

Office of Inspector General

# Semiannual Report to Congress

April 1, 2011 – September 30, 2011

# A Message From the Inspector General

HIS 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), U.S. Department of Health & Human Services (HHS), for the 6-month period ending September 30, 2011.

Over the past 6 months, OIG produced significant recommendations to improve HHS programs, investigated fraud and executed enforcement actions, and offered our industry stakeholders new compliance training. OIG realizes that technology has tremendous potential to enhance our program integrity capabilities. OIG is using data mining, predictive analytics, trend evaluation, and modeling to better analyze and target the oversight of HHS programs. Utilizing technologies, OIG is able to improve its strategic, tactical, and operational oversight of HHS programs. The integration of technology provides OIG with an analytical foundation to build upon and improve the enterprise view of activities, trends, patterns, predictive analytics, and prevention opportunities. We also continue to utilize our traditional approaches to conducting reviews and investigations, and combining traditional approaches with the many new tools available through technology, we aim to maximize the investment in our office and produce returns for the taxpayer.

OIG is an excellent investment. Our work results in the recovery of stolen and misspent funds, and our recommendations lead to increased efficiency and effectiveness and fraud prevention. Our results are tangible. For instance, our Medicare Fraud Strike Force activities continue to be successful. During this semiannual reporting period, Strike Force efforts resulted in the filing of charges against 70 individuals or entities, 77 convictions, and \$160.8 million in investigative receivables. Additionally, we have issued reports with respect to payments for prescription drugs that contain recommendations that when implemented could lead to substantial Federal health care program savings.

Our enforcement efforts are coupled with extensive outreach to providers to help them understand program rules and avoid running afoul of applicable statutes and regulations. We conducted provider compliance training around the country and posted the training and additional resources on our Web site. The response to this initiative has been extremely positive.

However, individuals and entities remain that seek to defraud the programs. OIG investigates fraud and works with the Department of Justice to hold accountable its perpetrators. Many of these instances are highlighted in this report. In many cases, OIG enters into corporate integrity agreements with providers as part of the settlement of False Claims Act cases to help ensure future compliance. However, if providers violate the terms of those agreements, OIG holds them accountable, such as by imposing penalties or, for serious breaches, by moving to exclude them from participating in Federal health care programs.

Another priority of our office is reducing improper payments. I testified during this reporting period about OIG's recommendations to the Department to reduce improper payments, including those for Medicaid personal care services, Medicare power wheelchairs, hospice care, and payments to hospitals.

The public health and welfare of HHS beneficiaries continues to be of paramount concern to our office. We issued reports during this reporting period regarding the Food and Drug Administration's monitoring of imported food recalls, oversight of the President's Emergency Plan for AIDS Relief, and access to

dialysis and mental health services at Indian Health Service and tribal facilities. Vulnerable populations and their access to necessary, safe, and high-quality services remain a focus of ongoing and future work.

The pervasiveness of cybersecurity breaches is a major challenge. During this reporting period, our office issued two reports identifying weaknesses in the protection of electronic patient health information. This will continue to be a concern as the provider community increasingly adopts electronic health information technology. OIG has a robust oversight agenda to ensure that sensitive information is protected from nefarious parties.

As we tackle an expanding mission to protect HHS's vital health and human service programs, I would like to express my appreciation to Congress and to the Department for their sustained commitment to supporting the important work of our Office.

Daniel R. Levinson
Inspector General

#### Highlights

The Department of Health & Human Services (HHS) Office of Inspector General (OIG) Semiannual Reports to Congress summarize our most significant findings, recommendations, investigative outcomes, and outreach activities in 6-month increments. This edition addresses work completed during the second half of fiscal year (FY) 2011 and provides FY 2011 summary data on key accomplishments. The Semiannual Report to Congress is one of OIG's three core publications. Our Work Plan describes work in progress and new projects that we plan to pursue during the fiscal year and beyond. Our Compendium of <u>Unimplemented Recommendations</u> describes open recommendations from prior periods that when implemented will save tax dollars and improve programs.

#### Summary of Fiscal Year 2011 Accomplishments

For FY 2011, we reported expected recoveries of about \$5.2 billion consisting of \$627.8 million in audit receivables and \$4.6 billion in investigative receivables (which includes \$952 million in non-HHS investigative receivables resulting from our work in areas such as the States' share of Medicaid restitution). We also identified about \$19.8 billion in savings estimated for FY 2011 as a result of legislative, regulatory, or administrative actions that were supported by our recommendations. Such savings generally reflect third-party estimates (such as by the Congressional Budget Office) of funds made available for better use through reductions in Federal spending.

We reported FY 2011 exclusions of 2,662 individuals and entities from participation in Federal health care programs; 723 criminal actions against individuals or entities that engaged in crimes against HHS programs; and 382 civil actions, which included false claims and unjust-enrichment lawsuits filed in Federal district court, civil monetary penalties (CMP) settlements, and administrative recoveries related to provider self-disclosure matters.

Following are highlights of significant activities, findings, and investigative outcomes that are included in the main body of the Semiannual Report for the second half of FY 2011.



#### **HFAT:** Health Care Fraud Prevention and **Enforcement Action Team**

The Health Care Fraud Prevention and Enforcement Action Team (HEAT) was started in 2009 by HHS and the Department of Justice (DOJ) to strengthen programs and invest in new resources and technologies to prevent and combat health care fraud, waste, and abuse.

#### Medicare Fraud Strike Force Teams Continue To Turn Up the HEAT

Medicare Fraud Strike Force teams coordinate law enforcement operations among Federal, State, and local law enforcement entities. These 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 several major cities. Recent accomplishments include the following.

- During FY 2011, Strike Force efforts resulted in the filing of charges against 283 individuals or entities, 184 convictions, and \$224.8 million in investigative receivables.
- In late August and early September 2011, Medicare Fraud Strike Force teams in eight cities executed a nationwide operation that resulted in charges against 91 defendants, including doctors, nurses, and other medical professionals, for their alleged participation in Medicare fraud schemes involving approximately \$295 million in false billing. In addition to making arrests, agents also executed 18 search warrants in connection with ongoing Strike Force investigations.

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 it can suspend payments to the perpetrators. During Strike Force operations, OIG and CMS work to impose payment suspensions that immediately prevent losses from claims submitted by Strike Force targets.

#### 50-year Prison Sentence Longest imposed in a Medicare Fraud Strike Force Case

FLORIDA – Lawrence Duran, one of several owners of American Therapeutic Corporation (ATC), was sentenced to 50 years of incarceration for his role in orchestrating a Medicare fraud scheme in which owners and operators of assisted living facilities, halfway houses, and patient brokers were actively recruited and paid kickbacks in exchange for delivering ineligible patients to ATC. This case was the first Community Mental Health Center investigation under the HEAT initiative to lead to an indictment, and Duran's 50-year prison sentence is the longest imposed in a Medicare Fraud Strike Force case. Marianella Valera, another ATC owner, and Margarita Acevedo, a senior-level ATC manager, were also sentenced to 35 and 7.5 years of incarceration, respectively, for their roles in the scheme. The three individuals and three business entities were ordered to pay more than \$87 million in restitution, jointly and severally. The now-defunct ATC was used to bill Medicare for mental health services that were not necessary or were not provided.

#### Incarceration and \$11.7 Million in Restitution Ordered for HIV Therapy Scheme

FLORIDA – Dr. Rene De Los Rios was sentenced to 235 months of incarceration and ordered to pay a minimum of \$11.7 million in restitution, jointly and severally with his co-defendants, for conspiracy to commit health care fraud and submission of false claims. De Los Rios was employed by Metro Med of Hialeah Corporation (Metro Med), a clinic that provided injection and infusion therapies to human immunodeficiency virus (HIV)-positive Medicare beneficiaries. Between April 2003 and October 2005, De Los Rios signed medical analysis and diagnosis forms and authorized treatments that were medically unnecessary or were never provided. The owner and operator of Metro Med, Damaris Oliva, and three other co-defendants, Estrella Rodriguez, Jose Diaz, and Lisandra Aguilera, were sentenced to 82 months, 57 months, 54 months, and 70 months of incarceration, respectively, for their roles in the scheme.

# OIG Trains Health Care Providers To Prevent Fraud and Improve Compliance

OIG's HEAT Provider Compliance Training initiative (HEAT PCT) provided free compliance training for providers, compliance professionals, and attorneys in Strike Force cities and elsewhere. HEAT PCT, which included presenters from OIG, CMS Regional Offices, CMS Program Integrity, United States Attorneys' Offices, and State Medicaid Fraud Control Units, held sessions in Houston, Tampa, Kansas City,



Baton Rouge, Denver, and Washington, D.C., training a total of 737 in-person attendees. The final HEAT PCT session in Washington, D.C., was Webcast live to 2,335 participants. Pictured above are OIG attorneys Amanda Walker and Meredith Williams. HHS/OIG developed comprehensive training materials to accompany HEAT PCT, and those materials are now available online, together with 16 video modules dividing the Webcast by subject area. The online training will continue reaching the health care community with our compliance message.

#### Prescription Drug Investigations and Reviews

#### Pharmaceutical Company Resolves False Claims Act Liability

MARYLAND – Serono Laboratories, Inc.; EMD Serono, Inc.; Merck Serono S.A.; and Ares Trading S.A. (collectively Serono), agreed to pay \$44.3 million plus interest and enter into a False Claims Act (FCA) settlement to resolve allegations that between January 2002 and December 2009, Serono paid illegal remuneration to health care professionals (for activities such as promotional speaking engagements, speakers' training, and charitable contributions) to induce them to prescribe their multiple sclerosis prescription drug called Rebif and, thereby, caused the submission of false claims to Medicare and other Federal health care programs. As part of a 2005 civil and criminal settlement relating to Serono's promotion of the drug Serostim, Serono entered into a corporate integrity agreement (CIA) with OIG. As part of the 2011 settlement, Serono entered into a 3-year addendum to the existing CIA.

# OIG Raises Concerns About Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents

FOR THE PERIOD JANUARY 1 THROUGH JUNE 30, 2007, 51 PERCENT OF MEDICARE CLAIMS FOR ATYPICAL ANTIPSYCHOTIC DRUGS DID NOT COMPLY WITH MEDICARE REIMBURSEMENT CRITERIA, AMOUNTING TO \$116 MILLION IN ERRONEOUS PAYMENTS. Atypical antipsychotic drugs are approved by the Food and Drug Administration (FDA) for treatment of schizophrenia and/or bipolar disorder. Fourteen percent of 2.1 million elderly (age 65 and older) nursing home residents had at least 1 claim for such drugs. Eighty-three percent of the claims were associated with off-label conditions (conditions other than schizophrenia and/or bipolar disorder), and 88 percent were associated with dementia (the condition specified in the FDA boxed warning). Twenty-two percent of claims were for drugs that were not administered in accordance with CMS standards for drug therapy in nursing homes. Our recommendations to CMS included that it facilitate Medicare's access to information necessary to ensure accurate coverage and reimbursement determinations and take appropriate action regarding the claims associated with the erroneous payments identified in our sample.

Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents. OEI-07-08-00150. Web Summary. Full Text. Inspector General's CNN Article. CBS News Video.

#### Cost of Alternative Drug Treatments for Age-Related Macular Degeneration

IF PHYSICIANS HAD TREATED ALL MEDICARE BENEFICIARIES WITH WET AGE-RELATED MACULAR DEGENERATION (WET AMD) WITH AVASTIN DURING CALENDAR YEARS (CY) 2008 AND 2009, MEDICARE PART B WOULD HAVE SAVED APPROXIMATELY \$1.1 BILLION. Conversely, if the same beneficiaries had been treated with Lucentis, Medicare Part B would have increased spending by approximately \$1.5 billion. Avastin and Lucentis (both manufactured by Genentech) are the most commonly administered Part B biologicals used to treat wet AMD, which is the leading cause of severe vision loss in people over age 65 in the United States. Given the significant difference in Medicare Part B reimbursements for the products, we questioned the sufficiency of CMS's authorities to limit Part B drug and biological expenditures effectively. Our recommendations included that CMS evaluate coverage and reimbursement policies and seek such additional authorities as are necessary.

Review of Medicare Part B Avastin and Lucentis Treatments for Age-Related Macular Degeneration. A-01-10-00514. Web Summary. Full Text.

# Higher Manufacturer Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicare Part D

ALTHOUGH PHARMACY REIMBURSEMENT AMOUNTS UNDER MEDICAID AND MEDICARE PART D WERE SIMILAR FOR MOST SELECTED BRAND-NAME DRUGS IN 2009, MEDICAID'S NET UNIT DRUG COSTS WERE MUCH LOWER THAN PART D'S BECAUSE MEDICAID HAS SUBSTANTIALLY HIGHER REBATES FOR BRAND-NAME DRUGS. Manufacturer rebates for generic drugs under both programs were negligible. We also found that State Medicaid agencies and Part D sponsors paid pharmacies roughly the same amount for brand-name drugs. However, after accounting for rebates, Medicaid's net costs for selected brand-name drugs were much lower than Part D's net costs. Medicaid recouped 45 percent of its drug spending on selected brand-name drugs in manufacturer rebates while Part D sponsors recouped 19 percent. We concluded that given the potential impact on beneficiary and Government expenditures, differences in how rebates are collected across Medicaid and Part D should be continually examined by CMS.

Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicare Part D. OEI-03-10-00320. Web Summary. Full Text.

#### Medicare Part A and Part B Reviews and Enforcement Actions

# Medicare Hospices That Focus on Nursing Facility Residents

MEDICARE SPENDING ON HOSPICE CARE FOR NURSING FACILITY RESIDENTS HAS GROWN NEARLY 70 PERCENT SINCE 2005. WE FOUND THAT HUNDREDS OF HOSPICES—MOST OF WHICH WERE FOR-PROFIT—HAD MORE THAN TWO-THIRDS OF THEIR BENEFICIARIES IN NURSING FACILITIES IN 2009. Hospices with a high percentage of their beneficiaries in nursing homes received more Medicare payments per



beneficiary than other hospices and had beneficiaries who spent more time in care. The high-percentage hospices typically enrolled beneficiaries whose diagnoses required less complex care and who already lived in nursing facilities. We recommended that CMS monitor hospices that depend heavily on nursing facility residents and modify the payment system for hospice care in nursing facilities. The current payment structure provides incentives for hospices to seek out nursing facility beneficiaries who often receive longer but less complex care. Medicare pays hospices the same rate for care provided in nursing facilities as it does for care provided in other settings, such as private

homes. However, unlike private homes, nursing facilities (which are often paid by third-party payers or Medicaid) are already staffed with professional caregivers and are required to provide personal care services (PCS) that are similar to hospice aide services.

Medicare Hospices That Focus on Nursing Facility Residents. OEI-02-10-00070. Web summary. Full Text. See also OIG's <u>Spotlight</u> and <u>Podcast</u> on Hospice Care; OIG's March 2011 <u>Compendium</u>, Part I, pp. 19 and 20; and report number <u>OEI-02-06-00221</u>, all available on our Web site.

#### **Changes in Skilled Nursing Facilities Billing**

ALTHOUGH CHANGES MADE TO THE SKILLED NURSING FACILITY (SNF) PAYMENT SYSTEM EFFECTIVE FY 2011 WERE INTENDED BE TO BE BUDGET NEUTRAL, UNANTICIPATED BILLING PATTERNS CONTRIBUTED TO A \$2.1 BILLION (16-PERCENT) INCREASE IN MEDICARE PAYMENTS. The increase occurred from the last half of FY 2010 to the first half of FY 2011. At the same time, several of the changes reduced billing for certain higher-paying groups. The data indicate that Medicare should adjust payment rates to address the significant increases in payments to SNFs. The data also show that Medicare should make changes to how SNFs account for group therapy. Further, the data highlight the need for changes to make Medicare payments more consistent with beneficiaries' care and resource needs. On the basis of this report, CMS has proposed a number of changes to the SNF payment system and will issue a final rule for FY 2012.

Changes in Skilled Nursing Facilities Billing in Fiscal Year 2011. OEI-02-09-00204. Web Summary. Full Text.

#### Manufacturer Resolves Noncompliance With Orthotic Shoe Insert Specifications

WISCONSIN – Rikco International, LLC, d/b/a Dr. Comfort (Dr. Comfort), agreed to pay \$27 million plus interest and enter into a 5-year CIA to resolve its liability under the FCA in connection with the alleged sale of durable medical equipment (DME) reimbursed by Medicare. Between June 2004 and March 2006, Dr. Comfort allegedly shipped diabetic orthotic shoe inserts to DME suppliers under the false pretense that the inserts were approved by Medicare for reimbursement and that the inserts met specifications established by CMS when, in fact, they did not meet the specifications.

#### Physician Settles Radiation Oncology Services-Related Billing Issues

NEVADA – Rakesh Nathu, M.D., and Nathu Compassionate Cancer Care, Chartered (collectively Nathu), agreed to pay \$5.7 million plus interest to settle allegations under the FCA for the false billing of radiation oncology services, including intensity modulated radiation therapy. Intensity modulated radiation therapy is a treatment for specific types of cancer where extreme precision is required to spare surrounding organs or healthy tissue. Between 2007 and 2009, Nathu allegedly submitted improper claims to Medicare, TRICARE, and the Federal Employees Health Benefits Plan by double-billing for procedures affiliated with radiation treatment plans. Nathu also allegedly billed for services that were medically unnecessary and billed higher reimbursement radiation services when a different, less expensive service should have been billed. This was a joint investigation with the Federal Bureau of Investigation.

<sup>&</sup>lt;sup>1</sup> OIG's Compendium of Unimplemented Recommendations (Compendium) describes recommendations that when implemented will save tax dollars and improve programs and operations.

#### Medicaid Reviews



#### States Urged To Refund Over \$61 Million in Federal Share of Improper Medicaid Payments for Personal Care Services

THREE STATES IMPROPERLY CLAIMED ABOUT \$61.3 MILLION OF FEDERAL MATCHING FUNDS FOR PCS THAT DID NOT MEET FEDERAL AND/OR STATE REQUIREMENTS. We set aside an additional \$34.8 million for further analysis and resolution by the States and CMS. We recommended that the States refund the Federal share and work with CMS to

resolve the amounts set aside. We also recommended improvements in guidance, controls, and monitoring. PCS, which are nonmedical services provided to assist with activities of daily living, such as bathing, dressing, and meal preparation, are generally furnished to individuals residing in their homes and not residing in institutional care settings, such as hospitals or nursing facilities. The three reviews completed in this semiannual period are part of OIG's larger body of work on PCS.

- NEBRASKA A-07-10-03152. (Refund \$169,000; resolve \$4.5 million set aside.) Web Summary. Full Text.
- NORTH CAROLINA A-04-10-04003. (Refund \$41.7 million.) Web Summary. Full Text.
- WASHINGTON STATE A-09-09-00030. (Refund \$19.4 million; resolve \$30.3 million set aside.) Web Summary. Full Text.

See also OIG's Spotlight on Personal Care Services and a related matter in our March 2011 Compendium, Part III, pp. 15 and 16, available on our Web site.

#### Illinois' Payments for One State-Owned Psychiatric Hospital

ILLINOIS IMPROPERLY CLAIMED AN \$82.9 MILLION FEDERAL SHARE OF PAYMENTS IT MADE TO A STATE-OWNED PSYCHIATRIC HOSPITAL THAT FAILED TO DEMONSTRATE COMPLIANCE WITH FEDERAL REQUIREMENTS. During the audit period, the hospital did not demonstrate compliance with special Medicare Conditions of Participation (CoP) because the State agency did not believe that such demonstration was necessary. We recommended that Illinois refund the \$82.9 million; work with CMS to evaluate an additional \$12.6 million that we set aside for further analysis and resolution; identify and refund the Federal share of any other payments associated with the same type of noncompliance; and ensure that with regard to psychiatric hospitals, it claims Federal matching funds only for those hospitals that can demonstrate compliance with the special Medicare CoP.

Review of Select Medicaid Inpatient Psychiatric Hospital Service Requirements for One Illinois State-Owned Psychiatric Hospital During the Period January 1, 2000, Through December 31, 2009. A-05-10-00046. Web Summary. Full Text.

#### Corporate Integrity Agreement **Enforcement Activities**

#### Two Firms Pay Penalties of \$272,500 for Violating Corporate Integrity Agreements

Many health care providers that enter into agreements with the Federal Government to settle potential liabilities under the FCA also agree to adhere to a separate CIA with OIG. In a CIA, a provider typically commits to establishing a program or taking other specified steps to ensure future compliance with Medicare and Medicaid rules. The compliance programs are designed, in part, to prevent a recurrence of the underlying fraudulent conduct. OIG monitors providers' compliance with these agreements.

During this reporting period, OIG imposed stipulated penalties totaling \$272,500 on two companies, Church Street Health Management (Church Street, formerly known as FORBA Holdings, LLC) and The SCOOTER Store, Inc., because they did not comply with requirements of their CIAs with OIG. A penalty of \$230,000 was imposed on Church Street because it failed to implement training, develop and distribute policies and procedures, submit an Independent Review Organization (IRO) report, and provide notice of Government investigations. Church Street also made false certifications. A penalty of \$42,500 was imposed on The SCOOTER Store, Inc., because it did not submit a timely IRO report, as required under its CIA.

#### Public Health Reviews

#### FDA's Monitoring of Imported Food Recalls Warrants Improvement

BECAUSE FDA'S FOOD RECALL GUIDANCE IS NONBINDING ON THE INDUSTRY, FDA CANNOT COMPEL FIRMS TO FOLLOW IT. THEREFORE, FDA CANNOT ENSURE THE SAFETY OF THE NATION'S FOOD SUPPLY. We reviewed 17 of 40 Class I recalls of imported food products conducted from July 1, 2007, through June 30, 2008. We found that firms did not promptly initiate recalls, their recall strategies were not submitted to FDA or were incomplete, they did not issue accurate and complete recall communications to their consignees, and they did not submit timely and complete recall status reports. FDA did not always follow its own procedures. It did not always conduct inspections of firms, obtain complete information on the contaminated products, conduct timely or complete audit checks of consignees, review recall strategies, promptly issue notification letters to firms conveying the review results and other essential instructions, witness the disposal of the products, or obtain the required disposal documentation. We recommended that FDA consider the results of this review in implementing the recently enacted FDA Food Safety Modernization Act and follow its procedures for monitoring recalls.

Review of the Food and Drug Administration's Monitoring of Imported Food Recalls. A-01-09-01500. Web Summary. Full Text.

#### CDC's Monitoring of AIDS-Relief Funds Is Insufficient

RECIPIENTS' USES OF PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF (PEPFAR) FUNDS WERE NOT ALWAYS MONITORED IN ACCORDANCE WITH DEPARTMENTAL AND OTHER FEDERAL REQUIREMENTS. Although the Centers for Disease Control and Prevention (CDC) performed some monitoring, most of the award files we reviewed did not include all required documents or evidence to demonstrate that all cooperative agreements were monitored to the extent required. Of the 30 cooperative agreements in our sample, only 1 file contained all required documents. To ensure proper stewardship over PEPFAR funds, we recommended that CDC follow departmental and other Federal requirements in monitoring recipients' use of such funds. PEPFAR strengthens health systems and builds sustainable HIV and acquired immunodeficiency syndrome (AIDS) programs in more than 75 countries in Africa, Asia, Central and South America, and the Caribbean. HHS receives PEPFAR funds from the Department of State through a memorandum of agreement.

Review of the Centers for Disease Control and Prevention's Oversight of the President's Emergency Plan for AIDS Relief Funds for Fiscal Years 2007 Through 2009. A-04-10-04006. Web Summary. Full Text.

#### National Institutes of Health Showed Mixed Compliance With Appropriations Laws

WE FOUND TIME AND AMOUNT ISSUES IN FOUR CONTRACTS THAT POTENTIALLY VIOLATED THE ANTIDEFICIENCY ACT (ADA). The ADA prohibits an agency from obligating or expending funds in advance of or in excess of an appropriation unless specifically authorized by law. From November 2008 through February 2009, an HHS internal review group assessed 176 HHS contracts, including 21 National Institutes of Health (NIH) contracts. Our reviews of the NIH contracts assess compliance with the purpose, time, and amounts requirements specified in appropriations statutes. For four of the contracts we completed in this semiannual period, NIH had a bona fide need for the items and appropriately funded the contracts and their modifications from the pertinent appropriations years. We found time and amount issues in four other contracts in which NIH's National Institute of Allergy and Infectious Diseases (NIAID) potentially violated the ADA. For the four reviews with time and amount issues, we recommended making monetary adjustments and reporting ADA violations as appropriate. (See Part IV, page 4 for report names and numbers.)

# Challenges to Receiving Mental Health and Kidney Dialysis Services at Indian Health Service and Tribal Facilities

SHORTAGES OF HIGHLY SKILLED PROVIDERS, REMOTE LOCATIONS, LACK OF RESOURCES, AND SMALL PATIENT POPULATIONS CONTRIBUTE TO THE LIMITED MENTAL HEALTH AND DIALYSIS SERVICES FOUND AT SOME INDIAN HEALTH SERVICE (IHS) AND TRIBAL FACILITIES. American Indians and Alaska Natives (AI/AN) rank first among ethnic groups as likely to suffer mental health disorders that can lead to suicide, such as anxiety and depression, and AI/ANs' rate of end stage renal disease (ESRD) is the second highest among all racial/ethnic groups. Two reviews in this period address these services and offer recommendations. View OIG's Spotlight on the Indian Health Service, available on our Web site.

- MENTAL HEALTH SERVICES Although 82 percent of facilities provide some type of mental health service and 39 percent of the facilities reported that they provide crisis intervention 24 hours a day, we found that shortages of highly skilled providers limit access to mental health services at those facilities. To help address shortages of licensed providers, 17 percent of IHS and tribal facilities use telemedicine for mental health services. Access to Mental Health Services at Indian Health Service and Tribal Facilities. OEI-09-08-00580. September, 2011. Web Summary. Full Text.
- KIDNEY DIALYSIS SERVICES Only 20 of 506 IHS and tribal facilities reported that dialysis services are
  provided at their facilities. Most AI/AN receive dialysis services at non-IHS/nontribal dialysis
  facilities. Many tribal facilities assist tribal members in accessing dialysis services by providing
  transportation and expanding access to specialists. Access to Kidney Dialysis Services at Indian
  Health Service and Tribal Facilities.
  - OEI-09-08-00581. September, 2011. Web Summary. Full Text.

