

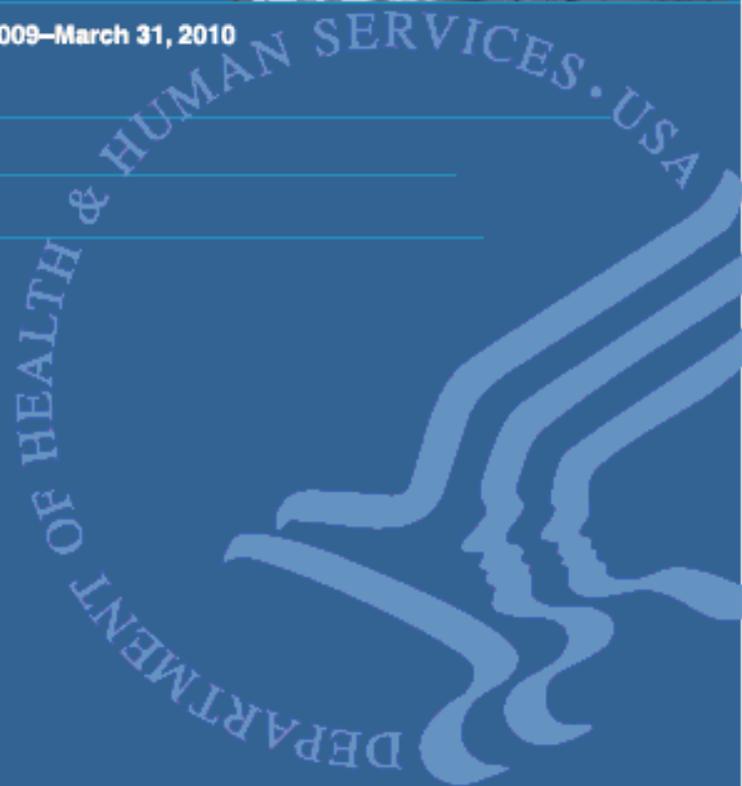


Department of Health and Human Services

# Semiannual

Report to Congress

October 1, 2009–March 31, 2010



**OIG** Office of Inspector General

# Message From the Inspector General



This report, submitted to Congress pursuant to the Inspector General Act of 1978, as amended, summarizes the activities of the Office of Inspector General (OIG), Department of Health & Human Services (HHS), for the 6-month period ending March 31, 2010.

The breadth and impact of HHS programs have always resulted in a robust agenda of OIG plenary oversight responsibilities. Over the past year, these responsibilities have significantly expanded as the result of legislation and of Administration and departmental initiatives. Likewise, OIG's investigative, audit, evaluative, and legal activities have evolved at a remarkable pace. With the passage of health care reform legislation and the expansion of our health care oversight resources, we are actively developing our operational strategy to successfully meet our growing oversight responsibilities.

Our foremost challenge ahead is implementation of the Patient Protection and Affordable Care Act. OIG is developing plans for implementing new OIG mandates and enforcement authorities and for issuing regulations. We also play a key role in oversight of HHS's implementation of its new programs and responsibilities, including reviewing departmental regulations and developing a plan for "early oversight" of HHS's health care reform activities.

Last year, as HHS began awarding \$165.4 billion in funds authorized by the American Recovery and Reinvestment Act of 2009 (Recovery Act), OIG worked with HHS management to minimize risk by reviewing spending plans and assessing internal controls to prevent fraud, waste, and abuse. We are now transitioning to work that assesses the quality of data reported by recipients and the appropriate use of Recovery Act funds. OIG is also investigating allegations of fraud involving Recovery Act funds; overseeing and managing the exclusions program to prohibit excluded individuals and entities from participating in programs involving HHS Recovery Act funds; and coordinating with the Recovery Accountability and Transparency Board; the Government Accountability Office; and other oversight and law enforcement agencies at the Federal, State, and local levels.

Our audit staff is also actively engaged in implementation of the President's Executive Order on reducing improper payments government-wide. Several HHS programs were identified as being "high priority." These high-priority HHS programs include Medicare fee-for-service programs and Parts C and D, Medicaid, Children's Health Insurance program, and the Temporary Assistance for Needy Families program.

The entire office continues to participate in the Health Care Fraud Prevention & Enforcement Action Team (HEAT). For example, Strike Force teams have continued to expand to additional fraud "hot spots" to shut down criminals masquerading as health care providers. The success of HEAT stems directly from our close partnerships with HHS, the Department of Justice, and State and local law enforcement agencies. We will continue to capitalize on these relationships and utilize innovative investigative

techniques so that we can build on HEAT successes and continue to eliminate sham providers from bilking scarce Federal health care dollars.

Our health care oversight activities also continue to review Medicare and Medicaid contractors, prescription drug fraud, and Medicare Advantage. Our oversight of the public health programs during this period includes conflict-of-interest reviews at the Centers for Disease Control and Prevention and the National Institutes of Health.

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

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Daniel R. Levinson  
Inspector General

# Highlights

## Summary of Accomplishments

For the first half of fiscal year (FY) 2010, the Department of Health & Human Services (HHS) Office of Inspector General (OIG) reported expected recoveries of about \$3.1 billion: \$667.3 million in audit receivables and \$2.5 billion in investigative receivables, which includes \$192.6 million in non-HHS investigative receivables resulting from OIG work (e.g., the States' share of Medicaid restitution).

Also for this semiannual period, OIG reported exclusions of 1,935 individuals and entities from participation in Federal health care programs; 293 criminal actions against individuals or entities that engaged in crimes against departmental programs; and 164 civil actions, which included False Claims Act Amendments of 1986 (FCA) and unjust enrichment lawsuits filed in Federal district court, Civil Monetary Penalties Law (CMPL) settlements, and administrative recoveries related to provider self-disclosure matters. The following are highlights of some of OIG's efforts during this semiannual period.

