective Payment System (IPPS) and the Outpatient Prospective Payment System .

Savings Potential—On the basis of CMS's Standard Analytical Files, we calculated about \$151 billion of actual IPPS payments made to hospitals for CY 2011. We did not determine the portion that would fall into our risk areas. Below are amounts questioned in individual reports for the risk areas selected.

2013 SEP Medicare Compliance Review of University of Miami Hospital. [A-04-12-07033](#). (\$3,717,557 questioned in selected inpatient risk areas.)

2013 AUG Medicare Compliance Review of Southcoast Hospitals Group for Calendar Years 2010 and 2011. [A-01-12-00523](#). (\$1,106,581 questioned in selected inpatient and outpatient risk areas.)

2013 JUN Baptist Medical Center South Complied With Most Medicare Requirements for Billing Inpatient and Outpatient Services for Calendar Years 2009 and 2010.

[A-04-12-00083](#). (\$1,784,982 questioned in selected inpatient and outpatient risk areas.)

2013 JUN Medicare Compliance Followup Review of Tufts Medical Center.
[A-01-12-00527](#). (\$1,086,047 questioned in selected inpatient risk areas.)

2013 JUN Medicare Compliance Review of Community Regional Medical Center.
[A-09-12-02071](#). (\$1,075,310 questioned in selected inpatient and outpatient risk areas.)

2013 MAY Medicare Compliance Review of Cedars-Sinai Medical Center for the Period January 1, 2008, Through June 30, 2011. [A-09-12-02048](#). (\$2,244,649 questioned in selected inpatient and outpatient risk areas.)

2013 MAY Medicare Compliance Review of Saint Thomas Hospital for Calendar Years 2009 and 2010. [A-04-12-03071](#). (\$1,092,248 in estimated overpayments in the risk areas for the audit period.)

05 Outpatient Therapy Services—An outpatient therapy supplier improperly billed most of its claims to Medicare; the supplier did not have a thorough understanding of Medicare’s requirements and did not have adequate policies and procedures in place to ensure correct billing.

Spectrum Rehabilitation, LLC, improperly claimed Medicare reimbursement for 83 of 100 claims in a random sample. Issues centered on physician certification, treatment notes, medical necessity, and deficient plans of care. Also, the billing therapists did not supervise or perform the services claimed.

Savings Potential—An overpayment of about \$3 million was estimated from a random sample of 100 claims. Corrective actions could result in Medicare savings at this supplier by recovering improperly paid amounts and by reducing future billing errors.

We recommend that the outpatient therapy supplier

- obtain a better understanding of the Medicare reimbursement requirements related to outpatient therapy services through such means as attending provider outreach and education seminars, strengthen its policies and procedures to ensure that outpatient therapy services are provided and documented in accordance with Medicare requirements, and refund the overpayments we identified to the Federal Government.

2013 JUN *Spectrum Rehabilitation, LLC, Claimed Unallowable Medicare Part B Reimbursement for Outpatient Therapy Services.* [A-02-11-01044](#).

06 Medical Equipment/Supplies—Diabetes Test Strips. Billing abuses continue in non-competitive-bidding areas and for non-mail-order purchases.

Recent investigations and prior Office of Inspector General studies have found that diabetes test strips is an area vulnerable to fraud, waste, and abuse. Our August 2013 report revealed that the Competitive Bidding Program for medical equipment and supplies appears to have reduced questionable billing for mail order test strips in Competitive Bidding Areas (CBAs). Similar reductions in questionable billing did not occur in non-CBA areas or for non-mail-order test strips.

Our findings included that suppliers in 10 geographic areas nationwide were responsible for 77 percent of questionable billing.

Savings Potential—In 2011, Medicare inappropriately allowed an estimated \$6 million for diabetic test strip claims with three types of errors.

We recommend that CMS

- enforce existing edits (system processes) to prevent inappropriate diabetes test strip claims, increase monitoring of suppliers' Medicare billing, provide more education to suppliers and beneficiaries about appropriate billing practices, and take appropriate action regarding inappropriate Medicare claims and suppliers with questionable diabetic test strip billing.

*2013 AUG Inappropriate and Questionable Medicare Billing for Diabetes Test Strips.
[OEI-04-11-00330.](#)*

07 Medical Equipment/Supplies—Diabetic Testing Supplies. One provider's CY 2011 claims billed at the higher non-mail-order rate illustrate the effect of prior payment policy, now revised.

For calendar year 2011, a medical equipment supplier properly submitted claims for diabetic testing supplies at the non-mail-order rate in accordance with Medicare billing requirements. All 100 sampled line items were properly paid at the higher rate because the supplier used company-owned vehicles instead of common carriers to deliver the supplies to Medicare beneficiaries at their homes, therefore qualifying for the higher non-mail-order rate.

CMS redefined "mail order" to include any item (for example, diabetic testing supplies) shipped or delivered to the beneficiary's home, regardless of the method of delivery. Thus, supplies delivered to beneficiaries' homes by supplier-owned vehicles will now be paid at the lower mail-order rate.

We issued this report without recommendations because CMS has redefined the term “mail order” for payment purposes. Delivery of diabetic testing supplies to the beneficiaries' homes using company-owned vehicles will no longer qualify for the higher non-mail-order rate.

2013 APR MedEnvios Healthcare, Inc., Submitted Claims for Diabetic Testing Supplies Without the KL Modifier in Accordance With Medicare Billing Requirements. A-09-12-02053.

08 Medical Equipment/Supplies—Lower Limb Prosthetics. Medicare overpaid lower limb prosthetics claims that did not meet local coverage determinations; the contractor lacked effective edits.

A Medicare contractor, CGS Administrators, LLC (CGS), made payments for lower limb prosthetic claims that did not meet local coverage determination requirements. A lower limb prosthesis is an artificial replacement for any or all parts of a leg; it enables an individual who has an amputated limb to perform functional tasks, particularly walking, that may not be possible without the device. Local coverage determinations specify under what clinical circumstances a service is considered to be reasonable and necessary. They are administrative and educational tools to assist providers in submitting correct claims for payment.

In 2012, the Centers for Medicare & Medicaid Services issued a technical direction letter that instructed Durable Medical Equipment Medicare Administrative Contractors to put in place claim edits for all requirements set forth in the local coverage determinations for lower limb prosthetics.

At the time CGS inappropriately paid for the claims, it did not have edits in place to evaluate whether the claims met all the local coverage determination requirements. CGS paid lines of service for lower limb prostheses in 2010 and 2011 that did not meet requirements consisting of missing or incorrect functional level modifiers, unallowable quantities of socket inserts, and unallowable combinations of components.

Savings Potential—We estimated that CGS overpaid about \$6 million in 2010 and 2011.

We recommend that CGS

- monitor the system edits developed in response to CMS's March 2012 technical direction letter to ensure that the edits are functioning correctly and recover the identified overpayments for lines of service for lower limb prostheses that did not meet local coverage determination requirements in 2010 and 2011.

2013 JUL CGS Administrators, LLC, Paid Unallowable Lower Limb Prosthetics Claims. A-06-12-00055.

09 Part B Drugs—Herceptin. Medicare overpays for the cancer drug Herceptin; incorrect units of service billed and supporting documentation are inadequate.

Herceptin, also known as trastuzumab, is a Medicare-covered drug used to treat breast cancer that has spread to other parts of the body. Herceptin comes in a multiuse vial of 440 milligrams. A multiuse vial contains more than one dose of medication and is labeled as such by the manufacturer. A vial of Herceptin, when reconstituted and properly stored, can be used for up to 28 days. For multiuse vials, Medicare pays only for the amount administered to a beneficiary and does not pay for any discarded drug. Therefore, a payment for an entire multiuse vial is likely to be incorrect. The audits in this *Semiannual Report* are part of a nationwide review of the drug Herceptin.

Savings Potential—Overpayments totaled about \$1.8 million in Medicare’s Jurisdiction 7 and about \$1 million in Medicare’s Jurisdiction 13 for selected line items.

We recommend that the payment contractors for Medicare’s Jurisdictions 7 and 13

- implement or update system edits that identify for review multiuse-vial drugs that are billed with units of service equivalent to the dosage of an entire vial, use the results of the audit in its provider education activities, recover identified overpayments, and identify and recover additional overpayments from the samples.

2013 APR Medicare Contractors’ Payments Made to Providers in Jurisdiction 7 for Full Vials of Herceptin Were Often Incorrect. [A-06-11-00068](#).

2013 MAY The Medicare Contractor’s Payments to Providers in Jurisdiction 13 for Full Vials of Herceptin Were Often Incorrect. [A-02-12-01003](#).

10 Part B Ambulance Services—Increased Utilization. Increases in the utilization of ambulance transports are disproportionate in relation to increases in the population of Medicare fee-for-service beneficiaries.

This report analyzed for informational purposes a number of ambulance utilization data factors. The review did not seek to determine whether the increase in transports during the period were medically necessary or met coding and documentation requirements for coverage. For the period 2002 through 2011, we found the following increases.

- The number of Medicare ambulance transports increased 69 percent.
- Medicare fee-for-service beneficiaries increased just 7 percent, but the number of beneficiaries who received ambulance transports increased 34 percent.
- The number of ambulance suppliers providing transports increased 26 percent. In particular, the number of ambulance suppliers that primarily provided basic life support nonemergency transports nearly doubled from 2002 to 2011.

- Though the percentage of beneficiaries with end-stage renal disease who received the transports varied little during the period, dialysis-related transports increased 269 percent, representing 22 percent of all transports. Although dialysis facilities are a covered destination, transports to them do not usually meet coverage requirements under Medicare.
- The number of transports to or from hospitals increased 55 percent, representing 79 percent of all transports. Notably, transports to hospitals originating from the scene of an accident or acute event increased 112 percent.

Savings Potential—In 2011, Medicare Part B paid \$4.5 billion for ambulance transports, an increase of 130 percent, compared to a 74-percent increase in overall Part B payments. In addition to service utilization, other factors that may contribute to the increase in payments include inflation and the transition to the national fee schedule for Medicare ambulance transports. Savings could be achieved by identifying and curbing inappropriate growth in utilization. The report is primarily informational and did not contain formal recommendations to CMS. A separate review will identify ambulance suppliers that exhibited characteristics of questionable billing and the geographic areas with high numbers of such suppliers.

2013 SEP Utilization of Medicare Ambulance Services. OIG-09-12-00350.

11 Management of Provider Data. Medicare provider enumeration and enrollment data are often inaccurate, are occasionally incomplete, and are generally inconsistent between Medicare’s two primary provider databases, hindering oversight and placing health care programs at risk of fraud and abuse.

OIG work has revealed ongoing problems with CMS’s oversight of provider enumeration and enrollment data, which may foster improper Medicare payments to fraudulently enrolled providers.

Our May 2013 report revealed that provider data were inconsistent between two primary databases¹ for 97 percent of records. Addresses, which are essential for contacting providers and identifying trends in fraud, waste, and abuse, were the source of most inaccuracies and inconsistencies. Finally, CMS did not verify most provider information in its data systems.

We recommend that CMS

- require contractors to implement program integrity safeguards for Medicare provider enrollment as established in the *Program Integrity Manual*, require more verification of enumeration and enrollment data, and detect and correct inaccurate and incomplete provider enumeration and enrollment data for new and established records.

¹ National Plan and Provider Enumeration System (NPPES) and Provider Enrollment, Chain and Ownership System (PECOS).

2013 MAY *Improvements Needed To Ensure Provider Enumeration and Medicare Enrollment Data Are Accurate, Complete, and Consistent.* [OEI-07-09-00440](#).

Maximize recovery of public funds

In conducting its Medicare work, OIG places priority on holding wrongdoers accountable and maximizing recovery of public funds. To this end, OIG activities routinely include:

- using statistical sampling and estimation planning to identify overpayments when possible,
- reviewing the most recent claims and conduct possible,
- focusing on the types of claims that are more likely to result in overpayment collection,
- ensuring timely referral of overpayment matters, and
- matching data across systems to maximize recovery efforts.

We also direct our resources to monitoring the effectiveness of CMS's efforts to identify overpayments and fraud and to recover public funds.

Significant problems, abuses, and deficiencies:

01 Overpayment Recoveries. Inaccurate provider types and contact information and other data gaps delay or prevent overpayment demand letters from reaching providers; not all overpayments are recovered.

Medicare identifies billions of dollars in overpayments to health care providers each year. However, not all overpayments are recovered. Overpayments for which the provider has not made a repayment for at least 6 months after the due date on the Medicare demand letter are classified as “currently not collectible” (CNC) and are not reported on CMS's annual financial statements. These overpayments are not reported on the financial statements because they are not likely to be recovered.

Our July 2013 report provides information about Medicare's CNC overpayments. CMS reported \$543 million in new CNC overpayments across all Medicare payment contractors in FY 2010. However, CMS provided detailed information on only \$69 million in CNC overpayments for 7 of its 39 contractors. For the seven contractors, 97 percent of the overpayments were not recovered. According to the contractors, inaccurate provider contact information delays or prevents some overpayment demand letters from reaching providers. In addition, CMS and contractors reported that expanding the types of provider identifiers used to recover payments could improve debt collection efforts.

Savings Potential—In FY 2010, Medicare overpaid \$9.6 billion, of which \$543,000 were new CNC overpayments.

We recommend that CMS

- ensure that the pertinent data variable for provider type is populated for all overpayments, ensure that demand letters are mailed to the contacts and addresses identified by the provider, and use tax identification numbers and provider transaction access numbers in addition to national provider numbers for the collection of overpayments.

2013 JUL Medicare's Currently Not Collectible Overpayments. [OEI-03-11-00670](#).

02 CMS Recovery Audit Contractors (RACs)—Output and Effectiveness.

Despite active identification of improper payments, high amounts of such payments continue; evaluation methods are lacking.

Recovery Audit Contractors (RAC) are designed to protect Medicare by identifying improper payments and referring potential fraud to CMS. Prior Government Accountability Office work has identified problems with CMS's actions to address improper payment vulnerabilities, and prior OIG work has identified problems with CMS's actions to address referrals of potential fraud. Further, OIG has identified vulnerabilities in CMS's oversight of its contractors. Given the critical role of identifying improper payments, effective oversight of RAC performance is important.

In FYs 2010 and 2011, RACs identified half of all claims they reviewed as having resulted in improper payments. CMS took corrective actions to address the majority of vulnerabilities it identified in FYs 2010 and 2011; however, it did not evaluate the effectiveness of these actions. As a result, high amounts of improper payments may continue. Additionally, CMS did not take action to address the six referrals of potential fraud that it received from RACs. Finally, CMS's performance evaluations did not include metrics to evaluate RACs' performance on all contract requirements.

Savings Potential— In FYs 2010 and 2011, RACs identified improper payments totaling \$1.3 billion. Recoveries, fraud referrals, and implementation of other corrective actions could be improved.

CMS should

- take action, as appropriate, on vulnerabilities that are pending corrective action and evaluate the effectiveness of implemented corrective actions; ensure that RACs refer all appropriate cases of potential fraud; review and take appropriate, timely action on RAC referrals of potential fraud; and develop additional performance evaluation metrics to improve RAC performance and ensure that RACs are evaluated on all contract requirements.

2013 SEP Medicare Recovery Audit Contractors and CMS's Actions To Address Improper Payments, Referrals of Potential Fraud, and Performance. [OEI-04-11-00680](#).

Promote quality, safety, and value

Medicare faces challenges in ensuring the safety and quality of care rendered to its beneficiaries. Despite increased attention to patient safety and quality, problems persist. OIG efforts to monitor quality, safety, and value routinely include

- ensuring that health care providers meet all Medicare conditions for coverage and participation;
- ensuring that health care professionals meet qualification and licensure requirements;
- strengthening provider accountability for quality of care;
- imposing appropriate sanctions;
- denying payments for services of such low quality that they are virtually worthless;
- excluding providers that fail to meet basic quality standards; and
- adopting electronic health records and electronic prescribing, which should improve quality of care, reduce medication errors, and otherwise promote patient safety.

CMS develops Conditions of Participation (CoP) and Conditions for Coverage (CfC) that health care organizations must meet to participate in and receive payment from Medicare. These health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries. CMS also ensures that the standards of accrediting organizations recognized by CMS meet or exceed the Medicare standards set forth in the CoPs and CfCs. Medicare contracts with State health agencies, referred to as State survey agencies, to perform survey and review functions on behalf of Medicare and certify that providers comply with Federal requirements. The types of health care organizations subject to CoP and CfC are listed on CMS's Web site at <http://www.cms.gov>.

Significant problems, abuses, and deficiencies:

01 Hospital Outpatient Stays. Hospital practices with regard to outpatient observation stays may limit beneficiaries' ability to access skilled nursing facility (SNF) care upon discharge.

Observation and other outpatient nights² in hospitals do not count toward the 3 nights needed for Medicare to pay for subsequent SNF care.³

² Medicare Part B pays hospitals for outpatient stays under the Outpatient Prospective Payment System.

³ Medicare Part A pays SNFs for services under the SNF Prospective Payment System.

Only inpatient nights⁴ may be used to qualify for Medicare payment of SNF care. Hospital physicians decide whether to admit beneficiaries as inpatients or to continue observation or other outpatient services. If beneficiaries do not have a 3-night inpatient stay, they still may choose to receive SNF care, but Medicare will not pay for it. SNF care can cost tens of thousands of dollars. The potential financial burden may discourage beneficiaries from accessing the SNF care they need.

We identified over 600,000 hospital stays lasting 3 nights or more that did not qualify the beneficiaries for SNF care because some nights were spent receiving observation or other outpatient services. Our July 2013 report revealed that some hospitals were more likely to admit beneficiaries, while other hospitals were likely to keep beneficiaries as outpatients. We also found that SNFs sometimes billed Medicare for SNF care even though the 3-night rule was not met.

Savings Potential—We found that for 4 percent of unqualified stays, beneficiaries received SNF services that were inappropriately billed to Medicare, amounting to about \$255 million in improper payments.

Because we plan more work in this area, **OIG did not make formal recommendations to CMS but provided options for consideration.** For example, CMS could

- ensure that beneficiaries with similar post-hospital care needs have the same access to and cost-sharing for SNF services; seek statutory authority, if needed, to allow nights spent as an outpatient to count toward the 3 nights needed to qualify for SNF services; ensure that Medicare does not inappropriately pay when beneficiaries do not qualify for SNF services; and recover \$255 million in payments for unallowable SNF care that we identified in our review.

2013 JUL Hospitals' Use of Observation and Short Inpatient Stays for Medicare Beneficiaries. [OEI-02-12-00040](#).

02 Survey and Certification of Home Health Agencies (HHAs). CMS's lack of surveys for oversight of State agencies' HHA survey performance could present a vulnerability to program effectiveness and quality of care for Medicare beneficiaries.

CMS is responsible for ensuring that HHAs comply with Federal requirements and provide quality care, and CMS relies on State agencies and accreditation organizations to verify HHAs' compliance through onsite surveys and complaint investigations.

To assess accreditation organizations' survey performance, CMS contracts with State agencies to conduct surveys of HHAs surveyed by accreditation organizations. However, Federal law does

⁴ Medicare Part A pays hospitals for inpatient stays under the Inpatient Prospective Payment System.

not require CMS to conduct, and CMS rarely conducts, similar surveys to assess State agency survey performance. CMS may conduct such surveys if it wishes. In such cases, CMS itself conducts the survey of an HHA, rather than contracting with another entity to do it. CMS then compares its results for an individual HHA with the State agency's results for the same HHA.

We recommend that CMS

- analyze survey data to determine whether it should routinely conduct surveys for oversight of State agencies, which conduct most HHA recertification surveys.

2013 MAY Home Health Agencies Received Timely Surveys and Corrected Deficiencies As Required. [OEI-06-11-00400](#).

03 Survey and Certification of Hospices. State recertification surveys of hospices are not sufficiently frequent to ensure compliance and quality of care.

The goals of hospice care are to help terminally ill patients live comfortably with minimal disruption and to support patients' families and other caregivers throughout the dying process.

State survey (review) agencies, contracted by CMS and following CMS's survey protocol and guidelines, conduct surveys of hospices at the time of initial certification, for recertification, and in response to complaints. Our August 2013 report revealed that the frequency of hospice recertification surveys has not improved since 2005; 17 percent of State-surveyed hospices had not been recertified within the last 6 years. We concluded that CMS's use of fluctuating annual targets does not ensure timely recertification surveys of all hospices and raises concerns about whether CMS and contracted State survey agencies can adequately oversee hospice compliance with Medicare CoPs and the quality-of-care requirements for hospices.

Our past and current research indicates that hospices are often out of compliance; a 2007 report found that almost half of hospices were cited with deficiencies when surveyed. More recent OIG reports identified quality-of-care concerns regarding hospice care provided in nursing homes.

This report did not make new recommendations to CMS but reiterated an earlier recommendation that CMS

- seek legislation or promulgate regulations to set specific timeframes for the frequency of hospice recertification surveys and consider setting the survey frequency standard at 3 years.

2013 AUG Frequency of Medicare Recertification Surveys for Hospices Is Unimproved. [OEI-06-13-00130](#).

04 Hospices—Use of General Inpatient Care. Medicare hospices' inconsistent use of general inpatient care raises questions about whether the hospices provide appropriate levels of care to beneficiaries.

Medicare paid more than \$1 billion for hospice general inpatient care in 2011. Our May 2013 report revealed that about 58 percent of general inpatient care stays for hospice beneficiaries were in hospices' own inpatient units, compared to 33 percent in hospitals and 8 percent in SNFs. Of all Medicare hospices, 23 percent used their own inpatient units. Hospices with inpatient units provided general inpatient care to more of their beneficiaries and for longer periods of time than hospices that used other settings. By contrast, 27 percent of all Medicare hospices did not provide any general inpatient care to their beneficiaries.

Long lengths of stay and the use of general inpatient care in inpatient units need further review to ensure that hospices are using general inpatient care as intended and are providing the appropriate level of care. OIG is committed to looking into these issues and will conduct a medical record review that will assess the appropriateness of general inpatient care provided in different settings.

Because OIG will be conducting related work in this area, we did not issue formal recommendations to CMS. However, we suggested options. For example, CMS could

- focus on hospices that do not provide general inpatient care and ensure that these hospices are providing beneficiaries access to needed levels of care at the end of their lives and adopt a quality measure regarding hospices' ability to provide all hospice services.

2013 MAY Medicare Hospice: Use of General Inpatient Care. OEI-02-10-00490.

05 Part B Drugs—Vaccines. Some Medicare beneficiaries are being given pneumococcal vaccinations more often than recommended by the Centers for Disease Control and Prevention (CDC).

For individuals other than those with certain immunocompromising medical conditions, one pneumococcal vaccination should be sufficient to confer immunity for a lifetime. However, CDC says that if more than one vaccination is given, they should be at least 5 years apart. We found 122,498 beneficiaries who received more than 1 pneumococcal vaccination of the same type within the 5-year period 2007–2011. Vaccines are not without risk. National vaccine surveillance program data show a number of adverse events in older beneficiaries associated with pneumococcal vaccinations. The data suggest a need to educate certain providers about repeat vaccinations.