#### Other HHS-Related Issues

#### Professional Athlete Ordered To Pay Almost \$1 Million in Child Support

ILLINOIS – Tyrone Lamont Nesby, a former NBA player, was sentenced to 5 years of probation and ordered to pay \$977,402 in restitution for unpaid child support obligations. Between 1999 and 2010, Nesby unlawfully failed to pay child support in three districts for his minor children. The districts included the District of Nevada, the Northern District of Indiana, and the Southern District of Illinois. Nesby pleaded guilty to the charges and agreed to pay restitution for unpaid child support in all three districts. At sentencing, the court strenuously recommended that Nesby speak to underprivileged

children in schools about the importance of family and the lessons he has learned from his experiences.

#### **Grants Fraud Prevention and Investigations**

In a July 2011 Grants.gov quarterly Webcast, Special Agents Brandon Trice (HHS OIG) and Ken Dieffenbach (DOJ OIG), pictured at right with Grants.gov Acting Program Manager, Boris DeSouza, gave a special presentation on grant fraud prevention that highlights three areas of interest: conflicts of interest, misuse of funds, and embezzlement. The session, which runs about 1 hour, includes discussion and audience questions and can be viewed on the OIG Web site. A CBS News video about fraudulent Federal grants can also be viewed on our Web site. In addition to grant fraud



prevention activities, our office actively pursues those who abuse Federal grant dollars as summarized below.

GEORGIA – Bernard Walker was sentenced to 33 months of incarceration after pleading guilty to theft or embezzlement from a program receiving Federal grant funding and money laundering. He fraudulently obtained and laundered checks from a federally funded not-for-profit program meant to feed low-income children. Walker used his position as a nutrition specialist for a Head Start program to obtain kickbacks from various vendors and submitted fraudulent invoices from nonexistent vendors to obtain payment. He also ordered food through the Head Start program for his personal catering company. In addition to Walker's sentencing, the district court ordered the forfeiture of Walker's Audi A6 Quattro and BMW 528I vehicles, which were purchased with the proceeds of his theft.

# OIG Identifies Weaknesses in the Department's Oversight of Electronic Protected Health Information

Two OIG reviews raised significant concerns about the security of electronic protected health information (ePHI).

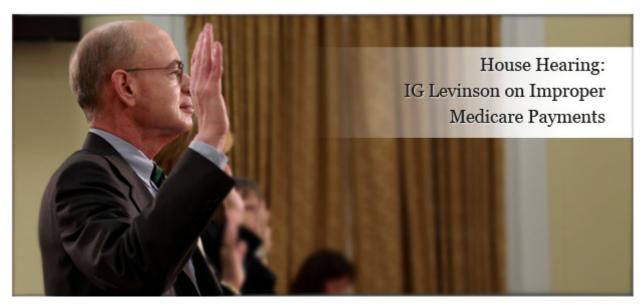
- OVERSIGHT OF THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT SECURITY RULE. The
  Department's oversight and enforcement of the Health Insurance Portability and Accountability
  Act of 1996 (HIPAA) Security Rule were not sufficient to ensure that covered entities, such as
  hospitals, effectively implemented the rule. Our audits of 7 hospitals throughout the Nation
  identified 151 vulnerabilities in the systems and controls intended to protect ePHI, of which 124
  were categorized as high impact. These vulnerabilities placed the confidentiality, integrity, and
  availability of ePHI at risk. Nationwide Rollup Review of the Centers for Medicare & Medicaid
  Services Health Insurance Portability and Accountability Act of 1996 Oversight. A-04-08-05069.
   Web Summary. Full Text.
- SECURITY CONTROLS IN HHS'S HEALTH INFORMATION TECHNOLOGY STANDARDS. Among the health
  information technology standards promulgated by HHS's Office of the National Coordinator
  (ONC), we found no standards that included general security controls. General security controls
  include encrypting data stored on mobile devices, such as compact disks and thumb drives;
  requiring two-factor authentication when remotely accessing a system; and updating the
  operating systems of computers that process and store electronic records. A lack of any of these
  or other security controls can expose systems to a host of problems. Our recommendations
  included that ONC broaden its focus to include well-developed general security controls for

supporting systems, networks, and infrastructures as well as emphasizing the importance of system security to medical practitioners. Audit of Information Technology Security Included in Health Information Technology Standards.

A-18-09-30160. Web Summary. Full Text

#### Congressional Testimony and Intergovernmental Leadership

During this semiannual period, we testified at three hearings conducted by committees of Congress on aspects of waste, fraud, and abuse in Medicare and Medicaid. The full text of the testimony is available on our Web site at <a href="http://www.oig.hhs.gov/testimony.asp">http://www.oig.hhs.gov/testimony.asp</a>.



- 07-28-2011 House of Representatives Committee on Oversight and Government Reform, Subcommittee on Government Organization, Efficiency, and Financial Management. Daniel R. Levinson, Inspector General (above), testified about the scope of improper payments in Medicare; OIG's oversight of the Department's measurement of Medicare improper payments; and OIG's role in preventing, detecting, and reducing improper payments. <u>Testimony</u>.
- 07-12-2011 Senate Committee on Homeland Security and Governmental Affairs, Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security. Lewis Morris, Chief Counsel to the Inspector General (second from left), testified on harnessing technology and innovation to cut waste and curb fraud in Federal health programs. Testimony.



04-05-2011 - House of Representatives Committee on Oversight & Government Reform, Subcommittee on Health Care, District of Columbia, Census and the National Archives. Gerald Roy, Deputy Inspector General for Investigations, presented his personal perspective on fraud, waste, and abuse within the Medicare and Medicaid Programs. Testimony. Video.

#### Inspector General Levinson Appointed to Government Accountability and **Transparency Board**

On July 28, 2011, HHS Inspector General Daniel R. Levinson was appointed by the President to the Government Accountability and Transparency Board. This Board is tasked with developing plans to enhance transparency in Federal spending and root out and stop waste, fraud, and abuse in Federal programs. (View the White House announcement.) Inspector General Levinson also serves on the Recovery Accountability and Transparency Board (RATB), which coordinates and conducts oversight of American Recovery and Reinvestment Act of 2009 (Recovery Act) funds to prevent fraud, waste, and abuse and to foster transparency by providing the public with accurate, user-friendly information. (View the <u>RATB Web site</u>.)

### Major Parts and Appendixes

Part I: Medicare Reviews

Part II: Medicaid Reviews

Part III: Legal and Investigative Activities Related to

Medicare and Medicaid

Part IV: Public Health and Human Services Reviews

and Other HHS-Related Issues

Appendix A: Savings Achieved by Implementation of Recommendations

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#### Part I

#### **Medicare Reviews**

The Office of Inspector General (OIG) relies on the Department of Health & Human Services (HHS) management, policymakers in the executive branch, States, and Congress to implement the recommendations reported in our reviews. Many of our recommendations are directly implemented by organizations within HHS, and some are acted on by States that collaborate with HHS to administer, operate, and/or oversee joint programs, such as Medicaid and Head Start program grants. Congress often incorporates our recommendations into legislative actions, resulting in substantial improvements in HHS programs and operations and in funds being made available for better use. Part I of this Semiannual Report to Congress summarizes the significant findings and recommendations reported in our reviews of the Medicare program, which is administered by HHS's Centers for Medicare & Medicaid Services (CMS).

#### Medicare Part A and Part B

#### Hospitals

#### Medicare Payments for Diagnostic Radiology Services in Emergency Departments

CLAIMS DOCUMENTATION DID NOT SUPPORT MEDICARE'S PAYMENTS OF NEARLY \$38 MILLION FOR PHYSICIANS' INTERPRETATIONS OF IMAGES AND REPORTS OF CLINICAL FINDINGS. These findings related to three common types of diagnostic radiology services (computed tomography (CT), magnetic resonance imaging (MRI), and x-rays). The diagnostic and radiology services we reviewed were conducted in hospital outpatient emergency departments. Medicare payments for such services have two components: technical and professional. We reviewed the professional component, which are payments to the interpreting physicians (i.e., emergency room physicians or radiologists). We found that in 2008, Medicare allowed \$29 million for interpretation and reports of CT and MRI services and almost \$9 million for interpretation and reports of x-ray services that did not have physicians' orders as part of the medical record documentation and/or did not have documentation to support that interpretation and reports were performed. Some physicians' interpretations and reports were performed after beneficiaries left the hospital outpatient emergency departments and many interpretations and reports did not follow one or more suggested documentation practice guidelines promoted by the American College of Radiology. Our recommendations focused on provider education, adopting uniform policies, and collecting any overpayments associated with claims lacking appropriate documentation.

2011 APR Medicare Payments for Diagnostic Radiology Services in Emergency Departments Report. OEI-07-09-00450. Web Summary. Full Text.

#### **Medicare Payments Exceeding Charges for Outpatient Services**

MEDICARE PAYMENTS FOR OUTPATIENT SERVICES THAT SIGNIFICANTLY EXCEED CHARGES MAY INDICATE POTENTIAL OVERPAYMENTS. Medicare uses an outpatient prospective payment system (OPPS) to pay certain outpatient providers. Under the OPPS, the billed charges (the prices that a provider sets for its

services) generally do not affect the current Medicare payment amounts. Billed charges generally exceed the amount that Medicare pays the provider. When we reviewed outpatient line items in which payment amounts exceeded billed charges by a significant amount, we found provider errors, including incorrect units of services, incorrect codes, a combination of those, unallowable services, and inadequate supporting documentation that caused Medicare to overpay for the services. Our recommendations to Medicare's payment contractors included recovering the overpayments, implementing system edits to identify line item payments that exceed billed charges by a prescribed amount, and using the results of our audits in provider education activities. Reviews completed during this semiannual period follow.

- **JURISDICTION 1: PALMETTO GBA, LLC.** Of 1,323 selected line items for outpatient services, 926 were incorrect and included overpayments of about \$7.5 million that had not been refunded by the beginning of our audit. Review of Medicare Payments Exceeding Charges for Outpatient Services Processed by Palmetto GBA, LLC, in Jurisdiction 1 for the Period January 1, 2006, Through June 30, 2009. A-09-10-02018. May, 2011. Web Summary. Full Text.
- **JURISDICTION 2: NORIDIAN ADMINISTRATIVE SERVICES, LLC.** Of 1,340 selected line items for outpatient services, 930 were incorrect and included overpayments of about \$6.2 million that had not been refunded by the beginning of our audit. Review of Medicare Payments Exceeding Charges for Outpatient Services Processed by Noridian Administrative Services, LLC, in Jurisdiction 2 for the Period January 1, 2006, Through June 30, 2009. A-09-10-02019. April, 2011. Web Summary. Full Text.
- JURISDICTION 3: NORIDIAN ADMINISTRATIVE SERVICES, LLC. Of 1,913 selected line items for outpatient services, 1,619 were incorrect and included overpayments of about \$5.8 million that had not been refunded by the beginning of our audit. Review of Medicare Payments Exceeding Charges for Outpatient Services Processed by Noridian Administrative Services, LLC, in Jurisdiction 3 for the Period January 1, 2006, Through June 30, 2009. A-07-10-04163. May, 2011. Web Summary. Full Text.
- **JURISDICTION 8: NATIONAL GOVERNMENT SERVICES** Of 1,407 selected line items for outpatient services, 957 were incorrect and included overpayments totaling \$7 million that had not been refunded by the beginning of our audit. Review of Medicare Payments Exceeding Charges for Outpatient Services Processed by National Government Services in Jurisdiction 8 for the Period January 1, 2006, Through June 30, 2009. A-05-10-00017. September, 2011. Web Summary. Full Text.
- **JURISDICTION 9: FIRST COAST SERVICE OPTIONS, INC.** Of 326 selected line items for outpatient services, 253 were incorrect and included overpayments of about \$1.7 million that had not been refunded by the beginning of our audit. Review of Medicare Payments Exceeding Charges for Outpatient Services Processed by First Coast Service Options, Inc., in Jurisdiction 9 for the Period January 1, 2006, Through December 31, 2007. A-04-10-06120. August, 2011. Web Summary. Full Text.
- JURISDICTION 12: HIGHMARK MEDICARE SERVICES. Of 739 selected line items for outpatient services, 418 were incorrect and included overpayments of about \$532,000 that had not been refunded by the beginning of our audit. Review of Medicare Payments Exceeding Charges By \$500 to \$1,000 for Outpatient Services Processed by Highmark Medicare Services in Jurisdiction 12 for the Period January 1, 2006, Through June 30, 2009. A-03-11-00004. August, 2011. Web Summary. Full Text.

# Review of Select Medicare Conditions of Participation and Costs Claimed at Richards Memorial Hospital from October 1, 2004, Through September 30, 2007

RICHARDS MEMORIAL HOSPITAL (THE HOSPITAL), A CRITICAL ACCESS HOSPITAL (CAH) IN ROCKDALE, TEXAS, DID NOT COMPLY WITH A MEDICARE CONDITION OF PARTICIPATION (COP), REPORTED UNALLOWABLE COSTS IN ITS MEDICARE COST REPORTS, AND DID NOT PROPERLY DISCLOSE RELATED-PARTY RENTAL COSTS. Contrary to Federal regulations, the hospital did not comply with a Medicare CoP because it did not maintain current and active network agreements with other hospitals during our audit period. The hospital also reported approximately \$1 million of unallowable costs in its fiscal year (FY) 2005, 2006, and 2007 Medicare cost reports. Specifically, the hospital reported \$804,000 in unsupported costs, \$198,000 in unallocable costs, and \$58,000 in costs unrelated to patient care. The hospital did not properly disclose \$213,000 in related-party rental costs in its Medicare cost reports. We recommended that the hospital establish and maintain network agreements with other hospitals; revise and resubmit its FY 2005, 2006, and 2007 Medicare cost reports; and ensure that it reports only allowable costs and properly discloses related-party transactions in future cost reports. This report is one of a series of reviews of CAHs' compliance with Medicare conditions of participation and other requirements.

2011 MAY Review of Select Medicare Conditions of Participation and Costs Claimed at Richards Memorial Hospital from October 1, 2004, Through September 30, 2007. A-05-08-00083. Web Summary. Full Text.

#### **Nursing Homes**

#### **Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents**

FOR THE PERIOD JANUARY 1 THROUGH JUNE 30, 2007, 51 PERCENT OF MEDICARE CLAIMS FOR ATYPICAL ANTIPSYCHOTIC DRUGS DID NOT COMPLY WITH MEDICARE REIMBURSEMENT CRITERIA, AMOUNTING TO ABOUT \$116 MILLION IN ERRONEOUS PAYMENTS. Atypical antipsychotic drugs are approved by the Food and Drug Administration (FDA) for treatment of schizophrenia and/or bipolar disorder. Fourteen percent of 2.1 million elderly (age 65 and older) nursing home residents had at least 1 claim for such drugs. Eighty-three percent of the claims were associated with off-label conditions (conditions other than schizophrenia and/or bipolar disorder) and 88 percent were associated with dementia (the condition specified in the FDA boxed warning). Twenty-two percent of claims were for drugs that were not administered in accordance with Federal standards for drug therapy in nursing homes. Recommendations included facilitating Medicare's access to information necessary to ensure accurate coverage and reimbursement determinations and taking appropriate action regarding the erroneous payments identified in our sample. Our review did not evaluate the medical decisions used to determine each resident's treatment.

2011 MAY Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents. OEI-07-08-00150. Web Summary. Full Text. Inspector General's CNN article. CBS's related news video.

#### Part B Services During Non-Part A Nursing Home Stays

THIS REVIEW PROVIDES INSIGHTS INTO PAYMENT AND UTILIZATION PATTERNS FOR PART B SERVICES IN NURSING HOMES, AS WELL AS GEOGRAPHIC DIFFERENCES, THAT WILL GUIDE FURTHER REVIEW OF PROVIDERS THAT WARRANT SCRUTINY BY OIG AND MEDICARE. Medicare paid \$4.9 billion in 2008 for Part B services during nursing home stays not paid for by Part A (referred to as non-Part A stays). Three service categories (therapy services, evaluation and management (E/M), and major and minor medical procedures) made up 58 percent of the total payment. We found that Medicare paid \$16.75 per day per beneficiary for Part B

services across all service categories and beneficiaries. The service category of dialysis services and the State of Louisiana exhibited the highest average daily payments.

2011 JUL Payments for Medicare Part B Services During Non-Part A Nursing Home Stays in 2008. OEI-06-07-00580. Web Summary. Full Text.

#### Changes in Skilled Nursing Facilities Billing in Fiscal Year 2011

ALTHOUGH CHANGES MADE TO THE SKILLED NURSING FACILITY (SNF) PAYMENT SYSTEM EFFECTIVE FY 2011 WERE INTENDED BE TO BE BUDGET NEUTRAL, UNANTICIPATED BILLING PATTERNS CONTRIBUTED TO A \$2.1 BILLION (16-PERCENT) INCREASE IN MEDICARE PAYMENTS. The increase occurred from the last half of FY 2010 to the first half of FY 2011. At the same time, we found that several of the changes reduced billing for certain higher-paying groups. The data indicate that Medicare should adjust payment rates to address the significant increases in payments to SNFs. The data also show that Medicare should make changes to how SNFs account for group therapy. Further, the data highlight the need for changes to make Medicare payments more consistent with beneficiaries' care and resource needs. Based on this report, CMS has proposed a number of changes to the SNF payment system and will issue a final rule for FY 2012.

2011 JUL Changes in Skilled Nursing Facilities Billing in Fiscal Year 2011. OEI-02-09-00204. Web Summary. Full Text.

#### **Hospice Services**

#### **Medicare Hospices That Focus on Nursing Facility Residents**

MEDICARE SPENDING ON HOSPICE CARE FOR NURSING FACILITY RESIDENTS HAS GROWN NEARLY 70 PERCENT SINCE 2005. WE FOUND THAT HUNDREDS OF HOSPICES—MOST OF WHICH WERE FOR-PROFIT—HAD MORE THAN TWO-THIRDS OF THEIR BENEFICIARIES IN NURSING FACILITIES IN 2009. Hospices with a high percentage of their beneficiaries in nursing homes received more Medicare payments per beneficiary than other hospices and had beneficiaries who spent more time in care. The high-percentage hospices typically enrolled beneficiaries whose diagnoses required less complex care and who already lived in nursing facilities. We recommended that CMS monitor hospices that depend heavily on nursing facility residents and modify the payment system for hospice care in nursing facilities. The current payment structure provides incentives for hospices to seek out nursing facility beneficiaries who often receive longer but less complex care. Medicare currently pays hospices the same rate for care provided in nursing facilities as it does for care provided in other settings, such as private homes. However, unlike private homes, nursing facilities (which are often paid by third-party payers or Medicaid) are already staffed with professional caregivers and are required to provide personal care services (PCS) that are similar to hospice aide services.

2011 JUL Medicare Hospices That Focus on Nursing Facility Residents. OEI-02-10-00070.

Web summary. Full Text. See also OIG's Spotlight on Hospice Care, OIG's March 2011

Compendium, Part I, pp. 19 and 20, and OEI-02-06-00221, all available on our Web site.

#### Home Health Services

#### Nonroutine Supplies Subject to Home Health Consolidated Billing

FOR CALENDAR YEARS (CY) 2007 AND 2008, MEDICARE FAILED TO RECOVER AN ESTIMATED \$3.4 MILLION IN OVERPAYMENTS TO DURABLE MEDICAL EQUIPMENT (DME) SUPPLIERS FOR NONROUTINE SUPPLIES SUBJECT TO HOME

HEALTH CONSOLIDATED BILLING. We identified \$24,000 in overpayments in our sample that Medicare had not recovered as of June 10, 2010. Based on our sample results, we estimated that Medicare failed to recover \$3.4 million overpaid to DME suppliers for CYs 2007 and 2008. We found that although a postpayment system edit consistently identified nonroutine supplies subject to home health consolidated billing, two Medicare payment contractors did not implement procedures to process and recover the associated overpayments in a timely manner.

Pursuant to consolidated billing, the home health agency (HHA) that establishes the beneficiary's plan of care is paid for the services and supplies (including nonroutine supplies) that are included in the home health prospective payment rate, regardless of whether they were furnished by the HHA, by an outside provider under arrangement with the agency, under any other contracting or consulting arrangement with the agency, or otherwise. Medicare payments made to outside suppliers (e.g., DME suppliers) for nonroutine supplies provided during home health care episodes are overpayments to be recovered. We recommended that Medicare recover identified and estimated overpayments for the nonsampled line items and implement procedures to ensure that Medicare's payment contractors process and recover this type of overpayment in a timely manner.

2011 APR Review of Medicare Home Health Consolidated Billing for Calendar Years 2007 and 2008. A-01-10-00505. Web Summary. Full Text.

#### Physician Therapy Services Provided During Home Health Episodes

MEDICARE REIMBURSEMENT POLICY PERMITS DUPLICATE PAYMENTS FOR PART B THERAPY PROVIDED TO A BENEFICIARY DURING A HOME HEALTH EPISODE—ONCE TO THE PHYSICIAN UNDER PART B AND AGAIN TO THE HHA UNDER THE HOME HEALTH PPS. Since 2003, Medicare has allowed Part B payments to physicians for therapy services furnished during episodes in which beneficiaries are receiving home health care. Medicare also includes physicians' therapy services in the home health PPS base rate paid to the HHA. As a result, Medicare pays twice. We recommended that Medicare eliminate duplicate payments when home health payments are rebased beginning in 2014 by adjusting the home health PPS rate to exclude physician-provided therapy services or by making such services subject to the home health consolidated billing requirement.

2011 MAY Review of Physician Therapy Services Provided During Home Health Episodes in Calendar Year 2008. A-01-09-00530. Web Summary. Full Text.

#### Medical Equipment and Supplies

# Use of Surety Bonds to Recover Overpayments Made to Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies: Early Findings

Our review revealed that Medicare had not recovered any DME overpayments through surety bonds. More than 2 years after publishing a January 2009 final rule requiring certain suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to obtain surety bonds, CMS had not finalized procedures for recovering overpayments through such bonds. The Balanced Budget Act of 1997 (BBA) mandated that all nonexempt DMEPOS suppliers obtain a surety bond of not less than \$50,000 to receive Medicare billing privileges. Requiring surety bonds is an important program integrity tool that not only limits fraudulent suppliers' access to the program, but also serves as a means for Medicare to guarantee recoupment of some overpayments. Not using this tool leaves Medicare vulnerable to losses from fraudulent suppliers. The report contained no recommendations.

2011 SEP Use of Surety Bonds to Recover Overpayments Made to Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies: Early Findings.

OEI-03-11-00351. Web Summary. Full Text.

#### Questionable Billing by Suppliers of Lower Limb Prostheses

IN 2009, MEDICARE INAPPROPRIATELY PAID \$43 MILLION FOR CERTAIN TYPES AND COMBINATIONS OF LOWER LIMB PROSTHESES THAT DID NOT MEET MEDICARE REQUIREMENTS. The improper payments could have been prevented by using claims processing system edits. Lower limb prostheses are designed to replace, as much as possible, the function of a missing limb. Medicare paid an additional \$61 million for beneficiaries for whom no claims were filed by their referring physicians, raising questions about whether the physician ever evaluated the beneficiary and whether these devices were medically necessary. We found suppliers that frequently billed for unusual combinations of prostheses or for beneficiaries who had no history of an amputation or missing limb. We recommended that Medicare implement necessary claims processing system edits, strengthen monitoring of billing, implement requirements for a face-to-face encounter to establish the beneficiary's need for prostheses, revise certain local coverage determination (LCD) requirements, enhance screening for currently enrolled suppliers, and take appropriate action on suppliers with questionable billing.

2011 AUG <u>Questionable Billing by Suppliers of Lower Limb Prostheses</u>. OEI-02-10-00170. Web Summary. Full Text.

# Most Power Wheelchairs in the Medicare Program Did Not Meet Medical Necessity Guidelines

AN ESTIMATED 61 PERCENT OF POWER WHEELCHAIRS PROVIDED TO MEDICARE BENEFICIARIES IN THE FIRST HALF OF 2007 WERE MEDICALLY UNNECESSARY OR HAD CLAIMS THAT LACKED SUFFICIENT DOCUMENTATION TO DETERMINE MEDICAL NECESSITY. The estimate was based on records submitted by suppliers that provided the power wheelchairs. Medical necessity and documentation errors varied by power wheelchair type, and prescribing physicians' records did not support the medical necessity of most power wheelchairs. We recommended that Medicare enhance reenrollment screening standards for current DMEPOS suppliers; review records from sources in addition to the supplier, such as the prescribing physician, to determine medical necessity; continue supplier and physician education; and review the suppliers of the sampled claims we found to be in error.

2011 JUL Most Power Wheelchairs in the Medicare Program Did Not Meet Medical Necessity
Guidelines. OEI-04-09-00260. Web Summary. Full Text. See also OEI-04-07-00403 and
OEI-04-07-00401; OIG's Spotlight on Power Wheelchairs; and OIG's March 2011
Compendium, Part I, pp. 67 and 68, all available on our Web site.

#### Other Practitioners and Suppliers

#### Independent Diagnostic Testing Facilities' Compliance with Medicare Standards

INDEPENDENT DIAGNOSTIC TESTING FACILITIES (IDTF) IN THE MIAMI AND LOS ANGELES AREAS DID NOT COMPLY WITH MEDICARE'S REQUIREMENT THAT THEY MAINTAIN THEIR PHYSICAL FACILITIES AT THE LOCATIONS ON FILE WITH CMS AND BE OPEN DURING BUSINESS HOURS. IDTFs that do not comply with Medicare standards are subject to administrative actions, including revocation of their Medicare billing privileges. In prior site visits in 1997, OIG found that 20 percent of IDTFs were not at the locations on file with CMS.

• MIAMI – Twenty-seven of 92 Miami-area IDTFs we visited failed to comply with selected Medicare standards. As a result of a special enrollment project and routine oversight, CMS took action

against 23 of the 27 noncompliant IDTFs that our report identified. However, three IDTFs continued to receive Medicare payments while CMS was revoking their billing privileges. We recommended periodically conducting unannounced site visits to IDTFs and immediately stopping payments to IDTFs whose billing privileges are being revoked. *Miami Independent Diagnostic Testing Facilities' Compliance with Medicare Standards*. OEI-05-09-00560. August, 2011. Web Summary. Full Text.