## Health Care Fraud Prevention & Enforcement Action Team

### Medicare Fraud Strike Force Activities

The interagency Health Care Fraud Prevention & Enforcement Action Team (HEAT), which is made up of top-level law enforcement and professional staff from the Department of Justice (DOJ) and HHS and their operating divisions, builds on existing partnerships to prevent fraud and enforce current anti-fraud laws around the country. The initiative is enhancing efforts like the Medicare Fraud Strike Force teams that coordinate law enforcement operations with other Federal, State, and local law enforcement entities. Strike Forces began in March 2007 and are operating in seven major cities—Miami, FL; Los Angeles, CA; Detroit, MI; Houston, TX; Brooklyn, NY; Baton Rouge, LA; and Tampa, FL. During this semiannual reporting period, Strike Force efforts have resulted in the filing of charges against 119 individuals or entities, 42 convictions, and \$16 million in investigative receivables. (Details on p. 34.)

In a recent example of a Strike Force outcome, two infusion therapy clinic managers were ordered to pay \$1,870,996 in restitution.

Managers at the infusion therapy clinics Xpress Center Inc. (XPC), and AR Group Services were both sentenced on charges of conspiracy to commit health care fraud. XPC manager Dulce Briceno was sentenced to 63 months' incarceration and ordered to pay \$1,789,234 in restitution. Briceno recruited and paid patients \$50 per visit to purport to have received legitimate services at XPC. XPC then billed Medicare for beneficiary medications and services that were medically unnecessary and/or not provided. AR Group Services manager Arturo Apolinar was sentenced to 63 months' incarceration and ordered to pay \$81,762 in restitution. Apolinar stole a doctor's provider enrollment

information, which he used to apply for a Medicare provider number, and then submitted false claims to the Medicare program for infusion therapy services that were never provided. In addition, one of the beneficiary patients involved in the XPC scheme, Darrell Brown, pleaded guilty to conspiracy to commit health care fraud and was ordered to pay \$173,732 in restitution. (Details on p. 34.)

## **Medicare and Medicaid Contractors**

### **Independent Review of Claims From the Comprehensive Error Rate Testing Program**

We determined that the Centers for Medicare & Medicaid Services' (CMS) independent medical reviews of a subsample of Medicare claims from the fiscal year (FY) 2008 Comprehensive Error Rate Testing (CERT) samples may not have provided assurance that the FY 2008 error rate was accurate. CMS's independent medical review found 116 erroneous claims that CMS's CERT contractor had not initially determined to be in error. Although we were unable to quantify the statistical effect of these results on the error rate, the results indicate the need for further CMS improvements in the Medicare error rate process. We recommended that CMS clarify documentation policies to reduce the number of differences in professional judgment, require the CERT contractor to obtain physician orders to support the medical necessity for diagnostic tests, and require the CERT contractor to develop a corrective action plan to reduce the number of incorrect determinations. CMS concurred with our recommendations. ([A-01-09-00511](#)) (Details on p. 15.)

### **Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse**

In our review of potential Medicare Part D fraud and abuse incidents identified by Medicare Drug Integrity Contractors (MEDIC) in FY 2008, we found that 87 percent were identified through external sources, such as complaints. The remaining 13 percent of potential fraud and abuse incidents were identified through proactive methods, such as data analysis. Additionally, 96 percent of investigations conducted by MEDICs in FY 2008 involved incidents identified through external sources. Problems with accessing and using data hindered MEDICs' ability to identify and investigate potential fraud and abuse incidents. MEDICs lacked the authority to directly obtain information, such as prescriptions and medical records from pharmacies, pharmacy benefit managers, and physicians. Also, MEDICs may not have been aware of some potential fraud and abuse incidents because plan sponsors are not required to refer them. MEDICs did not have CMS approval to conduct audits of plan sponsors' compliance plans in FY 2008. ([OEI-03-08-00420](#)) (Details on p. 19.)

# Medicare and Medicaid Prescription Drugs

## **Omnicare and IVAX Agree to Pay \$112 Million for Alleged Kickback Scheme**

Pharmacy services provider Omnicare, Inc., and generic drug manufacturer IVAX Pharmaceuticals, Inc., agreed to pay \$98 million plus interest and \$14 million plus interest, respectively, for allegedly engaging in kickback schemes. Omnicare allegedly engaged with several parties, including IVAX, in kickback schemes that resulted in submitting false or fraudulent claims to Medicare Part D and Medicaid. IVAX allegedly paid \$8 million to Omnicare to induce the company to purchase \$50 million in drugs from IVAX. (Details on p. 36.)

## **Mylan Pharmaceuticals and UDL Laboratories Pay \$118 Million to Settle False Claims Violations**

Mylan Pharmaceuticals, Inc., and UDL Laboratories, Inc., agreed to pay \$118 million plus interest to resolve allegations that the companies submitted false claims to the Medicaid program by underpaying rebates due to the States under the Medicaid Drug Rebate Program. Mylan and UDL allegedly sold more expensive innovator drugs that were manufactured by other companies and classified the drugs as noninnovator drugs for Medicaid rebate purposes. As a result of the improper classification of these drugs, the companies underpaid their rebate obligations under the Medicaid Drug Rebate Program. (Details on p. 36.)

## **Rebates for Brand-Name Drugs With Multiple Versions**

We calculated that from 1993 through 2007, States could have collected about \$2.5 billion in additional rebates for 65 brand-name drugs if the baseline average manufacturer prices (AMP) of new versions of those drugs had been reduced to reflect price increases in excess of inflation for the earliest versions of the drugs. For manufacturers' covered outpatient drugs to be eligible for Federal Medicaid funding, manufacturers must enter into rebate agreements and pay quarterly rebates to States. Federal law requires manufacturers to pay an additional rebate when the AMP for a brand-name drug increases more than inflation. Because the Medicaid program calculates rebates separately for each version of a drug, manufacturers could develop new versions of existing brand-name drugs solely to avoid paying additional rebates when they substantially increase prices. Unless the rebate law is modified, manufacturers could take increasing advantage of this potential loophole. We recommended that CMS continue to seek legislative authority to modify the rebate calculation to ensure that manufacturers would not be able to circumvent paying additional rebates by bringing new versions of existing brand-name drugs to market. CMS concurred. ([A-06-09-00033](#)) (Details on p. 25.)