We did not make formal recommendations to CMS but suggested that unnecessary vaccination could be reduced through providers' review of the medical histories of established patients. Tools such as electronic medical records may assist in this effort.

2013 JUN *Potentially Improper Frequency of Pneumococcal Vaccinations for Medicare Beneficiaries.* [OEI-07-13-00310](#).

Medicare Part C and Part D Reviews

This segment of the Department of Health and Human Services Office of Inspector General's *Semiannual Report to Congress* pertains to Medicare Part C and Medicare Part D. Part C is the Medicare Advantage program that provides care delivery and coordination options and Part D is Medicare's optional prescription drug program. Part D plans are administered by private companies, known as plan sponsors, that contract with CMS to offer prescription drug coverage to Medicare beneficiaries who enroll in a prescription drug plan.

Prevent and deter waste, fraud, and abuse

Significant problems, abuses, and deficiencies:

01 Part C Overpayments. Diagnoses submitted by two Medicare Advantage (MA) organizations resulted in risk score calculation errors and Medicare overpayments; causes include service provider errors, ineffective policies and procedures, and inadequate documentation.

MA Organization 1. CIGNA Healthcare of Arizona, Inc. (CIGNA), is an MA organization under contract with CMS to administer health care plans for approximately 31,677 beneficiaries. CMS makes monthly capitated payments (prepayments) to MA organizations for beneficiaries enrolled in an organization's health care plans (beneficiaries).

The diagnoses that CIGNA submitted to CMS for use in CMS's calculations did not always comply with Federal requirements, e.g., the documentation did not support the associated diagnoses and/or the diagnoses were unconfirmed. CIGNA's policies and procedures were not effective for ensuring that the diagnoses it submitted to CMS were compliant. CIGNA's health care providers often reported incorrect diagnoses to CIGNA as a result of data entry errors and reported diagnoses for conditions that did not exist at the time of beneficiaries' encounters.

Savings Potential—From our sample, we identified over \$150,000 in overpayments to CIGNA and projected \$28 million more to be reviewed for adjustments. Corrective actions could result in savings at this MA organization from refunds, adjustments, and reductions in future overpayments.

We recommend that MA Organization 1

- improve its current policies and procedures to ensure compliance with Federal requirements, refund to the Federal Government the overpayments identified for the sampled beneficiaries, and work with CMS to determine the correct contract-level adjustment for additional projected overpayments.

2013 MAY CIGNA Healthcare of Arizona, Inc. (Contract H0354), Submitted Many Diagnoses to the Centers for Medicare & Medicaid Services That Did Not Comply With Federal Requirements for Calendar Year 2007. A-07-10-01082.

MA Organization 2. Bravo Health Pennsylvania, Inc. (Bravo), was an MA organization, later acquired by other companies. Under one contract with CMS, Bravo administered health care plans for approximately 13,755 beneficiaries. The diagnoses that Bravo submitted to CMS for use in CMS's risk score calculations did not always comply with Federal requirements, i.e., the documentation did not support the diagnoses. Bravo did not provide the provider's signatures or credentials, or Bravo did not provide any supporting documentation. Bravo did not review the diagnosis codes received from providers before submitting the codes to CMS and therefore could not ensure that the diagnoses submitted to CMS complied with Federal requirements.

Savings Potential—On the basis of our sample, we identified over \$422,000 that was overpaid to Bravo and projected \$22 million more to be reviewed for adjustments. Corrective actions could result in savings at this MA organization from refunds, adjustments, and reductions in future overpayments.

We recommend that MA Organization 2

- work with CMS to make contract-level adjustments, modify its policies and procedures, improve its practices to ensure compliance with Federal requirements, and refund the overpayments we identified.

2013 SEP Bravo Health Pennsylvania, Inc. (Contract H3949), Submitted Many Diagnoses to the Centers for Medicare & Medicaid Services That Did Not Comply With Federal Requirements for Calendar Year 2007. A-03-09-00003.

02 Part D Investment Income. Medicare loses potential cost savings because Federal requirements governing Medicare Part D do not limit the ability of Part D plans to retain investment income earned on Medicare funds.

CMS makes advance capitated payments (prepayments) to Part D plans for each enrollee at the beginning of each month. Part D plans may invest these Medicare funds in interest-bearing instruments until the funds are needed to pay for drug costs and administrative services. Federal law does not currently limit the ability of Part D plans to retain as additional revenue the investment income earned on Federal funds. Part D plans must submit, annually, bid proposals containing their anticipated revenue requirements for providing drug coverage under each of their plans for the upcoming year.

Because Federal requirements governing Medicare Part D do not limit the ability of Part D plans to retain investment income earned on Medicare funds, Medicare loses potential cost savings. In contrast to the Federal requirements that govern Part D, the Federal Employees Health Benefits (FEHB) program limits the ability of companies to retain as additional revenue the investment income earned from Federal funds.

Savings Potential—Under one calculation, delaying prepayments could have saved about \$111 million in 2009. Reducing plans' revenue could have saved about \$5 million.

We recommend that CMS evaluate these results and in the context of its joint effort with the U.S. Department of the Treasury

- pursue legislation to adjust the timing of Medicare's prepayments to Part D plans to account for the time that these plans invest Medicare funds before paying pharmacy claims or develop and implement regulations that require Part D plans to reduce their revenue requirements in their bid proposals to account for anticipated investment income.

2013 APR. Impact on Medicare Program for Investment Income That Medicare Part D Plans Earned and Retained From Medicare Funds in 2009. [A-07-11-05017](#).

03 Part D Billing Patterns. Some Part D high-prescribing physicians have questionable billing patterns.

With the rise in prescription drug abuse, concerns about Medicare fraud, particularly prescriber fraud, have increased. We identified over 700 general-care physicians who had questionable prescribing patterns. Each of these physicians prescribed extremely high amounts for at least one of the five measures we developed. For example, many of these physicians prescribed extremely high numbers of prescriptions per beneficiary, which may indicate that these prescriptions are medically unnecessary. Moreover, more than half of the 736 general-care physicians with questionable prescribing patterns ordered extremely high percentages of Schedule II or III drugs, which have potential for addiction and abuse. Although some of this prescribing may be appropriate, such questionable patterns warrant further scrutiny.

We recommend that CMS

- instruct the Medicare Drug Integrity Contractor to expand its analysis of prescribers, provide sponsors with additional guidance on monitoring prescribing patterns, provide education and training for prescribers, and follow up on prescribers with questionable prescribing patterns.

2013 JUN Prescribers With Questionable Patterns in Medicare Part D. [OEI-02-09-00603](#).

04 Part D Unauthorized Prescribers. Medicare and Part D sponsors fail to detect many drugs, including controlled substances, that are being ordered by individuals without the authority to prescribe.

Nationwide, Part D inappropriately paid for drugs ordered by individuals who clearly did not have the authority to prescribe, such as massage therapists, athletic trainers, home contractors, interpreters, and transportation companies. This raises concerns about the appropriateness of Part D payments and about patient safety. We found that in 10 States, Part D inappropriately paid for drugs ordered by individuals without the authority to prescribe, such as counselors, social workers, and chiropractors. Tens of thousands of these drugs were controlled substances,

which are of particular concern because they have potential for abuse. Medicare should never pay for drugs ordered by individuals who do not have the authority to prescribe.

Savings Potential—Medicare paid about \$5.4 million for prescriptions ordered by the 14 types of unauthorized prescribers we reviewed.

We recommend that CMS

- require sponsors to verify that prescribers have the authority to prescribe drugs, increase the Medicare Drug Integrity Contractor’s monitoring of prescribers, ensure that Medicare does not pay for prescriptions from individuals without prescribing authority, and follow up on the individuals we identified without prescribing authority who ordered prescriptions.

2013 JUN Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority. [OEI-02-09-00608](#).

05 Part D Dual Eligibles—Mandatory Review. Prescription drug plans generally cover most drugs commonly used by individuals who are fully eligible for both Medicare Part D and Medicaid.

The Patient Protection and Affordable Care Act of 2010 requires OIG to annually review and report on the extent to which Medicare Part D prescription drug plans include drugs commonly used by full-benefit dual eligible individuals. Overall, we found that the rate at which Part D plan formularies include the drugs commonly used by dual eligibles is high, with some variation. On average, Part D plan formularies include 96 percent of the commonly used drugs. In addition, 64 percent of the commonly used drugs are included by all Part D plan formularies.

“Full-benefit dual eligibles” receive full Medicaid benefits and assistance with Medicare premiums and cost-sharing. Dual eligibles are a particularly vulnerable population tending to have low incomes and poor health. In January 2006, Medicare began covering outpatient prescription drugs for dual eligibles through Part D plans.

We did not make formal recommendations to CMS as a result of this report.

2103 JUN Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2013. [OEI-05-13-00090](#).

Medicaid Program Reviews

This segment of the Department of Health and Human Services (HHS) Office of Inspector General's (OIG's) *Semiannual Report to Congress (Semiannual Report)* pertains to reviews of the Medicaid program. States have considerable flexibility in designing and operating their Medicaid programs; however, to receive a Federal share of Medicaid costs, they must meet applicable State and Federal requirements. The Federal Government generally 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 various factors such as a State's relative per capita income.

As required by the Inspector General Act of 1978, as amended, the *Semiannual Report* identifies and describes significant problems, abuses, deficiencies (i.e., issues), and related recommendations for corrective action. For Medicaid, the issues fall into the following broad operational categories:

- addressing wasteful policies and practices;
- preventing and addressing improper State claims for the Federal share of Medicaid;
- preventing and deterring fraud and abuse; and
- promoting quality, safety, and value.

The Table of Contents lists the issues reported for each category. The body of the document provides corresponding background information and savings potential and identifies recommendations that would address each issue.

Address wasteful Medicaid policies and practices

The recommendations in this subsection address the wasteful spending that arises from shortcomings in current Medicaid-related policies or practices. "Waste" is a broad term that applies to situations in which Medicaid pays more than it should. Policies or practices sometimes result in waste when unintended loopholes or other inherent problems invite exploitation or hinder consistent payment determinations. Medicaid's supporting systems and practices sometimes result in waste by hindering timely and appropriate payment adjustments. Later subsections address improper State claims for the Federal share of Medicaid and address fraud and abuse, which are related forms and sources of wasteful spending.

Actions to reduce Medicaid costs generally provide mutual benefit to States and the Federal Government. OIG's audit and evaluation reports do not routinely project the annual program-level cost savings that could be realized from implementing the reports' recommendations. Instead, the reports indicate within the scope of each review the extent to which policies or practices may be ineffective and describe the corrective actions that OIG recommends. We describe the monetary findings of each report (which may result in receivables or funds made available better use) under the subheading "Savings Potential."

Significant problems, abuses, and deficiencies:

01 Medical Equipment/Supplies—Comparison of Medicare and Medicaid Payments. The Ohio, New York, New Jersey, Texas, and Illinois Medicaid fee-for-service programs paid significantly more for selected medical equipment/supplies items than Medicare paid for the same items in those States.

OIG issued four reports that compared States' maximum payment rates to pricing Medicare obtained through competitive bidding. A fifth review compared one State's Medicaid payment rates to Medicare's rate and to Medicaid reimbursements in a neighboring State. All the reports indicate that the States we reviewed could reduce their Medicaid costs for medical equipment and supplies. Reducing State costs for Medicaid provides mutual benefit to States and the Federal Government.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 mandated the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program (the Competitive Bidding Program). The Competitive Bidding Program sets lower payment rates than conventional Medicare payment rates for selected durable medical equipment and supplies (items) while ensuring access to quality items and services.

New York Audit Report. The State of New York implemented a preferred diabetic supply program that was structured to obtain enhanced rebates from preferred test strip manufacturers and reduce Medicaid program expenditures. The rebates achieved savings of about 51 percent.

We determined that the Medicare reimbursement rates for mail-order test strips obtained through competitive bids in nine competitive bidding areas were lower than New York's average Medicaid reimbursement rate after manufacturer rebates. Establishing a competitive bidding mail-order program similar to that in the Medicare program could result in additional savings of 36 percent in the price of test strips paid under New York's methodology.

Savings Potential—For a 1-year audit period, we estimated that the New York Medicaid program could have saved an additional \$5.9 million on test strips. We compared the amount that the State reimbursed providers less the amount of rebates received with the highest Medicare Competitive Bidding Area (CBA) test strip payment rate.

We recommend that New York

- establish a competitive bidding program similar to that in the Medicare program for the purchase of test strips.

2013 JUL The New York State Manufacturer Rebate Program Significantly Reduced Medicaid Costs for Home Blood-Glucose Test Strips But Could Achieve Additional Reductions. A-02-11-01042.

New Jersey Audit Report. In 2011, New Jersey made Medicaid fee-for-service payments totaling almost \$4 million for blood glucose test strips. During this same period, the four Medicaid MCOs in New Jersey paid providers \$6.4 million for test strips. Decreasing the Medicaid fee-for-service reimbursement rate to average retail price levels or establishing a competitive bidding mail-

order program similar to that in the Medicare program could result in a 46- to 68-percent reduction in the price of test strips paid under the New Jersey Medicaid fee-for-service program and a 49- to 70-percent reduction in the price of test strips paid by the four New Jersey Medicaid managed care organizations and related savings to the New Jersey Medicaid program.

Savings Potential—For a 1-year audit period, we estimated fee-for-service savings of \$1.8 million to \$2.7 million and managed care savings of \$3.1 million to \$4.5 million during the same period. New Jersey indicated that it could use the information to work with the MCOs to lower MCO test strip payment rates, which would lead to the State making lower monthly Medicaid capitated payments.

We recommend that New Jersey

- establish a competitive bidding program similar to that in the Medicare program for the purchase of test strips, reduce the Medicaid fee-for-service reimbursement rate for test strips to be comparable to the average retail price, or work with Medicaid managed care organizations (MCOs) to adjust payment rates for test strips to the average retail price or to Medicare competitive payment rates.

2013 SEP New Jersey Medicaid Program Could Achieve Savings by Reducing Home Blood-Glucose Test Strip Prices. A-02-12-01010.

Illinois Audit Report. This audit compared Illinois Medicaid’s reimbursement rates for test strips to Medicare’s rates in Illinois. We found that on average, Medicare’s rates were about 40 percent less than Illinois’ Medicaid rates. The audit also compared Illinois Medicaid’s net costs to Indiana Medicaid’s net costs; Indiana’s net costs were significantly lower.

Through its manufacturer rebate program, the Illinois Medicaid program significantly reduced the net cost of test strips purchased during State fiscal year (SFY) 2011, providing mutual benefit to the State and Federal Governments while maintaining access to test strips for Illinois Medicaid beneficiaries. However, Illinois’ manufacturer rebates offset only a portion of its comparatively high provider reimbursement rates. We concluded that by changing its provider reimbursement rates, Illinois could further lower its net costs for test strips.

Savings Potential—For one SFY, we estimated that Illinois could have saved an additional \$8.5 million.

We recommend that Illinois

- lower the net cost of test strips through changes to its provider reimbursement rates.

2013 MAY Illinois Significantly Reduced Medicaid Costs for Home Blood-Glucose Test Strips But Could Achieve Additional Reductions. A-05-12-00009.

Ohio Audit Report. In a separate audit, we identified an estimated \$8 million that the Ohio Medicaid program could have saved on diabetic test strips if it had obtained pricing similar to the pricing that Medicare obtained through the Competitive Bidding Program or if it had established a manufacturer rebate program. Because of the savings that we identified for diabetic test strips, we conducted this review of 43 other competitively bid items.

We determined that Medicare payment rates obtained through competitive bids in 2 Ohio competitive bidding areas for the 43 selected items were significantly lower than the Ohio Medicaid maximum payment rate.

Savings Potential—For a 1-year audit period, the Ohio Medicaid program could have saved an estimated \$3 million on selected durable medical equipment items by obtaining pricing similar to that in Medicare’s Competitive Bidding Program. We estimated that the State agency’s cost could have been reduced to \$7.4 million (from \$10.5 million) for the selected DME items.

We recommend that Ohio

- establish competitive bidding that functions similarly to Medicare’s Competitive Bidding Program for the purchase of selected durable medical equipment and supply items.

2013 APR The Ohio Medicaid Program Could Significantly Lower Payment Rates for Selected Durable Medical Equipment and Supplies. [A-05-12-00038](#).

Texas Program Evaluation Report. This report, which does not contain recommendations, compares Texas Medicaid fee-for-service payment amounts for selected medical equipment/supplies to Medicare payment amounts for the same items in Medicare’s Dallas/Fort Worth CBA. We found that the Texas Medicaid fee-schedule amounts exceeded the Medicare Competitive Bidding Program payment amounts in the CBA on almost all items we reviewed. The findings provide a tangible example of potential State and Federal savings for Medicaid programs if the programs were to use the Medicare Competitive Bidding payment amounts for durable medical equipment, prosthetics, and supplies items. Access to more timely Medicaid claims data would allow further analysis to better understand the full potential of limiting Federal reimbursement for State Medicaid spending on such items to Medicare payment rates.

Savings Potential—If Texas had used Medicare’s competitive bidding payment amounts for the Dallas/Fort Worth CBA during the 1-year review period, it could have saved approximately \$2 million (State and Federal shares combined) on 30 selected items.

2013 SEP Medicaid DMEPOS Costs May Be Exceeding Medicare Costs in Competitive Bidding Areas. [OEI-06-13-00470](#).

02 Prescription Drugs—Pricing Generics. The use of more aggressive State Maximum Allowable Cost (MAC) pricing formulas and inclusion criteria could help States achieve additional cost-savings for generic drugs.

To take advantage of lower market prices for certain multiple-source drugs, States may use the Federal upper limit (FUL) and/or State MAC programs. The Affordable Care Act required the Centers for Medicare & Medicaid Services (CMS) to begin calculating FULs using average manufacturer prices (AMPs). On that basis, post-implementation FUL amounts would have been lower, on average, than MAC prices in the aggregate. CMS said that it expects to implement the Affordable Care Act changes to the FULs in the near future.

MAC programs operate similarly to the FUL program in that States establish maximum reimbursement amounts for certain multiple-source drugs. However, unlike the FUL program,

State MAC programs give States flexibility in determining which drugs to include in the program and in setting reimbursement rates. We identified the State with the most aggressive MAC program (Wyoming) and calculated the potential national savings had all States used that MAC program. We found that 39 of 45 States could have achieved savings had they used Wyoming's MAC program.

Savings Potential—We estimated that using the Wyoming model, 39 of 45 States could have saved \$483 million on their Medicaid generic drug costs in the first half of 2011.

We recommend that CMS

- complete the implementation of the post-ACA FUL amounts and encourage States to reevaluate their MAC programs for additional cost-saving opportunities.

*2013 AUG Medicaid Drug Pricing in State Maximum Allowable Cost Programs.
OEI-03-11-00640.*

Prevent improper State claims for the Federal share of Medicaid

Improper payments are those that should not have been made or that were made in incorrect amounts, i.e., overpayments or underpayments. This segment focuses on instances in which the Federal Government overpaid its share of Medicaid as a result of 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 patients' conditions, the billings have administrative or policy errors, or other Federal and State requirements are not met.

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

Significant problems, abuses, and deficiencies:

01 Hospital Inpatient Care—High-Dollar Payments. Wisconsin and Indiana improperly claimed Federal reimbursement for unallowable high-dollar payments they made to hospitals for inpatient services; the hospitals had submitted incorrect charges, which they attributed to data entry errors.

Wisconsin and Indiana pay hospitals for inpatient services using a prospective payment system that includes an outlier payment for high-dollar claims. Under prospective payment systems, States pay hospital costs at predetermined rates for patient discharges. When hospitals' charges exceed thresholds, the States make what is known as outlier payments. Outlier payments are intended to protect hospitals against large financial losses associated with high-cost cases and

generally result in unusually high-dollar Medicaid payments. Prior OIG reviews found improper payments. In Wisconsin, 22 percent of the high-dollar payments we reviewed were unallowable; in Indiana, 92 percent were unallowable.

Savings Potential—For the separate audit periods, Wisconsin improperly claimed about \$1.1 million in Federal reimbursement for unallowable high-dollar payments that it made to hospitals for inpatient services. Indiana improperly claimed almost \$1 million.

We recommend that Wisconsin and Indiana

- use the results of this audit in their provider education activities related to data entry procedures and refund the Federal share of payments we estimated to be unallowable.

2013 JUN Wisconsin Claimed Medicaid Reimbursement for High-Dollar Inpatient Services That Were Unallowable. [A-05-11-00037](#).

2013 SEP Indiana Claimed Medicaid Reimbursement for High-Dollar Inpatient Services That Were Unallowable. [A-05-11-00040](#).

02 Hospital Inpatient Care—Psychiatric Services and Disproportionate Share Hospital Payments. Missouri and Indiana improperly claimed Federal reimbursement for certain payments to psychiatric hospitals that could not demonstrate compliance with Medicare Conditions of Participation (CoP).

For States to claim Federal reimbursement for their Medicaid inpatient psychiatric service and disproportionate share hospital (DSH) payments to psychiatric hospitals, the hospitals must comply with the Medicare basic CoP applicable to all hospitals and with special CoP that apply to psychiatric hospitals. DSH payments are made to hospitals that provide a disproportionate share of uncompensated care, e.g., to patients who cannot afford to pay.

To demonstrate compliance with the Medicare CoP, psychiatric hospitals must undergo review by qualified health care professionals. The Missouri hospital we reviewed generally demonstrated compliance with the basic Medicare CoP. However, it was never surveyed to demonstrate compliance with the special Medicare CoP for psychiatric hospitals. The Indiana hospital we reviewed could not demonstrate compliance because it had last been surveyed in October 1993, more than 14 years before the start of the audit period.

For periods in which compliance cannot be demonstrated, claims by the State for the Federal share would be inappropriate.

Savings Potential—No payments should be made to hospitals for periods in which compliance with CoP cannot be demonstrated. With regard to the reviews listed below, we questioned over \$22.7 million in Federal reimbursement for Medicaid inpatient psychiatric service and DSH payments made to the Missouri provider; in the first Indiana report, we questioned about \$7.9 million. In the second Indiana report, we questioned about \$7.1 million.

We recommend that Missouri and Indiana

- ensure that Federal reimbursement for the subject payments to psychiatric hospitals is claimed only if the hospitals can demonstrate compliance with the basic and special Medicare CoP, refund the Federal share of payments we estimated to be unallowable, and work with CMS to resolve other claims for which payment may have been unallowable.

2013 JUN Missouri Improperly Claimed Federal Reimbursement for Most Reviewed Medicaid Inpatient Psychiatric Hospital Service and Disproportionate Share Hospital Payments to Hawthorn Children's Psychiatric Hospital. [A-05-12-00050](#).

2013 MAY Indiana Improperly Claimed Federal Reimbursement for Most Medicaid Inpatient Psychiatric Hospital Service and Disproportionate Share Hospital Payments to Evansville Psychiatric Children's Center. [A-05-12-00040](#).