• Los Angeles – Forty-six of 132 Los Angeles-area IDTFs we visited failed to comply with selected Medicare standards. Twenty-four IDTFs were not at locations on file with CMS and 22 were not open during business hours. Twenty-five IDTFs submitted claims representing services performed on the same dates that site reviewers visited their locations. We recommended periodically conducting unannounced site visits to IDTFs, taking action against the noncompliant IDTFs identified by our site visits, and imposing a moratorium on the new enrollment of IDTFs in the Los Angeles area. Los Angeles Independent Diagnostic Testing Facilities' Compliance with Medicare Standards. OEI-05-09-00561. August, 2011. Web Summary. Full Text.

See also OIG's Spotlight on Independent Diagnostic Testing Facilities, available on our Web site.

#### Place-of-Service Coding for Physician Services Processed by Medicare Part B Contractors

MEDICARE CONTRACTORS OVERPAID PHYSICIANS AN ESTIMATED \$28.8 MILLION FOR INCORRECTLY CODED PLACES OF SERVICE DURING CYS 2009 AND 2008. Physicians incorrectly used nonfacility place-of-service codes for services that were actually performed in facilities such as hospital outpatient departments or ambulatory surgical centers (ASC). To account for the increased overhead expense that physicians incur by performing certain services in nonfacility locations, Medicare reimburses physicians at a higher rate. However, when physicians perform these same services in facility settings, Medicare reimburses the overhead expenses to the facility and the physician receives a lower reimbursement rate. Our recommendations included recovering the overpayments we identified in our sample; and, as appropriate, recovering any overpayments associated with nonsampled services; strengthening the physician education process; developing a data match that will identify physician services at high risk for place-of-service miscoding; and recovering any identified overpayments. The two reviews completed in this semiannual period for CY 2009 and 2008 follow.

- CY 2009 Medicare contractors nationwide overpaid physicians an estimated \$9.5 million for incorrectly coded place of service during CY 2009. Review of Place-of-Service Coding for Physician Services Processed by Medicare Part B Contractors During Calendar Year 2009. A-01-10-00516.
   September, 2011. Web Summary. Full Text.
- CY 2008 Medicare contractors nationwide overpaid physicians an estimated \$19.3 million for incorrectly coded place of service during CY 2008. Review of Place-of-Service Coding for Physician Services Processed by Medicare Part B Contractors During Calendar Year 2008.
   A-01-10-00513. September, 2011. Web Summary. Full Text.

#### Part B Prescription Drugs

#### Cost of Alternative Drug Treatments for Age-Related Macular Degeneration

IF MEDICARE REIMBURSEMENT FOR ALL BENEFICIARIES TREATED WITH AVASTIN OR LUCENTIS FOR WET AGE-RELATED MACULAR DEGENERATION (WET AMD) HAD BEEN PAID AT THE AVASTIN RATE DURING CYS 2008 AND 2009, MEDICARE PART B WOULD HAVE SAVED APPROXIMATELY \$1.1 BILLION AND BENEFICIARIES WOULD HAVE SAVED APPROXIMATELY \$275 MILLION IN COPAYMENTS. Conversely, we calculated that if Medicare reimbursement for all beneficiaries treated with Avastin or Lucentis for wet AMD had been paid at the Lucentis rate,

Medicare Part B would have increased spending by approximately \$1.5 billion and beneficiaries would have paid approximately \$370 million more in copayments. Our recommendations included evaluating coverage and reimbursement policies and seeking such additional authorities as are necessary to limit Part B drug and biological expenditures effectively. Avastin and Lucentis (both manufactured by Genentech) are the most commonly administered Part B biologicals used to treat wet AMD, which is the leading cause of severe vision loss in people over the age of 65 in the United States.

2011 SEP Review of Medicare Part B Avastin and Lucentis Treatments for Age-Related Macular Degeneration. A-01-10-00514. Web Summary. Full Text.

# Comparison of Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement of Part B Prescription Drugs

MEDICARE COULD HAVE SAVED MILLIONS OF DOLLARS ON DRUG COSTS IN RECENT YEARS IF AVAILABLE STATUTORY AUTHORITY TO ADJUST PAYMENTS HAD BEEN APPLIED. Federal law provides that if the average sales price (ASP) (which has been the basis for paying Part B drugs since 2005) of a drug exceeds the average manufacturer price (AMP) for the drug by a threshold of 5 percent, the Secretary may disregard the ASP for the drug when setting reimbursement and shall substitute the payment amount with the lesser of either the widely available market price (if any) or 103 percent of the AMP. Consistent with its statutory mandate, OIG compares ASP to AMP for Part B drugs. On the basis of our reviews, we have consistently recommended that Medicare develop a price substitution policy and lower reimbursement for drugs that exceed the 5-percent threshold. In July 2011, a proposed rule specified, among other things, the circumstances under which AMP-based price substitutions would occur. CMS plans to implement a price substitution policy beginning in the first quarter of 2012. We have also recommended expanding the price substitution policy; seeking a legislative change requiring all manufacturers of Part B-covered drugs to submit both ASPs and AMPs; and continuing to pursue appropriate actions against manufacturers that fail to comply with price-reporting requirements, including referring to OIG manufacturers that fail to submit timely ASP data.

Following are the ASP/AMP price comparison reports we issued during this semiannual period.

- OVERVIEW OF 2009 In 2009, the ASPs for 34 dug codes with complete AMP data exceeded AMPs by at least 5 percent in one or more quarters. If reimbursement amounts for these 34 codes had been lowered to 103 percent of the AMPs during the applicable quarters, Medicare expenditures would have been reduced by an estimated \$4.4 million from the third quarter of 2009 through the second quarter of 2010. Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2009. OEI-03-10-00380. April, 2011. Web Summary. Full Text.
- THIRD-QUARTER 2010 Impact on First Quarter 2011. We identified drug codes with ASPs that exceeded AMPs by at least 5 percent in the third quarter of 2010 and found that if reimbursement amounts for the codes with complete AMP data had been based on 103 percent of the AMPs during the first quarter of 2011, Medicare expenditures would have been reduced by an estimated \$10.3 million in that quarter alone. Comparison of Third-Quarter 2010 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2011. OEI-03-11-00160. May, 2011. Web Summary. Full Text.
- FOURTH-QUARTER 2010 Impact on Second Quarter 2011. We identified drug codes with ASPs that exceeded AMPs by at least 5 percent in the fourth quarter of 2010 and found that if reimbursement amounts for the codes with complete AMP data had been based on 103 percent of the AMPs during the second quarter of 2011, Medicare expenditures would have been reduced by an estimated \$1.3 million in that quarter alone. Comparison of Fourth-Quarter 2010 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second Quarter 2011 (OEI-03-11-00360). July, 2011. Web Summary. Full Text.

FIRST-QUARTER 2011 – Impact on Third Quarter 2011. We identified drug codes with ASPs that exceeded AMPs by at least 5 percent in the first quarter of 2011 and found that if reimbursement amounts for the codes with complete AMP data had been based on 103 percent of the AMPs during the third quarter of 2011, Medicare expenditures would have been reduced by an estimated \$788,000 in that quarter alone. This is OIG's 23rd report comparing ASPs to AMPs. Comparison of First-Quarter 2011 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2011. OEI-03-11-00540. August, 2011. Web Summary. Full Text.

#### Part A and Part B Program Administration

#### Review of Termination Claim for Postretirement Benefits Made by Blue Cross Blue Shield of Mississippi

BLUE CROSS BLUE SHIELD OF MISSISSIPPI'S (BCBS MISSISSIPPI) ENTIRE TERMINATION CLAIM OF \$4.2 MILLION IN POSTRETIREMENT BENEFIT (PRB) COSTS FOR THE MEDICARE PART A CONTRACT WAS UNALLOWABLE FOR MEDICARE REIMBURSEMENT. We recommended that BCBS Mississippi withdraw its termination claim of \$4.2 million in PRB costs because the claim was calculated on the basis of a retroactive change in accounting practice without CMS approval. Therefore and pursuant to BCBS Mississippi's Medicare contracts, none of the costs claimed were allowable. Medicare reimburses a portion of its contractors' PRB costs. In claiming PRB costs, contractors must follow cost reimbursement principles in the Federal Acquisition Regulation and applicable Cost Accounting Standards as required by their Medicare contracts.

Review of Termination Claim for Postretirement Benefits Made by Blue Cross Blue Shield of 2011 MAY Mississippi. A-07-11-00359. Web Summary. Full Text.

#### Medicare Contractor Information Security Program Evaluations – Fiscal Year 2009

PRICEWATERHOUSECOOPERS' (PWC) EVALUATIONS OF MEDICARE CONTRACTOR INFORMATION SECURITY PROGRAMS WERE ADEQUATE IN SCOPE AND WERE SUFFICIENT, AND IFED LLC'S (IFED) ASSESSMENTS FOR MOST OF MEDICARE DATA CENTERS TESTED WERE ADEQUATE IN SCOPE AND WERE SUFFICIENT. Federal law requires that each Medicare contractor have its information security program evaluated annually by an independent entity, and these evaluations must address eight major requirements of Federal law. OIG must submit to Congress annual reports on the results of these evaluations, to include assessments of their scope and sufficiency. PwC reported 94 security gaps at 21 Medicare contractors, and iFed reported 67 security gaps at 7 data centers. We recommended that CMS review all contractor documentation related to future data center technical assessments and ensure that the work performed complies with CMS contractual requirements. At a minimum, this should include a review of test plans to ensure that the contractor has completed all required testing procedures and a review of contractor working papers to verify that reported issues have been adequately supported.

2011 SEP Review of Medicare Contractor Information Security Program Evaluations for Fiscal Year 2009. A-18-10-30300. Web Summary. Full Text.

## Medicare Part D (Prescription Drug Program)

#### Part D Drug Pricing and Payment-Related Reviews

#### Review of Medicare Payments to Prescription Drug Plans on Behalf of Deceased Enrollees

MEDICARE MADE ABOUT \$3.6 MILLION IN UNALLOWABLE PAYMENTS TO PRESCRIPTION DRUG PLAN SPONSORS FOR COVERAGE PERIODS AFTER THE ENROLLEES' MONTHS OF DEATH. However, we note that the improper payments were made on behalf of far less than 1 percent of the deceased enrollees. Also, Medicare did not always recover such payments in a timely manner. We recommended that Medicare recoup the \$3.6 million, recover improper payments in a timely manner, and implement system enhancements to prevent and detect future improper payments for deceased enrollees. The improper payments occurred because Medicare's payment systems categorized these enrollees as alive or as having different dates of death than those listed in the Social Security Administration's death master file. Although Medicare's systems had correctly stopped payments for the vast majority of deceased enrollees, they did not always identify and prevent improper payments.

2011 MAY Review of Medicare Payments to Prescription Drug Plans on Behalf of Deceased Enrollees (A-05-09-00027. Web Summary. Full Text.

#### Part D Administration and Program Integrity

#### Part D Plans Coverage of Drugs Commonly Used By Dual Eligibles

OVERALL, THE RATE AT WHICH PART D PLAN FORMULARIES INCLUDE THE 191 DRUGS COMMONLY USED BY DUAL ELIGIBLES IS HIGH, WITH SOME VARIATION. Each Medicare prescription drug plan has a list of drugs it covers. This list is called a formulary. Dual eligibles are individuals who are eligible for both Medicare and Medicaid. On average, Part D plan formularies include 96 percent of the 191 commonly used drugs. In fact, 90 percent of dual eligibles are enrolled in Part D plans that use formularies that include at least 90 percent of the commonly used drugs. We found variation in the rate at which Part D plan formularies apply utilization management tools to the drugs commonly used by dual eligibles. This review was mandated in the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act).

2011 APR Part D Plans Generally Cover Drugs Commonly Used By Dual Eligibles. OEI-05-10-00390. Affordable Care Act. Web Summary. Full Text.

#### Medicare Prescription Drug Sponsors' Training To Prevent Fraud, Waste, and Abuse

NEARLY ALL PART D NETWORK PHARMACIES RECEIVED TRAINING TO PREVENT FRAUD, WASTE, AND ABUSE IN 2009; HOWEVER, NOT ALL SPONSORS DOCUMENTED THE TRAINING. As a condition of contracting with CMS, Part D sponsors must have plans that help them prevent fraud, waste, and abuse. These plans must include effective annual training and education on fraud, waste, and abuse for their network pharmacies. With a few exceptions, the content and source of most training materials reflected Medicare guidance, but most sponsors could not determine the extent to which the training was effective. We recommended reiterating to sponsors their responsibilities for network pharmacies' training on fraud, waste, and abuse. We also recommended that CMS use its monitoring authority to determine sponsors' compliance with training requirements and take steps to ensure that sponsors are providing training that is effective.

2011 JUL Medicare Prescription Drug Sponsors' Training To Prevent Fraud, Waste, and Abuse. OEI-01-10-00060. Web Summary. Full Text.

#### Part II

#### Medicaid Reviews

Pursuant to Title XIX of the Social Security Act, Medicaid provides medical assistance to low-income individuals and those with disabilities. The Federal and State Governments jointly fund and administer Medicaid. The Federal Government pays its share of a State's medical assistance expenditures under Medicaid based on the Federal Medical Assistance Percentage (FMAP), which varies depending on the State's relative per capita income. The FMAP for some categories of benefits or activities may be paid at an enhanced rate. For example, the FMAP for family planning expenditures is 90 percent, which is higher than the regular FMAP.

At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers the program. At the State level, State agencies administer their Medicaid programs in accordance with CMS-approved State plans. Although the States have considerable flexibility in designing and operating their Medicaid programs, they must comply with applicable Federal requirements to receive a Federal share of costs.

#### Prescription Drug Reimbursements and Rebates

#### Medicaid Drug Payment Policy: Replacing Average Wholesale Price

ALMOST HALF OF THE STATES THAT USED AVERAGE WHOLESALE PRICE (AWP) TO SET REIMBURSEMENT FOR PRESCRIPTION DRUGS IN THE FIRST QUARTER OF 2011 DID NOT HAVE DEFINITIVE PLANS FOR HOW THEY WOULD REIMBURSE DRUGS AFTER FIRST DATABANK, A PRIMARY SOURCE OF DATA, STOPPED PUBLISHING AWPS IN SEPTEMBER 2011. Most States (44 of 51) said they would prefer a single national benchmark to set Medicaid reimbursement rates, and 24 States specifically wanted a benchmark based on pharmacy acquisition costs. We recommended to CMS that it develop a national benchmark that accurately estimates acquisition costs and encourage States to consider it when determining Medicaid reimbursement for prescription drugs.

2011 JUL Replacing Average Wholesale Price: Medicaid Drug Payment Policy. OEI-03-11-00060. Web Summary. Full Text. See also OIG's March 2011 Compendium, Part III, pp. 17 through 19, available on our Web site.

#### Documentation for Pharmacy Prescription Drug Claims – Arkansas

FOR THE QUARTER ENDING DECEMBER 31, 2008, ARKANSAS REIMBURSED PHARMACIES AN ESTIMATED \$1.7 MILLION FOR MEDICAID OUTPATIENT DRUG CLAIMS THAT WERE NOT SUPPORTED BY PHARMACY RECORDS. Also, prescriptions were not always written on tamper-resistant pads as required by Federal statute, and pharmacies did not document verification of those prescriptions in accordance with Federal guidance. Our recommendations included that Arkansas determine the proper resolution for the unsupported claims we identified, remind pharmacies and physicians of CMS guidance to verify prescriptions that do not comply with Federal tamper-resistance requirements, and strengthen its review process to ensure that payments are made only for drugs that are supported by appropriate records.

2011 JUL Review of Arkansas Medicaid Prescription Drug Claims for the Quarter Ending December 31, 2008. A-06-09-00093. Web Summary. Full Text.

#### Medicaid's Manufacturer Rebates Offset Rising Prices for Brand-Name Drugs

ALTHOUGH PRICES AND PAYMENT AMOUNTS FOR MEDICAID BRAND-NAME DRUGS INCREASED AT ABOUT THREE TIMES THE INFLATION RATE BETWEEN 2005 AND 2010, THE SIGNIFICANT INCREASE WAS OFFSET BY SAVINGS GENERATED BY THE MEDICAID DRUG REBATE PROGRAM. Taken as a whole, the results of this review indicate that price increases for brand-name drugs may not necessarily translate to corresponding increases in Medicaid costs. Because of the savings generated by the drug rebate program, Medicaid's net costs for brandname drugs actually increased at a lower rate than other points of comparison, including the inflation rate. In fact, Medicaid's rebate-adjusted payment amounts for brand-name drugs declined at the median in 3 of 4 data years, lagging behind the inflation rate.

2011 AUG Medicaid Brand-Name Drugs: Rising Prices Are Offset by Manufacturer Rebates. OEI-03-10-00260. Web Summary. Full Text.

#### Medicaid's Rebates for Brand-Name Drugs Result in Lower Costs Compared to **Medicare Part D**

ALTHOUGH PHARMACY REIMBURSEMENT AMOUNTS UNDER MEDICAID AND MEDICARE PART D WERE SIMILAR FOR MOST SELECTED BRAND-NAME DRUGS IN 2009, MEDICAID'S NET UNIT DRUG COSTS WERE MUCH LOWER THAN PART D'S BECAUSE MEDICAID HAS SUBSTANTIALLY HIGHER REBATES FOR BRAND-NAME DRUGS. Manufacturer rebates for generic drugs under both programs were negligible. We also found that Part D sponsors and State Medicaid agencies paid pharmacies roughly the same amount for brand name drugs. However, after accounting for rebates, Medicaid's net costs for selected brand-name drugs were much lower than Part D net costs. Medicaid recouped 45 percent of its drug spending on selected brand-name drugs in manufacturer rebates while Part D sponsors recouped 19 percent. We concluded that given the potential impact on beneficiary and Government expenditures, differences in how rebates are collected across Medicaid and Part D should be continually examined by CMS. Unlike Medicaid, Part D sponsors (or contractors acting on their behalf) negotiate rebates with drug manufacturers without any statutory requirements on rebate amounts. In fact, the law establishing the Part D program expressly prohibits the Government from instituting a price structure for the reimbursement of covered Part D drugs. This review was required by the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), § 3313(b).

Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to 2011 AUG Medicare Part D. OEI-03-10-00320. Web Summary. Full Text.

#### Medicaid Drug Rebate Collections - Nationwide Review

IN A NATIONWIDE FOLLOWUP TO A 2005 REVIEW OF MEDICAID DRUG REBATE PROGRAMS, WE FOUND THAT MANY STATES STILL NEED TO MAKE IMPROVEMENTS. States lack adequate assurance that all drug rebates due them are properly recorded and collected. We also examined the extent to which States had established controls over collecting rebates on single-source (brand name) physician-administered drugs, as required by the Deficit Reduction Act of 2005 (DRA). We found that six States and the District of Columbia did not establish controls over collecting such rebates. We recommended continued emphasis on States' submitting accurate and reliable information, placing priority on their billing and collecting of rebates, and collecting rebates for single-source physician-administered drugs.

2011 AUG Nationwide Rollup Report for Medicaid Drug Rebate Collections. A-06-10-00011. Web Summary. Full Text. See also Multistate Review of Medicaid Drug Rebate Programs. A-06-03-00048. July 2005. Web Summary. Full Text.

#### Collection of Medicaid Rebates for Physician-Administered Drugs

MOST OF 49 RESPONDING STATES SELF-REPORTED THAT THEY MET OR EXCEEDED FEDERAL REQUIREMENTS TO COLLECT REBATES FOR CERTAIN PHYSICIAN-ADMINISTERED DRUGS; HOWEVER, 29 STATES REPORTED DIFFICULTIES WITH MANUFACTURER NONPAYMENT OF REBATES FOR THE DRUGS. The States attributed the difficulty mainly to inaccuracies in the drug code information that providers entered on claims. Because of incomplete and potentially inaccurate data provided by States, we were unable to calculate the total rebate dollars all States collected for physician-administered drugs and, therefore, could not determine the impact collecting such rebates had on reducing prescription drug expenditures. Federal law requires that States collect rebates on all claims for certain physician-administered drugs for Federal matching funds to be available. We recommended five steps to ensure States' compliance with rebate-related requirements for physician-administered drugs, including working with States to develop guidance for implementing system edits that increase the efficiency of physician-administered drug claim reviews.

2011 JUN States' Collection of Medicaid Rebates for Physician-Administered Drugs. OEI-03-09-00410. Web Summary. Full Text.

#### California's Rebates for Medicaid Compound Drug Expenditures

WE ESTIMATED THAT CALIFORNIA FAILED TO INVOICE MANUFACTURERS FOR AND COLLECT \$26.7 MILLION (\$13.6 MILLION FEDERAL SHARE) IN REBATES FOR ELIGIBLE COMPOUND DRUG INGREDIENTS FOR A 24-QUARTER PERIOD ENDING JUNE 30, 2009. Pharmacists create compound drugs by combining two or more prescription or nonprescription drug products and then repackaging them into a new form. California's Rebate Accounting Information System was not designed to invoice rebates for compound drug ingredients, and its electronic claims for such expenditures did not comply with Federal requirements related to invoicing manufacturers for rebates and reporting drug utilization data to CMS. We recommended that California invoice manufacturers for the estimated \$26.7 million in rebates; refund to CMS the Federal share of the rebates; and strengthen internal controls, including modifying its rebate accounting system, to invoice manufacturers for eligible compound drug ingredients and report drug utilization data to CMS.

2011 MAY Review of California's Invoicing of Rebates for Medicaid Compound Drug Expenditures-Electronic Claims. A-09-10-02006. Web Summary. Full Text.

#### 340B-Purchased Drugs: State Medicaid Policies and Oversight Activities

STATE MEDICAID AGENCIES LACK THE POLICIES AND INFORMATION THEY NEED TO OVERSEE REIMBURSEMENTS FOR DRUGS PURCHASED PURSUANT TO THE 340B Drug Discount Program (340B program). Our findings included that State Medicaid agencies do not have drug pricing information necessary to create prepayment system edits to prevent overpaying for 340B-purchased drugs and about half of States (25 of 51) do not have written policies for how 340B-covered entities are to bill Medicaid for reimbursement. The 340B program requires drug manufacturers to provide covered outpatient drugs to certain eligible health care entities at or below statutorily defined discount prices. Such entities include eligible community health centers, critical access hospitals, and children's hospitals. We recommended that the responsible Department of Health and Human Services (HHS) agencies direct all States to create 340B billing policies, inform States about tools to identify 340B-purchased drugs, share 340B ceiling prices with States, and improve the accuracy of 340B-related data tools. The Affordable Care Act requires the Secretary to issue new guidance describing methodologies available to covered entities for billing 340B-purchased drugs to State Medicaid agencies and develop procedures for covered entities to annually update their information in the Federal covered-entity database.

State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs. 2011 JUN OEI-05-09-00321. Affordable Care Act. Web Summary. Full Text.

#### Home, Community, and Personal Care Services

#### **New Jersey's Community Care Waiver Program Claims**

New Jersey improperly claimed an estimated a \$903,000 Federal share of Medicaid reimbursements for COMMUNITY CARE WAIVER (CCW) PROGRAM SERVICES PROVIDED BY ELWYN NEW JERSEY (ELWYN). New Jersey's CCW program is included in its Medicaid Home- and Community-Based Services (HCBS) waiver program. Elwyn, which was New Jersey's largest provider of CCW services during our calendar year (CY) 2005–2007 review period, filed claims that did not comply with level-of-care and other Federal and State requirements. We recommended that New Jersey refund the Federal share and that the State and Elwyn claim reimbursement only for CCW services that are documented and allowable. We also recommended that New Jersey ensure and document that all State beneficiaries approved for CCW services have been assessed and certified to need an Intermediate Care Facility for the Mentally Retarded (ICF/MR) level of care and ensure that such services are provided only to beneficiaries for whom there is a completed and approved individual habilitation plan.

Medicaid's HCBS waiver programs allow States to claim the Federal share of services not usually covered by Medicaid. HCBS are provided only to recipients who would, in the absence of such services, require the Medicaid-covered level of care provided in a hospital, nursing facility, or intermediate care facility for persons with mental retardation. New Jersey's CCW program provides reimbursement for services to individuals with intellectual disabilities who would otherwise require institutionalization in an ICF/MR.

2011 JUL Review of Medicaid Payments for Services Provided Under New Jersey's Section 1915(c) Community Care Waiver by Elwyn New Jersey From January 1, 2005, Through December 31, 2007. A-02-09-01033. Web Summary. Full Text.

#### Pennsylvania's Aging Services Waiver Claims – Administrative Costs

PENNSYLVANIA IMPROPERLY CLAIMED A \$2.1 MILLION FEDERAL SHARE OF MEDICAID ADMINISTRATIVE COSTS FOR ITS HCBS Waiver for Individuals Aged 60 and Over (Aging Waiver). Pennsylvania's Aging Waiver authorizes home- and community-based services for Medicaid beneficiaries aged 60 or older who are economically distressed and are clinically eligible for care in a skilled nursing facility. The \$2.1 million was not allowable because the State did not identify the claimed costs in the Aging Waiver or its cost allocation plan. The State also could not support a \$371,000 adjustment of a prior improper claim for training of skilled professional medical personnel. We set aside for further analysis and resolution a \$25.8 million Federal share of local agencies' administrative cost claims that were identified in the Aging Waiver but not the cost allocation plan and may have included costs that did not benefit the Aging Waiver. Our recommendations included that Pennsylvania refund \$2.1 million for administrative costs and \$371,000 to correct the adjustment error. We also recommended that Pennsylvania amend its cost allocation plan to identify all Aging Waiver administrative costs (including allocation methodologies) and work with CMS to resolve the \$25.8 million Federal share it claimed for local agencies' Aging Waiver administrative costs and adjust accordingly.

Review of Administrative Costs Claimed by Pennsylvania's Home and Community-Based 2011 JUN Waiver for Individuals Aged 60 and Over. A-03-10-00202. Web Summary. Full Text.

#### New York's Traumatic Brain Injury Waiver Program Claims

NEW YORK IMPROPERLY CLAIMED ABOUT \$1.6 MILLION FEDERAL SHARE OF MEDICAID REIMBURSEMENT FOR TRAUMATIC BRAIN INJURY (TBI) WAIVER PROGRAM SERVICES PROVIDED BY BELVEDERE OF ALBANY, LLC (BELVEDERE). The claims did not comply with Federal and State requirements during CYs 2005 through 2007. We set aside for further analysis and resolution about \$2.1 million in claims for a Federal share of TBI services provided by Belvedere that may not have complied with Federal and State requirements. We recommended that the State refund the \$1.6 million we identified as improper and work with CMS to resolve the \$2.1 million in claims that may have been unallowable. Other recommendations included that New York require treatment centers to ensure and document that all beneficiaries approved for services have been assessed by certified individuals and are eligible for TBI waiver program services, train assessors on the Federal and State TBI waiver program requirements, and ensure that the provider documents services billed and claims reimbursement only for allowable TBI waiver program services. New York's TBI waiver program allows the State to claim Federal Medicaid reimbursement for home- and community-based services provided to individuals with TBIs who would otherwise require institutionalization in a nursing home.