## Medicare Clinics

### **Infusion Clinic Employee Sentenced To Serve 78 Months in Prison, Pay \$14,051,221 in Restitution for Kickback Scheme**

Caridad Perez, a former infusion clinic employee, was sentenced to 78 months' incarceration and ordered to pay \$14,051,221 in restitution for her participation in a health care fraud conspiracy. Perez recruited Medicare beneficiaries and paid them cash kickbacks in exchange for allowing their Medicare numbers to be billed at numerous Miami-based infusion therapy clinics for medically unnecessary and nonrendered infusion therapy medication. (Details on p. 37.)

### **Health Care Clinic Operator Sentenced to 78 Months in Prison for Fraud, Must Pay \$1,558,620 in Restitution**

Vardges Egiazarian, who operated three health care clinics, was sentenced to 78 months' incarceration and ordered to pay \$1,558,620 in restitution for submitting claims to Medicare for office visits, physical therapy, and/or other procedures and diagnostic tests that were not needed and/or not rendered. He also paid kickbacks to "cappers," who recruited patients to come to the clinics in return for "freebies," such as durable medical equipment (DME) and cash payments. Egiazarian used false identification documents to establish bank accounts, using aliases to launder fraud proceeds. (Details on p. 38.)

## Medicare Part C

### **Beneficiaries Remain Vulnerable to Sales Agents' Marketing of Medicare Advantage Plans**

In our review of the marketing practices of six Medicare Advantage (MA) plan sponsors, we found that each sponsor did not follow at least one of the marketing regulations related to sales agent compensation and qualifications. Five of the selected plan sponsors in our review that employ independent sales agents had compensation practices that resulted in inappropriate financial incentives for sales agents and field marketing organizations (FMO). FMOs typically provide sales agents with enrollment leads and marketing assistance. Five of the six selected plan sponsors also did not ensure that all of their sales agents were qualified under CMS's regulations. We also found that the number and types of beneficiaries' complaints remained unchanged after implementation of sales agent marketing regulations. ([OEI-05-09-00070](#)) (Details on p. 18.)

# Public Health

## Compliance With Appropriations and Acquisition Requirements

In response to a congressional request, we found that the Centers for Disease Control and Prevention (CDC) did not comply with all appropriations and acquisition requirements when administering a contract and eight task orders awarded to a small business. CDC violated acquisition regulations and circumvented civil service laws by using contractor personnel for personal services. CDC also violated the bona fide needs statute by extending periods of performance beyond 1 year and expending \$1.1 million of annual appropriations outside their 1-year period of availability. We recommended that CDC, among other actions, correct the administration of any contracts or task orders being administered as personal service contracts, determine whether the \$1.1 million expended outside the 1-year period of availability violated the Anti-Deficiency Act and correct any such violations, and ensure compliance with requirements for the obligation and expenditure of funds. CDC disagreed that it had administered task orders as personal service contracts but agreed with most of our recommendations.

[\(A-04-08-01059\)](#) (Details on p. 45.)

## Department of Health & Human Services' Conflicts of Interest

In two reviews, we addressed conflict-of-interest issues within HHS. Key findings follow.

- **Special Government Employees Serving on Federal Advisory Committees at CDC** – We found that CDC and its Special Government Employees (SGE) did not comply with a number of ethics requirements in 2007. That is, for almost all SGEs, CDC did not ensure that Confidential Financial Disclosure Reports were complete in 2007, and most of these forms contained multiple omissions. CDC did not identify or resolve conflicts of interest for 64 percent of SGEs in 2007. Over one-fourth of SGEs had both unidentified and unresolved potential conflicts of interest on file. CDC also did not ensure that 41 percent of SGEs received required ethics training in 2007. Also, 15 percent of SGEs did not comply with ethics requirements during committee meetings in 2007. These SGEs either participated in meetings without having a current, certified Confidential Financial Disclosure Report on file, or they voted on committee matters in which they were prohibited from participating because of a documented conflict of interest. [\(OEI-04-07-00260\)](#) (Details on p. 43.)
- **Financial Conflicts-of-Interest Reporting by Grantee Institutions to the National Institutes of Health** – We found that a number of vulnerabilities existed in the National Institutes of Health (NIH) grantee institutions' identification, management, and oversight of financial conflicts of interest. For example, 90 percent of the grantee institutions relied solely on the researchers' discretion to determine which of their significant and financial interests were related to their research and were therefore required to be reported. We found that because nearly half of the grantee institutions did not require researchers to provide specific amounts of equity or

compensation on their financial disclosure forms, specific financial interests of NIH-funded researchers were often unknown. In addition, when researchers submitted information about their financial interests, grantee institutions did not routinely verify it. ([OEI-03-07-00700](#)) (Details on p. 49.)

## **Other Significant Work**

### **Pediatric Dental Clinic Chain Enters Into \$24 Million Settlement for False Claims Violations**

FORBA Holdings, LLC, which manages a nationwide chain of pediatric dental clinics commonly known as Small Smiles Centers, agreed to pay \$24 million plus interest and enter into a 5-year quality-of-care corporate integrity agreement (CIA) to resolve its liability for violations of the FCA. FORBA allegedly caused the submission of claims for reimbursement for dental services that were either not medically necessary or did not meet professionally recognized standards of care. (Details on p. 41.)

### **Chiropractor Excluded for 60 Years After Rape Conviction**

Chiropractor Gregory Dew was excluded for a minimum of 60 years based on his conviction for rape, corruption of a minor, and gross sexual imposition. Dew was sentenced to 43 years' incarceration. The Ohio State Chiropractic Board permanently revoked his license, and the State Medical Board of Ohio permanently revoked his license to practice as a physician assistant. (Details on p. 32.)