2013 JUN Indiana Improperly Claimed Federal Reimbursement for All Reviewed Medicaid Inpatient Psychiatric Hospital Service Payments to Evansville State Hospital. [A-05-12-00041](#).

03 Intermediate Care Facilities (ICFs)—Services to Individuals With Intellectual and Developmental Disabilities. Missouri's internal controls and procedures were inadequate to prevent it from improperly claiming Federal reimbursement for duplicate or unsupported payments.

State and privately operated ICFs provide housing and supportive services to individuals with intellectual and developmental disabilities. State Medicaid programs reimburse the facilities for services and report (i.e., claim) the amounts to the Federal Government to receive the Federal share of Medicaid. The amounts the States claim must be for actual expenditures with supporting documentation.

Missouri did not always claim Federal reimbursement for its payments to State-operated ICFs in accordance with Federal requirements. The State's controls did not specify that the State agency must reconcile payments to claimed costs to ensure that it did not claim duplicate or unsupported Medicaid payments.

Savings Potential—During SFY 2011, Missouri claimed \$7.2 million in Federal reimbursement for unallowable duplicate and unsupported payments.

We recommend that Missouri

- develop and implement sufficient internal controls and procedures, including those pertaining to reconciliations of payments to claimed costs, and refund the Federal share of payments we estimated to be unallowable.

2013 JUN Missouri Claimed Unallowable Medicaid Payments for Individuals With Intellectual and Developmental Disabilities in Intermediate Care Facilities. A-07-12-03180.

04 Home and Community-Based Services (HCBS)—Personal Care Services.

Maryland did not ensure that the State’s Department of Aging sufficiently monitored waiver program services and that only allowable claims were submitted for Federal reimbursement.

States may obtain waivers that allow them to furnish an array of services to Medicaid beneficiaries so that they can live in the community and avoid institutionalization. Maryland’s waiver for older adults, which is administered by the Maryland Department of Aging, authorizes services for individuals with low incomes who are aged 50 or older and who need the level of care provided by a nursing facility. The Department of Aging contracts with local area agencies to manage waiver program activities, including case management.

Twenty of 100 waiver program claims we reviewed were noncompliant with Federal and State requirements. For a majority of the errors, personal care aides did not meet at least one of the qualification requirements, including a background check. We also found that plans of care were unapproved or were missing and found that services were unauthorized. Though the Department of Aging says it cites providers for unallowable claims, it does not recoup the improper payments or determine whether the providers have taken corrective action.

Savings Potential—For a 2-year audit period, we estimated that Maryland improperly claimed at least \$10.9 million in Federal reimbursement for unallowable costs.

We recommend that Maryland

- work with Maryland’s Department of Aging to improve its controls over personal care services waiver claims to ensure compliance and refund the Federal share of payments we estimated to be unallowable.

2013 APR Maryland Improperly Claimed Personal Care Services Provided Under Its Medicaid Home and Community-Based Services Waiver for Older Adults. A-03-11-00201.

05 Home and Community-Based Services—Traumatic Brain Injuries (TBI).

New York’s TBI waiver program services were unallowable or potentially unallowable; beneficiary eligibility assessments were not conducted according to requirements, and providers did not ensure that they claimed reimbursement only for allowable, supported services.

New York’s TBI waiver program allows the State to claim a Federal share of its Medicaid payments for HCBS provided to individuals with TBIs who would otherwise require

institutionalization in a nursing home. In New York, the Department of Health, Office of Long-Term Care, administers the TBI waiver program through nine contracted regional resource development centers that serve specific counties throughout New York State (collectively referred to as “the centers”).

The recommendations below would help address the causes underlying the unallowable or potentially unallowable payments we found in our review.

Savings Potential—For a 3-year audit period, we estimated that New York improperly claimed at least \$54 million in Federal Medicaid reimbursement for TBI waiver program services that were unallowable.

We recommend that New York

- require its contracted development centers to ensure and document that all beneficiaries approved for TBI waiver program services have been assessed by certified individuals and are eligible for the services, require adequate training for assessors on the Federal and State requirements;; require providers to ensure that they document the services billed and claim reimbursement only for allowable ones, refund the Federal share of payments we estimated to be unallowable, and work with CMS to resolve other claims for which payment may have been unallowable.

2013 MAY New York's Claims for Medicaid Services Provided Under Its Traumatic Brain Injury Waiver Program Did Not Comply With Certain Federal and State Requirements. [A-02-10-01043](#).

06 Medicaid Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program—Residential Care Services. Wisconsin improperly claimed a Federal share of payments made under its EPSDT program using a noncompliant cost allocation methodology and estimates that it could not adequately support.

The Federal EPSDT law requires each State Medicaid program to provide periodic physical and mental examinations for all Medicaid enrollees under 21 years of age. Wisconsin’s EPSDT program is known as HealthCheck. HealthCheck purchases services from Residential Care Centers (RCC) throughout the State. RCCs are private, nongovernmental entities that provide custodial care and treatment for children, youth, and young adults.

Wisconsin’s Medicaid State Plan provides only that the State will establish “maximum allowable fees” for EPSDT services furnished by RCCs. However, we did not find a policy or method that the State used to calculate maximum fees for EPSDT services furnished by RCCs.

When Wisconsin began using an RCC allocation methodology, in the first year alone, the RCC payments claimed for Federal reimbursement increased by \$18.3 million (\$10.7 million Federal share). We found that during our audit period, most of Wisconsin’s RCC claims did not comply with Federal requirements.

Savings Potential—For a 2-year audit period, we estimated that about \$39.4 million (\$22.8 million Federal share) that the State claimed under HealthCheck was unallowable.

We recommend that Wisconsin

- work with CMS to identify payment and allocation methodologies for claiming allowable Medicaid RCC costs under HealthCheck and refund the Federal share of payments we estimated to be unallowable.

2013 SEP Wisconsin Improperly Claimed Federal Medicaid Reimbursement for Most Residential Care Center Payments. A-05-07-00036.

07 Family Planning Services—Sterilization Services. Missouri received excess Federal reimbursement for sterilization procedures; two types of errors made at the same time hindered differentiation of the effect of the errors.

Federal reimbursement for family planning services is made at an enhanced 90-percent rate. Such services include those that prevent or delay pregnancy or otherwise control family size and may also include sterilization procedures. The amounts States report to CMS for reimbursement must represent actual expenditures and be supported by documentation.

Missouri's reporting errors involved the difference between Federal reimbursement at the enhanced 90-percent rate and Federal reimbursement at the lower Federal medical assistance percentage rates. The incorrect claims occurred when Missouri moved sterilization costs from each of the report lines for inpatient hospital services, outpatient hospital services, and clinic services (initially used to record the costs) to the designated line. The State agency moved one-third of the total sterilization costs from each line instead of using the correct actual costs.

The ineffective adjustment process created incorrect costs for each line with amounts that were either more or less than the actual costs for each line. Because Missouri's errors simultaneously occurred on each report, the monetary effects of the errors were not differentiated.

Savings Potential—Missouri overstated the amount of Federal reimbursement reported on eight quarterly reports to CMS by almost \$1.5 million.

We recommend that Missouri

- ensure that future expenditures for family planning sterilization procedures are correctly claimed to CMS, refund the Federal share of payments we estimated to be unallowable, review family planning sterilization procedures for quarterly reporting periods after our audit period, and refund the Federal share of any unallowable payments.

2013 JUN Missouri Did Not Always Correctly Claim Costs for Medicaid Family Planning Sterilization Procedures for Calendar Years 2009 and 2010. A-07-12-01117.

08 Excluded Providers—California’s lack of procedures caused it to improperly claim a Federal share of payments for items or services that were furnished, ordered, or prescribed by excluded providers.

OIG may exclude certain individuals and entities from participation in federally funded health care programs. Such programs should not pay for items or services to the excluded provider, to anyone who employs or contracts with the excluded provider, or to any hospital or other provider where the excluded provider furnished items or services during the period of exclusion. The payment prohibition applies regardless of who submits the claims and applies to all administrative and management services furnished by the excluded provider. There is a limited exception permitting Federal payment to excluded physicians for the provision of certain emergency items or services not provided in a hospital emergency room. The exclusion period ends when OIG reinstates the provider.

Medicaid, as a federally funded health care program, does not pay for items and services furnished, ordered, or prescribed by excluded providers. To prevent improper Medicaid payments, CMS instructs States to conduct monthly searches of either of two Federal databases (one maintained by CMS and one maintained by OIG) to identify provider exclusions and reinstatements that have occurred since the last search.

We found that California made unallowable Medicaid payments because it did not implement policies and procedures to determine whether excluded providers were listed on the claims.

Savings Potential—For a 1-year audit period, California made unallowable Medicaid payments of \$1.9 million (\$1.2 million Federal share).

We recommend that California

- comply with CMS guidance to conduct monthly reviews to determine whether any furnishing, ordering, or prescribing providers listed on claims are excluded and deny the claims. California should refund the Federal share of payments we estimated to be unallowable and work with CMS to resolve other claims for which payment may have been unallowable.

*2013 APR California Made Unallowable Medicaid Payments for Items and Services Furnished, Ordered, or Prescribed by Excluded Providers.
[A-09-11-02016.](#)*

09 Home Health Services—New York improperly claimed Federal reimbursement for unallowable payments, physicians did not review plans of care as required, and other deficiencies were found.

Home health services are provided to beneficiaries at their places of residence pursuant to their physicians' orders and written plans of care that the physicians are to review every 60 days. Under New York’s home health program, Certified Home Health Agencies (CHHAs) provide

preventive, therapeutic, and/or rehabilitative services to Medicaid beneficiaries. Most CHHAs provide nursing care directly to beneficiaries and contract with one or more Licensed Home Care Services Agencies (LHCSAs) to provide other home health services, such as physical therapy and occupational therapy.

All of the CHHAs in our sample used the same form to document the certification periods on the basis of physicians' reviews and the plan of care for each Medicaid beneficiary. The certification periods represent the 60-day periods during which the plans of care are valid. Physician review is required at the end of each certification period.

Of 100 claims in our random sample, 15 claims (15 percent) did not comply with Federal and State requirements. Ten of the claims did not comply because the beneficiaries' physicians did not review the plans of care within the 60-day certification period. On average, the physicians reviewed the plans of care 118 days after the certification period ended. Without physician review, the services are not allowable. CHHS officials said it is difficult to coordinate plan-of-care reviews by physicians within the required 60-day period. The remaining five deficient claims were unallowable for other causes, such as the fact that no plan of care existed or the service was not documented.

Savings Potential—For a 2-year audit period, New York improperly claimed at least \$31.5 million in Federal Medicaid reimbursement.

We recommend that New York

- issue guidance to CHHAs in the State on Federal and State requirements for physicians' orders and plans of care and refund the Federal share of payments we estimated to be unallowable.

2013 SEP New York State Improperly Claimed Medicaid Reimbursement for Some Home Health Services Claims Submitted by Certified Home Health Agencies. A-02-11-01008.

10 Managed Care—Beneficiary Identifiers. New York improperly claimed a Federal share of unallowable payments to managed care organizations (MCOs); poor system interfaces contributed to the issuance of multiple Medicaid identification numbers to some Medicaid managed care enrollees.

New York pays MCOs a monthly fee to ensure that an enrolled beneficiary has access to a comprehensive range of medical services. For those beneficiaries not enrolled in the Medicaid managed care program, New York pays Medicaid providers on a fee-for-service basis for every Medicaid-eligible service provided to a beneficiary. We reviewed certain Medicaid managed care payments New York made to different MCOs for the same beneficiaries. Federal law authorizes payments to States for eligible Medicaid beneficiaries enrolled in MCOs and prohibits payments to MCOs for beneficiaries whose Medicaid eligibility has not been properly determined.

Of the 150 beneficiary records in our random sample, 107 had deficiencies. Most (98) had more than 1 Medicaid number, resulting in managed care payments to different MCOs for the same beneficiary under different Medicaid identification numbers for the same date of service. For 16 records, Medicaid numbers were issued to individuals who did not have valid Social Security numbers (SSNs), and for 7, there was no case record for at least 1 of the Medicaid numbers.

These deficiencies occurred because New York's two eligibility systems did not identify potential beneficiary matches between the systems. The recommendations below address the vulnerabilities we found.

Savings Potential—Over a period of about 5 years, New York claimed at least \$7.3 million in Federal Medicaid reimbursement for managed care payments that were unallowable.

We recommend that New York

- ensure that no beneficiary is issued multiple Medicaid identification numbers or develop one eligibility system that could be used to determine whether applicants are enrolled in any medical or public assistance program throughout New York State and require local departments of social services to ensure that applicants provide valid SSNs when required and maintain documentation to support eligibility determinations. New York should refund the Federal share of payments we estimated to be unallowable.

*2013 APR New York State Made Unallowable Medicaid Managed Care Payments for Beneficiaries Assigned Multiple Medicaid Identification Numbers.
[A-02-11-01006.](#)*

Prevent and deter fraud and abuse

Significant problems, abuses, and deficiencies:

01 Medicaid Fraud Control Units—OIG performs periodic onsite reviews to assess Unit performance and compliance with grant requirements..

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

Idaho Review. From FY 2009 through 2011, the Idaho Unit reported recoveries of \$5 million, convictions and civil judgments and settlements increased, and the Unit opened 326 cases. Idaho Unit case files consistently contained documentation of supervisory approval to open and close cases; documentation of at least one supervisory review; and documentation of additional, periodic supervisory reviews. The Idaho Unit could improve its safeguards to secure case files and should fully update its manuals to reflect current operations, laws, and practices. We identified an inappropriate stipulation in the Unit's memorandum of understanding with the State Medicaid agency that the Idaho Unit may be charged for data requests. Otherwise, we

found no evidence of noncompliance with applicable laws, regulations, policy transmittals, or standards.

*2013 APR Idaho State Medicaid Fraud Control Unit: 2012 Onsite Review.
[OEI-09-12-00220](#).*

Tennessee Review. For FYs 2009 through 2011, the Tennessee Unit obtained 96 criminal convictions and 22 civil settlements and reported recoveries of over \$181 million. We identified one instance in which the Unit investigated a case that was not eligible for Federal funding under Federal regulations. With regard to standards, we noted that the Unit referred all convicted health care providers to OIG for program exclusion but did not refer nonprovider convictions. Although the Unit had a training plan, it did not establish training hour requirements for each professional discipline. Otherwise, our review of compliance issues found no evidence of significant noncompliance with applicable laws, regulations, policy transmittals, or standards.

*2013 APR Tennessee State Medicaid Fraud Control Unit: 2012 Onsite Review.
[OEI-06-12-00370](#).*

New Jersey Review. From FY 2010 through FY 2012, the New Jersey Unit's recoveries increased but felony charges and convictions decreased. The Unit also investigated fewer cases of patient abuse and neglect in FY 2012 than in FY 2010. Though most case files included opening and closing documents, half lacked documentation of supervisory review. Further, the Unit did not refer 94 percent of convictions to OIG appropriately and did not meet the requirements of its training plan in FY 2012. The Unit identified as beneficial a case management tool that tracks tasks and deadlines and includes descriptions of investigative and legal issues that arise.

*2013 SEP New Jersey State Medicaid Fraud Control Unit: 2013 Onsite Review.
[OEI-02-13-00020](#).*

Arkansas Review. For FY 2010 through 2012, the Arkansas Unit obtained 27 criminal convictions and 43 civil settlements; and reported recoveries of nearly \$42 million. Our review of compliance issues found no evidence of significant noncompliance with applicable laws, regulations, or policy transmittals. However, we identified instances in which the Unit did not fully adhere to performance standards. Opportunities for improvement in the Unit's adherence to the performance standards include establishing policies and procedures specific to the Unit's operations; updating the Unit's memorandum of understanding with the State Medicaid agency to reflect current law; working with the State Medicaid agency to ensure an adequate number of referrals from the State Medicaid agency, including supervisory review and approval documentation in case files; ensuring that indirect costs are correctly reported; and establishing and maintaining an annual training plan.

*2013 SEP Arkansas Medicaid Fraud Control Unit: 2013 Onsite Review.
[OEI-06-12-00720](#).*

Illinois Review. The Illinois Unit reported total combined criminal and civil recoveries of nearly \$141 million for fiscal years (FY) 2009 through 2011. Settlements for "global" (i.e., multi-State) cases accounted for \$124 million of the total recoveries. While the number of referrals received by the Unit decreased during the review period, it obtained 97 criminal convictions. We identified instances of noncompliance with Federal regulations and instances when the Unit could have better adhered to performance standards. Specifically, the Unit's organizational

structure for its attorneys conflicted with the MFCU certification standards, and Unit attorneys were not eligible for Federal reimbursement. Further, the Unit did not report to OIG the identities of 56 convicted providers for the purpose of program exclusion. As a promising practice, the Unit identified its initiative to provide nursing home staff with drug diversion awareness training to reduce instances when caregivers divert residents' prescription drugs for personal use or sale.

2013 JUN Illinois Medicaid Fraud Control Unit: 2012 Onsite Review.
[OEI-07-12-00510](#)

02 Transformed Medicaid Statistical Information System (T-MSIS). Early evidence raised concerns about States' abilities to submit complete and accurate data to T-MSIS—Medicaid's only nationwide Medicaid eligibility and claims database.

Medicaid's national MSIS eligibility and claims database is intended for use in analytical research, program integrity, planning, budgeting, and policy analyses associated with Medicaid. The T-MSIS initiative is intended to correct longstanding data deficiencies and transform the MSIS into an effective system. Evidence from our early review of T-MSIS implementation indicates continued problems with completeness, accuracy, and other issues.

Complete, accurate, and timely national Medicaid data are essential to help protect the integrity of Medicaid. In previous reports, OIG identified problems with missing or outdated MSIS data that make it an inadequate tool for national Medicaid program integrity data analysis strategies.

CMS has multiple program integrity projects underway that require T-MSIS data to be fully functional. Also, OIG and other external stakeholders could more effectively protect Medicaid from problems, deficiencies, and abuse with complete, accurate, and timely national Medicaid data. The early outcomes of volunteer States' efforts to implement T-MSIS may also provide insight into the remaining 39 States' abilities to implement T-MSIS.

We recommended that CMS

- establish a deadline for when national T-MSIS data will be available; ensure that States submit required T-MSIS data; and ensure that T-MSIS data are complete, accurate, and timely upon implementation.

2013 SEP Early Outcomes Show Limited Progress for the Transformed Medicaid Statistical Information System. [OEI-05-12-00610](#).

Promote quality, safety, and value

Significant problems, abuses, and deficiencies:

01 Medicaid Home Health—Improper Restrictions of Eligibility. Eleven States have policies that improperly restrict eligibility for home health benefits; as a result, some beneficiaries’ access to the care they need may be hindered.

Federal regulations require that Medicaid services made available to any categorically or medically needy individual shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual. Furthermore, Federal regulations prohibit the arbitrary denial or reduction of the amount, duration, and scope of a required Medicaid service on the basis of a beneficiary’s diagnosis, type of illness, or condition.

In July 2000, CMS released a State Medicaid Director letter stating that although Medicare requires beneficiaries to be homebound to qualify for home health services, imposing a homebound requirement on Medicaid home health benefits violates CMS’s interpretation of Medicaid regulations related to “amount, duration, and scope of services” and “comparability of services.” In July 2011, CMS published a Notice of Proposed Rulemaking to codify its interpretation, but it remains to be implemented. (76 Fed. Reg. 41032, 41033, and 41038 (July 12, 2011).)

We identified 11 States with policies in their Medicaid State Plans or other written policy documents that restrict eligibility for the mandatory home health benefit to homebound individuals: Alabama, Arkansas, Indiana, Montana, Nebraska, New Mexico, North Dakota, Pennsylvania, South Dakota, Utah, and West Virginia.

This report did not include formal recommendations to CMS. However, the report encourages CMS to finalize its proposed rule, after which it could consider issuing guidance specific to home health services and homebound eligibility restrictions, explaining why such restrictions are improper.

2013 JUL Some States Improperly Restrict Eligibility for Medicaid Mandatory Home Health Services. OEI-07-13-00060.

CMS-Related Legal and Investigative Activities

For this semiannual period, we reported 413 criminal and 226 civil actions against individuals or entities that engaged in health-care-related offenses. We also reported \$1.35 billion in investigative receivables due to the U.S. Department of Health and Human Services (HHS) and \$379.8 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.

HHS OIG's 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:

<https://www.oig.hhs.gov/fraud/enforcement/cmp/index.asp>.

Chart 1- Actions: All HHS Programs

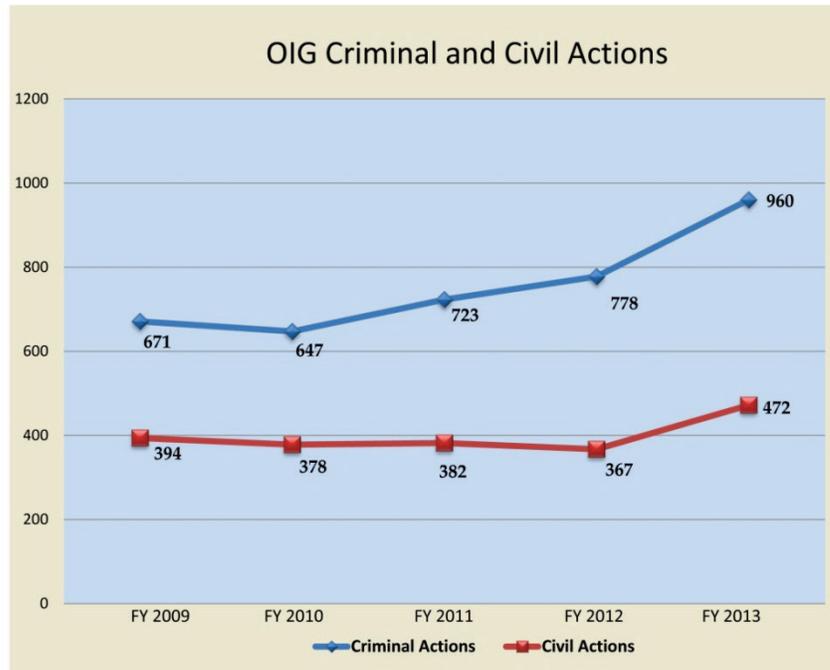
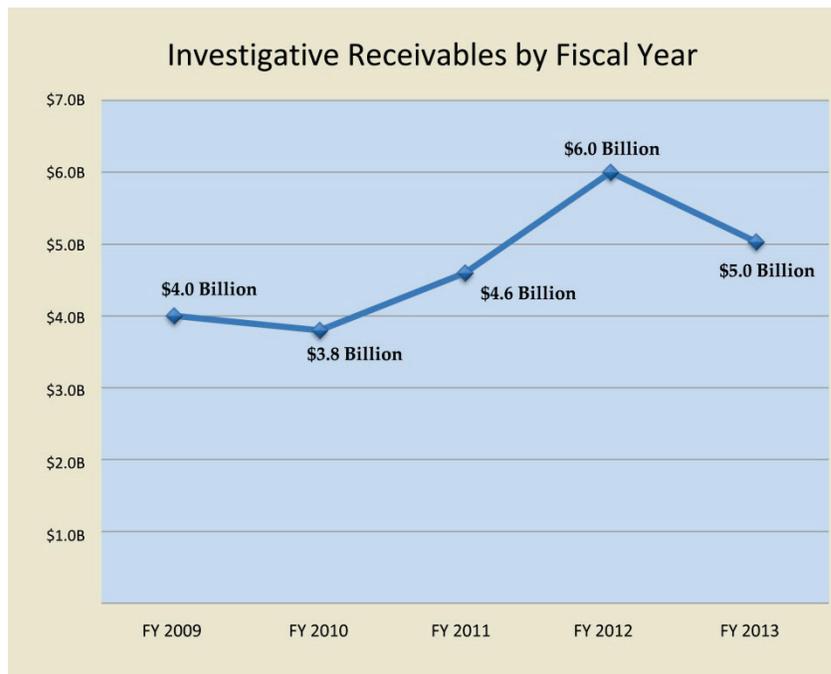


Chart 2 – Receivables: All HHS Programs



(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 April 1, 2013, to September 30, 2013, OIG received 24 requests for advisory opinions and issued 11 opinions.