2011 MAY Review of Medicaid Payments for Services Provided Under New York's Section 1915(c)
Traumatic Brain Injury Waiver at Belvedere of Albany, LLC, From January 1, 2005, Through
December 31, 2007. A-02-09-01006. Web Summary. Full Text.

#### Maryland's Residential Rehabilitation Services for Children

WE WERE UNABLE TO DETERMINE WHETHER THE DOCUMENTATION MARYLAND SUBMITTED AS SUPPORT FOR SAMPLED CLAIMS WAS SUFFICIENT BECAUSE ITS STATE PLAN WAS UNCLEAR ABOUT CERTAIN KEY DEFINITIONS AND REQUIREMENTS. Specifically, the State plan was unclear about the definition of a residential rehabilitative service and the requirements for documenting claims for such services. We recommended that Maryland work with CMS to amend its State plan to define the services provided under the residential rehabilitation program, define the necessary documentation requirements for each service, and adjust its reimbursement methodology if needed to reflect costs for services provided.

2011 AUG Review of Medicaid Residential Rehabilitation Services for Children in Maryland. A-03-08-00209. Web Summary. Full Text.

#### Federal Share of Medicaid Personal Care Services

THREE STATES IMPROPERLY CLAIMED ABOUT \$61.3 MILLION IN FEDERAL MATCHING FUNDS FOR PERSONAL CARE SERVICES (PCS) THAT DID NOT MEET FEDERAL AND/OR STATE REQUIREMENTS. We set aside an additional \$34.8 million for further analysis and resolution by the States and CMS. We recommended that the States refund the Federal share and work with CMS to resolve the amounts set aside. We also recommended improvements in guidance, controls, and monitoring. PCS, which are nonmedical services provided to assist with activities of daily living, such as bathing, dressing, and meal preparation, are generally furnished to individuals residing in their homes and not residing in institutional care settings, such as hospitals or nursing facilities. The three reviews completed in this semiannual period are part of the Office of Inspector General's (OIG) larger body of work on PCS.

- NEBRASKA (Refund \$169,000; resolve \$4.5 million set aside.) *Nebraska Medicaid Payments for Personal Care Services.* A-07-10-03152. June, 2011. Web Summary. Full Text.
- NORTH CAROLINA (Refund \$41.7 million.) Review of Medicaid Personal Care Services Claims Submitted by Providers in North Carolina. A-04-10-04003. June, 2011. Web Summary. Full Text.

WASHINGTON STATE – (Refund \$19.4 million; resolve \$30.3 million set aside.) Review of Medicaid Personal Care Services Claimed by Washington State. A-09-09-00030. May, 2011. Web Summary. Full Text.

See also OIG's Spotlight on Personal Care Services and a related matter in our March, 2011 Compendium, Part III, pp. 15 and 16, available on our Web site.

#### Medicaid Services Provided in an Adult Day Health Setting

FOR THE 12 STATE MEDICAID PROGRAMS THAT ALLOW NURSING- AND THERAPY-FOCUSED ADULT DAY HEALTH SERVICES, APPROXIMATELY 43 PERCENT OF THERAPY SERVICES WERE PROVIDED BY STAFF WHO LACKED REQUIRED SUPERVISION. Beneficiaries received at least one health service on 60 percent of service days in our sample. On 34 percent of service days, meals and/or snacks were the only documented services provided. In some cases, documentation lacked appropriate physician orders or was inconsistent with plans of care. Within broad Federal Medicaid requirements, individual States establish the specific requirements that must be met for Medicaid reimbursement of adult day health services. Our recommendations included directing States to enforce supervision requirements for staff who provide therapy services in Medicaid adult day health centers, specifying what services are required for Medicaid reimbursement of adult day health services, and taking appropriate action to address the service providers that did not respond to repeated data requests.

2011 JUL Medicaid Services Provided in an Adult Day Health Setting. OEI-09-07-00500. Web Summary. Full Text.

## **Medicaid Family Planning Programs**

#### States' Claims for Enhanced Federal Share of Family Planning Services

SOME STATES IMPROPERLY CLAIMED A 90-PERCENT FEDERAL SHARE FOR EXPENDITURES THAT WERE INELIGIBLE FOR THE ENHANCED RATE. We are reviewing family planning services claims in several States to determine whether enhanced Federal funding was improperly claimed and the resulting financial impact on the Medicaid program. Our recommendations, which vary somewhat among States, include refunding to the Federal Government both the improper reimbursements we identify in our reviews and those outside the scope of our reviews, establishing written procedures to ensure that future family planning costs are claimed correctly, ensuring that Medicaid Management Information System (MMIS) edits appropriately identify claims that are ineligible for reimbursement at the 90-percent enhanced rate, and discontinuing the claiming of ineligible expenditures at the enhanced rate. Reports of reviews completed in this semiannual period follow.

- OREGON (Refund \$1.5 million.) The overpayment occurred because Oregon's MMIS controls did not properly distinguish claims eligible for reimbursement at the 90-percent enhanced rate from claims eligible for reimbursement at the regular rate. In December 2008, Oregon implemented a new MMIS and changed its internal controls to properly identify these claims. Review of Medicaid Family Planning Services Claimed Under the Oregon Health Plan During the Period October 1, 2006, Through September 30, 2009. June 2011. A-09-10-02043. June, 2011. Web Summary. Full Text.
- Kansas (Refund \$2.4 million.) None of the 2,781 family planning claims related to child delivery and newborn services that were submitted by providers and claimed by Kansas at the enhanced 90-percent rate from July 1, 2005, through June 30, 2009, were allowable for the enhanced rate pursuant to Federal requirements. Review of Child Delivery Claims and Newborn Claims Included in the Kansas Medicaid Family Planning Program. A-07-10-04156. May, 2011. Web Summary. Full Text.

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- OKLAHOMA (Refund \$3.4 million.) From January 1, 2005, through December 31, 2009, Oklahoma improperly claimed \$17.4 million for hysterectomy expenditures at the enhanced family planning rate of 90 percent. The Federal Government pays its share of hysterectomy expenditures at the regular rate. Review of Medicaid Hysterectomy Expenditures Claimed as Family Planning in Oklahoma for Calendar Years 2005 to 2009. A-06-10-00047. May, 2011. Web Summary. Full Text.
- COLORADO. (Refund \$2 million.) For the quarters ended March 2007 through September 2009, the State claimed additional costs for the same sterilization procedures, which resulted in almost \$2 million in unallowable Federal reimbursement. Although the State had an informal adjustment process to claim the costs correctly, the process was not effective beginning with the quarter ended March 2007. Review of Additional Claims for Sterilization Procedures in the Colorado Medicaid Family Planning Program. A-07-11-01096. May, 2011. Web Summary. Full Text.

### Other Medicaid Expenditures and Costs

#### **Medicaid Hospital Outlier Payments Followup**

EIGHT STATE AGENCIES WE REVIEWED DID NOT CALCULATE MEDICAID INPATIENT HOSPITAL COST OUTLIER PAYMENTS IN A WAY THAT WOULD EFFECTIVELY LIMIT THE PAYMENTS TO EXTRAORDINARILY HIGH-COST CASES. To protect hospitals against large financial losses from extraordinarily high-cost cases, State agencies may supplement base payments with an additional "outlier" payment. Medicaid outlier payments are calculated using formulas that vary by State. The States we reviewed used outdated cost-to-charge ratios and did not reconcile Medicaid outlier payments upon settlement of cost reports. We recommended that CMS encourage all State agencies that make Medicaid outlier payments to use the most recent cost-to-charge ratios to calculate Medicaid outlier payments, reconcile Medicaid outlier payments upon cost report settlement or use an alternative method to ensure that outlier payments are more closely aligned with actual costs, and amend their State plans accordingly. The review is a followup to similar audits we conducted in 2004.

2011 JUL Medicaid Hospital Outlier Payment Followup for Fiscal Years 2004 Through 2006. A-07-10-04160. Web Summary. Full Text.

#### **Medicaid Payments for After-Hours Services Codes**

IN GENERAL, WE DID NOT FIND A LARGE PROBLEM WITH INAPPROPRIATELY PAID AFTER-HOURS ADD-ON CODES. After-hours add-on codes compensate providers for the additional costs associated with providing services outside posted or normal business hours. Three States—North Carolina, Kentucky, and Massachusetts—made 77 percent of the \$8.1 million total in payments for after-hours add-on codes. Nationwide, 6 of the 3,228 billers for after-hours add-on codes were responsible for more than 12 percent (\$1 million) of the payments, and 46 billers were responsible for 50 percent of all such payments. Twenty-one States inappropriately paid \$99,822 for after-hours add-on codes. One biller in Kentucky accounted for 68 percent of the \$99,822 in inappropriate Medicaid payments. For the purposes of this review, inappropriate payments occurred when providers were reimbursed for afterhours add-on codes for places of service not allowed by the respective State Medicaid programs. We did not make recommendations in this report.

2011 MAY Medicaid Payments for After-Hours Services. OEI-07-11-00050. Web Summary. Full Text.

#### Reconciliation of Expenditure Reports to Claims Data

MEDICAID EXPENDITURES THAT STATES REPORT QUARTERLY TO CMS ARE NOT ALWAYS CORRECT OR ADEQUATELY SUPPORTED. We are reviewing and reconciling line items on Medicaid quarterly expenditure reports in

selected States. All States must submit a Quarterly Medicaid Statements of Expenditures for the Medical Assistance Program (Form CMS-64) to CMS within 30 days after the end of each quarter. This form shows the disposition of Medicaid funds used to pay for medical and administrative expenditures for the quarter being reported and any prior-period adjustments. The expenditures reported on the Form CMS-64 report and its attachments must represent actual expenditures for which all supporting documentation, in readily reviewable form, has been compiled and is available at the time the claim is filed. Each State must maintain an accounting system and supporting fiscal records to ensure that claims reported on the CMS-64 report are in accordance with applicable Federal requirements. Reviews completed in this semiannual period follow.

- OKLAHOMA For the quarter ended December 31, 2008, Oklahoma generally claimed Federal reimbursement of about \$1 billion in Medicaid expenditures in accordance with Federal requirements. However, the State applied incorrect percentages, resulting in a Federal share overstatement of \$12,000; overlooked \$6,000 in expenditures, resulting in a Federal share understatement of about \$5,000; and received an enhanced family planning Federal share of \$127,000, the appropriate amount of which we could not determine. In addition, the State improperly received a \$2.1 million Federal share for additional payments in that quarter that were unallowable. We recommended that Oklahoma refund to the Federal Government \$2.1 million, claim a Federal credit of \$5,000 for overlooked expenditures, and work with CMS to resolve the allowability of the \$127,000 we questioned. We also recommended that the State improve coding and procedures and provide additional documentation to CMS. Review of the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program in Oklahoma. A-06-09-00097. July, 2011. Web Summary. Full Text.
- NEW YORK New York's claim for Federal reimbursement of Medicaid expenditures on the Form CMS-64 was adequately supported by actual recorded expenditures. Therefore, we made no recommendations. Review of the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program in New York State for the Quarter Ended September 30, 2009. A-02-10-01020. April 2011. Web Summary. Full Text.
- PUERTO Rico Puerto Rico's claim for Federal reimbursement of Medicaid expenditures on the Form CMS-64 was adequately supported by actual recorded expenditures. Therefore, we made no recommendations. Review of the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program in Puerto Rico for the Quarter Ended September 30, 2009. April 2011. A-02-10-01038. Web Summary. Full Text.

#### Missouri's Medicaid Expenditures for Medicare Part A and Part B Premiums

DURING FISCAL YEAR (FY) 2009, MISSOURI MADE CALCULATION AND DUPLICATION ERRORS CAUSING IT TO OVERCLAIM ABOUT \$1.5 MILLION FOR THE FEDERAL SHARE OF MEDICARE PART B PREMIUMS THE STATE PAID UNDER THE BUY-IN PROGRAM. However, the State's claims for the Federal share of its Part A premium payments were claimed correctly. Federal law allows States to pay Medicare premiums on behalf of certain individuals who are entitled to both Medicare and some form of Medicaid benefits. The State can then claim the Federal share of such premium expenditures under Medicaid. This provision, called buy-in, has the effect of transferring part of the medical costs for eligible individuals from the federally and State-funded Medicaid program to the federally financed Medicare program. We recommended that Missouri refund to the Federal Government the \$1.5 million and strengthen internal controls to ensure that all Medicaid expenditures claimed for Federal reimbursement are in accordance with Federal requirements.

Review of Medicaid Expenditures for Medicare Part A and Part B Premiums in Missouri. 2011 JUL A-07-10-03158. Web Summary. Full Text.

Part II: Medicaid Reviews

#### West Virginia's Medicaid School-Based Services Reimbursement Rates

WEST VIRGINIA WAS OVERPAID \$22.8 MILLION FOR THE FEDERAL SHARE OF SCHOOL-BASED SERVICES BECAUSE IT INCLUDED COSTS IN THE CALCULATION OF ITS RATES THAT WERE NOT INCLUDED IN THE REIMBURSEMENT METHODOLOGY DESCRIBED IN THE APPROVED STATE PLAN. The errors occurred because the State did not provide adequate oversight of its consulting firm during the rate calculation process. We recommended that the State refund \$22.8 million to the Federal Government for FYs 2001 through 2003 and work with CMS to determine unallowable costs for FYs 2004 to the present, make the appropriate refund, develop more accurate school-based service rates, and make necessary revisions to the State plan.

2011 APR Review of Medicaid Reimbursement Rates for School-Based Services in West Virginia. A-03-05-00203. Web Summary. Full Text.

#### Illinois' Payments for A State-Owned Psychiatric Hospital

ILLINOIS IMPROPERLY CLAIMED AN \$82.9 MILLION FEDERAL SHARE OF PAYMENTS IT MADE TO A STATE-OWNED PSYCHIATRIC HOSPITAL THAT FAILED TO DEMONSTRATE COMPLIANCE WITH FEDERAL REQUIREMENTS. During the audit period, the hospital did not demonstrate compliance with special Medicare Conditions of Participation (CoP) because the State agency did not believe that such demonstration was necessary. We concluded that Illinois should refund the \$82.9 million; work with CMS to evaluate an additional \$12.6 million that we set aside for further analysis and resolution; identify and refund the Federal share of any other payments associated with the same type of noncompliance; and ensure that with regard to psychiatric hospitals, it claims Federal matching funds only for those hospitals that can demonstrate compliance with the special Medicare CoP.

2011 AUG Review of Select Medicaid Inpatient Psychiatric Hospital Service Requirements for One Illinois State-Owned Psychiatric Hospital During the Period January 1, 2000, Through December 31, 2009. A-05-10-00046. Web Summary. Full Text.

## Pennsylvania's Medicaid Administrative Costs Claimed for the Department of Aging's Direct Care Worker Initiative.

PENNSYLVANIA IMPROPERLY CLAIMED A \$1.7 MILLION FEDERAL SHARE OF MEDICAID FOR UNAUTHORIZED ADMINISTRATIVE COSTS FOR THE DIRECT CARE WORKER INITIATIVE, A RECRUITMENT AND RETENTION PROGRAM OF THE STATE'S DEPARTMENT OF AGING. The costs were supplemental to payments to direct care workers for direct medical services and included training and other nonadministrative expenses. The costs were not incurred to operate the Medicaid program, and CMS specifically prohibits claiming them as administrative costs. Local agencies operating the initiative reported that the funds were spent on bonuses, training, and recognition events. We recommended that the State refund \$1.7 million in Federal Medicaid reimbursement, refund the improperly claimed Federal share of any such costs claimed after our audit period, and discontinue all future claims to Medicaid for such costs.

2011 JUL Review of Medicaid Administrative Costs Claimed for the Pennsylvania Department of Aging's Direct Care Worker Initiative. A-03-10-00206. Web Summary. Full Text.

# Pennsylvania's Medicaid Administrative Costs Claimed for the Department of Aging's Healthy Steps Program

PENNSYLVANIA IMPROPERLY CLAIMED \$1.2 MILLION (FEDERAL SHARE) OF MEDICAID ADMINISTRATIVE COSTS FOR THE HEALTHY STEPS FOR OLDER ADULTS (HEALTHY STEPS) PROGRAM. Administrative cost claims to Medicaid must be directly related to the administration of the Medicaid program. The claimed costs were for the Department of Aging's payments for services to help older adults remain active and were not for

the administration of the Medicaid program. We recommended that Pennsylvania refund the \$1.2 million, refund the Federal share of any unallowable Healthy Steps costs claimed after our audit period, and discontinue all future claims for a Federal share of Medicaid for unallowable Healthy Steps costs.

2011 JUL Review of Medicaid Administrative Costs Claimed for the Pennsylvania Department of Aging's Healthy Steps Program. A-03-10-00205. Web Summary. Full Text.

#### **Oregon's Medicaid Management Information System Expenditures**

OREGON IMPROPERLY CLAIMED \$566,000 (FEDERAL SHARE) OF CERTAIN EXPENDITURES RELATED TO ITS MMIS. WE SET ASIDE FOR FURTHER ANALYSIS AND RESOLUTION AN ADDITIONAL \$1.7 MILLION FEDERAL SHARE OF EXPENDITURES THAT MAY HAVE BEEN UNALLOWABLE. Of the \$31 million in MMIS expenditures we reviewed, Oregon claimed \$27.4 million correctly. The \$566,000 Federal share included employee salaries and fringe benefits and contractor and postage expenditures that were claimed at incorrect Federal reimbursement rates and unallowable contractor and employee expenditures. The \$1.7 million set aside for resolution was for contractor expenditures and employee salaries and fringe benefits that may have been unallowable. We recommended that Oregon refund \$566,000 to the Federal Government, work with CMS to determine which portions of the \$1.7 million were overpaid, and refund the amounts. We also recommended that Oregon strengthen its internal controls to ensure that its MMIS expenditures are claimed at correct reimbursement rates and are allowable for Medicaid reimbursement.

2011 AUG Audit of Oregon's Medicaid Management Information System Expenditures for the Period October 1, 2007, Through September 30, 2009. A-09-10-02017. Web Summary. Full Text.

### Medicaid-Related Program Administration

# Practitioner Compliance With Requirements of the Hurricane Katrina Health-Care-Related Professional Workforce Supply Grant – Greater New Orleans Area

FOR THE PERIOD MARCH 1, 2007, THROUGH JANUARY 31, 2009, LOUISIANA PAID AN ESTIMATED \$13.6 MILLION OF FEDERAL GRANT FUNDS TO PRACTITIONERS THAT WERE NOT IN COMPLIANCE WITH FEDERAL REQUIREMENTS. CMS awarded Louisiana a \$50 million Federal grant to restore access to health care in communities impacted by Hurricane Katrina. The grant provided payments to licensed health care professionals for retention and recruitment. Louisiana did not follow existing policies and procedures or did not have policies and procedures adequate to ensure that its contracts obligated practitioners to meet a 3-year service requirement, that practitioners were monitored for compliance. and that corrective actions were taken. We recommended that Louisiana refund \$13.6 million to the Federal Government, implement adequate policies and procedures, monitor practitioners' compliance, and take corrective actions for those practitioners not in compliance after our audit period.

2011 JUL Review of Practitioner Compliance With the Requirements of the Hurricane Katrina Health-Care-Related Professional Workforce Supply Grant for the Greater New Orleans Area.

A-06-09-00051. Web Summary. Full Text.

#### States' Oversight of Medicaid Electronic Health Records Incentive Payments

STATES' ABILITY TO ENSURE THE INTEGRITY OF MEDICAID ELECTRONIC HEALTH RECORD (EHR) INCENTIVE PAYMENTS IS LIMITED. EHR systems are computerized recordkeeping systems that contain patients' health-related information, including medical history. Pursuant to Federal law, State Medicaid agencies may make Medicaid incentive payments directly to eligible practitioners and hospitals to adopt, implement, or

upgrade certified EHR systems. Practitioners and hospitals self-report their eligibility information to the States. Although the States we reviewed said they plan to verify at least half of eligibility requirements prior to making EHR incentive payments, we found that depending on the eligibility requirement, States may have none, some, or all of the data they need to verify eligibility prior to making payments. The lack of data limits both the number of eligibility requirements that States plan to verify prior to payment and the completeness of those verifications. Most States do not plan to start collecting all the necessary data because the effort would be resource intensive and not logistically practical. All the States we reviewed said they plan to audit eligibility requirements after payment. Between 2011 and 2019, the Federal Government will spend an estimated \$13.4 billion for Medicaid EHR programs. The Federal Government provides 100 percent funding to States for the cost of the incentive payments they make to practitioners and hospitals and 90 percent funding for administrative expenses and planning activities related to States' EHR incentive programs.

2011 JUL Early Review of States' Planned Medicaid Electronic Health Record Incentive Program Oversight. OEI-05-10-00080. Web Summary. Full Text.

## Children's Health Insurance Program

#### Children's Health Insurance Program: Underpaid Premium Refunds in Florida

BECAUSE OF INSURER REPORTING ERRORS, FLORIDA DID NOT RECEIVE PREMIUM REFUNDS OF \$3.1 MILLION (\$2 MILLION FEDERAL SHARE). Florida contracts with Florida Healthy Kids Corporation (FHKC), a not-for-profit corporation created by the Florida legislature in 1990 to provide health insurance to children eligible for the Children's Health Insurance Program (CHIP). FHKC enters into multiyear medical service agreements with insurers to provide health care services to CHIP participants in exchange for per-member, per-month capitated payments (premiums). If an insurer's total medical expenses are less than 85 percent of its total premiums received, it must refund 50 percent of the shortfall. The underpaid refunds occurred primarily because Florida and FHKC did not have policies and procedures requiring personnel to review insurers' reports and reconcile them to supporting records. We recommended that Florida credit the Federal Government \$2 million for its share of underpaid refunds and develop and implement oversight procedures to ensure that required refunds and reconciliations occur.

2011 JUN Review of Florida's Children's Health Insurance Program Experience Adjustment and Refund Submission Reports. A-04-10-06123. Web Summary. Full Text.

### Part III

## Legal and Investigative Activities Related to Medicare and Medicaid

## **Investigative Outcomes**

For FY 2011, we reported 614 criminal and 381 civil actions against individuals or entities that engaged in health-care-related offenses. We also reported \$3.6 billion in Department of Health and Human Services (HHS) investigative receivables and \$947 million in non-HHS investigative receivables (such as from our work related to the States' share of Medicaid restitution). Such receivables, which represent expected recoveries, result from civil and administrative settlements or civil judgments related to Medicare, Medicaid, and other Federal, State, and private health care programs. Health-care-related investigative outcomes generally reflect the successful collaboration of our office and other enforcement entities.

## Advisory Opinions and Other Guidance

As part of the Office of Inspector General's (OIG) continuing efforts to promote the highest level of ethical and lawful conduct by the health care industry, we issue <u>advisory opinions and other guidance</u> to educate industry and other stakeholders on how to avoid fraud, waste, and abuse.

Pursuant to section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), OIG, in consultation with the Department of Justice (DOJ), issues advisory opinions to outside parties regarding the interpretation and applicability of certain statutes relating to Federal health care programs. This authority allows OIG to provide case-specific formal guidance on the application of the anti-kickback statute and safe harbor provisions and other OIG health care fraud and abuse sanctions. During this period, we received 44 requests for advisory opinions. We issued 12 new opinions and 2 modifications of earlier opinions.

The Web link to our advisory opinions is at <a href="http://oig.hhs.gov/compliance/">http://oig.hhs.gov/compliance/</a>. Other information that can be accessed at the same link includes voluntary compliance program guidance directed at various segments of the health care industry, open letters to health care providers from the Inspector General alerting them to OIG policies and processes, special fraud alerts and bulletins, the process providers should follow when voluntarily self-disclosing potential fraud, and corporate integrity agreements (CIA) with health care providers and other entities. Recent activity concerning self-disclosure, CIAs, and other administrative sanctions are discussed in this section of the Semiannual Report.

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

On May 20, 2009, HHS Secretary Kathleen Sebelius and Attorney General Eric Holder announced the creation of the Health Care Fraud Prevention and Enforcement Action Team (HEAT), an interagency effort focused specifically on combating health care fraud. HEAT includes senior officials from DOJ and HHS who are strengthening programs, as well as investing in new resources and technologies, to prevent and combat fraud, waste, and abuse.

#### **Strike Force Activities**

The Medicare Fraud Strike Force is a key component of HEAT. The Strike Force began 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 law enforcement operations among Federal, State, and local law enforcement entities. These teams have a proven record of success in analyzing data to quickly identify and prosecute fraud. During this reporting period, Strike Force efforts have resulted in the filing of charges against 70 individuals or entities, 77 convictions, and \$160.8 million in investigative receivables.

In late August and early September 2011, Medicare Fraud Strike Force teams in 8 cities executed a nationwide operation that resulted in charges against 91 defendants, including doctors, nurses, and other medical professionals, for their alleged participation in Medicare fraud schemes involving approximately \$295 million in false billing. This coordinated operation involved the highest amount of false Medicare billings in a single takedown in Strike Force history. In addition to making arrests, agents executed 18 search warrants in connection with ongoing Strike Force investigations.

The defendants charged are accused of various health care fraud-related crimes, including conspiracy to defraud the Medicare program, health care fraud, violations of the anti-kickback statutes, and money laundering. The charges are based on a variety of alleged fraud schemes involving various medical treatments and services, such as home health care, physical and occupational therapy, mental health services, psychotherapy, and durable medical equipment. In conjunction with this major Strike Force operation, OIG collaborated with CMS to impose payment suspensions that immediately prevented a loss of more than \$552,000 in claims submitted by Strike Force targets.

Additional examples of Strike Force efforts during this reporting period are highlighted below.