### **Aberrant Medicare Home Health Outlier Payment Patterns in Miami-Dade County and Other Geographic Areas in 2008**

We found that Miami-Dade County accounted for more home health outlier payments in 2008 than the rest of the Nation combined. More than 85 percent of home health providers that received outlier payments over \$100,000 per beneficiary and 67 percent of home health providers that received total outlier payments over \$1 million per beneficiary were in Miami-Dade County. We also found that in Miami-Dade County Medicare outlier payments for home health claims with a primary diagnosis related to diabetes were eight times the national average. More than half of home health providers in Miami-Dade County and 23 other counties that we identified were paid at least twice the national average for three or more of the five payment characteristics we reviewed. ([OEI-04-08-00570](#)) (Details on p. 7.)

### **Departmental Financial Statement Audit**

In an audit of the FY 2009 HHS financial statements, independent external auditors provided an unqualified opinion. This is the 11th consecutive year that the statements were deemed reliable and fairly presented. However, the report on internal controls noted two material weaknesses—one pertaining to financial reporting systems, analyses,

and oversight and the other to financial management information systems.  
([A-17-09-00001](#)) (Details on p. 59.)

## Background

At all levels, the Office of Inspector General (OIG) works in close cooperation with the Department of Health & Human Services (HHS) and its operating and staff divisions, the Department of Justice, other agencies in the executive branch, Congress, and States to bring about successful prosecutions, negotiated settlements, recovery of funds, and systemic improvements, which often include greater beneficiary protections, improved program oversight, or funds put to better use. Systemic results are usually achieved through modifications to administrative policies, processes, or procedures; changes to existing regulations and law; or improvements in information technology.

## Office of Inspector General Recommendations

OIG relies on HHS management and other governmental policymakers to decide which program recommendations are implemented. Although many OIG recommendations are directly implemented by organizations within HHS, some are acted on by States, which collaborate with HHS to administer, operate, and/or oversee designated programs, such as Medicaid. HHS and the States sometimes do not immediately implement OIG's recommendations for various reasons, including administrative complexities, the current policy environment, or a lack of statutory authority. In such cases, Congress may step in to weave OIG's recommendations into legislative actions, many of which result in substantial funds being made available for better use or in program improvements.

The body of this *Semiannual Report* describes the results of selected reviews and other efforts finalized during the period. Information about the estimated current or potential monetary impact of our recommendations is found in the appendixes. Some current outcomes relate to reports issued and corresponding actions taken in prior periods. Specifically, Appendix A includes data on management decisions that were made during the period to disallow questioned costs, thus creating audit receivables. Some of the questioned costs disallowed were identified as findings in reports that were issued in prior semiannual periods.

In addition to publishing the semiannual reports to Congress, OIG annually publishes the *Compendium of Unimplemented Recommendations*, which consolidates significant unimplemented monetary and nonmonetary recommendations that have been addressed previously to HHS and its pertinent operating and staff divisions. The *Compendium* provides information about outstanding recommendations that, if implemented, have the potential to result in cost savings and improvements to program efficiency and effectiveness. These recommendations, which are selected from audits and evaluations, require one or more of three types of actions: administrative, regulatory, or legislative. OIG performs routine followup with the Department to determine the status of actions being taken in response to our recommendations. The *Compendium* is available on OIG's Web site at:

<http://www.oig.hhs.gov/publications/compendium.asp>.

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NOTE: Summaries of OIG audit and evaluation reports in this publication contain rounded figures. Monetary amounts in case narratives are rounded to the next lower dollar, where appropriate.

## Centers for Medicare & Medicaid Services

The Office of Inspector General (OIG) allocates about 80 percent of its resources to work related to the Centers for Medicare & Medicaid Services (CMS), which administers the following programs:

- Medicare, which provides health insurance for people 65 years of age or older, people younger than 65 years old with certain disabilities, and people of any age with end stage renal disease. In fiscal year (FY) 2009, Medicare served an estimated 46 million enrollees at a cost of more than \$503.9 billion.<sup>1</sup> Medicare has four parts: Part A (Hospital Insurance), which helps cover inpatient care in hospitals, including critical access hospitals, skilled nursing facilities (SNF), and hospice and certain home health care; Part B (Supplementary Medical Insurance), which helps pay for physician services, outpatient care, and other medical services that Part A does not cover, such as certain services offered by physical and occupational therapists; Part C (Medicare Advantage (MA)), which offers a range of prepaid managed health care choices; and Part D (the Medicare Prescription Drug Benefit), which provides an optional prescription drug benefit to individuals enrolled in Medicare, generally through private prescription drug plans (PDP).
- Medicaid, a joint Federal-State program, supports States' coverage of medical care and other support services for low-income individuals. In FY 2009, the enrollment for Medicaid was estimated at 51.7 million beneficiaries; total Federal and State outlays were approximately \$380.9 billion, of which the Federal share was \$250.9 billion.
- The Children's Health Insurance Program (CHIP), a joint Federal-State program established in 1997 under Title XXI of the Social Security Act, provides health insurance for children who do not qualify for Medicaid but whose families are not able to afford private coverage. During FY 2009, an estimated 7.7 million children benefited from CHIP, at a Federal cost of \$7.5 billion.

OIG's focus on these health care programs reflects the spending of the Department of Health & Human Services (HHS): CMS expenditures account for more than 80 percent of the Department's budget. OIG's focus is also rooted in legislative mandates and funding sources, including the following:

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA), which established the Health Care Fraud and Abuse Control program (HCFAC) under the direction of the Attorney General and the Secretary of HHS to combat waste, fraud, and abuse in the Medicare and Medicaid programs. HCFAC funding constitutes a

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<sup>1</sup> The \$503.9 billion figure represents total outlays for Medicare health care and program administrative overhead (the latter being in the \$6.6 billion range for FY 2009). Lower Medicare outlay estimates found in budget documents typically subtract particular income items classified as offsetting receipts in the Federal budget, mainly from Part B premiums. Medicare premiums (Parts A, B, and D) go directly into one of two pertinent trust funds.

major portion of OIG's annual operating budget and must be used for work related to Medicare and Medicaid.