Health care fraud prevention and enforcement

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.

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

02 Medicare Fraud Strike Force Activities

The Medicare Fraud Strike Force (Strike Force) is a key component of HEAT. 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 and investigative intelligence to quickly identify fraud and bring prosecutions. During this reporting period, Strike Force efforts resulted in the filing of charges against 126 individuals or entities, 112 criminal actions, and \$139.3 million in investigative receivables.

03 Nationwide Strike Force Takedown

The Medicare Fraud Strike Force charged 89 individuals for approximately \$223 million in false billing. In May 2013, a nationwide takedown by Medicare Fraud Strike Force operations in eight cities resulted in charges against 89 individuals, including doctors, nurses, and other licensed medical professionals, for their alleged participation in Medicare fraud schemes involving approximately \$223 million in false billings. The defendants charged were accused of various health-care-fraud-related crimes, including conspiracy to commit health care fraud, violations of the anti-kickback statutes, and money laundering. The charges were based on a multitude of alleged fraud schemes involving various medical treatments and services, primarily home health care, but also mental health services, psychotherapy, physical and occupational therapy, durable medical equipment (DME), and ambulance services. This coordinated operation was the sixth national Medicare fraud takedown in Strike Force history.

04 Additional Examples of Strike Force Efforts

Florida – Twelve defendants have been sentenced for their roles in a \$56 million health care fraud scheme. Health Care Solutions Network, Inc. (HCSN), operated community mental health centers in Florida (HCSN-FL) and North Carolina (HCSN-NC). These facilities allegedly provided partial hospitalization program (PHP) services to individuals suffering from mental illness. According to court documents, the clinical director of the PHP at HCSN-FL submitted claims to Medicare under her personal Medicare provider number for individual therapy she purportedly provided, while knowing that HCSN-FL was simultaneously billing for PHP services for the same patients. HCSN-FL personnel fabricated patient medical records to support false and fraudulent billing to Medicare and Florida Medicaid. A majority of the fabricated notes were created at the HCSN-FL facility for patients admitted to the PHP HCSN-NC facility. The defendants either submitted, or caused the submission of, approximately \$56 million in false and fraudulent claims to the Medicare and Florida Medicaid programs. To date, Wondera Eason, Paul Layman, Dana Gonzalez, Gema Pampin, Alexandra Haynes, Armando Gonzalez, John Theon, Daniel Martinez, Serena Joslin, Ivon Perez, Raymond Rivero, and Sarah Keller have been sentenced to a combined 70 years of incarceration and ordered to pay \$186 million in joint and several restitution.

Florida — Three executives of Hollywood Pavilion LLC, an inpatient psychiatric hospital in Broward County, Florida, were sentenced for their roles in a \$67 million Medicare fraud scheme. Evidence at trial showed that the defendants and their co-conspirators paid illegal bribes and kickbacks to patient brokers to recruit Medicare beneficiaries as patients at Hollywood Pavilion, though these patients did not qualify for psychiatric treatment. Hospital executive Daisy Miller facilitated the payment of bribes to patient recruiters and oversaw the fraudulent admissions and treatment of unqualified patients. Executive Karen Kallen-Zury created false documents to make it appear as if legitimate services were being rendered. Executive Christian Coloma also facilitated the payment of bribes and kickbacks and, he supervised the creation of false documents to conceal the bribery scheme. Between 2003 and 2012, Hollywood Pavilion submitted approximately \$67 million in false claims to Medicare based on these fraudulent acts. Miller, Kallen-Zury, and Coloma were sentenced to 15, 25, and 12 years of incarceration, respectively. Kallen-Zury and Miller were also ordered to pay more than \$39 million in restitution, joint and several, while Coloma was ordered to pay more than \$20 million in restitution, joint and several.

Florida – Manuel Sanz was sentenced to 14 years of imprisonment and ordered to pay \$30 million in restitution after pleading guilty to charges of conspiracy to commit health care fraud and conspiracy to pay health care kickbacks. Sanz was co-owner of Ideal Home Health, Inc., a company that purportedly provided skilled nursing services and home health aides to Medicare beneficiaries. According to the indictment, Sanz offered and paid kickbacks and bribes to recruiters and employees of Ideal Home Health for recruiting Medicare beneficiaries to be placed at Ideal Home Health in order for the company to bill Medicare for home health services that were not medically necessary and were not provided. Sanz then instructed nurses at Ideal Home Health to falsify patient medical records to make it appear that Medicare beneficiaries qualified for and received home health services when, in fact, the services were not medically necessary and were not provided.

New York – Aleksandr Kharkover was sentenced to 2 years of incarceration and ordered to pay \$4.6 million in restitution after pleading guilty to charges of health care fraud. Kharkover was a physical therapist who operated a private practice in at least two locations in Brooklyn, New York. From around January 2005 through July 2010, Kharkover billed Medicare for approximately \$11.9 million for purportedly providing medically necessary physical therapy services to Medicare beneficiaries. However, according to court documents, Kharkover allegedly hired individuals who were not certified as physical therapy assistants to provide the physical therapy. Kharkover also allegedly submitted claims to Medicare for services that were not actually provided.

Michigan – Husband and wife Raymond and Emelitza Arias were both sentenced after pleading guilty to charges of conspiracy to commit health care fraud. Raymond Arias was the owner of Elite Wellness, LLC, and Carefirst Occupational & Rehab Center, Inc. Elite Wellness was a purported HIV infusion therapy clinic, while Carefirst was a purported physical therapy and infusion therapy center. Emelitza Arias was part owner of Carefirst and assisted in the operations of Elite Wellness. According to the indictment, Emelitza offered and paid kickbacks and bribes to Medicare beneficiaries to undergo purported injection or infusion therapy. Elite Wellness and Carefirst then submit claims to Medicare seeking reimbursement for the cost of injection and infusion therapy purportedly furnished to the beneficiaries under the care of a physician. Raymond Arias caused the submission of over \$13 million in false claims by Carefirst and Elite Wellness for infusion and injection therapy and other services that were not medically necessary and/or were not actually provided. Medicare reimbursed the companies over \$3.8 million, of which the couple transferred \$2.6 million to accounts in Mexico and Panama. Raymond Arias was sentenced to 8 years and 4 months of incarceration and ordered to pay \$5.4 million in restitution, joint and several. Emelitza was sentenced to 1 year and 1 day of incarceration and ordered to pay \$531,883 in restitution, joint and several.

Other criminal and civil enforcement activities

01 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 the fraudulent billing of medical equipment and supplies, infusion therapy, and physical therapy, as well as other types of Medicare and Medicaid fraud. Case examples include:

Texas – Julian Kimble was sentenced to 6 years of incarceration and ordered to pay \$3.6 million in restitution after pleading guilty to charges of conspiracy to commit health care fraud, conspiracy to commit money laundering, and tax evasion. According to published reports, from March 2008 through December 2010, Kimble owned and operated four ambulance companies and used these companies to routinely bill Medicare for basic life support (BLS) ambulance transports that were not provided, not needed, or not ordered by the treating physicians. Investigators determined that none of the four ambulance companies operated by Kimble owned licensed ambulance vehicles necessary to provide the BLS transports for which he billed Medicare. Instead, Kimble and his co-conspirators transported multiple beneficiaries at the same time in vans or sedans, fraudulently billing Medicare for allegedly providing individual transports in ambulances under the attention of qualified emergency medical personnel. In addition, Kimble received kickbacks from the owners of various community mental health centers in exchange for supplying patients to their facilities.

Texas – Robert Baker was sentenced to 1 year and 6 months of incarceration and ordered to pay \$173,653 in restitution, joint and several, after pleading guilty to conspiracy to violate the anti-kickback statute. According to court documents, Baker was a Medicare beneficiary who, from March 2007 through April 2012, visited Adom Rehabilitation Services, Inc., and Healthcare and Wellness Medical Clinic, Inc. These clinics purportedly provided medical services, such as physical therapy, diagnostic testing, and mental health services. However, Baker did not have a medical need for the services; rather he would allow his Medicare benefits to be billed in exchange for cash. Baker also was paid cash to recruit Medicare and Medicaid beneficiaries to the clinics. The owners and operators of the medical clinics then submitted claims to Medicare for payment using Medicare information from Baker and his co-conspirators. The owner and operator of the clinics, along with two clinic employees were previously sentenced for their roles in the scheme.

Connecticut – Alan Bradley was sentenced to 2 years in prison and ordered to pay \$151,898 in restitution after pleading guilty to charges of health care fraud. According to published reports, Bradley was a certified alcohol and drug abuse counselor who obtained the Medicaid identification numbers of various Medicaid clients and used the identification numbers to submit hundreds of claims to Connecticut's Department of Social Services. The claims alleged that Bradley provided 75- to 80-minute individual psychotherapy sessions to these Medicaid clients at his office in Norwalk, Connecticut. However, hundreds of the counseling sessions never occurred, and during the time for which he billed Medicare for many of them, Bradley was actually living and attending school in Florida. In addition to receiving his sentencing, Bradley was suspended from participating in the Medicaid program.

02 Most Wanted Fugitives Listed on OIG's Web Site

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 continuously 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>. During this reporting period, three fugitives were captured.

California – Captured fugitives included Won Suk Lee, who was arrested in June 2013 after he arrived at Los Angeles International Airport. In July 2012, Lee was indicted on charges of health care fraud, aiding and abetting, and causing an act to be done. According to the indictment, Lee owned and operated Won Suk Lee Acupuncture and Herb, Inc. (aka Huntington Park Acupuncture Clinic and Variety Choice, Inc.), two clinics in Huntington Park, a suburb of Los Angeles. Lee, an acupuncturist, and his staff allegedly billed Medicare for purportedly providing services that were not covered by Medicare. According to court documents, Lee also received kickbacks for providing Medicare beneficiaries' health identification cards and other personal and medical information to a clinic enrolled as a Medicare provider for physical therapy services that then allegedly submitted false claims to Medicare for Medicare-covered services, such as physical therapy, though the beneficiaries did not receive any services from the clinic. Lee's co-conspirators allegedly created patient files for the beneficiaries that included false documentation for covered services and received approximately \$1.2 million from Medicare for the fraudulent claims.

Because of the success of OIG's Most Wanted Fugitives Web site, OIG 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, thus causing 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

01 Prescription Drugs

Michigan – Twenty-six defendants have been convicted for their roles in a widespread scheme to defraud Medicare and Medicaid of nearly \$58 million. According to the indictment, Babubhai Patel was a licensed pharmacist who either owned or controlled 26 pharmacies in Michigan. Patel concealed his ownership and control over many of his pharmacies through the use of straw owners. Patel offered and paid kickbacks, bribes, and other inducements to prescribers in exchange for their writing fraudulent prescriptions for patients with Medicare, Medicaid, and private insurance and directing the patients to fill their prescriptions at one of Patel's pharmacies. Patel and his pharmacists billed Medicare and other insurers for dispensing the medications, despite the fact that the medications were medically unnecessary and/or were

never provided. Since January 2009, Patel's pharmacies dispensed approximately 250,000 doses of Oxycontin, 4.6 million doses of Vicodin, 1.5 million doses of Xanax, and 6,100 pint bottles of codeine cough syrup. Patel's pharmacies falsely billed Medicare and Medicaid approximately \$57.8 million for medications purportedly provided to beneficiaries over the course of the scheme.

Patel was sentenced to 17 years in prison and ordered to pay \$18.9 million in restitution, joint and several. Mustak Vaid (physician), Komal Acharya (associate of Patel), Lokesh Tayal (pharmacist), Viral Thaker (pharmacist), Brijesh Rawal (pharmacist), and Ashwini Sharma (pharmacist) were sentenced to a combined 19 years in prison and ordered to pay more than \$8.4 million in restitution, joint and several. Nineteen additional defendants are awaiting sentencing.

Florida – Captured OIG Most Wanted Fugitives Carlos Rodriguez and Keilan Fife were sentenced during this reporting period after pleading guilty to charges related to health care fraud. The husband and wife team were fugitives from justice until they were arrested in November 2012 after arriving at Miami International Airport. Rodriguez was the owner and operator of Universal Scripts, Inc., while Fife was the owner and operator of Millennium Rx, Inc. Both pharmacies were based in Miami. According to court records, Fife, Rodriguez, and their co-conspirators were involved in a Medicare scheme in which kickbacks and bribes were paid to patient recruiters and beneficiaries for prescriptions that were then used to submit fraudulent claims to Medicare. Universal was paid approximately \$7 million from Medicare for medical items and services allegedly provided, while Millennium was paid approximately \$1.3 million from Medicare. Rodriguez was sentenced to 4 years and 9 months of incarceration and ordered to pay \$4.4 million in restitution, joint and several, while Fife was sentenced to 2 years and 6 months of incarceration and ordered to pay \$845,000 in restitution. Lazaro Betancourt, an employee at Universal who also participated in the scheme, was sentenced to 3 years and 10 months of incarceration and ordered to pay \$4.4 million in restitution, joint and several.

02 Durable Medical Equipment

Nevada – Alegria Phankonsy was sentenced to 4 years and 3 months of incarceration and ordered to pay over \$12 million in restitution after pleading guilty to charges of health care fraud and tax evasion. According to the indictment, Phankonsy simultaneously operated several medical equipment and supplies companies in Las Vegas using several alias names. The companies, Proforma Medical Source, Divine Health, and Freemotion Plus Medical Supply, received more than \$11 million from Medicare for equipment that was allegedly provided to Medicare beneficiaries. Phankonsy allegedly paid "marketers" in southern California to obtain patients for her various companies. The marketers provided patients with money in exchange for their Medicare information, which was used to bill Medicare for items not provided. Phankonsy also forged or caused to be forged prescriptions and falsified or caused to be falsified certificates of medical necessity to make it appear as if a physician had ordered a product for her customers. She then submitted and caused to be submitted false claims to Medicare for medical equipment that was not medically necessary, was not provided to her customers, and was not prescribed by a physician.

New York – Helene Michel was sentenced to 12 years of imprisonment and ordered to pay \$4.4 million in restitution for her role in a scheme to defraud Medicare by billing for durable

medical equipment that she did not provide. Michel, along with her husband, Etienne Allonce, owned and operated Medical Solutions Management, Inc. (MSM), a medical equipment and supplies company purportedly specializing in high-end wound care supplies, braces, and orthotic shoes. Through MSM, Michel and Allonce fraudulently billed the accounts of nursing home residents from over 15 New York area nursing homes for equipment that was never ordered or provided. According to court documents, Michel entered these nursing homes falsely presenting herself in many roles, including physician, nurse practitioner, and wound care expert. She then stole original medical records, as well as altered and manufactured records, in an effort to justify MSM's medical billing. Evidence at trial showed that Michel and MSM had no relationship with the nursing homes and never provided medical equipment to any of their residents. The Government contends that between 2003 and 2007, MSM improperly received over \$6.5 million from Medicare for equipment that was never ordered or supplied.

Texas – Kenny Msiakii was sentenced to 8 years and 1 month of incarceration and ordered to pay \$2.5 million in restitution after being convicted on charges of health care fraud. Msiakii owned Joy Supply and General Services, a Louisiana-based entity that billed Medicare for orthotics, heat pads, power wheelchairs, and other medical equipment. According to the indictment, Msiakii submitted approximately \$467,000 in claims to Medicare for equipment purportedly prescribed by a doctor in Houston, Texas. However, the doctor never prescribed any of the equipment for which Msiakii billed Medicare. Msiakii also submitted more than \$6.7 million in claims to Medicare for equipment that was not medically necessary and, in some cases, was never provided.

03 Physicians

Washington – Sound Inpatient Physicians, Inc. (Sound), agreed to pay \$14.5 million to resolve allegations that it violated the FCA. Sound is a provider of hospitalists and other physicians to hospitals and other medical facilities. It employs more than 700 hospitalists and post-acute physicians who provide services at 70 hospitals and post-acute facilities in 22 States. Between January 2004 and December 2012, Sound allegedly submitted claims to Federal health care programs using codes for specific physician Evaluation and Management and related services furnished by Sound's hospitalists to beneficiaries when, in fact, the services performed did not meet the level billed and/or the available documentation did not support the level billed. In addition to entering into the monetary agreement, Sound entered into a 5-year corporate integrity agreement (CIA) with OIG.

Washington – Alfred Chan agreed to pay \$3.1 million to resolve allegations under the FCA. Chan was a medical doctor who specialized in hematology and oncology. He and his wife Judy operated the "Alfred H. Chan, M.D., P.C., Clinic" in Lakewood, Washington, until the clinic closed in February 2011. According to court documents, the Chans allegedly defrauded Medicare, Medicaid, and other Federal health care programs by intentionally submitting false and inaccurate claims for medications and services. Specifically, the Chans allegedly billed for quantities of drugs greater than those actually administered to patients, overstated chemotherapy drug infusion times, and double-billed for medications. They also falsified the patient charts to support the fraudulent billing. As a result of this conduct, Chan agreed to be excluded for a period of 15 years. In January 2012, Chan's license to practice as a physician and surgeon in the State of Washington was indefinitely suspended.

California – Licensed physician Joel I. Bernstein, M.D., agreed to pay approximately \$2.28 million to resolve allegations under the FCA. In addition, “Joel I. Bernstein, M.D., Inc.,” Bernstein’s professional corporation, pleaded guilty in a related criminal action to charges of health care fraud and aiding and abetting. The company was sentenced to probation and ordered to pay a \$500,000 fine and \$1.7 million in restitution. Bernstein’s practice specialized in the treatment of patients suffering from various forms of cancer. According to court records, Bernstein allegedly purchased non-FDA-approved prescription oncology drugs from a variety of sources that purported to contain the same active ingredient as oncology drugs sold in the United States. Bernstein administered these drugs to patients, including Medicare beneficiaries, and submitted and caused to be submitted false claims for payment to Medicare related to the administration of the drugs.

04 Kickbacks

Georgia – C.R. Bard, Inc., and its wholly owned subsidiary, ProSeed, Inc., agreed to pay \$48.26 million to resolve allegations that it provided illegal remuneration to certain customers and physicians to induce them to purchase their products. C.R. Bard is a multinational company that develops, manufactures, and markets medical devices, including brachytherapy seeds, which are used in the treatment of prostate cancer. C.R. Bard allegedly paid kickbacks to customers and physicians who performed prostate cancer treatment procedures using its brachytherapy seeds. The kickbacks included grants, guaranteed minimum rebates, conference fees, marketing assistance, or free medical equipment in an effort to secure and maintain sales of brachytherapy seeds.

05 Physical Therapy

Texas – A captured OIG Most Wanted Fugitive, Godwin Nzeocha, was sentenced to 9 years and 1 month of incarceration and ordered to pay more than \$26 million in restitution, joint and several, after pleading guilty to charges of conspiracy to commit health care fraud and money laundering. According to court documents, Nzeocha worked for City Nursing Services of Texas, Inc., where he signed his name as the provider of physical therapy services on City Nursing patient files, including blank treatment data forms, progress notes, and daily physical therapy records. However, Nzeocha was not licensed, trained, or otherwise qualified to provide physical therapy to patients. Nzeocha also signed documents that were prefilled with “4 units” of physical therapy treatment that he knew had not been provided and that he was not qualified to provide. Nzeocha said he knew that City Nursing was not providing any of the physical therapy services that were billed to Medicare and that all the money City Nursing received from Medicare as payment for physical therapy services was criminally derived. During the time Nzeocha worked at City Nursing, the company billed Medicare and Medicaid approximately \$3 million for physical therapy services that were not provided. Nzeocha was arrested by Nigerian authorities in 2011 and extradited to the United States in June 2012 to face health care fraud charges.

06 Personal Care Services

Illinois – Daniel Geary and Cynthia Harmon were each sentenced to time served (4 months and 25 days for Harmon, 4 months and 11 days for Geary) and ordered to pay \$421 after pleading guilty to false statements relating to health care matters. According to the indictment, Harmon

and Geary defrauded the State of Illinois Medicaid program by falsely claiming and taking payments for personal assistant services that were not actually performed. Between February and March 2012, Geary purportedly provided personal care services to Harmon, a Medicaid recipient, at her home. However, Harmon was incarcerated during the time that the services were supposed to be provided. Geary completed home services time sheets falsely stating that he performed 44.5 hours of personal assistant services for Harmon; he then billed Medicaid for the hours and received \$821 in reimbursement.

07 Hospitals

Utah – Intermountain Health Care, Inc., agreed to pay \$25.5 million plus interest to resolve allegations under the Physician Self-Referral Law (Stark Law) and FCA. Intermountain is a nonprofit entity that operates the largest health system in the State of Utah. Intermountain self-disclosed to the Government that it engaged in improper financial relationships with referring physicians, in violation of the Stark Law. The Government contended that Intermountain, through its subsidiary, Intermountain Medical Group, compensated certain employed physicians using a bonus formula that may have improperly taken into account the volume and value of the physicians' patient referrals to Intermountain, that it rented office space to certain physicians without written and executed leases that were in effect for the entire term and/or that may have had fair market value issues, and that it had compensation or other financial arrangements with certain physicians who provided services to Intermountain under which the parties' arrangements were not memorialized in a written and executed contract.

Montana – St. Vincent Healthcare and Holy Rosary Healthcare (collectively, the Hospitals) agreed to pay \$3.9 million to resolve allegations under the Stark Law. The Hospitals self-disclosed that between July 2003 and December 2010, they paid certain employed physicians incentive compensation that was based, in part, on the volume or value of referrals made to the Hospitals. More specifically, the physician formula for compensation included inappropriate revenue related to such designated health services as EKG and EMG services at the Hospitals. In addition, the Hospitals identified numerous arrangements or contracts it held with independent physicians or physician groups that the Government contended violated the Stark Law. These arrangements or contracts included violations relative to expired or unsigned contracts, unwritten agreements, untimely payment of rent under lease terms, and potential deviations from fair market value rental charges.