- FLORIDA Lawrence Duran, one of several owners of American Therapeutic Corporation (ATC), was sentenced to 50 years' incarceration for his role in orchestrating a Medicare fraud scheme. This case is the first Community Mental Health Center investigation under the HEAT initiative to lead to an indictment, and Duran's 50-year prison sentence is the longest imposed in a Medicare Fraud Strike Force case. Marianella Valera, another ATC owner, and Margarita Acevedo, a seniorlevel ATC manager, were also sentenced to 35 and 7.5 years' incarceration, respectively, for their roles in the scheme. In addition, Duran, Valera, and Acevedo, along with ATC and Medlink Professional Management Group Inc. (Medlink), which is also owned and operated by Duran and Valera, were ordered to pay more than \$87 million in restitution, jointly and severally. The now defunct ATC was a Florida corporation that purportedly provided intensive treatment programs for individuals with severe mental illness. Between 2002 and 2010, Duran and Valera used ATC to bill Medicare for mental health services that were not necessary or were never provided. The pair actively recruited and paid kickbacks to owners and operators of assisted living facilities, halfway houses, and patient brokers in exchange for delivering ineligible patients to ATC. Additionally, Duran and Valera caused the alteration of patient files and therapist notes to appear as if the ATC patients qualified for intensive treatment programs.
- MICHIGAN One of OIG's 10 most wanted fugitives, Reynel Betancourt, was sentenced to 77 months' incarceration and ordered to pay over \$6 million, jointly and severally, in restitution for his role in a health care fraud and money laundering scheme. Betancourt was an employee at the Dearborn Medical and Rehabilitation Center (DMRC) which purportedly specialized in infusion and injection therapy for human immunodeficiency virus (HIV)-positive patients. Betancourt recruited and paid Medicare beneficiaries to act as DMRC patients, and the patients, in return, signed medical documentation and reimbursement forms that DMRC could use to bill Medicare for services never rendered. Additionally, Betancourt owned a company called

**Perfect Data Request**, which he used to launder over \$400,000 in Medicare payments. Betancourt fled the United States to avoid being apprehended. Betancourt was arrested in the Dominican Republic on November 29, 2010, and transferred into custody of U.S. officials.

- FLORIDA **Dr. Rene De Los Rios** was sentenced to 235 months' incarceration and ordered to pay a minimum of \$11.7 million in restitution, jointly and severally, with his co-defendants for conspiracy to commit health care fraud and submission of false claims. De Los Rios was employed by **Metro MeD of Hialeah Corporation** (Metro Med), a clinic that provided injection and infusion therapies to HIV-positive Medicare beneficiaries. Between April 2003 and October 2005, De Los Rios signed medical analysis and diagnosis forms and authorized treatments that were medically unnecessary or were never provided. The owner and operator of Metro Med, **Damaris Oliva**, and three other co-defendants, **Estrella Rodriguez**, **Jose Diaz**, and **Lisandra Aguilera**, were each sentenced to 82 months, 57 months, 54 months, and 70 months of incarceration, respectively, for their roles in the scheme.
- MICHIGAN Maria Haber, co-owner of CompleteHealth, LLC, and Ritecare, LLC, was sentenced to 15 months' incarceration and ordered to pay \$1 million in restitution, jointly and severally, with her do-defendants for her role in a Medicare fraud scheme. CompleteHealth and Ritecare were nerve conduction clinics in Livonia, Michigan. Between September 2007 and June 2008, Haber and co-conspirators used the clinics to bill Medicare for unnecessary tests and services, including nerve conduction studies. Patient recruiters were paid \$100 to \$150 for every patient that was brought into the clinic, and the patients received \$50 to \$75 in exchange for subjecting themselves to the medically unnecessary tests.

#### **Provider Compliance Training Sessions**

OIG's HEAT Provider Compliance Training initiative (HEAT PCT) provided free high-quality compliance training for providers, compliance professionals, and attorneys in Strike Force cities and elsewhere. HEAT PCT, which included presenters from HHS/OIG, Centers for Medicare & Medicaid Services (CMS) Regional Offices, CMS Program Integrity, United States Attorneys' Offices, and State Medicaid Fraud Control Units, held sessions in Houston, Tampa, Kansas City, Baton Rouge, Denver, and Washington, D.C., training a total of 737 in-person attendees. The final HEAT PCT session in Washington, D.C., was Webcast live to 2,335 participants. OIG developed comprehensive training materials to accompany HEAT PCT, and those materials are now available online, together with 16 video modules dividing the Webcast by subject area. The online training will continue reaching the health care community with our compliance message.

#### Other Criminal and Civil Enforcement Activities

#### **Special United States Attorneys Program**

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 civil False Claims Act (FCA). A description of these enforcement authorities can be found in Appendix D. The successful resolution of false claims investigations often involves the combined investigative efforts and resources of OIG and other Federal and State law enforcement agencies. During this reporting period, DOJ and OIG continued their Special United States Attorneys program in which OIG Special Agents who are also attorneys are detailed full-time to DOJ's Criminal Division, Fraud Section, for temporary assignments, such as assignments with the Medicare Fraud Strike Force described above; others 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 durable medical equipment (DME), infusion therapy, physical therapy, and other types of Medicare and Medicaid fraud.

#### Most-Wanted Fugitives Listed on OIG's Web Site

Earlier this year, we published a Most-Wanted Fugitives list on our Web site. By the end of this reporting period, seven individuals had been captured. We continuously update the list and provide a means for the public to report tips regarding the whereabouts of the fugitives. Following is the link for accessing the Most-Wanted Fugitives list: <a href="http://oig.hhs.gov/fraud/fugitives/">http://oig.hhs.gov/fraud/fugitives/</a>.

Notable enforcement actions and related activities are described below. Summaries are organized by the sector of the health care industry involved or by the nature of the offense.

#### **Prescription Drugs**

- MARYLAND Serono Laboratories, Inc.; EMD Serono, Inc.; Merck Serono S.A.; and Ares Trading S.A. (collectively Serono), agreed to pay \$44.3 million plus interest and enter into an FCA settlement to resolve allegations that between January 2002 and December 2009, Serono paid illegal remuneration to health care professionals (for activities such as promotional speaking engagements, speakers' training, and charitable contributions) to induce them to prescribe their multiple sclerosis prescription drug called Rebif and, thereby, caused the submission of false claims to Medicare and other Federal health care programs. As part of a 2005 civil and criminal settlement relating to Serono's promotion of the drug Serostim, Serono entered into a corporate Integrity Agreement (CIA) with OIG. As part of the 2011 settlement, Serono entered into a 3-year addendum to the existing CIA.
- MISSOURI Cardinal Healthcare, Inc. (CHI), agreed to pay \$8 million plus interest to resolve its liability under the civil FCA for allegedly submitting false claims to Medicare Part D and Medicaid. CHI allegedly paid a kickback to Medicine Shoppe Pharmacies (Pharmacies) to secure Pharmacies' pharmaceutical acquisition business. Pharmacies allegedly received a kickback in the form of an up-front cash payment, or "prebate," to switch their drug purchasing from a competitor to CHI, resulting in the submission of tainted, false claims for prescription drugs to the Medicare and Medicaid programs.
- MICHIGAN eTEL-Rx, Inc. (eTEL-Rx), a pharmacy that provides drugs to nursing home facilities throughout the State, entered into a settlement agreement that includes restitution in the amount of \$650,000 to resolve its alleged liability under the civil FCA. Between January 1999 and December 2007, eTEL-Rx allegedly billed Medicaid directly for medications and nutritional supplements of terminally ill patients that should have been billed to the appropriate hospice providers. In addition, eTEL-Rx accepted the return of unused drugs paid for by Medicaid without crediting Medicaid for the returns. The pharmacy subsequently redispensed the returned drugs, resulting in Medicaid's paying eTEL-Rx again for the drugs already reimbursed by Medicaid. As part of the settlement, eTEL-Rx entered into a CIA with OIG.
- OHIO James Matheny, Jr., and Jacob McCoy, a Walgreens Pharmacy Technician and brother-in-law of Matheny, were sentenced to 27 months and 12 months and 1 day of incarceration, respectively, and ordered to pay \$6,131, jointly and severally, for their roles in a scheme to obtain controlled substances through using stolen identities and fraudulent prescriptions. Specifically, McCoy and Matheny obtained blank prescription pads in the name of Columbus Pain Management, a fictitious medical practice, and then wrote prescriptions for Class 2 controlled substances to include OxyContin and Percocet. McCoy also used his pharmacy's

computer system to obtain the identities of customers who possessed insurance benefits through Medicare, Medicaid, and Medicaid Managed Care Organizations (MCO). McCoy and Matheny then used this information to obtain the controlled substances at reduced prices. Matheny subsequently sold the prescription drugs on the street. Between March 2009 and June 2009, McCoy and Matheny diverted approximately 4,000 units of the prescription drugs.

#### Hospitals

- CONNECTICUT **Masonicare Health Center** (Masonicare) agreed to pay \$447,776 to resolve its liability for allegations under the FCA. The settlement agreement resolved allegations that Masonicare improperly overcharged the Medicare and Medicaid programs from January 1, 2001, through May 31, 2010, for Lupron injections, which are commonly used to treat prostate cancer in men and manage endometriosis in women. Using the Healthcare Common Procedure Coding System (HCPCS), Masonicare allegedly billed Medicare and Medicaid for Lupron injections provided to its male patients under an HCPCS code designated for female beneficiaries, which is reimbursed at double the rate. OIG reserved its right to exclude the entity.
- OKLAHOMA AHS Hillcrest Medical Center, LLC; AHS Tulsa Regional Medical Center, LLC; Ardent Health Services, LLC; and Ardent Medical Services, Inc. (collectively the Ardent Entities) entered into an FCA settlement agreement and agreed to pay \$3.85 million to resolve allegations that between January 2003 and December 2009, the Ardent Entities caused false claims to be submitted to Oklahoma Medicaid. Specifically, the Children and Adolescent Behavioral Health Services Unit of the Tulsa Regional Medical Center (renamed Oklahoma State University Medical Center in 2006) allegedly failed to provide inpatient psychiatric services to patients under the age of 21 in the intervals of time required by State regulations. Instead, shorter therapy sessions were allegedly provided and documented as if they had been appropriately provided. In connection with this settlement, AHS Hillcrest Medical Center, which assumed ownership and operation of the Unit in 2009, entered into a 5-year CIA. The CIA obligations include oversight by a board of directors and an Independent Review Organization's (IRO) review of the Unit's claims and quality control systems.

#### **Durable Medical Equipment**

- WISCONSIN Rikco International LLC, d/b/a Dr. Comfort (Dr. Comfort), agreed to pay \$27 million plus interest and enter into a 5-year CIA to resolve its liability under the FCA in connection with the alleged sale of DME that was reimbursed by Medicare. Between June 2004 and March 2006, Dr. Comfort allegedly shipped diabetic orthotic shoe inserts to DME suppliers under the false pretense that the inserts were approved by Medicare for reimbursement and that the inserts met specifications established by the Centers for Medicare & Medicaid Services (CMS) when, in fact, they did not meet the specifications.
- FLORIDA **Omar Perdomo**, owner and operator of **Eagles Pharmacy Corp.** (Eagles Pharmacy), was sentenced to 52 months' incarceration and ordered to pay \$3.9 million in restitution for health care fraud. Between August 2006 and April 2007, Perdomo used Eagles Pharmacy to submit false and fraudulent claims to Medicare, including claims for deceased beneficiaries. These claims sought reimbursement for the cost of DME, prescription medications, and other items and services for Medicare beneficiaries in Florida that were not prescribed by doctors or provided as claimed.
- TENNESSEE Ignace Tchamgoue, owner of Tigen Healthcare Solutions, Inc. (Tigen), was sentenced to 18 months' incarceration and ordered to pay \$156,052 in restitution for health care fraud and aiding and abetting. Tigen was a DME supplier in Memphis, Tennessee. Between February and

- December 2009, Tchamgoue electronically submitted false claims to Medicare for medically unnecessary enteral (tube feeding) products and supplies.
- FLORIDA Carlos Gomez was sentenced to 55 months' incarceration and ordered to pay \$1.66 million in restitution, portions of which are joint and several with co-defendants, for defrauding the Medicare program. From October 18, 2005, through June 1, 2007, Gomez owned and operated Carpio Medical Equipment Services, Inc. (Carpio Medical), a DME supply company. Between July 2006 and January 2007, Gomez caused Carpio Medical to submit false and fraudulent Medicare claims for DME items, such as pressure support ventilators, therapy pumps, and other DME that were not prescribed by physicians or received by Medicare beneficiaries.

#### **Practitioners**

- NEVADA Rakesh Nathu, M.D., and Nathu Compassionate Cancer Care, Chartered (collectively Nathu), agreed to pay \$5.7 million plus interest to settle allegations under the FCA for the false billing of radiation oncology services, including intensity modulated radiation therapy. Intensity modulated radiation therapy is a treatment for specific types of cancer in which extreme precision is required to spare surrounding organs or healthy tissue. Between 2007 and 2009, Nathu allegedly submitted improper claims to Medicare, TRICARE, and the Federal Employees Health Benefits Plan by double-billing for procedures related to radiation treatment plans. Nathu also allegedly billed for services that were medically unnecessary and billed higher reimbursement radiation services when a different, less expensive service should have been billed. This was a joint investigation with the Federal Bureau of Investigation.
- PENNSYLVANIA **Ronald Bailey, EdD,** a behavioral specialist consultant, was sentenced to 18 months of incarceration and ordered to pay \$164,640 in restitution for health care fraud. Bailey was employed by the Chester County Regional Educational Services, Inc. (CCRES), which contracted with the Chester County Intermediate Unit (CCIU). During that same time, Bailey was also employed with an organization called Devereux. While providing behavioral services to Devereux and CCIU, Bailey routinely prepared and submitted invoices that overstated the amount of time he spent with clients. Bailey's scheme included forging signatures of parents of Medicaid beneficiaries on encounter forms to appear as though he had spent the number of hours with the clients as listed on the forms. Bailey also prepared and submitted separate invoices to both Devereux and CCIU which, on many occasions, reflected that he was at two different locations at the exact same time seeing different Medicaid beneficiaries. Relying on the fraudulent invoices submitted by Bailey, CCIU, through CCRES, and Devereux issued check payments to Bailey for the claimed services with funds issued by the State Medicaid program. This was a joint investigation with the Pennsylvania Medicaid Fraud Control Unit.

#### Clinics

• NORTH CAROLINA – **Dr. Michael Nunn**, d/b/a **Community Wellness Center**, was ordered to pay restitution in the amount of \$297,215 and his practice was ordered to pay a fine of \$700,000 for health care fraud and money laundering. The court order also barred Nunn from engaging in business with HHS, the Department of Veterans Affairs (VA), and any other agency impacted by his offense. Between May 2003 and December 2004, Nunn operated three clinics in New Bern, Winterville, and Morehead City, North Carolina. Medicare, Medicaid, and VA patients frequently visited his clinics to obtain prescriptions for controlled substances. As a condition for receiving the prescriptions, Nunn required the patients to undergo various forms of physical and psychological therapy that were performed by unlicensed and unqualified personnel or provided by qualified practitioners without proper supervision. The therapy was subsequently billed to Medicare, Medicaid, and VA.

- VERMONT Dartmouth Hitchcock Clinic, Mary Hitchcock Memorial Hospital, and related entities (collectively Dartmouth), agreed to pay \$2.2 million to resolve its liability under the FCA for allegedly submitting improper claims to Medicare, Medicaid, TRICARE, and VA. Between February 1, 2001, and September 30, 2007, Dartmouth's Anesthesiology Department (AD) allegedly: submitted improper claims for services not supervised by attending physicians in the AD's Pain Clinic, submitted improper claims for services not supervised by attending physicians related to bedside procedures, and submitted improper claims for time-based billings in the AD's Critical Care Unit. According to Federal regulations and related guidelines, physicians are allowed to bill for certain services provided by residents, but only if those services are performed while a physician is present and the medical record documents physician presence. In addition, Dartmouth allegedly submitted improper supervision and interpretation claims for services provided by its Radiology Department. These claims were improper because they did not have sufficient medical record documentation to support the supervision component of these claims.
- CALIFORNIA **Susan Nahapetian** was ordered to pay restitution in the amount of \$994,109, jointly and severally, with her co-conspirator, **Rudik Avakyan**, for her participation in a widespread health care fraud scheme. Avakyan orchestrated the recruitment of physicians in northern and southern California to establish medical clinics throughout the State. Nahapetian served as the office manager for one of the clinics in San Jose, California. These clinics paid individuals known as cappers to recruit patients and entice them to visit the clinics by offering inducements, such as gift certificates and cash payments. The clinics subsequently billed Medicare for office visits, physical therapy, and other procedures and diagnostic tests that were unnecessary, were not rendered, or were rendered by unlicensed staff. The clinics also billed Medicare for patients that were deceased. Avakyan was sentenced on February 28, 2011, to 39 months' incarceration and restitution in the amount of \$2 million for his role in the conspiracy.

#### **Home Health Services**

• NEW JERSEY – Maxim Healthcare Services (Maxim), agreed to pay \$121 million plus interest over 8 years and enter a Corporate Integrity Agreement to resolve its liability for allegations under the False Claims Act. In addition, Maxim paid \$20 million in criminal fines. The settlement resolves allegations that, between 1998 and 2009, Maxim, one of the country's largest home health care agencies, filed false claims with state Medicaid programs and Veteran's Affairs for services that were not provided, not sufficiently documented to show that they were provided, or were delivered from unlicensed offices.

#### **Skilled Nursing Facility**

• WEST VIRGINIA – Genesis Rehabilitation Services (GRS), an affiliate of Genesis HealthCare LLC, agreed to pay \$1.5 million to resolve its liability under the FCA for allegedly submitting claims to Medicare and Medicaid for services provided by an unlicensed speech therapist. Between October 2006 and June 2010, GRS allegedly employed an unlicensed speech therapist who provided forged licenses and documentation to GRS to maintain her employment. GRS failed to verify the documentation. As a result, GRS routinely submitted claims to Medicare and Medicaid for services for licensed speech therapy services that were provided by an unlicensed therapist.

#### **Transportation Fraud**

• NORTH CAROLINA – **Dr. Janet Johnson-Hunter** was sentenced to 28 months incarceration and ordered to pay restitution to Medicare and Medicaid in the amount of \$428,924 and \$46,165, respectively. Johnson-Hunter and her husband, also a physician, owned **Coastline Care, Inc.** (CCI), an ambulance company based in Magnolia, North Carolina. Between January 2002 and August

2005, CCI, under Johnson-Hunter's direction, routinely conducted unnecessary transportation of patients to and from dialysis centers by ambulance that should have been transported by other means. Johnson-Hunter further instructed emergency medical technicians to omit the true condition of these patients from the ambulance call reports when she knew their conditions would not meet the Medicare and Medicaid reimbursement requirements.

- TEXAS Claudette Read and Robert Earl Read, owners of Priority One EMS (Priority One), were sentenced to 108 months' incarceration and ordered to pay \$1.7 million in restitution, jointly and severally, for submitting false claims to Medicare and Medicaid. Priority One was an ambulance transport business. Between January 2004 and November 2007, the Reads submitted, and instructed others to submit, claims to Medicare and Medicaid to obtain reimbursements for transporting dialysis patients who did not meet the required criteria for ambulance transportation. The Reads instructed employees on what information to include in the "reason for transport" section of the emergency medical service run sheets to ensure that the transports qualified for reimbursement by Medicare and Medicaid. The Reads also submitted claims for ambulance transportation to and from dialysis that falsely represented that the patients were transported individually when, in fact, multiple patients had been transported simultaneously in one ambulance. This was a joint investigation with the Texas Medicaid Fraud Control Unit.
- NEW YORK American Medical Response, Inc. (AMR), agreed to pay \$2.7 million plus interest and enter into a 5-year CIA to resolve its liability under the FCA. This settlement resolves allegations that between January 1, 2001, and December 31, 2005, AMR's three Brooklyn locations submitted upcoded claims for ambulance transportation services to Federal health care programs. Upcoding occurs when a provider bills for a level of service higher than medically necessary. This was a joint investigation with the VA OIG.
- TEXAS The city of Dallas agreed to pay \$2.47 million and enter a 3-year CIA to resolve its liability under the FCA related to allegations that it and ambulance billing company Southwest General Services of Dallas, LLC, improperly billed and obtained reimbursements from Medicare and Texas Medicaid for upcoded ambulance transports. The transports were provided by Dallas emergency management services between January 2006 and May 2010. OIG alleged that Dallas submitted false claims to Federal programs that were improperly coded as advanced life support, when, in fact, no such services were rendered and the patient did not require an advanced life support transport.

#### **Quality of Care**

ARIZONA – Arete Sleep, LLC; Arete Sleep Therapy, LLC; and Arete Holdings, LLC (collectively Arete) agreed to pay \$650,000 in a settlement to resolve FCA allegations. Between November 2002 and December 2009, Arete allegedly made false claims to Medicare for diagnostic sleep tests performed by technicians in its Arizona and Texas facilities who lacked the licenses or certifications required by Medicare rules and regulations. The settlement also resolves allegations that Arete further submitted false claims for medical devices, such as continuous positive airway pressure devices, resulting from the uncertified technicians' tests.

#### **Medicaid Fraud Control Units**

Under a delegation from the Secretary, OIG oversees and distributes funding to State Medicaid Fraud Control Units (MFCUs), which have the responsibility to investigate and prosecute Medicaid provider fraud and patient abuse and neglect. As part of its oversight responsibility, OIG ensures that the MFCUs are operating effectively and operating in a manner consistent with legal requirements, including those in the Social security Act, § 1903(q), and in Federal regulations at 42 CFR pt. 1007. In FY 2010, OIG awarded

\$193.6 million in Federal grant funds to 50 State MFCUs (including the District of Columbia), which employed a total of 1,827 individuals. MFCUs are key partners in the fight against fraud, waste, and abuse in State Medicaid programs. Collectively, in FY 2010, MFCUs reported 13,210 investigations, of which 9,710 were related to Medicaid fraud and 3,500 were related to patient abuse and neglect, including theft from personal funds accounts of nursing home patients. The cases resulted in 1,603 individuals' being indicted or criminally charged, including 1,048 for fraud and 555 for patient abuse and neglect. In total, 1,329 convictions were reported in FY 2010, of which 839 were related to Medicaid fraud and 490 were related to patient abuse and neglect. An interactive map of MFCU data by State is available on our Web site.

On March 17, 2011, OIG issued a Notice of Proposed Rulemaking, 76 Fed. Reg. 14637, that would amend a provision in HHS regulations that prohibits MFCUs from using Federal matching funds to identify fraud through screening and analysis of State Medicaid claims data, known as data mining. The provision, contained in 42 CFR § 1007.19, would be amended to permit Federal matching for data mining when MFCUs meet certain conditions. Comments on the proposal were due on May 16, 2011.

#### **Joint Investigations**

- CONNECTICUT **Dr. Mark W. Izard** and his corporation, **Mark W. Izard, M.D., P.C.,** agreed to pay \$2.2 million to resolve Izard's liability under the FCA for allegedly submitting improper claims to Medicaid and Medicare. Between July 2004 and April 2009, Izard allegedly billed for services provided to patients at nursing homes when, in fact, the patients were in the hospital on the alleged dates of services. In addition, Izard and his professional corporation allegedly submitted claims for attending physician services provided to hospital inpatients when the medical records did not support CMS's physical presence requirements for such claims. Izard allegedly billed for services that, according to the medical notes in the patients' charts, were performed by advanced-practice registered nurses or Hartford Hospital medical residents. Allegedly, it was Izard's regular practice to countersign the medical notes and not include his own note reflecting services he allegedly performed as the attending physician. As part of the agreement, Izard and his professional corporation both agreed to be excluded from the Federal health care programs for 7 years. This was a joint investigation with the Federal Bureau of Investigation (FBI) and the MFCU of Connecticut.
- MASSACHUSETTS **Aloysius Nsonwu**, owner of **Egleston Square Pharmacy** (Egleston), was sentenced in U.S. District Court to 9 months' time served and ordered to pay \$101,520 in restitution to Medicare and \$46,278.24 to Medicaid. In Massachusetts State Court, Nsonwu was sentenced to 4 years and 1 day in State prison, to be followed by 5 years' probation. He was also ordered to pay \$555,502 in restitution to Medicaid. Nsonwu's scheme included paying customers to bring their Medicare Part D and Medicaid cards to the pharmacy so that he could submit claims to CMS in their names. Nsonwu billed for prescription and refills of HIV/AIDS medications without physically dispensing the medication to the individuals. Many of the individuals whose insurance cards were improperly billed for were not, in fact, HIV positive. Nsonwu further used the identity of a licensed practicing physician without his knowledge to forge prescriptions for the medications. Nsonwu additionally paid cash to Medicaid beneficiaries in exchange for legitimate prescriptions. This was a joint investigation with the Medicaid Fraud Division of the Massachusetts Attorney General's Office and the Massachusetts State Police.

#### Provider Self-Disclosure Protocol

#### Self-Disclosure Guidance for Health Care Providers

OIG is committed to assisting health care providers and suppliers in detecting and preventing fraudulent and abusive practices. Since 1998, we have made available comprehensive guidelines describing the process for providers to voluntarily submit to OIG self-disclosures of fraud, waste, or abuse. The Provider Self-Disclosure Protocol gives providers an opportunity to minimize the potential costs and disruption that a full-scale OIG audit or investigation might entail if fraud is uncovered. In doing so, the self-disclosure also enables 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 (as opposed to honest mistakes that may have resulted in overpayments). 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 (e.g., an estimate of the losses to Federal health care programs). 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 <a href="http://www.oig.hhs.gov/fraud/selfdisclosure.asp">http://www.oig.hhs.gov/fraud/selfdisclosure.asp</a>.
- See also: Open Letters at <a href="http://www.oig.hhs.gov/fraud/openletters.asp">http://www.oig.hhs.gov/fraud/openletters.asp</a>

#### **Self-Disclosure Cases**

During this reporting period, self-disclosure cases resulted in \$8.4 million in HHS receivables. The following are examples:

- NEW YORK **St. Catherine of Siena Medical Center** (St. Catherine) agreed to pay \$2.5 million to resolve its liability under the Civil Monetary Penalties Law (CMPL). St. Catherine disclosed two improper financial arrangements, which created potential liability under the Stark Law and the anti-kickback statute. St. Catherine contracted with a physician-owned professional services company and had an employment agreement with a referring physician, both of which provided remuneration that was not consistent with the fair market value of the services provided.
- TEXAS The University of North Texas Health Science Center at Fort Worth (UNTHSC) agreed to pay \$859,500 to resolve its liability under the CMPL. Between October 1, 2005, and March 31, 2009, UNTHSC submitted claims for physicians' services provided to Federal health care beneficiaries using the provider identification numbers of 103 physicians who neither furnished the services nor personally supervised them.