- The Deficit Reduction Act of 2005 (DRA), which provides OIG annual funding of \$25 million in FYs 2006–2010 to undertake fraud and abuse control activities related to the Medicaid program.
- The American Recovery and Reinvestment Act of 2009 (Recovery Act), which provided OIG \$31.25 million in FY 2009, to remain available through FY 2011, for activities that ensure the proper expenditure of Medicaid funds.
- The Supplemental Appropriations Act of 2008, P.L. No. 110-252, provided additional funding to OIG to reduce fraud and abuse in the Medicaid program under Title XIX of the Social Security Act. This funding, which was provided for FY 2009 in addition to other amounts appropriated for Medicaid oversight, is available until expended.

This chapter on CMS-related work summarizes OIG's findings and recommendations related to the Medicare, Medicaid, and CHIP programs and provides examples of our outreach efforts, administrative sanctions, and criminal and civil enforcement activities.

## Medicare Part A and Part B (Traditional Medicare)

### Hospitals:

#### High-Dollar Payments for Inpatient Services

During the semiannual period, we issued two reports on high-dollar payments that fiscal intermediaries (FI) made to hospitals for inpatient services claimed under Medicare Part A. We defined high-dollar payments as those that were \$200,000 or more each. CMS contracts with FIs to, among other functions, process and pay Medicare Part A (inpatient) claims submitted by providers.

The results of our audits follow:

- **Intermediary for Alabama** – The FI overpaid Alabama hospitals \$1.5 million for inpatient services during calendar years (CY) 2004–2006. Contrary to Federal guidance, hospitals reported excessive units of service and charges that resulted in inappropriate outlier or add-on payments and failed to maintain documentation of all charges filed. Hospitals generally attributed the incorrect claims to data entry errors or insufficient documentation. The FI made these incorrect payments because neither the FI Standard System nor the Common Working File had sufficient edits in place to detect and prevent the overpayments. The FI overpaid one claim because it used an incorrect wage index when determining the payment. The FI attributed the overpayment to a data entry error.

We recommended that the FI (1) recover the \$1.5 million in identified overpayments, (2) use the results of this audit in its provider education activities, and (3) consider

implementing controls to identify and review all payments greater than \$200,000 for inpatient services. The FI agreed with our recommendations. [A-04-08-00039](#).

- **Intermediary for All States Except New York** – Of the 520 high-dollar Medicare payments that another FI made to hospitals for inpatient services for CYs 2004 through 2006, 42 were appropriate. The 478 remaining payments included net overpayments totaling \$4.7 million, which the hospitals had not refunded before the start of our audit.

Contrary to Federal guidance, hospitals inaccurately reported the number of billing units for blood clotting factor, reported incorrect diagnosis and procedure codes, and reported excessive charges that resulted in inappropriate outlier payments. Hospitals attributed most of the incorrect claims to data entry errors and insufficient documentation. The FI made these incorrect payments because neither the Fiscal Intermediary Standard System nor the Common Working File had sufficient edits in place to detect and prevent the overpayments.

We recommended that the FI (1) recover the \$4.7 million in identified net overpayments, (2) use the results of this audit in its provider education activities related to data entry procedures and proper documentation, and (3) consider implementing controls to identify and review all payments greater than \$200,000 for inpatient services. The FI described corrective actions that it had taken or planned to take to implement our recommendations. [A-05-08-00051](#).

### **High-Dollar Payments for Outpatient Services**

Our audit found that all 46 sampled high-dollar payments (\$50,000 or more) that an FI made to the outpatient departments (providers) of hospitals in Virginia and West Virginia during CYs 2003–2005 were inappropriate. The 46 payments included overpayments totaling \$3.5 million. Providers refunded \$554,000 of this amount before our audit and \$627,000 as a result of our audit. Providers had not refunded \$2.3 million in overpayments for 35 claims at the time of our audit. CMS contracts with fiscal intermediaries to process and pay Medicare Part B claims submitted by providers.

Providers received these overpayments by billing for excessive units of service or by billing for the wrong service or procedure. The FI made incorrect payments because neither the Fiscal Intermediary Standard System nor the Common Working File had sufficient edits in place during CYs 2003–2005 to detect and prevent the overpayments.

We recommended that the FI (1) recover the estimated \$2.3 million, and any additional amounts, for the 35 identified overpayments and (2) use the results of this audit in its provider education activities. The FI said that it had recouped \$2.33 million for the 35 identified overpayments, \$2,000 more than originally estimated, and that it was using its data analysis reports to identify similar billing errors.

[A-03-07-00015](#).

## **Outpatient Payments for Oxaliplatin**

For all 57 Medicare outpatient payments reviewed, 7 hospitals billed the FI for Virginia for the incorrect number of service units of Oxaliplatin, which is a chemotherapy drug used to treat colorectal cancer. As a result of the incorrect billing, the hospitals received overpayments totaling \$1.4 million during calendar year 2005. These overpayments occurred primarily because the hospitals did not update their systems after a change in Medicare billing guidance.

We recommended that the FI recover the \$1.4 million in overpayments to the hospitals. The FI agreed with our recommendation. [A-04-09-06103](#).

## **Adverse Events: Hospitals' Policies and Practices**

During the semiannual period, we issued a series of reports on adverse events at selected hospitals. For purposes of this project, the term "adverse event" refers to an undesirable event that may cause harm to a patient during the delivery of health care. Studies indicate that adverse events lead to thousands of patient deaths annually and billions of dollars in increased health care costs and lost productivity.

To participate in the Medicare program, hospitals are required to maintain an effective quality assessment and performance improvement program focused on improving health outcomes and preventing and reducing medical errors. Federal regulations allow hospitals to tailor their programs to their specific needs. During this project, we identified each selected hospital's policies and procedures to detect, report, and prevent adverse events and tested whether the hospital had followed those policies and procedures. We provided CMS with informational copies of our reports, which are considered sensitive and thus are not publicly available.

## **Adverse Events: Hospitals' Public Disclosure of Information**

OIG found only limited public disclosure of information about adverse events among entities reviewed, including State adverse event reporting systems, Patient Safety Organizations (PSO), and CMS. Publicly disclosing adverse event information can educate health care providers about causes of events, compel providers to correct vulnerabilities that lead to adverse events, and assist patients in making decisions about their care. All of the reviewed entities maintain policies, practices, and legal provisions to protect patient privacy.