08 Home Health Care

Florida – Nine defendants were sentenced for their roles in a home health care fraud scheme. According to the indictment, the president and an employee of Safe Home Health Care Agency, Inc., a Miami-based business that purported to provide home health services, along with a Miami resident co-conspirator and others, allegedly offered and paid kickbacks and bribes to patient recruiters in return for referring beneficiaries to Safe Home to serve as patients. Beneficiaries also received kickbacks for agreeing to serve as patients of Safe Home.

According to court records, Maria Rueda was the president of Safe Home. Jorge Sell was employed at Safe Home as an office administrator. The Government contended that Rueda and Sell used the beneficiary information to submit false claims from Safe Home to Medicare for home health services and prescriptions that either were never provided or were medically

unnecessary. Safe Home received \$9.5 million in reimbursements from these false claims. Miami resident Arminda Reyes was a co-conspirator. Manuela Rodriguez, Rene Suarez-Basanta, Cristobal Garcia, and Marta Gonzalez were Medicare beneficiaries who, along with Maria Valdez, Francisco Rizo, and others, solicited and accepted thousands of dollars in kickbacks and bribes for referring Medicare beneficiaries to Safe Home to serve as patients. During this reporting period, the nine defendants were sentenced to a combined 16 years and 2 months in prison and ordered to pay more than \$5.8 million in restitution, joint and several.

09 Transportation Fraud

Pennsylvania – William Hlushmanuk, aka Bill Le, was sentenced to 7 years and 8 months in prison and ordered to pay \$5.4 million in restitution after pleading guilty to health care fraud charges. Hlushmanuk operated Starcare Ambulance, Inc., a private ambulance company that transported patients almost exclusively on nonemergency calls. According to the indictment, from approximately 2006 until 2011, Hlushmanuk allegedly directed Starcare employees to transport by ambulance or private vehicle Medicare patients who were ineligible for Medicare-paid nonemergency transport because they either could walk or be transported by other means. Most of these patients were on dialysis and attended dialysis treatments several times a week. Starcare patients were directed to get onto a stretcher or were placed by Starcare employees on a stretcher, even though the patients were able to walk or be moved via wheelchair. Starcare then submitted fraudulent claims to Medicare for these medically unnecessary ambulance services and received more than \$5.4 million in reimbursement for these false claims.

10 Medicaid and Other Government Program Fraud

Minnesota – James and Cynthia Hood fraudulently applied for several types of government benefits, including Medicaid and Social Security. According to court records, James and Cynthia Hood, along with their three children, moved to Minnesota from Louisiana in 2005 after Hurricane Katrina. The Hoods claimed they were displaced by the storm and had difficulty finding adequate services for their children in New Orleans. During the application process for these benefits, Cynthia Hood stated that she was the sole legal guardian/custodian of the children, that she did not have any assets, that she lived separately from her husband, and that she was not employed. However, investigators determined that Cynthia Hood lived with her husband; had at least eight different bank accounts that either were in her name or were held jointly with James Hood, totaling approximately \$680,000; owned two vehicles; paid over \$860,000 in cash for a home in Minnesota co-owned with her husband; and owned another house in Louisiana valued in excess of \$270,000.

Investigators also determined that James Hood was a retired college professor who had retirement accounts, stocks, and other investments worth over \$11 million. He also owned a farm in Iowa. Investigators believe that James Hood assisted in the fraud by preparing false federal income tax returns. From January 2006 to April 2011, the couple stole approximately \$480,000 in State and Federal Medicaid benefits and Social Security benefits. James Hood was sentenced to 3 years and 6 months of imprisonment after pleading guilty to charges of theft of public money, health care fraud, and mail fraud. Cynthia Hood was sentenced to 3 years of probation after pleading guilty to false statements for use in determining rights to a Social Security benefit and mail fraud. Both were ordered to pay \$483,312 in restitution, joint and several, and were fined \$500,000.

Iowa – Dennis Schuller agreed to pay \$100,000 to settle allegations that he submitted, or caused to be submitted, false claims for payment to Medicaid. Schuller practiced dentistry in Cedar Rapids, Iowa. According to court records, Schuller allegedly billed Medicaid from August 2008 through June 2010 for exams performed by a hygienist as though a dentist had performed the exams, medically unnecessary procedures, individual x-rays when whole mouth x-rays had been performed, occlusal guards (mouth guards) that were not medically necessary, and the use of desensitizing medication on patients when this medication was not medically necessary.

Medicaid Fraud Control Units

01 Funding and Accomplishments

Medicaid Fraud Control Units (MFCUs) are key partners with OIG in the fight against fraud, waste, and abuse in State Medicaid programs. In 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. MFCU accomplishment data for FY 2013 will be reported in OIG's spring 2014 *Semiannual Report*.

02 Joint investigations with MFCUs

Maine – John Perry was sentenced to 8 years of imprisonment and ordered to pay \$7,580 in restitution and a \$900 fine after pleading guilty to charges of conspiracy to possess with intent to distribute oxycodone; health care fraud, aiding and abetting; and unlawful distribution of oxycodone. Perry was a licensed podiatrist who owned and operated Atlantic Foot & Ankle, P.A., in Portland, Maine. According to court records, Perry prescribed controlled substances, including oxycodone, knowing that these substances were being further distributed by his co-conspirators. Perry would charge up to \$500 or more for each oxycodone prescription. Perry wrote prescriptions without any medical purpose; in the names of people to whom he never provided medical care; and in exchange for money and other controlled and illegal substances, including cocaine, for his personal use. Perry also wrote prescriptions with no legitimate medical purpose outside his medical office, including at bars and a strip club. Perry fabricated patient charts in his office to cover his improper prescriptions and then submitted false claims for these prescriptions to MaineCare. This was a joint investigation with the Drug Enforcement Administration, the Federal Bureau of Investigation (FBI), and the Maine MFCU.

California – Vincent Rubio was sentenced to 8 months of home confinement and ordered to pay \$10.6 million in restitution after pleading guilty to charges of conspiracy to pay kickbacks for patient referrals, causing an act to be done, and subscription to false tax return. Rubio was Chief Financial Officer of a hospital in Tustin, California. According to court documents, Rubio oversaw the issuance of checks to companies owned by co-conspirators for the referral of recruited

beneficiaries admitted to the hospital. The hospital executed sham “consultant” contracts with these companies to conceal the fact that the hospital was making kickback payments to them for the referrals. The hospital then billed Medicare and Medi-Cal for hospital stays and related services provided to the recruited beneficiaries, including admissions that were medically unnecessary. Medicare and Medi-Cal paid the hospital more than \$10.5 million in reimbursement for these false claims. This was a joint investigation with the Internal Revenue Service, the FBI, and the California MFCU.

Sanction authorities and other 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. 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 1,605 administrative sanctions in the form of program exclusions or administrative actions for alleged fraud or abuse or other activities that posed a risk to Federal health care programs and their beneficiaries. Exclusion and penalty authorities are described in Appendix D and on our Web site at:

<http://oig.hhs.gov/fraud/enforcement/cmp/index.asp>.

01 Program Exclusions

During this semiannual reporting period, OIG excluded 1,553 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/>.

Florida – Joseph Burrell Wagner, Jr., a chiropractor, was excluded for a minimum period of 40 years on the basis of his convictions for health care fraud; conspiracy to illegally distribute and dispense, and cause to be distributed and dispensed, schedule III and IV controlled substances; and aiding and abetting transactional money laundering. Wagner billed, and caused bills to be sent to, Medicare, Medicaid, and private insurers for services that were rendered by him or his staff as though they were medical doctors. In actuality, Wagner used the name of a medical doctor to fraudulently bill for services that had never been performed or provided by the medical doctor. In addition, he conspired with others to distribute and dispense schedule III and IV controlled substances. As a licensed chiropractor, Wagner is not permitted to prescribe, distribute, or dispense controlled substances. As part of the scheme, Wagner used the name and DEA numbers of medical doctors to illegally prescribe controlled substances to patients with

no legitimate doctor-patient relationship. As a result of these crimes, Wagner was sentenced to 15 years and 8 months of incarceration and ordered to pay more than \$2 million in restitution. The Florida Board of Chiropractic Medicine ordered the voluntary relinquishment of Wagner's license to practice as a chiropractor.

Louisiana – Vadim Mysak, owner, manager, and technician of several medical clinics, was excluded for a minimum period of 25 years on the basis of his conviction. Mysak and his co-conspirators were involved in a scheme to defraud Medicare and Medicaid through fraudulent billing for diagnostic tests that were not medically necessary or were not performed. On the basis of this scheme, Mysak was convicted on charges of conspiracy to commit health care fraud and conspiracy to commit money laundering. He was sentenced to 4 years and 1 month of incarceration and ordered to pay more than \$6 million in restitution, joint and several. Mysak was also excluded from participation in Medicaid by the Louisiana Department of Health and Hospitals.

Kentucky – Deloris Williams, a registered nurse, was excluded for a minimum period of 20 years on the basis of her reckless homicide conviction. While employed as a registered nurse, Williams entered the room of a patient with a cigarette lighter. The cigarette lighter started a fire on the bedding of a patient who was in a complete vegetative state that left him unable to escape the fire. Williams made no attempt to contact anyone regarding the fire. The patient died at the hospital as a result of the fire. The court sentenced Williams to 5 years of incarceration. In addition, the Kentucky State Board of Nursing revoked her license to practice as a registered nurse.

Florida – Joseph Pastorek, a medical doctor, was excluded for a minimum period of 10 years on the basis of his conviction for conspiracy to knowingly and willfully dispense, and cause to be dispensed, schedule IV controlled substances. Pastorek purported to provide pain management treatment for chronic pain patients in various clinics in Louisiana and Florida. However, in actuality, Pastorek engaged in a conspiracy to unlawfully dispense controlled substances outside the course of legitimate medical practice. From about January 2004 to about February 2008, Pastorek conspired with others to dispense controlled substances that involved a mixture and substance containing methadone. Pastorek was sentenced to 12 months of incarceration followed by 12 months of home detention.

Massachusetts – Brian Awbrey, a medical doctor, was excluded for an indefinite period on the basis of the loss of his license to practice medicine in Massachusetts. Awbrey allegedly entered into a sexual relationship with a patient whom he treated from about 1989 to about 2007. In addition, Awbrey also allegedly failed to comply with the standard of care in relation to a number of patients regarding his prescribing of medications. As a result, the Massachusetts Board of Registration in Medicine revoked his license to practice medicine.

02 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.

03 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 \$8 million in CMPs and assessments.

Massachusetts – Trustees of Tufts College and Tufts University School of Dental Medicine (TUSDM) agreed to pay \$841,120 for allegedly violating the CMPL. TUSDM submitted claims to Medicare for various services from four of its clinics. However, OIG alleged that these claims were improper because the services had been provided by dentists who were not credentialed by Medicare or the services were not supported by sufficient medical record documentation.

Georgia – Dr. Matthew James Britton and C.F. Health Management, Inc., d/b/a Gainesville Pain Management (GPM), agreed to pay \$1.5 million for allegedly violating the CMPL. OIG alleged that GPM submitted false or fraudulent claims by inappropriately using certain service code modifiers to submit claims for payment for multiple units when only a single unit may be billed per patient encounter and by inappropriately billing for higher paying service codes when less expensive services were actually provided.

Pennsylvania – Bravo Health Pennsylvania, Inc. (Bravo), agreed to pay \$225,000 to resolve its liability under the CMP provisions applicable to Medicare Advantage (MA) organizations. OIG alleged that Bravo provided patient medical records to OIG's Office of Audit Services as part of an audit. However, the medical records were intentionally altered prior to their submission or resubmission. Specifically, Bravo added apparent diagnoses notations or signatures to the patient medical records.

New York – Sergey Lugina and Executive Medical Care, P.C. (EMC), agreed to pay \$74,000 for allegedly violating the CMPL. OIG alleged that EMC submitted, or caused to be submitted, claims for medical services that had not been provided as claimed and/or were false or fraudulent. OIG alleged that these services had not been provided as claimed because Lugina was on travel outside the United States during the periods when he claimed to have rendered services to beneficiaries.

Missouri – Paul Lux, M.D., agreed to pay \$63,900 for allegedly violating the CMPL provisions applicable to physician self-referrals and kickbacks. OIG alleged that Lux received remuneration from a medical device manufacturer in return for recommending the purchase of the manufacturer's medical devices.

04 Patient Dumping

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

Georgia – Donalsonville Hospital, Inc. (Donalsonville), agreed to pay \$25,000 to resolve its liability under the patient dumping statute. OIG alleged that Donalsonville failed to provide an adequate medical screening examination to a patient who arrived at its emergency department complaining of shortness of breath and chest pain. The patient did not receive any medical examination from a physician and was told that he was required to pay a minimum fee of \$100 to continue further treatment. The patient chose not to pay the fee and was discharged without receiving an appropriate medical screening examination.

Georgia – Emory University Hospital (Emory) agreed to pay \$50,000 to resolve its liability under the patient dumping statute. OIG alleged that Emory refused to accept the appropriate transfer of a patient who required Emory's specialized capabilities.

Iowa – Mercy Hospital of Franciscan Sisters (MHFS) entered into a \$20,000 settlement agreement to resolve its liability under the CMPL for a violation of EMTALA. MHFS's liability arose from its failure to provide a medical screening examination, stabilizing treatment, or an appropriate transfer to a patient who arrived at the emergency department after ingesting window deicer, a product containing the toxin methanol.

Provider Self-Disclosure Protocol

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

<https://oig.hhs.gov/compliance/self-disclosure-info/index.asp>.

During this reporting period, self-disclosure cases resulted in \$28.1 million in HHS receivables. Following are examples of provider self-disclosure settlements.

California – Sonora Regional Medical Center agreed to pay \$597,193 to resolve its liability under the Civil Monetary Penalty Law. Sonora self-disclosed to OIG that a physician at its oncology outpatient center routinely submitted upcoded claims for evaluation and management services, resulting in his receipt of reimbursement at a higher level than that of the code that was applicable to the services he actually provided.

Florida – SpecialtyCare Surgical Assist, LLC (SCSA), agreed to pay \$247,024 for allegedly violating the CMPL. SCSA self-disclosed to OIG that it had knowingly presented to Medicare, Medicaid,

and TRICARE claims for items or services that it knew, or should have known, were not provided as claimed. Specifically, OIG contended that SCSA billed Federal health care programs for assistant-at-surgery services provided by certified surgical assistants and registered nurse first assistants when these programs reimburse such services only if provided by physicians and/or physician assistants.

California – Sutter Health Sacramento Sierra Region (SHSSR) agreed to pay \$130,308 for allegedly violating the CMPL. SHSSR self-disclosed to OIG that it employed an individual that it knew, or should have known, was excluded from participation in Federal health care programs.

Oregon – Radiology Associates, P.C. (RA), and Oregon Imaging Centers, LLC (OIC), agreed to pay \$189,045 for allegedly violating the CMPL. OIC self-disclosed to OIG that it had inappropriately billed Medicare for certain diagnostic tests provided by radiology practitioner assistants employed by RA that required personal supervision by a physician but that instead had been provided under a lesser level of supervision.

Public Health, Human Services, and Other HHS Issues

This segment of the Department of Health and Human Services (HHS) Office of Inspector General's (OIG) *Semiannual Report to Congress* pertains to public health, human services, and other selected HHS issues.

Public health activities and programs represent the country's primary defense against acute and chronic diseases and disabilities and provide the foundation for the Nation's efforts to promote and enhance the health of the American people. Our reviews of public health agencies within HHS generally include the following:

- **Agency for Healthcare Research and Quality (AHRQ).** AHRQ sponsors and conducts research that provides evidence-based information on health care outcomes, quality, costs, use, and access.
- **Centers for Disease Control and Prevention (CDC).** CDC operates a health surveillance system to monitor and prevent disease outbreaks, including bioterrorism; implements disease prevention strategies; and maintains national health statistics.
- **Food and Drug Administration (FDA).** FDA is responsible for ensuring the safety of the Nation's food, drugs, medical devices, biologics, cosmetics, and animal food and drugs.
- **Health Resources and Services Administration (HRSA).** HRSA maintains a safety net of health services for people who have low incomes or are uninsured or who live in rural areas or urban neighborhoods where health care is scarce.
- **Indian Health Service (IHS).** IHS provides or funds health care services for American Indians and Alaska Natives.
- **National Institutes of Health (NIH).** NIH supports medical and scientific research examining the causes of and treatments for diseases, such as cancer, human immunodeficiency virus (HIV), and acquired immunodeficiency syndrome (AIDS).
- **Substance Abuse and Mental Health Services Administration (SAMHSA).** SAMHSA funds services to improve the lives of people who have, or are at risk for, mental and substance abuse disorders.

The HHS agencies that administer human services programs are the Administration for Community Living (ACL), which includes the Administration on Aging, to provide services such as meals, transportation, and caregiver support to older Americans at home and in the community through a nationwide network, and the Administration for Children and Families (ACF), which promotes the economic and social well-being of children, families, and communities, including Temporary Assistance for Needy Families (TANF); the national child support enforcement (CSE) system; the Head Start program for preschool children; and assistance for child care, foster care, and adoption services. Other HHS issues include those functions managed by the Office of the Secretary or new initiatives being implemented pursuant to the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act).

Public health reviews

Significant problems, abuses, and deficiencies:

01 CDC—President's Emergency Plan for AIDS Relief (PEPFAR). In seven reports, OIG's recommendations included that improved oversight, guidance, controls, and procedures are needed to ensure that PEPFAR funds are used as intended by law.

HHS receives PEPFAR funds from the State Department through a memorandum of agreement. In addition, it also receives direct HHS funding for its Global HIV/AIDS Program. HHS's Centers for Disease Control and Prevention works in more than 75 countries with ministries of health and other in-country partners to strengthen health systems and build sustainable HIV/AIDS programs. CDC's offices in host countries are responsible for PEPFAR funds awarded to government agencies and for-profit and nonprofit organizations (recipients).

In this semiannual period, we issued seven PEPFAR-related reports with recommendations for corrective action as follows.

CDC Vietnam. In general, CDC Vietnam monitored recipients' use of PEPFAR funds in accordance with HHS and other Federal requirements. We recommended that CDC's Vietnam office implement standard operating procedures specific to monitoring recipients' use of PEPFAR funds, including, but not limited to, documenting CDC's review of progress reports. Savings Potential—CDC awarded \$28.2 million of PEPFAR funds to 19 recipients in Vietnam during FY 2009. Risk of misuse of funds can be mitigated through improved monitoring procedures.

2013 APR CDC Vietnam—The Centers for Disease Control and Prevention's Vietnam Office Generally Monitored Recipients' Use of the President's Emergency Plan for AIDS Relief Funds. A-04-12-04023.

Vietnam Ministry of Health. The Ministry did not always manage PEPFAR funds or meet program goals in accordance with requirements for returning interest income and used PEPFAR funds to pay for potentially unallowable value-added taxes (VAT) on purchases. We recommended that the Ministry strengthen controls to ensure accurate and timely reporting, return interest income to CDC, record adjustments to the general ledger account in a timely manner, ensure that all the provinces obtained the tax identification (tax ID) required to receive a VAT refund, and resolve whether the VAT payments we questioned were allowable expenditures. Savings Potential—Savings could be realized through improved compliance and returns and recoveries of amounts questioned. We questioned almost \$18,000 in unreturned interest and about \$30,000 in VAT payments.

2013 JUN The Vietnam Administration for HIV/AIDS Control Did Not Always Manage the President's Emergency Plan for AIDS Relief Funds or Meet Program Goals in Accordance With Award Requirements. A-06-11-00057.

Potentia Namibia Recruitment Consultancy (Potentia). Potentia generally managed PEPFAR funds and met program goals in accordance with award requirements. Potentia made small

financial errors, used some funds for potentially unallowable VAT, and did not submit a required annual progress report. We recommended that Potentia implement policy and procedures to prevent other errors, refund unallowable expenditures, and resolve whether the VAT expenditures were allowable. Savings Potential—Findings included over \$173,000 of potentially unallowable VAT and minor transaction errors. (Transactions totaling about \$185,000 were allowable.)

2013 APR Potentia Namibia Recruitment Consultancy Generally Managed the President's Emergency Plan for AIDS Relief Funds and Met Program Goals in Accordance With Award Requirements. A-06-11-00056.

South African National Department of Health (Ministry). The Ministry's mission is to ensure the delivery of quality, affordable, and accessible health services in accordance with the national 10-point plan for health. The Ministry did not always accurately report PEPFAR expenditures, did not obtain an annual financial audit, and claimed some unallowable and potentially unallowable expenditures. We recommended that the Ministry develop and implement policies and procedures to address our findings, use correct exchange rates, submit timely audits, resolve costs we questioned, and refund unallowable amounts to CDC. Savings Potential—Findings included about \$75,000 in potentially unallowable VAT and over \$3,000 in unallowable expenditures that lacked supporting documentation. (Transactions totaling about \$1.9 million were allowable.)

2013 AUG The South African National Department of Health Did Not Always Manage President's Emergency Plan for AIDS Relief Funds or Meet Program Goals in Accordance With Award Requirements. A-05-12-00022.

Southern African Catholic Bishops' Conference AIDS Office (SACBC). SACBC generally managed PEPFAR funds and met program goals in accordance with award requirements but did not submit a required financial audit. We recommended that the SACBC AIDS Office implement policies and procedures to prevent performance, progress, and audit issues; refund unallowable expenses; and resolve whether VAT was allowable. Savings Potential—We questioned transactions totaling more than \$18,000 and potentially unallowable VAT payments totaling more than \$25,000. (Transactions totaling \$442,083 were allowable.)

2013 JUL The Southern African Catholic Bishops' Conference AIDS Office Generally Managed President's Emergency Plan for AIDS Relief Funds and Met Program Goals in Accordance With Award Requirements. A-05-12-00023.

South Africa—National Health Laboratory Service (NHLS). NHLS provides cost-effective and professional laboratory medicine through state-of-the-art technology to all South Africans. Deficiencies included unallowable transactions, inaccurate reporting, and failure to submit an annual financial audit. We recommended that NHLS develop and implement policies and procedures to address our findings, use correct exchange rates, submit timely audits, resolve costs we questioned, and refund unallowable amounts to CDC. Savings Potential—We questioned transactions totaling more than \$185,000, of which more than \$183,000 were for unallowable expenditures. (Transactions totaling almost \$600,000 were allowable.)

2013 AUG National Health Laboratory Service Did Not Always Manage President's Emergency Plan for AIDS Relief Funds or Meet Program Goals in Accordance With Award Requirements. [A-05-12-00024](#).

South Africa—Aurum Institute for Health Research (Aurum). Aurum, a nonprofit organization incorporated under the laws of the Republic of South Africa, conducts health research and provides care and treatment for tuberculosis and HIV. Aurum inappropriately requested, received, and maintained cash advances in excess of its immediate needs; did not accurately report expenditures; and did not fully report progress on its objectives. We recommended that Aurum develop and implement policies and procedures to address our findings, use correct exchange rates, file an amended financial report, and refund unallowable amounts to CDC. Savings Potential—We identified more than \$1.6 million of unallowable expenditures. (Transactions totaling about \$869,000 were allowable.)

2013 AUG Aurum Institute for Health Research Did Not Always Manage President's Emergency Plan for AIDS Relief Funds or Meet Program Goals in Accordance With Award Requirements. [A-05-12-00021](#).