## Office of Inspector General Administrative Sanctions

During this reporting period, OIG imposed 1,825 administrative sanctions for fraud or abuse or other activities that pose a risk to Federal health care programs and their beneficiaries (see Appendix D for an explanation of OIG's sanction authorities). These sanctions include the exclusion of individuals and entities from Federal health care programs and the imposition of civil monetary penalties (CMP) for submitting false or 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 or patient dumping statute). During this semiannual reporting period, OIG excluded 1,779 individuals and entities

from Medicare, Medicaid, and other Federal health care programs. Examples of program exclusions follow.

#### **Program Exclusions**

- KANSAS **Stephen Schneider**, an osteopath, and **Linda Schneider**, a licensed practical nurse, were excluded for a minimum of 95 years each for their convictions related to conspiracy to commit health care fraud resulting in death, aiding and abetting the unlawful distribution of controlled substances resulting in serious bodily injury and death, unlawful distribution of controlled substances resulting in serious bodily injury, health care fraud resulting in death, health care fraud, and money laundering. The Schneiders owned and operated Schneider Medical Clinic, LLC, which they used to distribute and dispense controlled substances illegally and defraud patients of money by operating it as, in essence, a prescription mill and a narcotics delivery system, commonly known as a pill mill. The Schneiders engaged in this scheme for a 6-year period, during which numerous patients were hospitalized and numerous patients died because of overdoses of prescribed drugs. Additionally, the Schneiders were previously ordered to pay restitution in the amount of \$5 million and sentenced to 360 and 396 months of incarceration, respectively.
- OREGON **Sean Cluver**, a certified nurse assistant, was excluded for a minimum of 35 years based on his convictions of sodomy, attempted rape, sexual abuse, and criminal mistreatment. Cluver sexually abused two patients that were incapable of giving consent because of a mental disability. Cluver was sentenced to 175 months of incarceration, and his certificate to practice as a nurse assistant was revoked by the Oregon State Board of Nursing.
- CALIFORNIA **Vardges Egiazarian**, business owner and operator of three health care clinics in Sacramento, Richmond, and Carmichael, California, was excluded for a minimum of 30 years based on his health care fraud conviction. Over a 2-year period, Egiazarian participated in a scheme to defraud Medicare by submitting claims for office visits and testing that were not needed or rendered. Egiazarian used individuals known as cappers to recruit patients to his clinics. The patients were paid for their time and for the use of their Medicare eligibility. In addition, some of the patients for whom billings were submitted were deceased on the date that they were allegedly receiving services. Egiazarian was sentenced to 78 months' incarceration and ordered to pay \$1.5 million in restitution.
- FLORIDA On July 12, 2011, an HHS Departmental Appeals Board Administrative Law Judge (ALJ) upheld OIG's exclusion of **Michael D. Dinkel** from participation in all Federal health care programs under section 1128(b)(7) of the Social Security Act for 8 years. The exclusion was based on Dinkel's submission of false claims to the Medicare and Medicaid programs for current procedural terminology code 36005, a procedural code that corresponds to injection for extremity venography. The procedure denoted by this code was never performed at Dinkel's radiology company, **Drew Medical**. Specifically, the ALJ found that Dinkel caused the submission of nearly 9,500 false claims to Medicare and Medicaid for reimbursement. DOJ previously entered into a civil FCA settlement with Dinkel; Drew Medical; and Central Florida Radiology, Inc.
- CALIFORNIA In 2008, **Dr. Kamron Hakhamimi** was convicted of sexual exploitation of a patient and battery of that same patient. On the basis of Hakhamimi's conviction, OIG excluded him for a minimum of 12 years under section 1128(a)(2) of the Social Security Act. The length of exclusion was increased beyond the mandatory minimum of 5 years because two aggravating factors were present: (1) the acts underlying Hakhamimi's conviction consisted of premeditated and nonconsensual sexual acts and (2) Hakhamimi was the subject of other adverse action by the Medical Board of California and the California Department of Health Care Services. Hakhamimi appealed his exclusion and the ALJ upheld it as reasonable, finding that Hakhamimi's conviction

involved abuse of a patient in connection with the delivery of a health care item or service. Hakhamimi appealed the ALJ's decision and on August 25, 2011, the Appellate Division of the Departmental Appeals Board (DAB) upheld the ALJ's decision. The DAB found that the evidence shows that Hakhamimi "took advantage of his professional position for personal gratification" and they agreed with the ALJ that this "renders [Hakhamimi] manifestly untrustworthy to provide care to program beneficiaries and recipients of program funds."

#### **Corporate Integrity Agreements**

Many health care providers that enter agreements with the Federal Government to settle potential liabilities under the FCA also agree to adhere to a separate CIA with OIG. Under a CIA, a provider typically commits to establishing a program or taking other specified steps to ensure future compliance with Medicare and Medicaid rules. The compliance programs are designed, in part, to prevent a recurrence of the underlying fraudulent conduct. OIG monitors providers' compliance with these agreements.

During this reporting period, OIG imposed stipulated penalties totaling \$272,500 on two companies, Church Street Health Management (Church Street, formerly known as FORBA Holdings, LLC) and The SCOOTER Store, Inc., because they did not comply with requirements of their CIAs with OIG. A penalty of \$230,000 was imposed on Church Street because it failed to implement training, develop and distribute policies and procedures, submit an Independent Review Organization (IRO) report, and provide notice of Government investigations. Church Street also made false certifications. A penalty of \$42,500 was imposed on The SCOOTER Store, Inc., because it did not submit a timely IRO report, as required under its CIA.

#### **Civil Monetary Penalties Law**

The CMPL authorizes OIG to impose administrative penalties 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 reporting period, OIG concluded cases involving more than \$10 million in penalties and assessments.

- FLORIDA **Daniel Herrington** paid \$124,141 to resolve his liability for allegations under the CMPL. Herrington allegedly submitted false claims for diabetic shoe inserts through his DME company, One Source Medical Services. Herrington allegedly billed Medicare for custom-molded diabetic shoe inserts but, in fact, provided prefabricated inserts to beneficiaries.
- MASSACHUSETTS Beth Israel Deaconess Medical Center (Beth Israel) paid \$233,932 to resolve its liability under the CMPL for allegedly submitting improper claims to Medicare for Lupron drug injections. Specifically, Beth Israel allegedly submitted claims for Lupron injections under a code that reimbursed at approximately double the rate as the code under which the claims should have been submitted.
- INDIANA Internal Medicine Associates (IMA) paid \$58,573 to resolve its liability under the CMPL
  for allegedly employing a registered nurse who was excluded from participation in Federal health
  care programs.

#### **Patient Dumping**

Some of the CMP cases that OIG resolved between April 1, 2011, and September 30, 2011, were pursued under EMTALA, a statute designed to ensure patient access to appropriate emergency medical services. The following are examples of settlements under this statute.

- TEXAS Dallas County Hospital District, d/b/a Parkland Health and Hospital System (Parkland), paid \$50,000 to resolve its CMP liability for failing to provide an appropriate medical screening examination and treatment for a patient who presented himself to Parkland's emergency department with an emergency medical condition. The patient had severe abdominal pain and waited for approximately 15 hours to receive a physical examination. The physician providing the physical examination determined that the patient required an electrocardiogram (EKG), laboratory studies, and imaging. Parkland did not perform the EKG nor did it perform any intravenous access or monitoring. Approximately 18 hours after arriving at the emergency department, the patient died of a heart attack. OIG alleged the delay in evaluation, treatment, and performance of diagnostic examinations was inappropriate and violated EMTALA.
- CALIFORNIA Santa Clara Valley Medical Center (SCVMC), an acute care facility in San Jose, agreed to pay \$48,000 to resolve its liability for violating EMTALA. On April 6, 2009, a 62-year-old male presented to SCVMC's emergency department after receiving a referral from a nearby urgent care facility that diagnosed him with severely abnormal hemoglobin results that were suspected to be the result of serious internal bleeding. The patient provided medical documents from the urgent care facility to an SCVMC triage nurse illustrating severely low hemoglobin results and complained to the nurse of dizziness, blurred vision, and fatigue. The triage nurse stated that the patient did not appear to be in distress because he could walk. The nurse also stated that the referral documents from the urgent care facility were difficult to read. As a result, the patient was triaged as nonemergent. The patient waited in the waiting room for 7 hours while his heart rate steadily increased. There is no record that SCVMC notified a physician of the patient's heart rate. The patient ultimately died in the waiting room without receiving a medical screening examination or stabilizing medical treatment.

#### Part IV

## Public Health and Human Services Reviews and Other HHS-Related Issues

## **Public Health Reviews**

#### Centers for Disease Control and Prevention

#### **President's Emergency Plan for AIDS Relief Funds**

RECIPIENTS' USES OF PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF (PEPFAR) FUNDS WERE NOT ALWAYS MONITORED IN ACCORDANCE WITH DEPARTMENTAL AND OTHER FEDERAL REQUIREMENTS. Although the Centers for Disease Control and Prevention (CDC) performed some monitoring, most of the award files we reviewed did not include all required documents or evidence to demonstrate that all cooperative agreements were monitored to the extent required. Of the 30 cooperative agreements in our sample, only 1 file contained all required documents. To ensure proper stewardship over PEPFAR funds, we recommended that CDC follow departmental and other Federal requirements in monitoring recipients' use of such funds. PEPFAR strengthens health systems and builds sustainable human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) programs in more than 75 countries in Africa, Asia, Central and South America, and the Caribbean. The Department of Health & Human Services (HHS) receives PEPFAR funds from the Department of State through a memorandum of agreement.

2011 JUN Review of the Centers for Disease Control and Prevention's Oversight of the President's Emergency Plan for AIDS Relief Funds for Fiscal Years 2007 Through 2009. A-04-10-04006. Web Summary. Full Text.

#### **Shelf-Life Extension Program**

OF 17 DRUG LOTS WE REVIEWED THAT WERE ELIGIBLE FOR THE SHELF-LIFE EXTENSION (SLEP) PROGRAM, 9 WERE EITHER DESTROYED OR RETURNED TO THE DRUG MANUFACTURER FOR CREDIT BY CDC. THE FOOD AND DRUG ADMINISTRATION (FDA) TESTED THE REMAINING DRUG LOTS AND EXTENDED THEIR STOCKPILE EXPIRATION DATES. The Strategic National Stockpile contains significant amounts of pre-positioned drugs for use in responding to emergencies throughout the United States. The SLEP is a joint Department of Defense (DoD) and FDA program that was created to enable DoD to defer drug replacement costs by delaying the replacement of certain drugs that have useful lives beyond their expiration dates. This report contains no recommendations.

2011 AUG Audit of the Centers for Disease Control and Prevention's Shelf-Life Extension Program. A-04-11-01001. Web Summary. Full Text.

## Food and Drug Administration

#### **Monitoring of Imported Food Recalls**

BECAUSE FDA'S FOOD RECALL GUIDANCE IS NONBINDING ON THE INDUSTRY, FDA CANNOT COMPEL FIRMS TO FOLLOW IT. THEREFORE, FDA CANNOT ENSURE THE SAFETY OF THE NATION'S FOOD SUPPLY. We reviewed 17 of 40 Class I recalls of imported food products conducted from July 1, 2007, through June 30, 2008. We found that firms did not promptly initiate recalls, their recall strategies were not submitted to FDA or were incomplete, they did not issue accurate and complete recall communications to their consignees, and they did not submit timely and complete recall status reports. FDA did not always follow its own procedures. It did not always conduct inspections of firms, obtain complete information on the contaminated products, conduct timely or complete audit checks of consignees, review recall strategies, promptly issue notification letters to firms conveying the review results and other essential instructions, witness the disposal of the products, or obtain the required disposal documentation. We recommended that FDA consider the results of this review in implementing the FDA Food Safety Modernization Act (signed in January 2011) and follow its procedures for monitoring recalls.

2011 JUN Review of the Food and Drug Administration's Monitoring of Imported Food Recalls. A-01-09-01500. Web Summary. Full Text.

#### Health Resources and Services Administration

#### Ryan White Funding and Payer-of-Last-Resort Requirement

FIVE OF 9 STATES WE REVIEWED CLAIMED UNALLOWABLE GRANT COSTS TOTALING \$33.4 MILLION BECAUSE THEY DID NOT COMPLY WITH PAYER-OF-LAST-RESORT OR ELIGIBILITY REQUIREMENTS. The Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (CARE Act) provides funding, referred to as "Ryan White" funds, for health care and support services for people who have HIV/AIDS and who have no health insurance or are underinsured. The HHS Health Resources and Services Administration (HRSA) administers the CARE Act. States may not use Ryan White funds to pay for items or services provided to medically or financially ineligible individuals or individuals that are eligible for coverage by other health insurance (Medicaid and other public or private health insurance plans). Our recommendations to HRSA included requiring States to identify Ryan White clients who obtain Medicaid coverage, to process retroactive Medicaid claims for individuals eligible for Medicaid at the time Ryan White funds were used to pay their claims, and to credit the Ryan White program for any Medicaid payments.

2011 SEP Review of Ryan White Part B Funding and Payer-of-Last-Resort Requirement. A-05-10-00088. Web Summary. Full Text.

#### Indian Health Service

# Internal Controls Over Monitoring Recipients' Compliance With Requirements of the American Indians Into Psychology Program

THE INDIAN HEALTH SERVICE'S (IHS) INTERNAL CONTROLS FOR THE AMERICAN INDIANS INTO PSYCHOLOGY PROGRAM (PSYCHOLOGY PROGRAM) WERE NOT ADEQUATE TO MONITOR WHETHER SCHOLARSHIP RECIPIENTS HAD MET CERTAIN SCHOLARSHIP REQUIREMENTS. As a result, IHS could not ensure that all scholarship recipients were in compliance with program requirements. We recommended developing and implementing the

necessary policies and procedures to ensure that recipients complete their approved programs and fulfill the required service obligation. Pursuant to the Psychology Program, colleges and universities receive grants to develop and maintain psychology career recruitment programs to encourage American Indians to enter the mental health field. Each scholarship recipient must maintain full-time or part-time enrollment until completion of the program and fulfill a minimum service obligation.

Audit of the Indian Health Service's Internal Controls Over Monitoring of Recipients' 2011 MAY Compliance With Requirements of the American Indians Into Psychology Program. A-09-10-01007. Web Summary. Full Text.

#### Internal Controls Over Monitoring of Recipients' Compliance With Requirements of the Indian Health Professions Scholarship Program

IHS DID NOT HAVE ADEQUATE INTERNAL CONTROLS TO MONITOR RECIPIENTS' COMPLIANCE WITH CERTAIN REQUIREMENTS OF THE INDIAN HEALTH PROFESSIONS SCHOLARSHIP PROGRAM. IHS did not always follow its own policies and procedures to verify that scholarship recipients completed approved education programs and were fulfilling their required service obligations. As a result, IHS could not ensure that all recipients were in compliance with program requirements. We recommended that IHS follow its established policies and procedures. The Indian Health Professions Scholarship program provides scholarship grants to American Indians who are enrolled full or part time in appropriately accredited schools and pursuing courses of study in the health professions. Each recipient of scholarship funds must sign a contract with IHS in which he or she agrees to complete an approved education program and fulfill a minimum 2-year active duty service obligation.

Audit of the Indian Health Service's Internal Controls Over Monitoring of Recipients' Compliance With Requirements of the Indian Health Professions Scholarship Program. A-09-09-00044. Web Summary. Full Text.

#### Access to Mental Health and Kidney Dialysis Services at Indian Health Service and Tribal **Facilities**

SHORTAGES OF HIGHLY SKILLED PROVIDERS, REMOTE LOCATIONS, LACK OF RESOURCES, AND SMALL PATIENT POPULATIONS CONTRIBUTE TO THE LIMITED MENTAL HEALTH AND DIALYSIS SERVICES FOUND AT SOME INDIAN HEALTH SERVICE AND TRIBAL FACILITIES. American Indians and Alaska Natives (AI/AN) rank first among ethnic groups as likely to suffer mental health disorders that can lead to suicide, such as anxiety and depression, and AI/ANs' rate of end stage renal disease (ESRD) is the second highest among all racial/ethnic groups. Two reviews in this semiannual period address these services and offer recommendations that include developing plans to provide guidance and technical assistance to help tribes improve services, expand telemedicine capabilities, and create a database of all IHS and tribal health care facilities. View OIG's Spotlight On the Indian Health Service, available on our Web site.

- MENTAL HEALTH SERVICES Although 82 percent of facilities provide some type of mental health service and 39 percent of the facilities reported that they provide crisis intervention 24 hours a day, we found that shortages of highly skilled providers limit access to mental health services at those facilities. To help address shortages of licensed providers, 17 percent of IHS and tribal facilities use telemedicine for mental health services. Access to Mental Health Services at Indian Health Service and Tribal Facilities. OEI-09-08-00580. September, 2011. Web Summary. Full Text.
- KIDNEY DIALYSIS SERVICES Only 20 of 506 IHS and tribal facilities reported that dialysis services are provided at their facilities. Most AI/ANs receive dialysis services at non-IHS/nontribal dialysis facilities. Many tribal facilities assist tribal members in accessing dialysis services by providing transportation and expanding access to specialists. Access to Kidney Dialysis Services at Indian Health Service and Tribal Facilities. OEI-09-08-00581. September, 2011. Web Summary. Full Text.

#### National Institutes of Health

#### **National Institutes of Health Compliance With Appropriations Laws**

WE FOUND TIME AND AMOUNT ISSUES IN FOUR CONTRACTS THAT POTENTIALLY VIOLATED THE ANTIDEFICIENCY ACT (ADA). The ADA prohibits an agency from obligating or expending funds in advance of or in excess of an appropriation unless specifically authorized by law. From November 2008 through February 2009, an HHS internal review group assessed 176 HHS contracts, including 21 National Institutes of Health (NIH) contracts. Our reviews of the NIH contracts assess compliance with the purpose, time, and amounts requirements specified in appropriations statutes. For four of the contracts we completed in this semiannual period, NIH had a bona fide need for the items and appropriately funded the contracts and their modifications from the pertinent appropriations years. We found time and amount issues in four other contracts (Avecia Biologics Limited, NexBio, Inc., SRI International, and the University of California San Francisco) in which NIH's National Institute of Allergy and Infectious Diseases (NIAID) potentially violated the ADA. For the four reviews with time and amount issues, we recommended making monetary adjustments and reporting ADA violations as appropriate.

The NIH contract reviews we completed during this semiannual period were:

- AVECIA BIOLOGICS LIMITED A-03-10-03117. September, 2011. (Recommendations: deobligate \$26 million of fiscal year (FY) 2004 appropriations and \$5.3 million of FY 2005 appropriations and return the canceled funds to the Treasury; record the remaining \$31.3 million of the \$71.3 million contract obligation against current FY appropriations.) Web Summary. Full Text.
- NEXBIO, INC. A-03-10-03119. September, 2011. (Recommendations: deobligate \$10.0 million of FY 2007 funds and \$10.0 million of FY 2009 funds; record the remaining \$30.0 million of the \$49.8 million Contract obligation against FY 2006 funds.) Web Summary. Full Text.
- SRI INTERNATIONAL A-03-10-03114. April, 2011. (Recommendations: deobligate \$11.6 million of FY 2007 funds, \$2.4 million of FY 2008 funds, and \$2.8 million of FY 2009 funds; deobligate any additional funds appropriated for years other than FY 2006 that NIAID may have obligated for the contract after our audit; record the remaining \$35.2 million of the \$56.9 million contract obligation against FY 2006 funds.) Web Summary. Full Text.
- UNIVERSITY OF CALIFORNIA SAN FRANCISCO A-03-10-03120. June, 2011. (Recommendations: deobligate \$99.5 million in funds for FYs 2002 through 2006 and record the remaining \$99.5 million of the \$134.8 million Contract obligation against current FY appropriations; deobligate \$58.2 million in funds for FYs 2008 and 2009; deobligate appropriations for subsequent FYs that NIAID may have obligated for the contract modification after our audit; and record the remaining \$180.2 million of the \$220.5 million contract obligation against FY 2007 funds.)
   Web Summary. Full Text.
- JACOBS FACILITIES INC. A-03-10-03103. June, 2011. (This report contains no recommendations.) Web Summary. Full text.
- HIGGINS DEVELOPMENT PARTNERS LLC A-03-10-03105. May, 2011. (This report contains no recommendations.) Web Summary. Full Text.
- WORLD TRAVEL SERVICE A-03-10-03113. April, 2011. (This report contains no recommendations.) Web Summary. Full Text.
- COMPUTER PACKAGES INC. A-03-10-03102. April, 2011. (This report contains no recommendations.) Web Summary. Full Text.

# Superfund Financial Activities at the National Institute of Environmental Health Sciences, Fiscal Year 2010

During FY 2010, the National Institute of Environmental Health Sciences administered its annual Superfund appropriations in accordance with applicable laws and regulations. Accordingly, this report made no recommendations. The Federal law that established the Hazardous Substance Response Trust Fund (commonly known as the Superfund) required that the Inspectors General of Federal organizations with Superfund responsibilities audit all uses of the Superfund.

2011 JUN Superfund Financial Activities at the National Institute of Environmental Health Sciences-Fiscal Year 2010. A-04-11-01099. Web Summary. Full Text.

## Public-Health-Related Legal Actions and Investigations

#### **Health Education Assistance Loan program**

Pursuant to the Health Education Assistance Loan (HEAL) program, HRSA guarantees commercial loans to students seeking education in health-related fields. The students are allowed to defer repayment of the loans until after they have graduated and begun to earn income. Although the HHS Program Support Center (PSC) takes steps to ensure repayment, some loan recipients do not resolve their indebtedness. After PSC has exhausted efforts to secure repayment of a debt, it declares an individual in default. The Social Security Act permits exclusion thereafter from Medicare, Medicaid, and all other Federal health care programs for nonpayment of these loans. Exclusion means that the individual may not receive reimbursement under these programs for professional services rendered; nor can any other provider receive reimbursement for services ordered or prescribed by the individual. OIG has authority to exclude individuals who have defaulted on HEAL loans from participation in Federal health care programs.

#### **HEAL Exclusions**

During the period covered by this report, 31 individuals and related entities were excluded as a result of an HHS 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, 2,358 individuals have chosen to enter into settlement agreements or completely repay their debts. That figure includes the 43 individuals who have entered into such settlement agreements or completely repaid their debts during this reporting period.

The amount of money being repaid through settlement agreements or through complete repayment is about \$178 million. Of that amount, about \$4.69 million is attributable to this reporting period.

Each of the following individuals entered into a settlement agreement to repay the amount indicated:

- Michigan Medical Doctor \$87,472
- Florida Osteopath \$43,651

### **Human Services Reviews**

#### Administration for Children and Families

#### Incorrect Claims for Federal Share of Title IV-E Adoption Assistance

Some States' Claims for Federal Reimbursement of Adoption Assistance Subsidies do Not comply with Eligibility Requirements. The Federal Government pays its share of a State's adoption assistance payments based on the Federal medical assistance percentage (FMAP), which varies depending on the State's relative per capita income. The adoption assistance program provides Federal funds to States to facilitate the timely placement of children whose special needs or circumstances would otherwise make them difficult to place with adoptive families. Monthly adoption subsidies assist adoptive families with the care of eligible children who were either involuntarily or voluntarily removed from their homes. The reports below that were issued during this semiannual period are part of a series of reviews concerning adoption assistance costs related to the Social Security Act, Title IV-E.

- MASSACHUSETTS In FY 2006 through 2008, Massachusetts claimed \$4.2 million Federal share for unallowable adoption assistance payments for 258 children whose eligibility lacked adequate documentation. Massachusetts did comply with the Federal requirements we reviewed when it claimed adoption assistance payments for 1,242 of the 1,500 children we selected for review. We recommended that Massachusetts make a financial adjustment of \$4.2 million (Federal share) or provide the Administration for Children and Families (ACF) with additional documentation to support the allowability of those claims, discontinue claiming adoption assistance payments for children whose eligibility they cannot support, review documentation for adoption assistance claims after FY 2008, and make a financial adjustments for any unallowable payments found. Review of Massachusetts Title IV-E Adoption Assistance Costs for Federal Fiscal Years 2006 Through 2008. A-01-11-02500. August, 2011. Web Summary. Full Text.
- TENNESSEE Tennessee received about \$2.1 million Federal share for payments it incorrectly claimed for 83 children who did not meet Federal eligibility requirements for the Title IV-E adoption assistance program. We set aside for resolution an additional \$7.5 million Federal share of payments for children for which the State did not provide documentation to support eligibility. We made several recommendations, including that the State agency refund the \$2.1 million to the Federal Government for FYs 2006 through 2008, identify and adjust the Federal share of payments made for the same ineligible children in FYs 2009 and 2010, and work with ACF to resolve the \$7.5 million Federal share in costs that we set aside for further analysis. Review of Title IV-E Adoption Assistance Maintenance Payments in Tennessee for the Period October 1, 2005, Through September 30, 2006. A-07-10-02752. April, 2011. Web Summary. Full Text.
- GEORGIA We estimated that Georgia claimed about \$14.7 million Federal share for unallowable adoption assistance payments for 1,026 children in FYs 2006 through 2008. We estimated that unallowable claims for the same children for FYs 2009 and 2010 totaled \$10.4 million (\$7.4 million Federal share). We further estimated that the Federal share of savings associated with no longer claiming payments for these children in FY 2011 would be \$2.8 million. Our recommendations included that Georgia adjust \$23.8 million (\$14.7 million Federal share) on its next quarterly expenditure report; review and adjust the estimated \$7.4 million Federal share payments it claimed for FYs 2009 and 2010 for the same ineligible children; and ensure compliance with Federal eligibility requirements, thus saving an estimated \$2.8 million Federal share for FY 2011. The unallowable payments occurred because the State misinterpreted record retention

requirements, did not always follow Federal requirements for determining adoption assistance eligibility, did not have an adequate process for stopping payments after a child reached the age of 18, and did not have adequate controls to prevent duplicate payments. Review of Georgia's Title IV-E Adoption Assistance Costs. A-04-09-03524. May, 2011. Web Summary. Full Text.