This memorandum report is one in a series to fulfill the requirements of the Tax Relief and Health Care Act of 2006 (TRHCA), which requires that OIG report to Congress on never events among Medicare beneficiaries. The term "never events" refers to a specific list of 28 serious reportable events developed by the National Quality Forum. For this series of reports, we expand beyond never events to address "adverse events," defined as harm experienced by a patient as a result of medical care. This memorandum report examines 17 State adverse event reporting systems, 8 PSOs overseen by the Agency for Healthcare Research and Quality (AHRQ), and CMS regarding its Medicare claims data to analyze policies, practices, and plans for publicly disclosing information about

adverse events and protecting patient privacy. We selected these entities because many State systems have a history of collecting and analyzing adverse event data; PSOs represent a significant, recent Federal effort to collect national adverse event data; and CMS has claims data that document hospital stays of Medicare beneficiaries, a specific population of interest identified in the TRHCA.

Among these State systems, seven disclosed more extensive information than others. Such disclosure included analysis of the causes of adverse events, guidance for reducing future occurrences, and information about improvements made by hospitals. Three other State systems disclosed less extensive information about adverse events. AHRQ plans to disclose information about adverse events from PSO data once its Network of Patient Safety Databases (NPSD) is operational. AHRQ expects NPSD to become available in early 2011, although it has no timeline for its additional plans to expand data collection. In addition, possible barriers to submission of adverse event information exist, including that some hospitals questioned the value of participating with a PSO. CMS is considering public disclosure of information about hospital-acquired conditions experienced by Medicare beneficiaries during hospital stays, a subset of adverse events.

The more extensive disclosure practices of the seven State systems can serve as models for other entities. Although PSOs are expected to provide AHRQ with national data that can be used to improve patient safety, AHRQ will want to address barriers that could limit PSO data. CMS's plans to supplement Medicare claims data that have potential to generate new and useful information about hospital-acquired conditions.

[OEI-06-09-00360](#).

### **Adverse Events: Hospitals' Methods for Identifying Events**

Overall, the methods that we reviewed were found to be useful for identifying events that harmed Medicare beneficiaries in hospitals. These methods include: nurse reviews of medical records, interviews of Medicare beneficiaries, two types of analysis of hospital billing data, and reviews of internal hospital incident reports. For hospitalizations with possible events identified by the five screening methods, physicians reviewed medical records to determine whether actual events occurred. However, physician reviewers determined that 62 percent of the possible events identified by the five screening methods were not associated with actual events.

For this project, the term "never events" refers to a specific list of 28 serious reportable events developed by the National Quality Forum. For the series of reports, we expand beyond never events to address "adverse events," defined as harm experienced by a patient as a result of medical care. This report provides an in-depth examination of the five methods used in a two-county case study for identifying possible adverse events experienced by Medicare beneficiaries.

We also found that shortcomings in two of the methods have implications for Medicare payments and Federal initiatives to identify, track, and monitor events. First, patient diagnosis codes were inaccurate or absent for 7 of the 11 Medicare hospital-acquired conditions (HAC) identified by physician reviewers. These problems would prevent

Medicare from identifying HACs, result in Medicare overpayments, and inhibit use of billing data to monitor quality of care in hospitals. Second, reviewed hospitals did not generate incident reports for 93 percent of the events, including some of the most serious events involving death or permanent disability to the patient. The lack of such reports could prevent hospitals from tracking events as required by Federal regulation and suggests that hospital incident-reporting systems may be an unreliable source of information for PSOs, entities that aggregate and analyze hospital data about events.

We recommend that CMS and AHRQ explore opportunities to identify adverse events when conducting medical record reviews for other purposes. Additionally, CMS should (1) ensure that hospitals code claims accurately and completely to allow for identification of Medicare HACs and (2) provide guidelines for State survey agencies that assess hospital compliance with requirements to track and monitor adverse events. Finally, AHRQ should inform PSOs that internal hospital incident-reporting systems may be insufficient for providing information about events to PSOs. AHRQ concurred with the report as written. CMS agreed with each recommendation addressed to CMS. [OEI-06-08-00221](#)

## **Nursing Homes:**

### **Medicare Part B Services During Non-Part A Nursing Home Stays: Enteral Nutrient Pricing**

This report presents findings based on our review of Part B enteral nutrient payments during non-Part A nursing home stays in 2006. We found that Medicare's fee schedule amounts for nutrients provided during non-Part A stays exceeded prices available to nursing home suppliers and other purchasers by more than double.

Medicare Part A covers nursing home care for up to 100 days in a SNF. If nursing home care is still needed after the 100 days or the beneficiary did not qualify for a Part A SNF stay, Medicare Part B may provide coverage for certain medical and other health services. In these situations, the stays are termed "non-Part A nursing home stays," and Medicare Part B coverage during such stays includes enteral nutrition therapy (ENT), as well as equipment and supplies necessary for ENT administration.

To control Part B expenditures for ENT, we recommended that CMS take steps to adjust the Medicare fee schedule amounts for enteral nutrients to more accurately reflect supplier prices. CMS agreed with our recommendation and cited the resumption of the competitive bidding program and consideration of adjustment of the Medicare fee schedule for enteral nutrients, once sufficient data are available from the bidding process, as its opportunities to address enteral pricing concerns. [OEI-06-07-00590](#).

## Home Health Agencies:

### **Aberrant Medicare Home Health Outlier Payment Patterns in Miami-Dade County and Other Geographic Areas in 2008**

We found that Miami-Dade County accounted for more home health outlier payments in 2008 than the rest of the Nation combined. Twenty-three other counties nationwide also exhibited aberrant home health payment patterns similar to that of Miami-Dade County, but to a lesser extent.