02 FDA—Drug Manufacturers Settled Allegations. The United States alleged that companies submitted false data to FDA and failed to meet various FDA requirements.

Maryland – Ranbaxy Laboratories Limited, which has headquarters in Gurgaon, India, agreed to pay \$350 million plus interest to resolve allegations under the False Claims Act. Ranbaxy admitted to violations of introducing adulterated drugs into interstate commerce, delivering unapproved new drugs into interstate commerce, failing to make required reports to the Food and Drug Administration, and causing drugs to be adulterated while the drugs were held for sale after being shipped in interstate commerce, in violation of the Federal Food, Drug and Cosmetic Act. From April 2003 through September 2010, Ranbaxy allegedly falsified records and other data with FDA in order to obtain approval to sell generic drugs in the United States. In addition, Ranbaxy allegedly submitted false data to the United States in order to gain approval for substandard generic antiretroviral drugs, which were purchased under the President's Emergency Plan for AIDS Relief. As a result of this conduct, Ranbaxy entered into an extensive consent decree with FDA, which includes extensive auditing, monitoring, and review of Ranbaxy's current Good Manufacturing Practices and data integrity program.

Oklahoma – Wyeth Pharmaceuticals, Inc., a subsidiary of Pfizer, Inc., agreed to pay \$490 million to resolve its criminal and civil liability arising from its unlawful marketing of the drug Rapamune. Rapamune is an immunosuppressive drug that prevents the body's immune system from rejecting a transplanted organ. According to published reports, Wyeth received FDA approval in 1999 for Rapamune for use in renal (kidney) transplant patients. However, Wyeth also allegedly trained its sales force to promote Rapamune in nonrenal patients, despite the fact that the drug was not approved by FDA for this use. Wyeth allegedly provided its sales staff with training materials regarding nonrenal transplant use and trained them on how to use these materials in presentations to transplant physicians. In addition, Wyeth allegedly offered financial

incentives to its sales staff to target all transplant patient populations in an effort to increase sales of Rapamune.

New York – As part of a global settlement, ISTA Pharmaceuticals, Inc., agreed to pay \$33.5 million to resolve its criminal and civil liability involving the marketing, distribution, and sales of its drug Xibrom. FDA approved the use of Xibrom, an ophthalmic, nonsteroidal, anti-inflammatory drug, for treating inflammation of post-cataract surgery and for reducing ocular pain after cataract surgery. However, some ISTA employees promoted Xibrom to physicians for uses that were not approved by FDA, such as post-Lasik surgery, post-Photorefractive Keratectomy surgery, post-glaucoma surgery, and other eye-related laser surgeries. Some ISTA employees also provided physicians with post-operative instruction sheets and sponsored medical education programs for uses of Xibrom that were not approved by FDA as safe and effective. ISTA also allegedly instructed employees not to memorialize in writing certain interactions with physicians regarding unapproved new uses and not to leave certain printed materials regarding unapproved uses in physicians' offices in order to prevent their conduct relating to unapproved new uses from being detected. In addition, ISTA allegedly offered and paid kickbacks to physicians in order to induce them to prescribe Xibrom.

03 FDA—Use of High-Risk Compounded Sterile Preparations (CSPs) and Outsourcing by Hospitals That Use Them. The use of CSPs is widespread in hospitals, although the use of the highest risk products is limited to about one-quarter of hospitals, most commonly larger facilities.

Pharmaceutical compounding is the creation of prescription drugs tailored to meet the needs of individual patients. This work was particularly important following the meningitis outbreak resulting from contaminated injections of compounded drugs. An OIG survey revealed that in 2012, use of the highest risk CSPs—those involving preparation of sterile products from nonsterile components—is limited to about one-quarter of hospitals, most commonly larger facilities.

Although most hospital pharmacies prepared sterile-to-sterile products onsite, hospitals outsource the preparation of most nonsterile-to-sterile CSPs. Hospitals tend to rely upon a limited number of external pharmacies for CSPs, especially for nonsterile-to-sterile products. Often these pharmacies are located in other States. We found that hospitals took limited steps to ensure the quality of outsourced CSPs but had few identified problems with the quality of CSPs from outside pharmacies. Also, 56 percent of hospitals made changes, or planned to make changes, to CSP sourcing practices in response to the fall 2012 meningitis outbreak.

We did not make formal recommendations to FDA. We plan additional work to further examine the safety and quality of pharmaceutical compounding in hospitals, including work examining Federal oversight mechanisms.

2013 APR High-Risk Compounded Sterile Preparations and Outsourcing by Hospitals That Use Them. [OEI-01-13-00150](#).

04 FDA—Clearance of Medical Devices. FDA should complete the classification process for all types of Class III preamendment medical devices; classification of such devices is in progress.

Medical devices are those used in diagnosis, cure, mitigation, treatment, or prevention of disease. FDA is required to classify devices by the level of control needed to provide reasonable assurance of device safety and effectiveness (i.e., Class I, II, or III). Class I devices include tongue depressors and stethoscopes and Class II devices include syringes and electrocardiographs. Class III devices support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury; implantable pacemakers and atrial defibrillators are examples of Class III devices.

FDA's premarket notification process (the 510(k) process) is a faster and less stringent method to obtain clearance to market medical devices than its Premarket Approval process (the PMA process). Class I and Class II devices are reviewed under the 510(k) process. Pursuant to the 510(k) process, sponsors do not have to submit scientific evidence demonstrating that the device is safe and effective for its intended use, as is required under the PMA process. Instead, sponsors must submit information demonstrating a device's substantial equivalence to a device already being legally marketed (i.e., the predicate device). Most Class III devices must be approved through the PMA process, although some continue to be cleared through the 510(k) process using regulatory categories of devices (Class III preamendment device types). The Safe Medical Devices Act of 1990 requires FDA to either reclassify Class III preamendment device types as Class II or I or keep them as Class III and require a PMA review.

Consistent with the Food and Drug Administration Safety and Innovation Act of 2012, FDA should finish classifying Class III preamendment device types no later than July 9, 2014. We found that as of July 9, 2012, FDA had not finished classifying all types of Class III preamendment devices. Also, FDA had not consistently documented the review of devices it had cleared through the 510(k) process in 2010 and had not provided complete administrative files during our data collection, thereby demonstrating deficiencies in its filing system. An adequate process for maintaining administrative files requires transparency regarding the location of documents and the completeness of the files. The lack of such a process could lead to confusion and human error.

We recommended that FDA

- finish classifying the remaining types of Class III preamendment devices that include devices still used as predicates in the 510(k) process, improve its maintenance of administrative files for devices, and continue to implement new policies on how to compile an administrative file.

*2013 SEP FDA's Clearance of Medical Devices Through the 510(k) Process.
OEI-04-10-00480.*

05 HRSA—Health Center Program Funds. At two grantee organizations in Wisconsin and New York, Federal funds were found at risk of not being properly accounted for or not being used in accordance with requirements.

The Health Center Program, consolidated under section 330 of the Public Health Service Act, 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.” The Health Resources and Services Administration administers the program.

Also, the American Recovery and Reinvestment Act of 2009 (Recovery Act) provided funding to support the Health Center Program. HRSA received \$2.5 billion—\$2 billion of which was to expand the Health Center Program by serving more patients, stimulating new jobs, and meeting the expected increase in demand for primary health care services among the Nation’s uninsured and underserved populations. HRSA awarded a number of grants using Recovery Act funding, including Increased Demand for Services (IDS) and Capital Improvement Program (CIP) grants.

Wisconsin. Our review of a grantee organization in Wisconsin found that the IDS and CIP costs were allowable, but we questioned certain section 330 costs. The grantee organization did not maintain a financial management system that adequately identified the source and application of costs and did not adequately support, with personnel activity reports, the distribution of salaries and wages. The grantee did not have policies and procedures to ensure that the use of grant funds complied with Federal requirements. As a result, we could not determine the allowability of salary, wage, and fringe benefit costs. We also found misappropriation of program income.

With regard to the Wisconsin grantee, we recommended that HRSA impose special award conditions on the Wisconsin grantee so that it takes corrective actions to ensure that financial records adequately identify the source and application of Federal program funds, ensure that personnel activity reports for employees working on Federal awards are maintained, and ensure that segregation of duties is adequate to safeguard assets. We also recommended that HRSA require the grantee to refund the improperly claimed costs we estimated or work with the grantee to determine whether any of the costs were allowable. HRSA should ensure that any monetary recoveries related to misappropriated funds are applied to services and activities consistent with the scope of the health center program. Savings Potential—We questioned almost \$6 million in claimed costs and \$754,731 in misappropriated program income.

2013 APR Milwaukee Health Services, Inc., Claimed Unallowable Costs Under Health Resources and Services Administration Grants. [A-05-12-00015](#).

New York. Our review of a grantee organization in New York revealed that it misinterpreted the grant award terms and conditions and claimed unallocable and duplicate costs. We could not determine the allowability of some other costs because it did not properly maintain personnel activity reports for employees charged to the IDS grant. Although the grantee maintained

personnel activity reports for employees who it stated worked on the IDS grant, the employees' personnel activity reports reflected that the employees worked entirely on another HRSA grant (the section 330 grant). In addition, the grantee drew down CIP grant funds for which it did not have an immediate cash need.

With regard to the New York grantee, we recommended that HRSA educate grantee officials in New York on Federal requirements for the proper period to charge costs and supporting salaries and wages, ensure that the grantee maintains personnel activity reports for each employee who works on Federal awards, and ensure that the grantee adheres to its policies and procedures for drawing down Federal funds. HRSA should also require the grantee to refund amounts we estimated related to the IDS and CIP grants or work with the grantee to determine whether any of the costs claimed against the grant were allowable. Savings Potential—We questioned over \$1.6 million in costs.

2013 APR Mount Vernon Neighborhood Health Center, Inc., Claimed Unallowable Federal Grant Expenditures. A-02-11-02013.

06 HRSA—Health Education Assistance Loan Program. OIG excludes individuals who have defaulted on HEAL loans from participation in Federal health care programs.

Under the Health Education Assistance Loan (HEAL) program, the Health Resources and Services Administration 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 of such individuals from Medicare, Medicaid, and all other Federal health care programs for nonpayment of the loans.

Exclusion means that the individual may not receive reimbursement under these programs for professional services rendered, nor may any other provider receive reimbursement for services ordered or prescribed by the 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, 37 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 2,502 individuals chose to enter into settlement agreements or completely repay their debts. That figure includes 22 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 \$195 million. Of that amount, \$4.3 million is attributable to this semiannual reporting period.

07 NIH—Clinical Trials Data and Safety Monitoring Boards (DSMBs).

Although DSMBs meet guidance, issues concerning independence, access to certain data, and recruitment and training of experts challenge DSMB effectiveness.

DSMBs are committees of experts responsible for reviewing clinical trial data on an ongoing basis to ensure the safety of study subjects and validity and integrity of the data. Although DSMBs for National Institutes of Health (NIH) clinical trials are generally meeting operational guidelines, we found some issues concerning independence, access to certain data, and recruitment and training of experts.

In particular, we found that NIH participation in closed DSMB meetings diminishes the appearance of independence; NIH faces challenges in recruiting and training DSMB members; and not all of NIH's Institutes and Centers' (IC) policies reference DSMB access to "unmasked data" (meaning DSMB members know which subjects are in which treatment group—something the researchers and subjects themselves do not generally know). Unmasked data is essential to DSMBs' ability to review evidence of adverse events and interim treatment outcomes to recommend whether trials should be continued, altered, or terminated.

We recommended that NIH

- direct ICs to articulate the circumstances in which IC staff should participate in DSMB meetings, direct ICs to explicitly reference DSMB access to certain data in their DSMB policies, and identify ways to recruit and train new DSMB members.

2013 JUN Data and Safety Monitoring Boards in NIH Clinical Trials: Meeting Guidance But Facing Some Issues. [OEI-12-11-00070](#).

08 NIH—University Management of Grant Funds. Not all of the selected costs that were charged to HHS awards by a university grantee were allowable.

This audit was limited to grants, contracts, and other agreements between the University of Colorado Denver and certain HHS agencies: NIH, CDC, and HRSA. We did not evaluate transactions charged to the university's agreements with other Federal departments and agencies. The majority of our sample transactions related to NIH awards.

The university's oversight did not ensure that all costs claimed were allowable. Although its finance and accounting procedures often incorporated text from the applicable cost principles, the University left it largely to the discretion of its individual colleges, departments, and principal investigators to interpret the university's policies and procedures for correctly charging costs to Federal awards and complying with Federal regulations and guidance.

Savings Potential— Savings could be realized from improved oversight and from recoveries of questioned costs. Of about \$42.4 million in costs covered by our review, we estimated that the University improperly charged at least \$1.2 million in unallowable salary and nonsalary costs to HHS awards during FY 2010. We also estimated that it improperly charged other unallowable costs totaling about \$185,000 for two awards.

We recommended that the university

- exercise more stringent oversight of charges to Federal awards to ensure compliance with Federal regulations and refund questioned amounts to the Federal Government.

2013 JUN The University of Colorado Denver Did Not Always Claim Selected Costs Charged Directly to Department of Health and Human Services Awards in Accordance With Federal Regulations. A-07-11-06013.

09 SAMHSA—Grants Management. A Massachusetts grantee failed to meet requirements or fully support its claimed costs.

The Substance Abuse and Mental Health Services Administration is the principal Federal agency charged with increasing access to substance abuse and mental health services. The Children’s Health Act of 2000 created and reauthorized programs for such services. SAMHSA provides funding for the services to States, political subdivisions of States, Indian tribes and tribal organizations, and other public or nonprofit private entities.

We found that a nonprofit organization in Massachusetts claimed costs that were unallowable under the terms of the grant and inadequately supported salary and related fringe benefit and overhead costs, e.g., it did not prepare personnel activity reports for employees whose time was charged to the grant. Further, the grantee inappropriately allocated costs for facilities charges and related overhead costs on the basis of the grant award budgets instead of on the basis of the relative benefit of the grant awards received.

Savings Potential—Savings could be realized from improved procedures and methodologies and from recoveries of questioned costs. We questioned about \$1.3 million on the basis of our sample.

We recommended that SAMHSA

- require the grantee to develop written procedures for reporting time-and-effort on the basis of actual effort expended on programs and develop a documented methodology for allocating facility costs on the basis of the relative benefits received to all of its locations. Also, SAMHSA should either require grantee to refund to the Federal Government the amounts we questioned or work with the grantee to determine whether any of the costs it claimed were allowable.

2013 APR Latin American Health Institute Did Not Always Claim Costs in Accordance With Federal Requirements. A-01-12-01501.

Human services reviews

Significant problems, abuses, and deficiencies:

01 ACF—License-Exempt Child Care Providers in the Child Care and Development Fund (CCDF) Program. Gaps in health and safety requirements and gaps in monitoring represent vulnerabilities that could lead to harm for children in care.

Pursuant to the Child Care and Development Block Grant Act of 1990 and the Social Security Act, § 418, the CCDF program assists low-income families; families receiving temporary public assistance; and families transitioning from public assistance to obtain child care so that family members can work, attend training, or receive education.

States are required to have health and safety standards in place for all providers. The standards must cover three areas: prevention and control of infectious disease, building and physical premises safety, and health and safety training.

States may and do exempt many kinds of providers from licensing, for example, individuals who provide child care services in the child's own residence and providers caring for relatives. Such providers, however, are still required to adhere to Federal health and safety requirements in order to be eligible for CCDF payments.

We found that not all States required license-exempt child care providers to meet Federal health and safety requirements. Further, we found insufficient procedures in effect to ensure that license-exempt child care providers comply with applicable State or local health and safety requirements. Some States reported allowing providers to self-certify compliance and reported limited monitoring, limited use of background checks, and provider nonreporting of serious injuries.

We believe that these gaps in health and safety requirements and gaps in monitoring represent vulnerabilities that could lead to harm for children in care, including care financed by the Federal Government.

We did not issue formal recommendations. ACF issued a proposed rule that included regulations to strengthen health and safety requirements for and oversight of CCDF providers. (78 Fed. Reg. 29441 (May 20, 2013).)

2013 JUL License-Exempt Child Care Providers in the Child Care and Development Fund Program. [OEI-07-10-00231](#).

02 ACF—Child Care and Development Funds in Connecticut. Providers did not always comply with applicable State licensing requirements to ensure the health and safety of children.

We audited 20 licensed family day care homes (providers) that received CCDF funding in Connecticut to determine whether health and safety risks exist at those locations.

Although Connecticut conducted the required inspections at all of the 20 providers that we reviewed, the State’s onsite monitoring did not ensure that providers that received CCDF funds complied with State licensing requirements related to the health and safety of children. We determined that all 20 of the providers that we reviewed did not comply with 1 or more State licensing requirements to ensure the health and safety of children. Specifically, we found that 19 of the 20 providers did not always comply with 1 or more requirements related to the physical conditions of the family homes and that 8 of the providers did not comply with required criminal records and protective services checks. Two of the providers voluntarily surrendered their licenses after our review.

We recommended that Connecticut

- ensure, through more frequent onsite monitoring, that providers comply with health and safety regulations; develop a mandatory training program to improve provider compliance with health and safety regulations; and further define “household member” for the purposes of criminal record and protective services check requirements by adding examples of situations when it would be necessary for a provider to contact the State licensing agency and obtain the required checks.

2013 SEP Connecticut Family Day Care Home Providers Did Not Always Comply With State Health and Safety Licensing Requirements. (A-01-12-02504).

03 ACF—Child Care and Development Funds in Nebraska. Nebraska’s policies and procedures were inadequate to correctly identify allowable expenditures.

CCDF provides discretionary funding for three targeted funds known as Infant and Toddler, Quality, and School Age Resource and Referral funds. These targeted funds are used for activities that improve the availability, quality, and affordability of child care and for supporting the administration of these activities. The funds are 100 percent federally funded.

Nebraska improperly obligated targeted funds after the obligation period had ended, improperly claimed expenditures that were not for targeted funds activities, and did not refund to the Federal Government targeted funds that either were returned by the grantee after the obligation period had ended or remained unliquidated after the liquidation period ended. The errors occurred because Nebraska did not have policies and procedures in place to direct adequate oversight of the obligation and liquidation of the targeted funds. In the absence of

necessary policies and procedures, it could not correctly identify which expenditures would be allowable for a particular fiscal year.

Savings Potential—Savings could be realized from improved practices and recoveries of questioned costs. During a 5-year audit period, Nebraska claimed Federal reimbursement for an estimated \$2.9 million of unallowable CCDF.

We recommended that Nebraska

- develop policies and procedures to monitor the obligation and liquidation of CCDF targeted funds to ensure that expenditures are properly obligated and liquidated. Nebraska should also refund to the Federal Government targeted funds that were not properly obligated, expenditures that were not for targeted funds activities, and targeted funds that were returned by the grantee after the obligation period had ended or were not properly liquidated.

2013 APR Nebraska Improperly Claimed Some Child Care and Development Targeted Funds. A-07-12-03175

04 ACF—Child Support Enforcement.

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

Because of the success of OIG's Most Wanted Fugitives Web site, OIG 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. The Web site lists deadbeat parents and is updated frequently. The site includes information on OIG's role in pursuing parents who fail to pay court-ordered child support and has a reporting button to turn in deadbeat parents.

OIG investigations of child support cases nationwide resulted in 32 criminal actions and court-ordered restitution and settlements of \$2.1 million during this semiannual period. Following are examples of child support enforcement cases.

New York – Robert Sand was sentenced to 2 years and 7 months of incarceration and ordered to pay \$903,789 in restitution after pleading guilty to charges of failure to pay child support for his two children. Sand was arrested after accruing more than \$1 million in unpaid child support obligations, penalties, and interest. According to court documents, Sand admitted that he initially relocated from New York to Florida and then fled the United States in order to evade his child support obligations following the issuance of arrest warrants in both State and Federal courts in 2000 and 2002. Sand was profiled on OIG's Web site of OIG Most Wanted Fugitives. While overseas, Sand operated a business in Thailand, but was arrested upon entering the Philippines without proper identification documents. In December 2012, he was returned to the United States, where he was taken into custody and arraigned.

New York – George Ely was sentenced to 12 months and 1 day of incarceration and ordered to pay \$8,934 in restitution after pleading guilty to charges of failure to pay lawful child support. From August 2006 through April 2010, Ely failed to make any child support payments for his child, despite the fact that he held several jobs during that time. Ely pleaded guilty to the failure to pay child support charge in October 2011, but he then failed to appear for his sentencing on several occasions. Ely was deemed a fugitive and posted on HHS OIG’s child Support Enforcement Web site. In February 2013, Ely was apprehended, was charged, and pleaded guilty to charges of failure to appear.

Indiana – Theodore Cerneant, Jr., was sentenced to 4 years of probation and ordered to pay \$66,614 in restitution after pleading guilty to charges of failure to pay child support. In May 2002, Cerneant was ordered by the Macomb County Circuit Court in Michigan to pay child support for his child. According to court documents, Cerneant’s last child support payment was in February 2010 and his payments prior to that date were infrequent and insufficient, despite the fact that he was gainfully employed at that time. After the child support court order, the mother and child moved to Indianapolis, Indiana, while Cerneant moved to Columbia, South Carolina.

05 ACF—Identity Theft. A recipient of Temporary Assistance to Needy Families concealed earnings by using his son’s social security number.

Maine – Mark Judd was sentenced to 4 years of imprisonment and ordered to pay \$29,791 in restitution after pleading guilty to charges of theft of Federal funds, social security fraud, aggravated identity theft, and a false statement on a loan application. According to court records, in 2003, Judd began receiving welfare assistance from the State of Maine. Between August 2010 and April 2012 and during the time when he was still employed, Judd received Temporary Assistance to Needy Families, Supplemental Nutrition Assistance Program (SNAP) benefits, and MaineCare from the Maine Department of Health & Human Services because he concealed his earnings by using his son’s social security number. TANF is an HHS-funded program designed to help needy families achieve self-sufficiency. SNAP is a nutrition assistance program administered by the Department of Agriculture. Judd also received housing benefits and an automobile loan using his child’s social security number. In August 2010, Judd began working, but he continued to receive welfare assistance by using his son’s social security number on his job and job-related tax forms. Judd also used his son’s social security number while employed at another job in 2011.

06 ACL—Senior Medicare Patrol (SMP). OIG’s annual report of performance data indicates that despite fewer volunteers, the ACL-funded SMP program increased its public contacts to combat Medicare waste, fraud, and abuse.

SMP projects receive grants from the Administration for Community Living to recruit and train retired professionals and other senior citizens to recognize and report instances or patterns of

health care fraud. In 2012, the 54 SMP projects had 5,137 active volunteers, a 9-percent decrease from 2011. Despite the decrease, the volunteers conducted 113,457 one-on-one counseling sessions and 14,748 group education sessions, a 71-percent and 33-percent increase from 2011, respectively.