# Title IV-E Foster Care Costs Claimed on Behalf of Delinquent Children in Los Angeles County, California

CALIFORNIA CLAIMED UNALLOWABLE TITLE IV-E FOSTER CARE COSTS TOTALING \$5.7 MILLION FEDERAL SHARE ON BEHALF OF DELINQUENT LOS ANGELES COUNTY CHILDREN FOR FISCAL YEARS 2005 AND 2006. THE FEDERAL SHARE CONSISTED OF \$2.2 MILLION IN MAINTENANCE PAYMENTS AND \$3.5 MILLION IN ASSOCIATED ADMINISTRATIVE COSTS. Deficiencies included that the children were not eligible, documentation was insufficient, or the services claimed were unallowable or were not provided. We recommended that the State agency refund \$5.7 million to the Federal Government and ensure compliance with Federal requirements. A delinquent child is one who is adjudicated a ward of the court either because of the child's incorrigible behavior or because of acts committed by the child that would be considered criminal if committed by an adult.

2011 MAR Review of Title IV-E Foster Care Costs Claimed on Behalf of Delinquent Children in Los Angeles County, California. A-09-08-00023. Web Summary. Full Text.

#### Head Start: Compliance With Health and Safety Regulations in the District of Columbia

UNITED PLANNING ORGANIZATION (UPO), WHICH IS THE DISTRICT OF COLUMBIA'S (THE DISTRICT) DESIGNATED COMMUNITY ACTION AGENCY, DID NOT FULLY COMPLY WITH FEDERAL AND DISTRICT REQUIREMENTS ON ENSURING THE HEALTH AND SAFETY OF CHILDREN IN ITS CARE. As of August 2009, 57 of 127 employee files lacked certain background-related documentation or contained evidence that employees had convictions for offenses that should have disqualified the individuals from employment in jobs working with children. Other deficiencies pertained to noncompliance with requirements for drivers and the safety of materials, equipment and facilities. Our recommendations included that UPO develop and consistently follow procedures to ensure that all employee files contain specified documentation, no applicants are hired if they have been convicted of an offense listed in District of Columbia regulations, and all drivers, materials, equipment, and facilities meet requirements. UPO provides services to about 500 Head Start eligible children through a variety of programs, facilities, and delegate agencies.

2011 MAR Review of the United Planning Organization's Compliance With Health and Safety Regulations for Head Start Programs. A-03-09-00369. Web Summary. Full Text.

#### Early Head Start: Most Teachers Have the Required Credentials, But Challenges Exist

OVERALL, 81 PERCENT OF EARLY HEAD START TEACHERS HAD THE REQUIRED CREDENTIALS THAT WERE EQUIVALENT TO OR EXCEEDED A CHILD DEVELOPMENT ASSOCIATE (CDA) CREDENTIAL. MORE THAN HALF OF TEACHERS WITHOUT THE REQUIRED CREDENTIALS WERE PURSUING THEM. Approximately one-third of Early Head Start programs employed only teachers with the required credentials. We recommend that ACF work with Early Head Start programs to ensure that all teachers have the required credentials and provide guidance to programs about training teachers. Early Head Start provides comprehensive services to low-income pregnant mothers and infants and toddlers from birth to age 3. In the 2009-2010 program year, more than 100,000 infants and toddlers were served through almost 1,000 Early Head Start grantees.

2011 AUG Most Early Head Start Teachers Have the Required Credentials, But Challenges Exist. OEI-05-10-00240. Web Summary. Full Text.

## **Child Support Enforcement**

#### States' Reporting of Undistributable Child Support Collections as Program Income

IN A SERIES OF 23 AUDITS, WE FOUND THAT 21 STATES DID NOT RECOGNIZE AND/OR REPORT UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS AS PROGRAM INCOME IN ACCORDANCE WITH FEDERAL REQUIREMENTS. These deficiencies occurred because States did not classify undistributable child support collections as abandoned and/or did not require that abandoned property be transferred to the States' abandoned-property accounts. Certain States were not aware of Federal reporting requirements. An undistributable child support collection occurs when the State agency receives a child support payment but cannot identify or locate the custodial parent or return the funds to the noncustodial parent. Seventeen States did not recognize and report undistributable child support collections of \$32.8 million (\$21.3 million Federal share) as abandoned and 14 States did not report \$16.6 million (\$11 million Federal share) as program income after the States recognized the funds as undistributable child support collections. We recommended that ACF either develop a uniform Federal policy for reporting undistributable child support as program income or provide increased oversight and guidance in accordance with State laws and regulations.

2011 SEP Rollup Review on States' Reporting of Undistributable Child Support Collections as Program Income. A-05-11-00025. Web Summary. Full Text.

## **Child Support Enforcement Investigations**

Congress annually appropriates funds to OIG to detect, investigate, and prosecute noncustodial parents who fail to pay court-ordered child support. These activities are priorities for OIG. OIG works closely with the Office of Child Support Enforcement (OCSE); the Department of Justice (DOJ); U.S. Attorneys' Offices; the U.S. Marshals Service; and other Federal, State, and local partners to expedite the collection of child support.

#### **Child-Support Task Forces**

In 1998, OIG and OCSE initiated Project Save Our Children, a child support initiative that united the efforts of multiagency, multijurisdictional investigative task forces for child-support enforcement. The task forces are designed to identify, investigate, and prosecute egregious criminal nonsupport cases on the Federal and State levels by coordinating law enforcement, criminal justice, and child-support office resources. Task force screening units receive child support cases from the States; conduct preinvestigative analyses; and forward the cases to the investigative task force units, where they are assigned and investigated. The task force approach streamlines the process by which the cases best suited for criminal prosecution are identified, investigated, and resolved.

#### **Examples of Child-Support Investigative Outcomes**

OIG investigations of child support cases nationwide resulted in 35 convictions and court-ordered restitution and settlements of \$2.5 million during this semiannual period. Examples of OIG's enforcement results for failure to pay child support include the following:

ILLINOIS – Tyrone Lamont Nesby, a former NBA player, was sentenced to 5 years of probation and ordered to pay \$977,402 in restitution for unpaid child support obligations. Between 1999 and 2010, Nesby unlawfully failed to pay child support in three districts for his minor children. The districts included the District of Nevada, the Northern District of Indiana, and the Southern District of Illinois. Nesby pleaded guilty to the charges and agreed to pay restitution for unpaid child support in all three districts. At sentencing, the court strenuously recommended that Nesby

- speak to underprivileged children in schools about the importance of family and the lessons he has learned from his experiences.
- MAINE Jackie Darrell Taylor, Jr., was sentenced to 6 months' incarceration and ordered to pay restitution in the amount of \$99,406. Taylor previously pleaded guilty on March 7, 2011, to one count of failing to pay a lawful child support order. Taylor owed child support in Maine.
- LOUISIANA Billy Marvin Allen, Jr., was sentenced to 5 years' probation and ordered to pay restitution in the amount of \$110,905 in the U.S. District Court, District of Hawaii, based on his guilty plea to one felony count of failure to pay legal child support obligations. Allen was indicted in the U.S. District Court, Western District of Louisiana.

Highlights of recent enforcement actions (including child support investigations) to which OIG has contributed are posted on OIG's Web site at: <a href="http://www.oig.hhs.gov/fraud/enforcement/criminal/">http://www.oig.hhs.gov/fraud/enforcement/criminal/</a>.

## Administration on Aging

#### Performance Data for the Senior Medicare Patrol Projects: May 2011 Performance Report

SENIOR MEDICARE PATROL PROJECTS HAD AN ALMOST 12-PERCENT INCREASE IN THE NUMBER OF ACTIVE VOLUNTEERS IN 2010. Fifty-five Projects, which receive Federal grants to help beneficiaries detect and report fraud, waste, and abuse in the Medicare program, had almost 5,000 active volunteers in 2010. The volunteers educated beneficiaries in 8,300 group education sessions and held 70,789 one-on-one counseling sessions. Despite the increase in volunteers, total savings to Medicare, Medicaid, beneficiaries, and others substantially decreased in 2010. However, we continue to emphasize that the number of beneficiaries who have learned from the Senior Medicare Patrol Projects and who subsequently call the Office of Inspector General (OIG) fraud hotline or other contacts cannot be tracked. Therefore, the projects may not be receiving full credit for the savings and sentinel effect attributable to their work. Senior Medicare Patrol Projects receive grants from the Administration on Aging (AoA) to recruit retired professionals to serve as educators and resources in helping beneficiaries to detect and report fraud, waste, and abuse in the Medicare program. At least 1 project is in each of the 50 States, as well as in the District of Columbia, Puerto Rico, Guam, and the Virgin Islands.

2011 MAY Performance Data for the Senior Medicare Patrol Projects: May 2011 Performance Report. OEI-02-11-00110. Web Summary. Full Text.

## Other HHS-Related Issues

#### Conflicts of Interest

#### Conflict-of-Interest Waivers Granted to HHS Employees in 2009

FIFTY-SIX PERCENT OF THE HHS EMPLOYEE CONFLICT-OF-INTEREST WAIVERS WE REVIEWED WERE NOT DOCUMENTED AS RECOMMENDED BY SELECTED GOVERNMENT WIDE FEDERAL ETHICS REGULATIONS AND THE HHS SECRETARY'S INSTRUCTIONS. Although not required, 18 percent of the waivers we reviewed included employees' signatures and dates. We recommended that HHS require its agencies to document conflict-of-

interest waivers as recommended, develop additional guidance and training in documenting the waivers, take action to revise the waivers in our review that were not documented as recommended, expand the review of waivers for special Government employees serving on committees;, and require all employees to sign and date their waivers or otherwise document that they received and acknowledged them. HHS employees are prohibited from participating in certain official Government matters affecting their personal financial interests. These interests may include outside employment, grants, and stock ownership. Waivers permit employees who have conflicts of interest to act in an official Government capacity on matters in which they would otherwise be prohibited from participating.

2011 AUG Conflict-of-Interest Waivers Granted to HHS Employees in 2009. OEI-04-10-00010. Web Summary. Full Text.

### Information Systems

#### Oversight of Health Insurance Portability and Accountability Act Security Rule

THE DEPARTMENT'S OVERSIGHT AND ENFORCEMENT OF THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 SECURITY RULE WERE NOT SUFFICIENT TO ENSURE THAT COVERED ENTITIES, SUCH AS HOSPITALS, EFFECTIVELY IMPLEMENTED THE RULE. Our audits of 7 hospitals throughout the Nation identified 151 vulnerabilities in the systems and controls intended to protect electronic protected health information (ePHI), of which 124 were categorized as high impact. These vulnerabilities placed the confidentiality, integrity, and availability of ePHI at risk. Outsiders or employees at some hospitals could have accessed, and at one hospital did access, systems and beneficiaries' personal data and performed unauthorized acts without the hospitals' knowledge.

2011 MAY Nationwide Rollup Review of the Centers for Medicare & Medicaid Services Health Insurance Portability and Accountability Act of 1996 Oversight. A-04-08-05069. Web Summary. Full Text.

#### Security Controls in HHS's Health Information Technology Standards

AMONG THE HEALTH INFORMATION TECHNOLOGY STANDARDS PROMULGATED BY HHS'S OFFICE OF THE NATIONAL COORDINATOR (ONC), WE FOUND NO STANDARDS THAT INCLUDED GENERAL SECURITY CONTROLS. General security controls include encrypting data stored on mobile devices, such as compact disks and thumb drives; requiring two-factor authentication when remotely accessing a system; and updating the operating systems of computers that process and store electronic records. A lack of any of these or other security controls can expose systems to a host of problems. In prior reviews, we had also found a lack of general security controls at Medicare contractors, State Medicaid agencies, and hospitals. Those vulnerabilities, combined with our findings in this audit, raise concern about the effectiveness of security for electronic health information. Our recommendations included that ONC broaden its focus to include well-developed general security controls for supporting systems, networks, and infrastructures as well as emphasizing the importance of system security to medical practitioners.

2011 MAY Audit of Information Technology Security Included in Health Information Technology Standards. A-18-09-30160. Web Summary. Full Text.

#### Non-Federal Audits

In this semiannual period, OIG's National External Audit Review Center reviewed 1,025 reports that covered \$1.7 trillion in audited costs. Federal dollars covered by these audits totaled \$701.9 billion, about \$256.6 billion of which was HHS money.

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

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

Non-Federal Audit Reports Reviewed and Issued During This Reporting Period		
Not requiring changes or with minor changes	932	
Requiring major changes	88	
With significant technical inadequacies	5	
Total	1,025	

The 1,025 reports included 3,248 recommendations for improving management operations. In addition, these audit reports provided information for 44 special memorandums that identified concerns for increased monitoring by management.

#### **Contract Audits**

The National Defense Authorization Act for FY 2008, § 845, requires each Inspector General appointed under the Inspector General Act of 1978 to submit, as part of the semiannual report submitted to Congress pursuant to section 5 of such Act, information on final, completed contract audit reports issued to the contracting activity containing significant audit findings issued during the period covered by the semiannual report concerned. Significant findings in this semiannual reporting period include time and amount issues in four NIH contracts that potentially violated the ADA, which prohibits an agency from obligating or expending funds in advance of or in excess of an appropriation unless specifically authorized by law. See page Iv-4.

#### Grantee Fraud and Misconduct

In a July 2011 Grants.gov quarterly Webcast, Special Agents from the HHS and DOJ OIGs gave a special presentation on grants fraud prevention that highlights three areas of interest: conflicts of interest, misuse of funds, and embezzlement. The <u>session</u>, which runs about 1 hour, includes discussion and audience questions and can be viewed from our Web site. A <u>CBS News video</u> about fraudulent Federal grants can also be viewed from our Web site. The following is an example of an investigative outcome concerning grantee fraud.

GEORGIA – Bernard Walker was sentenced to 33 months' incarceration and ordered to pay \$173,257 in restitution after pleading guilty to theft or embezzlement from a program receiving Federal grant funding and money laundering for fraudulently obtaining and laundering checks from a federally funded not-for-profit program meant to feed low-income children. Walker used his position as a nutrition specialist for a Head Start program to obtain kickbacks from various vendors and submitted fraudulent invoices from nonexistent vendors to obtain payment. He also ordered food through the Head Start program for his personal catering company. In addition to Walker's sentencing, the district court ordered the forfeiture of Walker's Audi A6 Quattro and BMW 528I vehicles, which had been purchased with the proceeds of his theft.

## **Recovery Act Retaliation Complaint Investigation**

Section 1553 of the American Recovery and Reinvestment Act of 2009 (Recovery Act) prohibits non-Federal employers that have received Recovery Act funding from retaliating against employees who disclose evidence of mismanagement of Recovery Act funds or any violation of law related to Recovery Act funds. Section 1553 also requires OIGs to include in their semiannual reports to Congress the retaliation complaint investigations that they decided not to conduct or continue during the reporting period. OIG did not discontinue or decline to conduct any Recovery Act whistleblower retaliation complaint investigations during this reporting period.

## Legislative and Regulatory Reviews

The Inspector General Act of 1978 (IG Act) requires us 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 recommendations tell HHS and its pertinent 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 <u>Semiannual Report to Congress</u> describes findings and recommendations from recently completed reviews, most of which focus on existing laws and regulations.
- Our <u>Compendium of Unimplemented Recommendations</u>, 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 <u>Work Plan</u>, 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 other operating and staff divisions in the review and development of HHS regulations through a well-established HHS process. Our audits, evaluations, and investigations are sometimes cited in regulatory preambles as influencing HHS regulations. In addition, we provide independent, objective technical assistance on a bipartisan, bicameral basis to congressional committees and members who request it.

## **Appendixes**

Appendix A: Savings Achieved Through Implementation of

Recommendations

Appendix B: Questioned Costs and Funds To Be Put to

Better Use

Appendix C: Peer Review Results

Appendix D: Summary of Sanction Authorities

Appendix E: Reporting Requirements

Appendix F: Public Proposals for New and Modified Safe

Harbors

Appendix G: Acronyms and Abbreviations

## Appendix A Savings Achieved Through Implementation of Recommendations

After laws involving Department of Health & Human Services (HHS) programs are enacted, the Office of Inspector General (OIG) analyzes them to identify provisions that were supported by our recommendations and the associated cost savings. A similar process occurs with respect to administrative changes implemented by HHS management through regulations or other directives. The savings reported in this appendix generally reflect third-party estimates of funds made available for better use through reductions in Federal spending, deobligation of funds, and/or avoidance of unnecessary expenditures.

To identify administrative savings, we use estimates developed by or in consultation with HHS operating or staff divisions. To identify legislative savings, we use estimates that the Congressional Budget Office (CBO) prepared to inform Congress of the potential impact of legislation under consideration. CBO projects the annual increases and/or reductions in Federal spending that it expects would result from enacting legislation. Implemented legislative and administrative actions reflect not only OIG's recommendations, but also the contributions of others, such as HHS staff and operating divisions and the Government Accountability Office (GAO).

Savings estimated for fiscal year (FY) 2011 that were supported by OIG recommendations totaled \$19,826 million (\$19.8 billion).

#### Centers for Medicare & Medicaid Services

OIG Recommendation	Implementing Action	Savings (millions)
State-Enhanced Payments Under Medicaid Upper Payment Limit Requirements. The Centers for Medicare & Medicaid Services (CMS) should move as quickly as possible to issue regulatory changes to the upper payment limit (UPL) rules governing enhanced payments to local government providers. The recommendation related to findings in OIG report number A-03-00-00216.	In 2001, CMS issued revisions to the UPL regulations that, among other things, created new payment limits for local-government-owned providers. This final rule significantly affects a State's ability to reap windfall revenues by reducing the available funding pool from which to make enhanced payments to local-government-owned providers. Savings were projected through FY 2011.	\$8,400
Medicaid Enhanced Payments to Local Providers. Reconsider capping the aggregate UPL at 100 percent for all facilities, rather than the 150-percent allowance for non-State-owned Government hospitals. The recommendation relates to findings in OIG report number A-03-00-00216.	CMS 2001 final rule that modified the Medicaid UPL provisions removed the 150-percent UPL for services furnished by non-State-owned or operated hospitals. Savings were projected through FY 2011.	\$3,300

OIG Recommendation	Implementing Action	Savings (millions)
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 relates to findings in the following OIG reports:  OEI-03-96-00420 OEI-03-97-00290 OEI-03-97-00293 A-06-00-00023 A-06-01-00053 A-06-02-00041	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. Under the MMA, most drugs were to be paid at 85 percent of the April 1, 2003, AWP effective January 1, 2004, through December 31, 2004, unless they met certain exceptions. Since January 1, 2005, most drug prices have been based on the average sales price or competitive acquisition instead of AWP.	\$2,200
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 related to findings in the following OIG reports:  A-02-98-01036  A-04-92-02057  A-09-89-00162  A-10-86-62005	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 related to OIG's work that were implemented by the Balanced Budget Act (BBA), Omnibus Budget Reconciliation Act (OBRA) 1993, OBRA 1990, and OBRA 1989.	\$1,100
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 recommendation related to findings in the following OIG reports: A-09-89-00031 A-09-93-00056	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.	\$1,100
Payments for Durable Medical Equipment. Take steps to reduce payments for a variety of durable medical equipment (DME) and related supplies. The recommendation related to findings in the following OIG reports: OEI-03-01-00680 OEI-03-02-00700	Section 302 of the MMA froze payments for certain DME items, including prosthetics and orthotics, effective January 1, 2004.	\$900

OIG Recommendation	Implementing Action	Savings (millions)
OEI-07-96-00221 OEI-03-96-00230 OEI-03-94-00021 OEI-06-92-00861 OEI-06-92-00866		
Medicare Home Health Payments. Reduce the Home Health Agency (HHA) 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 related to findings in report number A-04-99-01194.	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.	\$900
Payment for Services Furnished in Ambulatory Surgical Centers. Set rates that are consistent across sites and 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 related to findings in the following OIG reports:  OEI-05-00-00340 OEI-09-88-01003 A-14-98-00400 A-14-89-00221	Section 626 of the MMA limited the ASC update starting April 1, 2004, then froze updates for a period beginning the last quarter of FY 2005, effectively reducing the payment advantage to ASCs for those procedure codes that are more highly paid in the surgical center compared to 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 the costs of procedures performed in hospital outpatient departments, which CMS implemented by regulation effective January 1, 2008.	\$500
Medicare Advantage Payments. Modify payment rates to a level fully supported by empirical data considering the effects of the multiple elements that impact total payments. The recommendation that Medicare Advantage (MA) payment rates be fully supported by empirical data mirrors a body of past and continuing OIG work. The source report for this recommendation was A-14-00-00212.	Section 5301 of the Deficit Reduction Act of 2005 (DRA) amended the Social Security Act, § 1853(k), to phase out risk adjustment budget neutrality in determining the amount of payments to MA organizations. The DRA defined the applicable amount in calculating benchmark amounts, codified the phaseout schedule for the budget neutrality adjustment, and identified the adjustments to be made to the budget neutrality calculation during the phaseout years. CBO estimated the provision would reduce spending by about \$6.5 billon through FY 2010 and projected \$300 million in reduced spending for FY 2011.	\$300

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 explanatory report for this recommendation was A-06-09-00033.	Section 2501(d) of the Patient Protection and 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 \$300 million attributed to the effect of the amendment in FY 2011.	\$300
Capped Rental Durable Medical Equipment. Eliminate the semiannual maintenance payment allowed for capped rental DME, pay only for repairs when needed, eliminate the 15-month rental option, and convert rentals to purchases after the 13 <sup>th</sup> month. The recommendation related to findings in report number OEI-03-00-00410.	Section 5101 of the DRA revised the payment rules for capped rental DME to require that ownership of the item transfer to the beneficiary after the 13 <sup>th</sup> month and that Medicare pay for maintenance services on a cost-reimbursement basis.	\$200
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 related to findings in report number OEI-03-05-00310.	Section 112 of the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Extension Act of 2007 establishes a revised calculation method for calculating volume weighted average sales prices for Medicare Part B drugs that comports with OIG's recommendation.	\$200
Medicaid Third Party Liability. Determine whether legislation is needed to explicitly include pharmacy benefit management companies in the Medicaid definition of a 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 recommendation related to findings in report number OEI-03-00-00030.	Section 6035 of the DRA made several changes to strengthen Medicaid's third-party liability provisions, including clarification regarding pharmacy benefit managers. The section also includes requiring States to ensure that health insurers, as a condition of doing business in the State, 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 on which the item or service was furnished.	\$200

Medicare Secondary Payer. Implement stronger followup procedures for employers who fail to respond to data requests, exercise civil monetary penalty (CMP) authority, and seek necessary legislative authority for mandatory data reporting. Related reports include: A-02-98-01036; A-02-02-01037; A-02-02-01038; A-04-01-07002; A-09-89-00100.

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 that this provision would result in savings of \$1.1 billion over 10 years, with \$100 million attributed to FY 2011.

\$100

#### Medicaid Drug Rebates—Sales to Repackagers Excluded From Best Price Determinations.

Require drug manufacturers that excluded sales to health maintenance organizations (HMO) from their best price calculations to repay the rebates and evaluate the policy guidance relating to exclusion of sales to other (non-HMO) repackagers from best price determinations. Medicaid rebates were lost because sales to HMOs were improperly excluded from drug manufacturers' best price determinations in FYs 1998 and 1999. The recommendation related to findings in report number A-06-00-00056.

CMS issued Medicaid Drug Rebate Program Release #47 in July 2000, reiterating that section 1927(c) of the Social Security Act requires that manufacturers include in the best price the lowest price available to, among other entities, any wholesaler, retailer, provider, and HMO. The release specifically stated that this includes sales to organized health care settings, such as HMOs.

\$81

#### **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 recommendation related to findings in report number OEI-03-02-00660.

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).

\$20

#### Administration for Children and Families

OIG Recommendation	Implementing Action	Savings (millions)
Triennial Reviews of Child Support Orders and Medical Support by Parents. Ensure that more periodic reviews are initiated and take action to increase medical support by parents. OIG reviewed the effects of 1996 legislation that no longer required States to conduct periodic reviews and adjustments of child support orders (unless requested by a State agency or parent) and found that many States had, in effect, discontinued the reviews. The recommendations related to findings in report number OEI-05-98-00100.	Section 7302 of the DRA implemented our recommendation to increase periodic reviews by requiring States to adjust child support orders of families on the Temporary Assistance for Needy Families program every 3 years. CBO estimated net savings resulting from section 7302 as \$20 million in 2011. Section 7307 of the DRA requires, for court orders issued or amended after enactment, that all States assess the ability of either or both parents to provide medical support for their children. CBO estimated savings from section 7307 as \$5 million in FY 2011.	\$25

# Appendix B Questioned Costs and Funds To Be Put to Better Use

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

#### Table 1: 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 Accomplishment section at the beginning of the Semiannual Report. Superscripts indicate end notes.

Audit Reports	Number of Reports	Dollar Value Questioned	Dollar Value Unsupported
Section 1			
Reports for which no management decision had been made by the beginning of the reporting period <sup>1</sup>	160	\$1,171,671,000	\$85,125,000
Reports issued during the reporting period	88	\$339,552,000	\$12,007,000
Total Section 1	248	1,511,223,000	\$97,132,000
Section 2			
Reports for which a management decision was made during the reporting period <sup>2, 3</sup>			
Disallowed costs	120	\$405,369,000	\$6,753,000
Costs not disallowed	11	\$408,076,000	\$8,180,000
Total Section 2	131	\$813,445,000	\$14,933,000

Section 3			
Reports for which no management decision had been made by the end of the reporting period (Sec. 1 minus Sec. 2)	117	\$697,778,000	\$82,199,000
Section 4			
Reports for which no management decision was made within 6 months of issuance <sup>4</sup>	55	\$409,714,000	\$70,192,000

#### Table 2: Funds Recommended To Be Put to Better Use

Recommendations from audit reports that funds be put to better use are recommendations 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. Implemented recommendations are reported in Appendix A.

Audit Reports	Number of Reports	Dollar Value
Section 1		
Reports for which no management decision had been made by the beginning of the reporting period <sup>1</sup>	21	\$3,612,138,000
Reports issued during the reporting period	9	\$959,423,000
Total Section 1	30	\$4,571,561,000
Section 2		
Reports for which a management decision was made during the reporting period <sup>2</sup>		
Value of recommendations agreed to by management		
Based on proposed management action	5	\$239,842,000
Based on proposed legislative action		
Value of recommendations not agreed to by management <sup>3</sup>	2	\$377,796,000
Total Section 2	7	\$617,638,000

Section 3		
Reports for which no management decision had been made by the end of the reporting period <sup>4</sup> (Sec. 1 minus Sec. 2)	23	\$3,953,923,000

#### End Notes to Tables 1 and 2

#### Table 1 End Notes

- A-o6-o3-75545, State of Louisiana. In fiscal year (FY) 2007, the Centers for Medicare & Medicaid Services (CMS) disallowed \$312,343,358 because the State claimed Federal financial participation (FFP) for disproportionate share hospital (DHS) payments to State hospitals in excess of the hospitals' actual uncompensated care costs for State FYs 1996 through 2006. In FY 2009, CMS amended its initial decision and increased its disallowance to \$362,053,628. In August 2011, CMS provided a second amended decision reflecting a Departmental Appeals Board decision (Decision No. 2350 dated December 20, 2010), which reduced the disallowance to \$239,639,169, including accrued interest.
- A-07-92-00608, Denied Outpatient Claims at Blue Cross Blue Shield of Missouri. CMS reversed a
  1992 disallowance because it was unable to determine whether \$960,615 in overpayments had
  been recovered. According to information provided by CMS, Blue Cross Blue Shield of Missouri
  left the Medicare program in 1992 and successor contractors were not able to provide
  information on recovered amounts.