In October 2000, CMS adopted a prospective payment system that pays a predetermined rate for 60-day episodes of home health care. The payments are adjusted for beneficiaries' health conditions and care needs, as well as for geographical wage differences. There are no limits to the number of 60-day episodes eligible beneficiaries may receive. Medicare makes other payments, known as outlier payments, to home health providers that make services available to beneficiaries who incur unusually high costs. There is no limit, or cap, on outlier payments to individual home health providers, but total outlier payments for home health services may not exceed 5 percent of annual projected total home health payments.

We found that more than 85 percent of home health providers that received outlier payments over \$100,000 per beneficiary were in Miami-Dade County. In addition, 67 percent of home health providers that received total outlier payments over \$1 million were in Miami-Dade County. We also found that in Miami-Dade County Medicare outlier payments for home health claims with a primary diagnosis related to diabetes were eight times the national average. More than half of home health providers in Miami-Dade and the 23 other counties we identified were paid at least twice the national average for three or more of the five payment characteristics we reviewed.

We recommended that CMS (1) continue efforts to institute a cap on the total outlier payments an individual home health provider may receive annually, (2) review home health providers that show aberrant outlier payment patterns and respond appropriately based on the findings, and (3) continue efforts to strengthen enrollment standards for home health providers to prevent illegitimate home health agencies from obtaining billing privileges.

CMS concurred with all three recommendations. At the time of its comments, CMS was analyzing public comments on a proposed rule that would, among other things, cap outlier payments at 10 percent per agency. The final rule was published in the Federal Register on November 10, 2009, and were effective January 1, 2010. CMS has also taken steps to address widespread abuse of Medicare outlier payments to home health agencies in Miami-Dade County. [OEI-04-08-00570](#).

## Renal Dialysis Facilities:

### Dosage Protocols for Administering Erythropoiesis-Stimulating Agents

We found that 93 percent of Medicare-certified dialysis facilities had protocols in place for administering erythropoiesis-stimulating agents (ESA), but only 56 percent of the facilities' protocols explicitly address the target hemoglobin range found on the Food and Drug Administration (FDA) boxed warning and in Medicare guidance. We could not determine whether the remaining 44 percent of protocols were consistent with the boxed warning on FDA-approved labeling and Medicare's benefit policy because they do not specify a target hemoglobin range. Of the protocols that state a target hemoglobin range, 94 percent are consistent with the boxed warning and the Medicare benefit policy for ESAs.

While they are not required to do so, dialysis facilities may develop their own protocols for administering ESAs to patients with chronic kidney failure. The protocols may define target hemoglobin levels and dosage instructions for administering ESAs. According to the boxed warning on ESAs' labels, maintaining higher rather than lower hemoglobin levels in a patient with chronic kidney failure can adversely affect the patient's health and increase the risk of death. The boxed warning states that providers should administer ESAs "to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL." The Medicare benefit policy for ESAs reflects the target hemoglobin range specified in the boxed warning. A separate Medicare policy for monitoring ESA payments states that CMS will reduce reported dosages upon which ESA claims are paid when patients' hemoglobin levels exceed 13g/dL.

Members of Congress have raised concerns that dialysis facilities' protocols for administering ESAs may not be consistent with the boxed warning for these drugs.

Our review of protocols to determine whether they are consistent with selected guidelines on ESAs' labels revealed that some protocols contain information that differs from labeling guidelines for starting doses, dose adjustments, and withholding ESA doses. We also found that all of the protocols that include a target hemoglobin range or level at which to increase ESA doses conform with CMS's monitoring policy.

We concluded that although our review does not address the amount of ESAs that providers actually administer to patients at their dialysis facilities, it does demonstrate that just over half of facilities' protocols for administering ESAs are consistent with the boxed warning and Medicare's benefit policy for ESAs. However, since almost half of the dialysis facilities did not have protocols or did not specify a target hemoglobin range in their protocols, we cannot determine whether these facilities' policies target the hemoglobin range outlined in the boxed warning that FDA requires on ESA labels. [OEI-03-09-00010](#).

### Laboratory Tests for Beneficiaries With End Stage Renal Disease

We estimated, based on our sample results, that Medicare overpaid a laboratory \$5.4 million for separately billed laboratory tests provided to end stage renal disease

(ESRD) beneficiaries at one company's dialysis facilities during CYs 2004–2006. The laboratory is a wholly owned subsidiary of the company. Federal regulations require that all tests covered by Medicare be ordered by the physician who is treating the beneficiary and that the physician who ordered the tests maintain documentation of medical necessity in the beneficiary's medical record. However, of the 100 beneficiary quarters that we sampled, 24 beneficiary quarters contained errors for separately billed tests that, based on an independent medical review by a Medicare contractor, were not reasonable and necessary and 12 beneficiary quarters contained errors for separately billed tests that were not reasonable and necessary because they were not ordered by the treating physician.

We recommended that (1) the laboratory refund to the Medicare program \$5.4 million in overpayments for CYs 2004–2006 and (2) both the laboratory and the company's dialysis facilities strengthen their policies and procedures to ensure that all tests billed are reasonable and necessary in compliance with Medicare requirements. The company disagreed with our recommendations. We maintain that our findings and recommendations are valid. [A-01-08-00511](#).

## **Practitioners and Suppliers:**

### **Reassignment of Medicare Benefits to Third Parties**

Seventy-seven percent of practitioners, or 517,936 practitioners, had reassigned Medicare benefits to at least 1 third party. Thirty-seven percent of the 833,016 Medicare reassignments of benefits in 2007 should not have been active. We identified \$140,488 in payments through 16 sampled reassignments that should not have been active. Medicare regulations require that contractors distribute payments directly to practitioners who render services, unless those practitioners' benefits are reassigned to third parties. Reassignment of benefits is a mechanism by which Medicare practitioners allow third parties to bill and receive payment for services that they rendered. Contractors process reassignments, adhering to the safeguards established in the *Medicare Program Integrity Manual* and may employ more safeguards, as needed.