In 2012, for the first time the SMP performance measures included expected recoveries (i.e., investigative receivables) from criminal actions, settlements, civil judgments, or overpayments that resulted in part from SMP activities. Expected recoveries represent the amount of money that was ordered or agreed upon to be returned or paid and better reflects the impact of SMPs' work and the potential savings to Medicare, Medicaid, and beneficiaries. The SMPs reported nearly \$6 million in expected recoveries identified in 2012.

However, there was a more than 50-percent decrease in cost avoidance on behalf of the Medicare, Medicaid, beneficiaries, and others. Cost avoidance means the person, program, or entity was relieved of responsibility for payment as a result of the projects—for example, when a beneficiary discovers charges for services he or she did not receive and, on behalf of the beneficiary, a project contacts the provider and a corrected billing statement is issued.

We continue to emphasize that it is not always possible to track referrals to Medicare contractors or law enforcement from beneficiaries who have learned to detect fraud, waste, and abuse from the projects. Therefore, the projects may not be receiving full credit for savings attributable to their work. In addition, the projects are unable to track the substantial savings derived from a sentinel effect whereby fraud and errors are reduced by Medicare beneficiaries' scrutiny of their bills.

We did not make formal recommendations to ACL. OIG annually reviews and reports SMP projects' performance.

2013 JUL Performance Data for the Senior Medicare Patrol Projects: July 2013 Performance. [OEI-02-13-00170](#).

Other HHS issues

Significant problems, abuses, and deficiencies:

01 Affordable Care Act—Consumer Operated and Oriented Plan Program Loans (CO-OPs). CMS awarded loans in accordance with Federal requirements, but startup funding is at risk of being exhausted before CO-OPs become operational; we found little evidence of private support to loan applicants.

The Patient Protection and Affordable Care Act (Affordable Care Act), § 1322, established the Consumer Operated and Oriented Plan (CO-OP) program to provide loans to help establish new consumer-governed, nonprofit health insurance issuers, referred to as CO-OPs. We reviewed the CO-OP program because of the large amount of funding for this new program and the short timeframe in which the CO-OPs must be established and initiated. Total appropriated funding for the CO-OP program is approximately \$2 billion.

CMS awarded loans in accordance with Federal requirements. However, we identified several factors that could affect the CO-Ops. Private support is one of the three selection factors that the Affordable Care Act specifies will have priority in the selection process. We saw little evidence of private monetary support in any of the 16 applications we reviewed. Additionally, 11 of 16 CO-OPs reported estimated startup expenditures in their applications that exceeded the total startup funding ultimately provided by CMS. If unforeseen circumstances (such as limited enrollment) or barriers (such as uncertainty about operations of State-based or federally facilitated marketplaces or a State's denial of insurance licensure) impede CO-OPs from becoming operational, there is a risk that CO-OPs could exhaust all startup loan funding before they are fully operational or before they earn sufficient operating income to be self-supporting. This may affect the CO-OP program in the long term.

We recommended that CMS

- monitor CO-OPs to ensure that startup funds are not exhausted before the CO-OPs become fully operational and monitor CO-OPs' solicitation of additional private monetary support.

2013 JUL The Centers for Medicare & Medicaid Services Awarded Consumer Operated and Oriented Plan Program Loans in Accordance With Federal Requirements, and Continued Oversight Is Needed. [A-05-12-00043](#).

02 Affordable Care Act—CO-OP Implementation. As new entities, CO-OP entities had made progress, meeting 90 percent of milestones; however, they may face financial and operational challenges in a competitive insurance market; unpredictable factors create risk.

We found that despite challenges, CO-OPs have made progress toward achieving licensure and met 90 percent of their milestones during the period of our review. CMS's oversight strategy includes frequent monitoring and early intervention to ensure that CO-OPs adhere to program requirements and goals. Although CO-OPs appear to be making progress, at the time of our review, they were still hiring staff, obtaining licensure, and building necessary infrastructure. The extent to which any particular CO-OP can achieve program goals depends on a number of unpredictable factors, such as each State's Exchange operations, market competition, and enrollment. As of January 2, 2013, the Centers for Medicare & Medicaid Services had awarded loans totaling \$1.98 billion to 24 CO-OPs.

This report, which is primarily informational, did not include formal recommendations to CMS.

2013 JUL Early Implementation of the Consumer Operated and Oriented Plan Loan Program. [OEI-01-12-00290](#).

03 Affordable Care Act—Health Insurance Exchange Data Services Hub. During the development of the Data Services Hub, CMS was addressing

and testing security controls; several critical information security tasks were in progress at the time of review.

This review assessed the information technology (IT) security controls that CMS was implementing for the Hub, adequacy of the testing activities being performed during its development, and the coordination between CMS and Federal and State agencies during the development of the Hub.

At the time of our review, CMS and its contractors were continuing to develop the Hub and work with its Federal and State partners in testing the Hub to ensure its readiness in time for the initial open enrollment, which was scheduled to begin on October 1, 2013.

At the time of our review, several critical tasks remained to be completed in a short period of time, such as the final independent testing of the Hub's security controls, remediating security vulnerabilities identified during testing, and obtaining the security authorization decision for the Hub.

This report, which is primarily informational, did not include formal recommendations to CMS.

2013 AUG Observations Noted During the OIG Review of CMS's Implementation of the Health Insurance Exchange—Data Services Hub. A-18-13-30070.

04 Oversight of Insurers' Submissions to Plan Finder in 2011-2012.

Though most data displayed on the Plan Finder matched the information provided by insurers' representatives, vigilant oversight will be needed.

The Plan Finder was the first comprehensive, online portal that assists consumers in comparing their health insurance coverage options. All private health insurers in the individual and small group markets were required to submit information to populate the Plan Finder. The data collection to populate the Plan Finder represented the first national attempt to identify these insurers and the products and plans they offer.

To realize the benefits of expanded consumer information, the data must be complete and accurate. We found that when products and plans were available and recognized on the Plan Finder, 81 percent of the data displayed on the Plan Finder matched the information provided by insurers' representatives. Most private insurers reported data to the Plan Finder. However, gaps existed in compliance with reporting requirements. The data displayed on the Plan Finder for the sample of products and plans contained some inconsistencies that could confuse consumers. The products and plans displayed were not always available for sale or were not always recognized by insurers' representatives.

We recommended that CMS

- establish and implement procedures to identify and pursue private insurers that do not submit required data, ensure that each private insurer's Chief Executive Officer or Chief Financial Officer certifies to the completeness of data submitted, design and implement

additional strategies to ensure data accuracy, and validate that products and plans submitted are available for sale.

2013 APR *Oversight of Private Health Insurance Submissions to the HealthCare.gov Plan Finder.* [OEI-03-11-00560](#).

05 Non-Federal Audits. OIG reviews audits conducted by non-Federal auditors of entities receiving Federal awards.

In this semiannual period, OIG’s National External Audit Review Center reviewed 1,472 reports covering \$2.3 trillion in audited costs. Federal dollars covered by these audits totaled \$716.3 billion, of which about \$289.8 billion were HHS funds.

Office of Management and Budget Circular A-133 establishes audit requirements for State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards. Under this circular, covered entities must conduct annual organization-wide “single audits” of all Federal money they receive. These audits are conducted by non-Federal auditors, such as public accounting firms and State auditors.

OIG reviews the quality of these audits and assesses the adequacy of the entities’ management of Federal funds.

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

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

Non-Federal Audits, April 1, 2013, through September 30, 2013

Number of Non-Federal Audits:

➤ Not requiring changes or having minor changes	1,376
➤ Requiring major changes	90
➤ Having significant technical inadequacies	6
Total	1,472

The 1,472 reports included 3,184 recommendations for improving management operations. In addition, these audit reports provided information for 44 OIG special memorandums that identified concerns for increased monitoring by management.

06 HHS Grant Funds—Misuse. The director of a nonprofit organization based in Maine conspired to divert HHS grant funds to personal use.

Maine – Thomas Nelson was sentenced to 2 years and 6 months of incarceration and ordered to pay more than \$1.3 million in restitution after pleading guilty to charges of conspiracy to embezzle funds from a federally funded program and tax evasion. Nelson was the executive director of the York County Community Action Corporation (YCCAC), a nonprofit organization based in Maine that purportedly provided social service, health, and educational programs to York County individuals and families living in poverty. Between 2006 and 2011, YCCAC received more than \$25 million in Federal funds from HHS, including funds awarded under the American Recovery and Reinvestment Act of 2009.

According to court documents, between 2005 and 2009, Nelson conspired with a consulting firm to divert approximately \$413,000 from YCCAC to the firm in a kickback scheme. Specifically, Nelson directed payments to the consulting firm that overpaid the firm relative to the amount of work actually performed. In addition, Nelson diverted and caused to be diverted more than \$400,000 from YCCAC and York County Financing to a previously defunct nonprofit organization, New England Community Action Association (NECAA). NECAA acted as a joint resource for community action programs in New England. However, it had not conducted business in years until Nelson acted as treasurer and began diverting YCCAC funds through NECAA. Nelson used these funds to pay personal expenses, including credit card payments, personal mortgage payments, and gambling debts. Nelson admitted that he recorded fraudulent payments as donations, consulting, or other expenses on the YCCAC books. He also admitted to forging the signature of a YCCAC employee on the checks payable to NECAA.

07 HHS Contract Audits. Reporting requirement.

National Defense Authorization Act for Fiscal Year 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 section 845 criteria during this semiannual period.

08 Recovery Act Retaliation Complaint Investigations. Reporting requirement.

The Recovery Act, § 1553, prohibits non-Federal employers that have received Recovery Act funding from retaliating against employees who disclose evidence of mismanagement of

Recovery Act funds or any violation of law related to Recovery Act funds. OIGs are required to include in their *Semiannual Reports to Congress* the retaliation complaint investigations that they decided not to conduct or continue during the reporting period. During this reporting period, OIG closed an investigation into an HHS grantee after determining that the complaint did not involve Recovery Act funds.

09 Legislative and Regulatory Reviews. Reporting requirement.

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.

10 Employee Misconduct—Abuse of Retention Bonuses.

District of Columbia – Michael Balady was sentenced to 6 months of incarceration and ordered to pay \$94,940 in restitution after pleading guilty to charges of wire fraud. Balady worked in HHS's Office of the Assistant Secretary for Preparedness and Response (ASPR) as the director of Acquisition Management Systems in ASPR's Biological Advance Research and Development Authority. HHS is authorized to give monetary incentives, or "retention bonuses," to employees deemed essential to its mission who would likely leave in the absence of such a bonus. Requirements for receiving a retention bonus include producing a current offer of employment

for a position in the private sector or another government agency. According to court documents, from October 2008 through around June 2012, Balady conspired with a colleague in the private sector to fabricate employment offers from the colleague's communications firm in order for Balady to receive fraudulent retention bonuses from HHS. Specifically, Balady requested and received on several occasions for the colleague to provide him with a fake job offer. Balady then submitted the fake offer to HHS human resources personnel, and consequently, received a \$30,000 or more retention bonus. In total, Balady received \$94,940 in retention bonuses due to these fake job offers, and he submitted a fraudulent request for an additional \$38,875 bonus that was prevented by the OIG investigation.

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Appendixes

- A Savings Decisions Supported by OIG Recommendations
- B Questioned Costs and Funds To Be Put to Better Use
- C Peer Review Results
- D Summary of Sanction Authorities
- E Reporting Requirements in the Inspector General Act of 1978
- F Anti-kickback Statute—Safe Harbors

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Appendix A

Savings Decisions Supported by OIG Recommendations

The table below lists policy decisions reflected in legislation, regulations, or other directives from prior periods that are supported by Office of Inspector General (OIG) recommendations and for which cost savings were estimated, usually by third parties, such as the Congressional Budget Office (CBO) or actuaries of the Department of Health and Human Services (HHS). Of the savings estimated for the decisions below, nearly \$19.4 billion was attributed to fiscal year (FY) 2013. This figure reflects the most recent available savings estimates issued by the third party appraiser; actual savings may be higher or lower.

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

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

Centers for Medicare & Medicaid Services (CMS) Programs

OIG Recommendations	Policy Decisions	Estimated Savings (millions)
<p>Medicare Part C Prepayments. Modify monthly capitated payments to a level fully supported by empirical data. The recommendation reflected findings in OIG report number A-14-00-00212.</p>	<p>Section 3201 of the Patient Protection and Affordable Care Act (Affordable Care Act) reduced the Medicare Advantage (MA) benchmark percentages that are applied to Medicare fee-for-service, resulting in cost savings for Part C as compared to prior law. CBO estimated Part C savings through FY 2019, including \$1.8 billion for FY 2011, \$6 billion for FY 2012, and \$9.4 billion for FY 2013. CBO produced</p>	<p>\$9,400</p>

OIG Recommendations	Policy Decisions	Estimated Savings (millions)
<p>Payment Reform for Part B Drugs and Biologicals. Reexamine drug reimbursement methodologies based on average wholesale price (AWP) with the goal of reducing payments in both Medicare and Medicaid. The recommendation reflected findings in the following OIG reports:</p>	<p>its estimate in 2010, prior to two significant implementation decisions by HHS that affect the actual savings; however, neither CBO nor HHS has calculated a revised estimate.¹</p>	
<p>OEI-03-96-00420 OEI-03-97-00290 OEI-03-00-00310 OEI-03-97-00293 A-06-00-00023 A-06-01-00053 A-06-02-00041</p>	<p>Sections 303 through 305 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) revised the current payment methodology for Part B-covered drugs and biologicals that were not paid on a cost or prospective payment basis. Since January 1, 2005, most drug prices have been based on the average sales price or competitive acquisition instead of AWP. CBO estimated savings of \$3.1 billion for FY 2013.</p>	\$3,100
<p>Medicare Secondary Payer. Ensure sufficient resources and contractor training for retroactively examining paid claims to identify other payer sources and initiating recovery action on all related overpayments. The recommendation reflected findings in the following OIG reports:</p>	<p>Section 301 of the MMA clarifies the Secretary’s authority to make certain reimbursable conditional payments and to take recovery actions against all responsible entities, including collection of damages, under Medicare Secondary Payer provisions. This section builds on other program improvements implemented by the Balanced Budget Act of 1997 (BBA), the Omnibus Budget Reconciliation Act (OBRA) 1993, OBRA 1990, and OBRA 1989. CBO estimated</p>	\$1,300
<p>A-02-98-01036 A-04-92-02057 A-09-89-00162</p>		

¹ One implementation decision related to a nationwide quality bonus payment demonstration, which GAO found would reduce MA savings. (See GAO-12-409R.) The other was a change in policy about how HHS calculates the fee-for-service rate against which MA payments are benchmarked that would increase the savings associated with the reduced benchmark. (See CMS’s Medicare Advantage Rate Announcement from April 1, 2013.)

OIG Recommendations	Policy Decisions	Estimated Savings (millions)
A-10-86-62005	savings of \$1.3 billion for FY 2013.	
<p>Clinical Diagnostic Laboratory Tests. Seek legislation to allow across-the-board adjustments in Medicare laboratory fee schedules, bringing them in line with the prices that laboratories charge physicians in a competitive marketplace, and periodically evaluate the national fee schedule levels. The recommendations reflected findings in the following OIG reports: A-09-89-00031 and A-09-93-00056.</p>	<p>Section 628 of the MMA froze annual updates for FY 2004 through FY 2008. This action builds on prior legislative actions in the BBA, OBRA 1993, OBRA 1990, and legislation in 1984 that were also responsive to OIG’s recommendations to curb excessive clinical laboratory test reimbursements by Medicare. CBO estimated savings of \$1.3 billion for FY 2013.</p>	\$1,300
<p>Medicare Home Health Payments. Reduce the Home Health Agency update factor to account for the high error rate found in OIG’s review. The annual update was defined as the home health market basket percentage increase. The recommendation reflected findings in OIG report number A-04-99-01194.</p>	<p>Section 701 of the MMA changed the updates of home health rates from fiscal year to calendar year beginning in 2004, with the update for the last three quarters of 2004 equal to the market basket increase minus 0.8 percent. CBO estimated savings of \$1.1 billion for FY 2013.</p>	\$1,100
<p>Payments for Durable Medical Equipment. Take steps to reduce payments for a variety of durable medical equipment and related supplies. The recommendation reflected findings in the following OIG reports: OEI-03-01-00680 OEI-03-02-00700 OEI-07-96-00221 OEI-03-96-00230 OEI-03-94-00021 OEI-06-92-00861 OEI-06-92-00866</p>	<p>Section 302 of the MMA froze payments for certain items, including prosthetics and orthotics, effective January 1, 2004. CBO estimated savings of \$1 billion for FY 2013.</p>	\$1,000
<p>Payment for Services Furnished in Ambulatory Surgical Centers (ASCs).</p>	<p>Section 626 of the MMA limited the ASC update starting April 1, 2004, then froze</p>	\$500

OIG Recommendations	Policy Decisions	Estimated Savings (millions)
<p>Set rates that are consistent across sites and that reflect only the costs necessary for the efficient delivery of health services, and establish parity among ambulatory surgical centers (ASC) and outpatient departments. The recommendation reflected findings in the following OIG reports:</p> <p>OEI-05-00-00340 OEI-09-88-01003 A-14-98-00400 A-14-89-00221</p>	<p>updates for a period beginning the last quarter of FY 2005, effectively reducing the payment advantage to ASCs for those procedure codes that are paid at a higher rate for the surgical center compared to the rate for outpatient departments. Section 626 also mandated that CMS implement a new payment system that takes into account disparities in the costs of procedures performed in ASCs and in hospital outpatient departments. CBO estimated savings of \$500 million for FY 2013.</p>	
<p>Excessive Medicaid Payments to New York Developmental Centers. Ensure that New York’s Medicaid daily rate for State-operated developmental centers meets the Federal requirement that payment for services be consistent with efficiency and economy. The recommendation reflected findings in OIG report number A-02-11-01029.</p>	<p>New York’s Medicaid State Plan Amendment 12-03, effective April 1, 2013, limits payment to costs with projected savings of nearly \$1.2 billion in FYs 2013 and 2014 (\$399 million for FY 2013). The State expects to issue another amendment for FYs 2015–2017 with additional savings for those years, projected at \$799 million per year.</p>	\$399
<p>Part B Drugs Average Sales Price. Adopt an alternate calculation of volume-weighted average sales price (ASP) that is consistent with the results set forth in section 1847A(b)(3) of the Social Security Act. The recommendation reflected findings in OIG report number OEI-03-05-00310.</p>	<p>Section 112 of the Medicare, Medicaid, and State Children’s Health Insurance Program (SCHIP) Extension Act of 2007 establishes a revised method for calculating volume-weighted ASPs for Medicare Part B drugs that comports with OIG’s recommendation. CBO estimated savings of \$300 million for FY 2013.</p>	\$300
<p>Reductions in Medicare Bad Debt Reimbursement. Seek legislative authority to eliminate (or reduce) Medicare payments to hospitals for bad debt associated with beneficiaries’ failure to pay their deductibles and coinsurance. The</p>	<p>Section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012 applied percentage reductions in bad debt reimbursement to all providers eligible to receive bad debt reimbursement. CMS estimated savings to Medicare of \$10.92 billion over</p>	\$240

OIG Recommendations	Policy Decisions	Estimated Savings (millions)
<p>recommendations reflected findings in OIG report number A-14-90-00339 and subsequent reviews.</p>	<p>10 years with \$240 million attributed to FY 2013. (77 Fed. Reg. 67523, November 9, 2012.)</p>	
<p>Medicaid Third Party Liability. Determine whether legislation is needed to explicitly include pharmacy benefit management companies in the Medicaid definition of "third party," require third parties to match their eligibility files with Medicaid's eligibility files, and allow Medicaid up to 3 years to recover payments from liable third parties. The recommendations reflected findings in OIG report number OEI-03-00-00030.</p>	<p>Section 6035 of the Deficit Reduction Act (DRA) made several changes to strengthen Medicaid's third-party liability provisions, including clarification regarding pharmacy benefit managers. The section also requires States to ensure that health insurers provide requested coverage data; accept the State's right of recovery; and agree, conditionally, not to deny a claim solely on the basis of date of submission of the claim when the claim is submitted by the State within a 3-year period beginning on the date of service. CBO estimated savings of \$220 million for FY 2013.</p>	\$220
<p>Additional Rebates for Brand-Name Drugs With Multiple Versions. OIG recommended that CMS continue to seek legislative authority to modify the rebate formula calculation to ensure that manufacturers cannot circumvent additional rebates by bringing new versions of existing brand-name drugs to market. The recommendation reflected findings in OIG report number A-06-09-00033.</p>	<p>Section 2501(d) of the Affordable Care Act Affordable Care Act, as amended by section 1206(a) of the Health Care and Education Reconciliation Act of 2010, addresses this issue. CBO estimated savings of \$200 million for FY 2013.</p>	\$200
<p>Capped Rental Durable Medical Equipment. Eliminate the semiannual maintenance payment allowed for capped rental equipment, pay only for repairs that are needed, eliminate the 15-month rental option, and convert rentals to purchases after the 13th month. The recommendations reflected</p>	<p>Section 5101 of the DRA revised the payment rules for capped rental equipment to require that ownership of the item transfer to the beneficiary after the 13th month and that Medicare pay for maintenance services on a cost-reimbursement basis. CBO estimated savings of \$200 million for FY 2013.</p>	\$200

OIG Recommendations	Policy Decisions	Estimated Savings (millions)
findings in report number OEI-03-00-00410.		
<p>Medicare Secondary Payer. Implement stronger followup procedures for employers who fail to respond to data requests, exercise civil monetary penalty authority, and seek necessary legislative authority for mandatory data reporting. The recommendations reflected findings in the following OIG reports:</p> <p>A-02-98-01036 A-02-02-01037 A-02-02-01038 A-04-01-07002 A-09-89-00100</p>	Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 amended the Medicare secondary payer provisions of the Social Security Act, § 1862(b), to provide for mandatory reporting for various categories. CBO estimated savings of \$100 million for FY 2013.	\$100
<p>Rebates for Physician-Administered Drugs. Encourage States to take action to collect rebates on physician-administered drugs, especially single-source drugs. States should either use National Drug Codes (NDC) instead of procedure codes or link procedure codes to NDCs for single-source drugs. The recommendations reflected findings in OIG report number OEI-03-02-00660.</p>	Section 6002 of the DRA requires States to provide for the collection and submission of utilization data needed to secure rebates for physician-administered drugs and provides that the utilization data for single source and specified multiple-source physician-administered drugs be submitted using NDC numbers (unless the Secretary specifies an alternative coding system). CBO estimated savings of \$15 million for FY 2013.	\$15

Administration for Children and Families Programs

OIG Recommendations	Policy Decisions	Estimated Savings (millions)
<p>Triennial Reviews of Child Support Orders and Medical Support by Parents. Ensure that more periodic reviews are initiated and take action to increase medical support by</p>	Section 7302 of the DRA required States to adjust child support orders of families enrolled in the Temporary Assistance for Needy Families program every 3 years. Section 7307 requires States to assess	\$25

parents. The recommendations reflected findings in OIG report number OEI-05-98-00100.

the ability of either or both parents to provide medical support for their children. CBO estimated savings (combined) of \$25 million.