Not detailed are net reductions to previously reported disallowed costs totaling \$53,434.

<sup>&</sup>lt;sup>4</sup> Because of administrative delays, some of which were beyond management control, resolution of the following 55 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-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, \$58,987,755
CIN: A-03-07-00560	PENNSYLVANIA FOSTER CARE MAINTENANCE PAYMENTS – PHILADELPHIA –
	UNDER \$300, MAY 2008, \$56,513,439
CIN: A-09-06-00023	REVIEW OF LOS ANGELES COUNTY APPROVAL PROCESS OF RELATIVE FOSTER
	FAMILY HOMES, OCT 2009, \$45,520,603

<sup>&</sup>lt;sup>1</sup> The opening balance was adjusted upward by \$50.1 million because of a reevaluation of previously issued recommendations.

<sup>&</sup>lt;sup>2</sup> During the period, revisions to previously reported management decisions included:

<sup>&</sup>lt;sup>3</sup> Included are management decisions to disallow \$48.7 million in questioned costs that were identified by non-Federal auditors in audits of State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards. The audits were conducted in accordance with Office of Management and Budget (OMB) 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.

NATIONWIDE REVIEW OF INPATIENT REHABILITATION FACILITIES PATIENT ASSESSMENT INSTRUMENTS, JUN 2010, \$39,247,645
REVIEW OF INPATIENT REHABILITATION CARE FACILITIES MEDICARE CLAIMS FOR COMPLIANCE WITH CMS TRANSFER CLASSIFICATION REQUIREMENTS FOR
OCTOBER 1, 2003, THROUGH SEPTEMBER 30, 2007, JUN 2010, \$34,051,807 AUDIT OF STATE OF CALIFORNIA DSH PROGRAM FOR FY 1998, MAY 2003, \$33,318,976
REVIEW OF RATE SETTING METHODOLOGY FOR MEDICAID SCHOOL-BASED HEALTH SERVICES – CONNECTICUT, MAY 2003, \$32,780,146
AUDIT OF PENNSYLVANIA TITLE IV-E FOSTER CARE ALLEGHENY COUNTY, JAN 2011, \$28,307,142
AUDIT OF KERN MEDICAL CENTER DSH PAYMENTS FOR FY 1998, SEP 2002, \$14,165,950
PENNSYLVANIA FOSTER CARE MAINTENANCE PAYMENT – PHILADELPHIA – OVER \$300/DAY, DEC 2007, \$11,693,989
AUDIT OF PENNSYLVANIA FOSTER CARE MAINTENANCE PAYMENTS – CASTILLE SAMPLE, SEP 2007, \$11,611,822
REVIEW OF MEMBERHEALTH'S 2006 AND 2007 DIRECT AND INDIRECT REMUNERATION REPORTS, OCT 2010, \$9,339,013
AUDIT OF UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS IN TENNESSEE FOR THE PERIOD OCTOBER 1, 1998 TO DECEMBER 31, 2007, FEB 2009, \$5,768,243
REVIEW OF SEPARATELY BILLED CLINICAL LABORATORY SERVICES PROVIDED TO ESRD BENEFICIARIES BY FMCNA, MAR 2010, \$5,410,712
REVIEW OF TITLE IV-E ADOPTION ASSISTANCE MAINTENANCE PAYMENTS IN FLORIDA FOR THE PERIOD OCTOBER 1, 2004, THROUGH SEPTEMBER 30, 2007, MAY 2009, \$4,413,264
AUDIT OF UCSDMC NATE DSH PAYMENTS FOR SFY 1998, SEP 2002, \$3,776,054
REVIEW OF GROUP HEALTH'S GHCPS REPORTING OF ESRD, APR 1997, \$2,763,498
REVIEW OF MISSOURI ACF TRAINING COSTS, AUG 2009, \$2,556,099
RYAN WHITE PAYER OF LAST RESORT – PENNSYLVANIA, NOV 2010, \$2,162,998
REVIEW OF CAPITAL BLUE CROSS 2008 DIR, OCT 2010, \$1,818,249
MISSOURI TITLE IV-E TRAINING COSTS FOR RESIDENTIAL TREATMENT CENTERS
AND FOSTER CARE PARENTING, SEP 2009, \$569,663
HEAD START MATCHING COSTS – COMMUNITY ACTION COMMITTEE OF
LANCASTER FAIRFIELD COUNTY, JAN 2010, \$547,019
UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS – INDIANA, MAR 2007, \$461,430
AUDIT OF MEDICAID ADMINISTRATIVE COSTS CLAIMED BY THE COMMONWEALTH OF MASSACHUSETTS – OCTOBER 1, 2005 THROUGH
SEPTEMBER 30, 2007, FEB 2010, \$448,968 REVIEW OF COST FOR TEXAS MEDICAL FOUNDATION AUDITEE, MAY 2008, \$403,581
PAYMENTS TO INTER VALLEY FOR INSTITUTIONAL BENEFICIARIES, MAY 2002, \$319,355
MISSOURI CLAIM FOR TITLE IV-E TRAINING COSTS FOR LONG TERM TRAINING, FEB 2010, \$301,187
PAYMENTS FOR M+C ORGANIZATION FOR INSTITUTIONAL BENEFICIARIES, OCT 2005, \$293,885
UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS – MICHIGAN, AUG 2006, \$257,859

CIN: A-05-01-00094	PAYMENTS TO KAISER OF OAKLAND FOR INSTITUTIONAL BENEFICIARIES, OCT 2002, \$229,656
CIN: A-07-06-01035	AUDIT OF QUALITY IMPROVEMENT ORGANIZATION – IOWA, OCT 2007, \$208,974
CIN: A-09-05-00077	REVIEW OF PACIFICARE'S USE OF ADDITIONAL CAPITATION UNDER THE MMA
	OF 2003, MAR 2006, \$135,000
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 05 04 00004	PAYMENTS TO UNITED HC OF FLORIDA FOR INSTITUTIONAL BENEFICIARIES, SEP
CIN: A-05-01-00091	•
	2002, \$121,023
CIN: A-04-07-01045	COSTS CLAIMED FOR ESRD NETWORK 6 OPERATIONS, AUG 2009, \$116,728
CIN: A-05-97-00017	FHP, INC. – HMO INSTITUTIONAL STATUS PROJECT, JUN 1998, \$109,114
CIN: A-05-01-00079	PAYMENTS TO BLUE CARE MID-MICHIGAN FOR INSTITUTIONAL BENEFICIARIES,
CIN: A 03 01 000/9	,
	JUN 2002, \$100,692
CIN: A-01-10-02504	RCA OF THE COMMUNITY ACTION AGENCY OF NEW HAVEN, INC., FEB 2011,
	\$90,851
CIN: A-05-01-00090	PAYMENTS TO AETNA U.S. HEALTHCARE PENNSYLVANIA FOR INSTITUTIONAL
	BENEFICIARIES, JUL 2002, \$87,516
CIN: A 03 08 00011	REVIEW OF DUPLICATE PAYMENTS TO PHARMACIES FOR MEDICARE PART D
CIN: A-03-08-00011	
	DRUGS – BARON DRUGS, SEP 2009, \$79,489
CIN: A-02-06-01023	AUDIT OF QUALITY IMPROVEMENT ORGANIZATION – NEW YORK, MAR 2008,
	\$77,358
CIN: A-09-06-00039	MEDICARE INTEGRITY – AUDIT OF QUALITY IMPROVEMENT ORGANIZATION –
, , , , , ,	WASHINGTON STATE, FEB 2008, \$73,636
CIN: A-01-10-00600	REVIEW OF VERMONT'S COMPLIANCE WITH CMS REIMBURSEMENT OF
CIN. A-01-10-00000	
	MEDICARE PART D DRUG DEMONSTRATION PROJECT REQUIREMENTS, SEP
	2010, \$70,027
CIN: A-05-01-00086	PAYMENTS TO HMO OF NORTHEASTERN PENNSYLVANIA FOR INSTITUTIONAL
	BENEFICIARIES, MAY 2002, \$62,432
CIN: A-04-06-00023	REVIEW OF QUALITY IMPROVEMENT ORGANIZATIONS – TENNESSEE, JUL 2008,
cii (17 04 00 0002)	\$30,654
CINI A - O	
CIN: A-08-03-73541	SOUTH DAKOTA FOUNDATION FOR MEDICAL CARE, JAN 2003, \$28,573
CIN: A-07-02-00150	PAYMENTS TO COVENTRY- PITTSBURG FOR INSTITUTIONAL BENEFICIARIES, JUN
	2003, \$26,000
CIN: A-05-01-00078	PAYMENTS TO HEALTH NET-TUCSON, AZ FOR INSTITUTIONAL BENEFICIARIES,
- ,	APR 2002, \$21,233
CINI: 1 08 04 76770	COLORADO FOUNDATION FOR MEDICAL CARE, DEC 2003, \$18,925
CIN: A-08-04-76779	
CIN: A-05-01-00100	PAYMENTS TO FALLON HEALTH FOR INSTITUTIONALIZED BENEFICIARIES, MAY
	2002, \$18,842
CIN: A-05-01-00095	PAYMENTS TO HUMANA OF ARIZONA FOR INSTITUTIONAL BENEFICIARIES, JUN
	2002, \$18,645
CIN: A-07-03-00151	REVIEW OF MEDICARE PAYMENTS FOR BENEFICIARIES WITH INSTITUTIONAL
c	STATUS, JUN 2003, \$18,400
CINI. A am a service	
CIN: A-07-04-01011	PAYMENTS FOR UNITED HEALTHCARE FOR INSTITUTIONAL BENEFICIARIES,
	MAR 2005, \$13,128
CIN: A-05-06-00043	REVIEW OF OHIO KEPRO, FEB 2008, \$11,874
CIN: A-05-01-00070	PAYMENTS FOR BENEFICIARIES WITH INSTITUTIONAL STATUS – MISSOURI
•	GROUP HEALTH PLAN, JAN 2002, \$11,089

TOTAL NUMBER OF REPORTS: 55 TOTAL AMOUNT: \$409,714,000

#### Table 2 End Notes

A-04-09-04039, Review of Jurisdiction C Medicare Payments for Selected Durable Medical Equipment Claims With the KX Modifier for Calendar Year 2007. In October 2010, CMS agreed to consider implementing a prepay claims documentation edit proposed by CIGNA Government Services, the durable medical equipment (DME) Medicare contractor for Jurisdiction C, to improve the effectiveness of the KX modifier. The proposed edit was in response to an OIG finding that the KX modifier was not effective in ensuring that suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) had the required supporting documentation on file. In September 2011, CMS informed OIG that funds were not available to implement this edit and avoid costs estimated by OIG at \$137 million. Because CMS acknowledged that the amount of potential savings from implementing this edit is substantial, we continue to recommend that CMS implement our recommendation when funds become available.

 $^3$  A-07-10-01080, Rollup Review of Impact on Medicare Program for Investment Income That Medicare Advantage Organizations Earned and Retained From Medicare Funds in 2007. CMS did not concur with the OIG recommendation that it either (1) pursue legislation to adjust the timing of Medicare prepayments to Medicare Advantage Organizations (MAO) to account for the time that these organizations invest Medicare funds before paying providers for medical services or (2) develop and implement regulations that require Medicare Advantage (MA) organizations to reduce their revenue requirements in their bid proposals to account for anticipated investment income. OIG estimated that Medicare could have earned approximately \$450 million of interest income in calendar year (CY) 2007 prepayments to MA plans if payments had been delayed until after the beginning of the beneficiary's coverage period by the same number of days that we estimated MA organizations held Medicare funds before using them to pay for services. Alternatively, OIG estimated that Medicare could have saved about \$376 million had MA organizations reduced the revenue requirements in bid proposals to account for anticipated investment income. CMS nonconcurred with the OIG's recommendation and stated that it continued to believe that implementing either option recommended by OIG would cause most MA organizations to increase their bid proposals in order to recoup investment income that they would lose. CMS noted that if MA organizations were to increase their bid proposals to account for the proposed offsets, these higher costs would be recognized in the bid proposals and would result in a decrease in most or all of the estimated cost savings. OIG continues to recommend that CMS act on this recommendation in its Compendium of Unimplemented Recommendations.

<sup>4</sup>Management decisions were not made within 6 months on 11 reports. Discussions with management are continuing, and it is expected that the following audits will be resolved by the next semiannual reporting period:

CIN: A-06-09-00033	REVIEW OF ADDITIONAL REBATES OF NEW BRAND-NAME DRUGS, MAR 2010,
	\$2,500,000,000
CIN: A-02-07-02000	OPEN AND INACTIVE GRANTS ON THE PAYMENT MANAGEMENT SYSTEM – ACF,
	FEB 2009, \$472,155,156
CIN: A-04-06-03508	UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS – FLORIDA, JAN 2008,
	\$7,881,447
CIN: A-05-05-00033	UNDISTRIBUTED CHILD SUPPORT COLLECTIONS – MI, AUG 2006, \$4,397,133
CIN: A-06-00-00073	MANAGED CARE ADDITIONAL BENEFITS – NYLCARE HEALTH PLANS OF THE
	SOUTHWEST CY 2000, MAR 2002, \$4,000,000
CIN: A-03-10-03121	TIGER TEAM – CONTRACT HHSN278-2008-00012C, NOV 2010, \$3,460,879

<sup>&</sup>lt;sup>1</sup>The opening balance was adjusted downward by \$153,000 because of a reevaluation of previously issued audit recommendations.

<sup>&</sup>lt;sup>2</sup> During the period, a previously reported management decision was revised:

CIN: A-09-09-00055	MEDICAID – REVIEW OF CALIFORNIA DRUG EXPENDITURES (MANUAL CLAIMS),
	JUN 2010, \$1,096,464
CIN: A-05-06-00038	UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS – IN, MAR 2007, \$871,677
CIN: A-05-01-00070	PAYMENTS FOR BENEFICIARIES WITH INSTITUTIONAL STATUS – MISSOURI
	GROUP HEALTH PLAN, JAN 2002, \$98,689
CIN: A-05-06-00023	UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS – MN, SEP 2006, \$28,240
CIN: A-09-09-01007	REVIEW OF IDAHO'S TITLE IV-E ADOPTION ASSISTANCE COSTS FOR FEDERAL
	FISCAL YEARS 2006 THRU 2008, JUL 2009, \$17,764

TOTAL NUMBER OF REPORTS: 11 TOTAL AMOUNT: \$2,994,007,449

#### Appendix C Peer Review Results

The Inspector General Act of 1978, as amended, requires Offices of Inspector General (OIG) to report the results of peer reviews of their operations conducted by other OIGs or 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 were conducted by another OIG organization on the Department of Health & Human Services (HHS) OIG's Office of Audit Services (OAS) and OAS did not conduct a peer review on other OIGs. Listed below describes OAS's peer review activities during prior reporting periods.

Date	Reviewing Office	Office Reviewed	Findings
June 2009	U.S. Postal Service OIG	HHS-OIG, OAS	The system of quality control for the audit organization of HHS OIG in effect for the year ending September 30, 2008, 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.
December 2009	HHS-OIG, OAS	U.S. Department of Defense (DoD) OIG	The system of quality control for the audit organization of DoD-OIG in effect for the year ending March 31, 2009, has been suitably designed and complied with to provide DoD-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. DoD-OIG received a peer review rating of pass.
			HHS OIG recommended that DoD-OIG continue to improve its system of quality control, including audit supervision, audit documentation, and report content, by ensuring compliance with audit standards and its policies and procedures. The DoD-OIG indicated that it has completed the corrective

Date	Reviewing Office	Office Reviewed	Findings
			actions to improve its quality control system that were underway during December 2009.

#### Office of Investigations Peer Review Results

During this semiannual reporting period, no peer reviews were conducted by another OIG organization on HHS OIG's Office of Investigations (OI). OI conducted one peer review on another OIG. Listed below is information concerning OI's peer review activities during the current and prior reporting periods.

Date	Reviewing Office	Office Reviewed	Findings
March 2009	U.S. Department of Labor 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, 2008, was in full compliance with the quality standards established by CIGIE and the Attorney General's guidelines.
January 2010	HHS-OIG, OI	U.S. Department of Justice (DOJ) OIG	The system of internal safeguards and management procedures for the investigative function of DOJ-OIG in effect for the year ending September 30, 2009, was in full compliance with the quality standards established by CIGIE and the Attorney General's guidelines.
January 2011	HHS-OIG, OI	U.S. 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.
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.

## Appendix D Summary of Sanction Authorities

The Inspector General Act of 1978, as amended, sets forth specific 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) has the authority 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 the imposition of 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 & Human Services (HHS) Departmental Appeals Board and Federal district and appellate courts regarding the basis for the exclusion and the length of the exclusion.

#### **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 civil monetary penalties (CMP) 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.

#### Civil Monetary Penalties Law

The Civil Monetary Penalties Law (CMPL) of the Social Security Act, 1128A (42 U.S.C. § 1320a-7a), provides 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 CMPs. These include, among other conduct, knowingly making, or causing to be made, any false statements or omissions in any application, bid, or contract to participate as a provider in a Federal health care program (including Medicare and Medicaid managed care programs and Medicare Part D) for which the Affordable Care Act authorizes a penalty of up to \$50,000 for each false statement, as well as activities relating to fraudulent marketing by managed care organizations, their employees, or their agents.

### 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; 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.

#### Appendix E Reporting Requirements

#### 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. Page numbers in the table indicate pages in this report. The word "None" appears where there are no data to report under a particular requirement.

Section	Requirement	Location
Section 4		
(a)(2)	Review of legislation and regulations	Part IV, Other HHS-Related Issues.
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	See the OIG Compendium of Unimplemented Recommendations
(a)(4)	Matters referred to prosecutive authorities	Part III: Legal and Investigative Activities
(a)(5)	Summary of instances in which information was refused	None
(a)(6)	List of audit reports	Submitted to the Secretary under separate cover
(a)(7)	Summary of significant reports	Throughout this report
(a)(8)	Statistical Table 1 – Reports With Questioned Costs	Appendix B
(a)(9)	Statistical Table 2 – Funds Recommended To Be Put to Better Use	Appendix B
(a)(10)	Summary of previous audit reports without management decisions	Appendix B
(a)(11)	Description and explanation of revised management decisions	Appendix B
(a)(12)	Management decisions with which the Inspector General is in disagreement	None

Section	Requirement	Location
(a)(13)	Information required by the Federal Financial Management Improvement Act of 1996	Reported annually in the spring Semiannual Report to Congress.
(a)(14)-(16)	Results of peer reviews of HHS-OIG conducted by other OIGs or the date of the last peer review, outstanding recommendations from peer reviews, and peer reviews conducted by HHS OIG of other OIGs.	Appendix C

#### Other Reporting Requirements

Section	Requirement	Location
§ 845	Significant contract audits required to be reported pursuant to the National Defense Authorization Act for FY 2008 (P.L. No. 110-181), § 845.	Part IV: Other HHS-Related Issues
§205	Pursuant to the Health Insurance Portability and Accountability Act (HIPAA), (P.L. No. 104-191) § 205, the Inspector General is required to solicit proposals annually via a Federal Register notice for developing new and modifying existing safe harbors to the antikickback 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.	Appendix F

## Appendix F Status of Public Proposals for New and Modified Safe Harbors to the Anti-Kickback Statute

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.

In crafting safe harbors for a criminal statute, it is incumbent upon the Office of Inspector General (OIG) to engage in a complete and careful review of the range of factual circumstances that may fall within the proposed safe harbor subject area to uncover all potential opportunities for fraud and abuse by unscrupulous providers. Having done so, OIG must then determine, in consultation with the Department of Justice (DOJ), whether it can develop effective regulatory limitations and controls not only to foster beneficial or innocuous arrangements but also to protect the Federal health care programs and their beneficiaries from abusive practices. In response to the 2010 annual solicitation, OIG received the following proposals related to safe harbors:

# Proposal New safe harbor that parallels the exemption to the civil monetary penalties (CMP) statute for remuneration "which promotes access to care and poses a low risk of harm to patients and Federal health care programs." OlG is not adopting this suggestion at this time. The CMP and anti-kickback statutes are different in nature and scope, and it may not be appropriate to promulgate a safe harbor that mirrors this CMP exception.

New safe harbor that parallels the exemption to the CMP statute for coupons, rebates, or other rewards by a retailer that are offered or transferred on equal terms to the general public and are not tied to the provision of other items or services reimbursed in whole or in part by the program under a Federal health care program.

OIG is considering this suggestion.

Modify the existing safe harbor for electronic prescribing items and services to: (1) include the provision of electronic prescribing items and services by a community health clinic to its employees and contractors; and (2) require that the items and services meet the standards and certifications issued by the Office of the National Coordinator for Health Information Technology (ONC) that are required for participation in the Medicare and Medicaid electronic health records (EHR) program.

OIG is not adopting these suggestions. The scope of the safe harbor for electronic prescribing items and services is consistent with the scope mandated by statute.

Modify the safe harbor for EHR arrangements to remove the sunset provisions and make it a permanent safe harbor.	OIG is considering this suggestion.
Modify the EHR safe harbor to remove laboratories as protected donors.	OIG is considering this suggestion.
New safe harbor protecting shared savings and gainsharing arrangements.	OIG is considering this suggestion.
New safe harbor protecting free continuing medical education programs offered by hospitals to physicians.	OIG is not adopting this suggestion. The concept of "free programs" could vary greatly and should be addressed on a case-by-case basis, such as under the advisory opinion process.
New waivers or safe harbors to the anti- kickback statute regarding the organization of accountable care organizations (ACO). New safe harbors to antitrust laws regarding the organization of ACOs.	OIG, in conjunction with the Centers for Medicare & Medicaid Services (CMS), issued an interim final rule with comment period establishing waivers of the anti-kickback statute and certain other laws to specified arrangements involving ACOs under the Medicare Shared Savings Program. See 76 Fed. Reg. 67,992 (Nov. 2, 2011). OIG is considering the suggestion for waivers with respect to the application of the anti-kickback statute for CMS Innovation demonstration programs. OIG is also considering the suggestion to issue safe harbors to the anti-kickback statute regarding ACOs. OIG has no authority to promulgate a safe harbor related to the anti-trust laws.

#### Appendix G **Acronyms and Abbreviations**

Following are selected acronyms and abbreviations commonly used in the Semiannual Report(s) to Congress. Public laws are listed at the end of the appendix.

#### Terms, Titles, and Organizations

340B drug pricing program (section 340B of the Public Health Service Act) 340B

ACF Administration for Children and Families

ADAP AIDS Drug Assistance Program

Administration for Healthcare Research and Quality AHRQ

acquired immunodeficiency syndrome AIDS

**AMP** average manufacturer price AoA Administration on Aging ASC ambulatory surgical center

**ASP** average sales price

CDC Centers for Disease Control and Prevention CDPAP Consumer Directed Personal Assistance Program Comprehensive Error Rate Testing (program) CERT

CHIP Children's Health Insurance Program CIA corporate integrity agreement

civil monetary penalty CMP

CMS Centers for Medicare & Medicaid Services

Common Working File **CWF** 

CY calendar year

DEA Drug Enforcement Administration durable medical equipment DME DOJ Department of Justice

**FAR** Federal Acquisition Regulation FBI Federal Bureau of Investigation FDA Food and Drug Administration

**FEHB** Federal Employees Health Benefits (program)

**FMAP** Federal medical assistance percentage

Medicaid Statement of Expenditures for the Medical Assistance Program Form CMS-64

FΥ fiscal year

HAC hospital-acquired condition

**HCPCS** Healthcare Common Procedure Coding System

**HEAL** Health Education Assistance Loan

**HEAT** Health Care Fraud Prevention and Enforcement Action Team

HHS Department of Health & Human Services

HIV human immunodeficiency virus

Health Resources and Services Administration HRSA

Indian Health Service IHS **IRS** Internal Revenue Service MA Medicare Advantage

MAC Medicare administrative contractor

MFCU Medicaid Fraud Control Unit

MMIS Medicaid Management Information System

NDC National Drug Codes (Directory)
NIH National Institutes of Health

OCSE Office of Child Support Enforcement

OIG Office of Inspector General

OMB Office of Management and Budget
OPM Office of Personnel Management
OPPS outpatient prospective payment system

PDE prescription drug event

P.L. Public Law

PERM Payment Error Rate Measurement (program)

PPI Producer Price Index
PSC Program Support Center

QIO Quality Improvement Organization

RUG resource utilization group SNF skilled nursing facility U.S.C. United States Code

#### **Public Laws**

ACA See Affordable Care Act below.

Affordable Patient Protection and Affordable Care Act of 2010, P.L. No. 11-148, as amended by the Health Care and Education Reconciliation Act of 2010, P.L. No. 111-52

CARE Act Ryan White Comprehensive AIDS Resources Emergency Act of 1990,

P.L. No. 101-381

CFO Act Chief Financial Officer Act of 1990, P.L. No. 101-576

EMTALA Emergency Medical Treatment and Labor Act of 1986, P.L. No. 99-272

FCA False Claims Act Amendments of 1986, P.L. No. 99-562 (Updated in

P.L. No. 111-203)

FDCA Federal Food, Drug, and Cosmetic Act of 1938, P.L. No. 75-717

FFMIA Federal Financial Management Improvement Act of 1996, P.L. No. 110-181

HIPAA Health Insurance Portability and Accountability Act of 1996, P.L. No. 104-191

IG Act Inspector General Act of 1978, as amended by P.L. No. 111-25, 5 U.S.C. App.

MIPPA Medicare Improvements for Patients and Providers Act, P.L. No. 110-275

MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003,

P.L. No. 108-173

Public Health Service Act of 1944 PHS Act

Recovery

Act

American Recovery and Reinvestment Act of 2009, P.L. No. 111-5