<http://oig.hhs.gov>

Appendix B

Questioned Costs and Funds 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 decision, have agreed should not be charged to the Federal Government, commonly referred to as disallowed costs, as part of the expected recoveries in the "Highlights" section at the beginning of OIG's *Semiannual Reports to Congress*. Superscripts indicate end notes.

Table 1 follows.

Table 1 – Audit Reports With Questioned Costs

	Number of Reports	Dollar Value Questioned	Dollar Value Unsupported
Section 1			
Reports for which no management decisions had been made by the beginning of the reporting period ¹	170	\$632,411,000	\$31,424,000
Reports issued during the reporting period	107	\$483,552,000	\$3,534,000
Total section 1	277	\$1,115,963,000	\$34,958,000
Section 2			
Reports for which management decisions were made during the reporting period ^{2,3}			
Disallowed costs	133	\$328,382,000*	\$813,000
Costs not disallowed	8	\$ 27,397,000	\$7,265,000
Total section 2	141	\$355,779,000	\$8,078,000
Section 3			
Reports for which no management decisions had been made by the end of the reporting period (sec. 1 minus sec. 2)	136	\$760,184,000	\$26,880,000
Section 4			
Reports for which no management decisions were made within 6 months of issuance ⁴	50	\$312,126,000	\$23,762,000

* Audit receivables (expected recoveries).

Audit Reports With Funds Recommended To Be Put to Better Use

Recommendations that funds be put to better use mean 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

	Number of Reports	Dollar Value
Section 1		
Reports for which no management decisions had been made by the beginning of the reporting period ¹	20	\$51,491,000
Reports issued during the reporting period	13	\$1,312,683,000
Total section 1	33	\$1,364,174,000
Section 2		
Reports for which management decisions were made during the reporting period:		
Value of recommendations agreed to by management		
Based on proposed management action	17	\$19,691,000
Based on proposed legislative action	0	0
Value of recommendations not agreed to by management	1	\$1,073,000
Total section 2	18	\$20,764,000
Section 3		
Reports for which no management decisions had been made by the end of the reporting period ² (sec. 1 minus sec. 2)	15	\$1,343,410,000

End Notes

Table 1 End Notes

¹ The opening balance was adjusted downward by \$145.6 million because of a reevaluation of previously issued recommendations.

² Revisions to previously reported management decisions included:

- The Centers for Medicare & Medicaid Services (CMS) determined that it could not recoup disallowances totaling \$11,538,177 associated with seven audits because Federal regulations at 42 CFR 405.980(b) prevented it from reopening claims beyond 4 years after its initial determination.
- A-01-10-95476 State of Maine. Subsequent documentation provided by the State identified \$2,865,944 as Federal share refunded by the State during submission of the CMS 64 QE 3/31/20013. Disallowed cost was reduced by \$1,802,249.
- A-05-08-00051, *Review of High-Dollar Payments for Inpatient Services Processed by Wisconsin Physicians Services for CYs 2004 Through 2006-Hospitals With Five or More High-Dollar Payments*. Subsequent review of Wisconsin Physicians Services high-dollar claims resulted in an increase of disallowed cost by \$1,202,954.
- A-05-09-91337 State of Indiana. Subsequent review by CMS determined that faculty physician payments were allowable and reduced disallowed cost by \$26,087,500. In addition, CMS determined that \$10,843,643 was allowable because of an adjustment on the CMS 64 document. Disallowed cost was reduced by total of \$36,931,143.
- A-07-08-03114 *Review of Missouri ACF Training Costs*. As result of an appeal by the State and subsequent review of additional documentation provided, the disallowed cost was reduced by \$2,063,088.
- Not detailed are net reductions to previously reported disallowances totaling \$2,795,462.

³ Included are management decisions to disallow \$42.1 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.

⁴ Because of administrative delays, some of which were beyond management control, resolution of the following 50 audits was not completed within 6 months of issuance of the reports; however, agency management has informed us that the agency is working to resolve the outstanding recommendations before the end of the next semiannual reporting period:

CIN: A-07-12-01116 REVIEW OF MEDICARE PAYMENTS FOR UNLAWFULLY PRESENT
BENEFICIARIES, JAN 2013, \$91,620,548

CIN: A-09-06-00023	REVIEW OF LOS ANGELES COUNTY APPROVAL PROCESS OF RELATIVE FOSTER FAMILY HOMES, OCT 2009, \$45,520,603
CIN: A-07-12-01113	REVIEW OF MEDICARE PAYMENTS FOR INCARCERATED BENEFICIARIES, JAN 2013, \$33,587,634
CIN: A-01-02-00006	REVIEW OF RATE SETTING METHODOLOGY FOR MEDICAID SCHOOL-BASED HEALTH SERVICES - CT, MAY 2003, \$32,780,146
CIN: 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, \$30,595,545
CIN: A-07-10-06004	REVIEW OF PART D DRUGS PRESCRIBED BY EXCLUDED PROVIDERS, DEC 2011, \$15,079,608
CIN: A-03-09-00019	REVIEW OF MEMBERHEALTH'S 2006 AND 2007 DIRECT AND INDIRECT REMUNERATION REPORTS, OCT 2010, \$9,339,013
CIN: A-01-11-00534	NATIONWIDE REVIEW OF INPATIENT REHABILITATION FACILITIES PATIENT ASSESSMENT INSTRUMENTS FOR CALENDAR YEARS 2009 AND 2010, SEP 2012, \$7,700,700
CIN: 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
CIN: A-04-08-03521	AUDIT OF UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS IN TENNESSEE FOR THE PERIOD OCTOBER 1, 1998, TO DECEMBER 31, 2007, FEB 2009, \$5,768,243
CIN: A-03-12-00004	REVIEW OF HORIZON'S 2009 AND 2010 BONA FIDE SERVICE FEES, MAR 2013, \$4,344,417
CIN: A-01-11-02500	REVIEW OF MASSACHUSETTS' TITLE IV-E ADOPTION ASSISTANCE COSTS FOR FEDERAL FISCAL YEARS 2006 THROUGH 2008, AUG 2011, \$4,242,540
CIN: A-04-11-01095	ADMINISTRATIVE AND CLERICAL COSTS CHARGED TO FEDERAL GRANTS AND CONTRACTS, JUL 2012, \$2,977,548
CIN: A-03-11-00002	REVIEW OF NEW ENGLAND JOINT ENTERPRISE 2009 DIR REPORTS, APR 2012, \$2,710,732
CIN: A-07-11-03163	REVIEW OF CCDF TARGETED FUNDS IN IOWA, MAR 2012, \$2,654,238
CIN: A-03-12-00006	REVIEW OF TAHMO'S 2009 AND 2010 BONA FIDE SERVICE FEES, MAR 2013, \$2,355,532
CIN: A-03-12-00007	REVIEW OF ARCADIAN'S 2009 AND 2010 BONA FIDE SERVICE FEES, FEB 2013, \$2,048,967

CIN: A-03-12-00005	REVIEW OF WINDSOR'S 2009 AND 2010 BONA FIDE SERVICE FEES, JAN 2013, \$1,948,737
CIN: A-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
CIN: A-03-12-00008	REVIEW OF XL HEALTH DIR, JAN 2013, \$1,410,342
CIN: A-01-12-02500	REVIEW OF CONNECTICUT'S TITLE IV-E ADMINISTRATIVE/TRAINING COSTS AND MAINTENANCE PAYMENTS, DEC 2012, \$1,316,684
CIN: A-04-12-04019	REVIEW OF NAMIBIA MOH FY 09 PEPFAR COOP AGREEMENT 5UGPS001094-2, JAN 2013, \$807,754
CIN: A-03-11-00501	AUDIT OF SOUTHEASTERN TIDEWATER OPPORTUNITY PROGRAM HEAD START PROGRAM, FEB 2013, \$726,746
CIN: A-02-11-02005	LIMITED HEAD START REVIEW OF INCLUDED EDUCATIONAL SERVICES, JUL 2012, \$588,830
CIN: A-07-11-04181	REVIEW OF THE MEDICARE PAYMENTS TO PROVIDERS FOR THE ORAL FORM OF THE DRUG EMEND FOR JULY 2007 THROUGH DECEMBER 2010, DEC 2012, \$530,769
CIN: A-09-11-01007	REVIEW OF CSBG RECOVERY ACT COSTS CLAIMED BY HI FOR HCAP, FEB 2013, \$513,649
CIN: A-01-11-02505	NEON - HEAD START LIMITED SCOPE REVIEW - ALLOCATING OF COSTS - ARRA, JAN 2012, \$406,434
CIN: 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
CIN: A-06-11-00034	RCA OF THE ECONOMIC OPP. DEV. CORP. OF ATASCOSA, KARNES, WILSON COUNTIES, SEP 2012, \$372,081
CIN: A-01-10-02505	RESULTS OF LIMITED SCOPE REVIEW OF CTE, INC., MAY 2011, \$293,870
CIN: A-05-05-00033	UNDISTRIBUTED CHILD SUPPORT COLLECTIONS - MI, AUG 2006, \$257,859
CIN: A-09-09-00045	RISK ADJUSTMENT DATA VALIDATION OF PAYMENTS MADE TO PACIFICARE OF CALIFORNIA FOR CALENDAR YEAR 2007 (CONTRACT H0543), NOV 2012, \$224,388
CIN: A-05-09-00044	RISK ADJUSTMENT DATA VALIDATION OF PAYMENTS MADE TO PARAMOUNT CARE, INC., FOR CALENDAR YEAR 2007 (CONTRACT NUMBER H3653), SEP 2012, \$205,534

CIN: A-06-09-00012	RISK ADJUSTMENT DATA VALIDATION - PACIFICARE H4590, MAY 2012, \$183,247
CIN: A-04-11-01004	NORTHEAST FLORIDA COMMUNITY ACTION AGENCY, INC.'S CSBG FUNDS AWARDED UNDER THE AMERICAN RECOVERY AND REINVESTMENT ACT OF 2009, SEP 2012, \$165,795
CIN: A-02-09-01014	RISK ADJUSTMENT DATA VALIDATION OF PAYMENTS MADE TO EXCELLUS HEALTH PLAN, INC. FOR CALENDAR YEAR 2007 (CONTRACT H3351), OCT 2012, \$157,777
CIN: A-04-11-03538	HEAD START HIGH RISK GRANTEE - MOBILE COMMUNITY ACTION AGENCY, INC., DEC 2011, \$147,587
CIN: A-09-09-01007	REVIEW OF IDAHO'S TITLE IV-E ADOPTION ASSISTANCE COSTS FOR FEDERAL FISCAL YEARS 2006 – 2008, JUL 2009, \$124,046
CIN: A-06-11-00058	REVIEW OF CSBG ARRA COSTS CLAIMED BY CROWLEY'S RIDGE DEVELOPMENT COUNCIL, AUG 2012, \$115,420
CIN: A-04-11-01010	FLORIDA'S ADMINISTRATION OF CSBG RECOVERY ACT PROGRAM AND COSTS CLAIMED BY THE AGRICULTURAL AND LABOR PROGRAM INC., FEB 2013, \$58,437
CIN: A-05-11-00051	MEDICARE MADE PAYMENTS TO UNITED HEALTHCARE OF WISCONSIN, INC. UNDER PART D FOR DRUGS THAT WERE ALREADY COVERED UNDER PART C, NOV 2012, \$53,439
CIN: A-05-11-00083	REVIEW OF IL CSBG RECOVERY ACT COSTS CLAIMED (CITY OF CHICAGO), MAR 2013, \$40,247
CIN: A-09-12-01000	REVIEW OF CSBG RECOVERY ACT ADMINISTRATIVE COSTS CLAIMED BY HI OFFICE OF COMMUNITY SERVICES, JUN 2012, \$34,861
CIN: A-03-10-03110	TIGER TEAM - CONTRACT HHSN267-2007-00014C, OCT 2011, \$27,707
CIN: A-02-11-02000	DIRECT COST REVIEW - SUNY ALBANY, OCT 2011, \$27,384
CIN: A-09-11-01014	REVIEW OF CSBG RECOVERY ACT COSTS CLAIMED BY HI FOR THE HAWAII COUNTY ECONOMIC OPPORTUNITY COUNCIL, JUL 2012, \$22,602
CIN: A-02-11-02008	DIRECT COST REVIEW - SUNY STONY BROOK, AUG 2012, \$18,254
CIN: A-05-11-00042	MEDICARE PART D MADE SOME INCORRECT PAYMENTS TO COMMUNITY INSURANCE INC FOR INSTITUTIONAL BENEFICIARIES IN 2008, AUG 2012, \$13,346
CIN: A-05-11-00053	THE COLUMBUS URBAN LEAGUE CLAIMED SOME UNALLOWABLE COSTS TO HEAD START, SEP 2012, \$13,102

CIN: A-01-12-02501 REVIEW OF CSBG RECOVERY ACT COSTS CLAIMED - CFC, FALL RIVER, MA,
AUG 2012, \$10,769

TOTAL NUMBER OF REPORTS: 50

TOTAL AMOUNT: \$312,126,000

Table 2 End Notes

¹The opening balance was adjusted downward by \$427.7 million because of reevaluation of previously issued recommendations.

- A-04-1003059, *Obstacles to Collections of Millions in Medicare Overpayments*. The uncollected disallowed cost totaling \$416.3 million was reported in prior semiannual periods. A downward adjustment was made to avoid double-counting.
- Not detailed is \$11.4 million in downward adjustments due to changes in previously issued recommendations.

² 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:

CIN: A-06-10-00059 REVIEW OF HOSPICE COVERED DRUGS NATIONWIDE, JUNE 2012,
\$33,638,137

CIN: A-05-05-00033 UNDISTRIBUTED CHILD SUPPORT COLLECTIONS - MICHIGAN, AUGUST
2006, \$4,397,133

CIN: A-05-06-00023 UNDISTRIBUTED CHILD SUPPORT COLLECTIONS - MINNESOTA,
SEPTEMBER 2006, \$28,240

CIN: A-09-09-01007 REVIEW OF IDAHO'S TITLE IV-E ADOPTION ASSISTANCE COSTS FOR
FEDERAL FISCAL YEARS 2006 THROUGH 2008, JULY 2009, \$17,764

TOTAL NUMBER OF REPORTS: 4

TOTAL AMOUNT: \$38,081,274

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, outstanding recommendations from peer reviews, and peer reviews conducted by the OIG of other OIGs in the semiannual period. Peer reviews are conducted by member organizations of the Council of the Inspectors General on Integrity and Efficiency (CIGIE). The required information follows.

Office of Audit Services peer review results

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

OAS	Date	Reviewing Office	Office Reviewed
	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
	May 2012	HHS OIG, OAS	U. S. Environmental Protection Agency (EPA)

The system of quality control for the audit organization of EPA OIG in effect for the year ending September 30, 2011, has been suitably designed and complied with to provide EPA OIG with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Federal audit organizations can receive a rating of pass, pass with deficiencies, or fail. EPA OIG received a peer review rating of pass.

Office of Investigations peer review results

During this semiannual reporting period, the U.S. Postal Service (USPS) Office of Inspector General conducted a peer review of HHS OIG’s Office of Investigations (OI). OI did not conduct a peer review of another OIG during this reporting period. Listed below is information concerning OI’s peer review activities during this and 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	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.

Program Exclusions

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

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 (HHS) Departmental Appeals Board and Federal district and appellate courts regarding the basis for and the length of the exclusion.

Civil Monetary Penalties Law

The 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); 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 (1) referring an individual to a person or an entity for the furnishing, or arranging for the furnishing, of any item or service payable under the Federal health care programs or (2) purchasing, leasing, or ordering, or arranging for or recommending the purchasing, leasing, or ordering, of any good, facility, service, or item payable under the Federal health care programs 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 to false claims submitted to contractors or grantees of the Federal Government.

<http://oig.hhs.gov>

Appendix E

Reporting Requirements in the Inspector General Act of 1978

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

Section	Requirement	Location
Section 4		
(a)(2)	Review of legislation and regulations	"Other HHS-Related Issues" section
Section 5		
(a)(1)	Significant problems, abuses, and deficiencies	Throughout this report
(a)(2)	Recommendations with respect to significant problems, abuses, and deficiencies	Throughout this report
(a)(3)	Prior significant recommendations on which corrective action has not been completed	<i>OIG Compendium of Unimplemented Recommendations</i>
(a)(4)	Matters referred to prosecutive authorities	"Legal and Investigative Activities" section
(a)(5)	Summary of instances in which information requested by OIG was refused	None
(a)(6)	List of audit reports	Submitted to the Secretary under separate cover
(a)(7)	Summary of significant reports	Throughout this report
(a)(8)	Statistical Table 1 – Reports With Questioned Costs	Appendix 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	Appendix B

Section	Requirement	Location
	management decisions	
(a)(12)	Management decisions with which the Inspector General disagrees	None
(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" section
(a)(14)-(16)	Results of peer reviews of HHS-OIG conducted by other OIGs or the date of the last peer review, outstanding recommendations from peer reviews, and peer reviews conducted by HHS-OIG of other OIGs.	Appendix C

Other Reporting Requirements

Section	Requirement	Location
845	Significant contract audits required to be reported pursuant to the National Defense Authorization Act for fiscal year 2008 (P.L. No. 110-181), § 845.	"Other HHS-Related Issues" section
205	Pursuant to the Health Insurance Portability and Accountability Act (P.L. No. 104-191), § 205, the Inspector General is required to solicit proposals annually via a Federal Register notice for developing new and modifying existing safe harbors to the anti-kickback statute of the Social Security Act, § 1128(b), and for developing special fraud alerts. The Inspector General is also required to report annually to Congress on the status of the proposals received related to new or modified safe harbors.	Reported annually in the fall <i>Semiannual Report</i> . Appendix F
1553	Pursuant to the American Recovery and Reinvestment Act of 2009, § 1553, OIG reports to Congress the retaliation complaint investigations it decided not to conduct or continue during the period.	"Other HHS-Related Issues" section

Appendix F

Anti-Kickback Statute—Safe Harbors

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

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

Public Proposals for New and Modified Safe Harbors

In response to the 2012 annual solicitation, OIG received the following proposals related to safe harbors:

Proposal	OIG Response
Modification of the electronic health records (EHR) safe harbor to (1) remove the sunset provisions and make it a permanent safe harbor, (2) extend the sunset date to 2016 to align it with the EHR incentive payments program timeline, or (3) extend the sunset date by 4 or more years.	On April 10, 2013, OIG issued a Notice of Proposed Rulemaking (NPRM) (78 Fed. Reg. 21314), which proposed extending the date of the sunset provision and making certain other modifications to this safe harbor. The comment period for this NPRM closed on June 10 th , and we are considering the comments received in preparation for issuing a final rule
A new safe harbor protecting, in certain circumstances, (1) free continuing medical education (CME) programs offered by hospitals to physicians or (2) free or reduced-cost CME programs provided by institutional Medicare Part A providers to their staff physicians.	OIG is not adopting this suggestion. The concept of free or reduced cost programs could vary greatly and should be addressed on a case-by-case basis, such as under the advisory opinion process.
A new safe harbor protecting certain motivational incentives offered to patients by Federally Qualified Health Centers (FQHCs) or FQHC look-alikes to	OIG is considering the adoption of generally applicable safe harbors regarding rewards for patient compliance

Proposal	OIG Response
<p>either encourage patients to obtain medically necessary treatment, reward compliance with a treatment plan, or reward achievement of treatment-related goals.</p>	<p>with prevention and treatment regimens.</p>
<p>A new safe harbor that would apply to discounts on Medicare Part A-covered services offered by independent providers (such as mobile x-ray service providers) to skilled nursing facilities that have the ability to refer to these independent providers business covered by Medicare Part B.</p>	<p>OIG is not adopting this suggestion. The arrangement described poses a risk of abuse under the anti-kickback statute and should be evaluated on a case-by-case basis, such as under the advisory opinion process.</p>
<p>Modification of the safe harbor for investments in group practices to (1) either (a) provide that it does not apply to revenues from anesthesia services if any equity owner of the group practices in a medical specialty other than anesthesiology or pain management or (b) limit application of the safe harbor to profits generated by the services provided by the equity owners of the group practice and from their employees who provide services in the same medical specialty as the equity owners of the group practice, and (2) to provide that anesthesia services are not “in-office ancillary services” for purposes of the safe harbor.</p>	<p>OIG is not adopting these suggestions at this time as they require further study.</p>
<p>Modification of the safe harbor for investments in ambulatory surgical centers to explicitly exclude from its protection profits from anesthesia services.</p>	<p>OIG is not adopting this suggestion. The existing safe harbor does not protect profits from anesthesia services.</p>
<p>Modification of the safe harbor for employee compensation to (1) explicitly exclude from protection certain employment arrangements in which physicians employ physicians in other specialties to whom the former group would otherwise refer or (2) to introduce to the safe harbor requirements of</p>	<p>OIG is not adopting these suggestions. The employee compensation safe harbor is statutory, and OIG has no authority to modify the substantive elements of the statutory exception.</p>

Proposal	OIG Response
<p>commercial reasonableness and of compensation not varying with the volume or value of referrals from the employing/referring physicians.</p>	
<p>A new safe harbor that would permit health care providers and suppliers in certain circumstances to compensate individuals in clinical trials and to provide services related to the clinical trials at no cost, including the waiver of cost-sharing obligations.</p>	<p>OIG is considering this suggestion.</p>
<p>A new safe harbor that would allow rural providers to offer annual retrospective reimbursement for cost-sharing obligations as a reward for patients' compliance with prevention and treatment regimens.</p>	<p>OIG is not adopting this suggestion at this time but is considering the adoption of generally applicable safe harbors regarding rewards for patient compliance with prevention and treatment regimens.</p>
<p>Create an exemption to the civil monetary penalties provision relating to beneficiary inducements at section 1128A(a)(5) of the Social Security Act for complimentary transportation which takes into account not just patient financial need, but also concerns such as incapacitation and scarcity of local treatment options.</p>	<p>OIG is considering the adoption of a safe harbor to the anti-kickback statute that would apply to free or discounted local transportation. This safe harbor to the anti-kickback statute, if adopted, would be incorporated as an exception to the CMP, pursuant to section 1128A(i)(B).</p>
<p>Modification of the safe harbor for obstetrical malpractice insurance subsidies to include additional types of physicians and subsidies when there is documented need and the subsidy amount is limited in scope and duration.</p>	<p>OIG is not adopting this suggestion at this time as it requires further study.</p>
<p>New safe harbor for retention payments by hospitals to practitioners.</p>	<p>OIG is not adopting this suggestion. Retention arrangements are subject to abuse and should be evaluated on a case-by-case basis, such as under the advisory opinion process.</p>
<p>Modification of the safe harbor for hospital recruitment payments to practitioners to protect arrangements outside Health Professional Shortage</p>	<p>OIG is considering this suggestion.</p>

Proposal	OIG Response
Areas and to permit payments to an existing practice for recruiting a practitioner to join the practice.	
Modification of the safe harbor for space rental to expand the definition of “fair market value” to take into account costs incurred in leasehold maintenance and improvements.	OIG is considering this suggestion.