For 92 percent of the reassignments that should not have been active, practitioners were once employed with the third parties to which their reassignments were made, but had since terminated their employment. For the remaining 8 percent of reassignments that should not have been active, practitioners had no knowledge of the third parties to which their benefits had been reassigned or indicated that they had applied for positions with the third parties but had never been employed there. However, Medicare payments made through reassignments that should not have been active were low. We identified \$140,488 in Medicare payments in 2007, made through 16 sampled reassignments that should not have been active. We also found that CMS contractors reported using safeguards to ensure correct processing of reassignments, but several factors may limit their effectiveness. These limitations include (1) failure of many practitioners to update their contact information with CMS, (2) failure of many practitioners to review claims that were billed on their behalf, and (3) failure of Provider

Transaction Access Numbers to automatically deactivate when reassignments are deactivated.

Based on these findings and CMS's recent efforts, we recommended that CMS (1) implement its plans to revalidate practitioner enrollment information; (2) educate practitioners on the need to provide current information; (3) implement plans to update the Provider Enrollment, Chain, and Ownership System (PECOS) from the Multiple Carrier System; and (4) follow up with practitioners for whom payments were made through reassignments that should not have been active.

After we completed data collection, CMS staff members told us of new policies that might address the limitations that we identified. These policies include periodic revalidation of practitioner contact information and implementing communication from the Multiple Carrier System to PECOS. CMS described actions it has taken or plans to take to address all four recommendations. [OEI-07-08-00180](#).

### **Organ Acquisition Costs Reported by One Organization in Fiscal Year 2006**

An independent organ procurement organization (OPO) in California did not fully comply with Medicare requirements for reporting selected organ acquisition overhead costs and administrative and general costs in its FY 2006 Medicare cost report. Of the \$3.2 million of costs we reviewed, \$2.6 million was allowable. The remaining \$531,000 represents \$291,000 of unallowable costs and \$240,000 of unsupported costs. As a result, the OPO overstated its Medicare reimbursement in the FY 2006 Medicare cost report by an estimated \$297,000.

We recommended that the OPO (1) submit a revised FY 2006 Medicare cost report to the FI to correct the estimated Medicare overstatement of \$297,000 and (2) develop and implement procedures to ensure that costs reported in future Medicare cost reports are allowable, supportable, and in compliance with Medicare requirements. The OPO partly agreed and partly disagreed with our findings. The OPO stated that it was unable to implement the first recommendation because the FI has never allowed OPOs to reopen closed reports. The OPO agreed with the second recommendation.

After reviewing the OPO's comments and additional documentation, we revised our findings and modified our first recommendation. Nothing in the comments and additional documentation caused us to revise our other findings. The FI informed us that it could reopen the cost report at the provider's request. [A-09-08-00033](#).

### **Medical Equipment and Supplies: Power Wheelchair Claims Frequently Did Not Meet Documentation Requirements**

Three out of five claims for standard and complex rehabilitation power wheelchairs did not meet Medicare documentation requirements during the first half of 2007. Power wheelchair claims that did not meet all documentation requirements accounted for \$112 million in improper Medicare payments, out of \$189 million total allowed by Medicare during the 6-month period. Beneficiaries were responsible for paying \$22 million of this amount.

For any item to be covered by Medicare, it must meet all applicable Medicare statutory and regulatory requirements. Medicare requires power wheelchair suppliers to maintain specific documentation to support the beneficiary's need for, and the appropriateness of, a power wheelchair.

We found that 60 percent of Medicare claims for standard and complex rehabilitation power wheelchairs in the first half of 2007 did not meet one or more documentation requirements. Two out of five power wheelchair claims had multiple errors. In addition, suppliers submitted incomplete documents almost three times as often as they failed to submit required documents. The specialty evaluation report was one of the documents most often not submitted by complex rehabilitation power wheelchair suppliers. We also found that Medicare documentation error rates varied by power wheelchair type and supplier volume. Complex rehabilitation power wheelchair claims had a higher documentation error rate than standard power wheelchair claims. Standard power wheelchair claims submitted by low-volume suppliers had a higher documentation error rate than those submitted by high-volume suppliers.

Based on the results of our review, we recommended that CMS improve compliance with Medicare's power wheelchair documentation requirements and suggested the following methods for improving compliance: (1) conduct additional reviews of standard and complex rehabilitation power wheelchair claims, (2) recover overpayments and consider further actions against suppliers that do not meet documentation requirements, and (3) increase education for suppliers and prescribing physicians about documentation requirements.

We also recommended that CMS take appropriate action on sampled claims found to be in error. CMS concurred with both of our recommendations. CMS noted that it has multiple efforts underway or planned that align with each suggested method to improve compliance with Medicare's power wheelchair documentation requirements. CMS will also forward to contractors the sampled claims we found to be in error to identify and recover overpayments. We will forward information on these claims to CMS under separate cover. [OEI-04-07-00401](#).

### **Medical Equipment and Supplies: Vulnerabilities in Medicare Payments for Pressure Reducing Support Surfaces**

We found that in 2007, Medicare paid for 72 percent of all pressure reducing support surface (support surface) claims with GA or GZ modifiers. Suppliers use these modifiers when they expect that Medicare will deny the claim as not reasonable and necessary. Medicare potentially inappropriately paid \$4.4 million for such claims. Support surfaces are used for the care or prevention of pressure ulcers and are covered under the Medicare Part B benefit.

Suppliers also use GA and GZ modifiers when they are providing an upgrade. An upgrade is an item of durable medical equipment that contains a component, such as an equipment feature, that is in excess of the beneficiary's medical needs. We found that

suppliers submitted only four claims for support surfaces upgrades in 2007, indicating that they may not be using the appropriate modifiers when providing upgrades.

Further, for a number of other claims, Medicare inappropriately paid for more than one support surface for the same beneficiary on the same service date. These claims amounted to \$68,785 in inappropriate payments in 2007. In several other instances, Medicare paid for a higher-priced support surface, as opposed to a lower-priced support surface. These claims amounted to an additional \$73,022 in potentially inappropriate payments.

Taken together, these results indicate that Medicare contractors may not have appropriate safeguards in place to pay for Part B claims with GA or GZ modifiers. They also show that Medicare contractors do not have controls in place to flag claims for multiple support surfaces for the same beneficiary on the same service date. The results also demonstrate that suppliers may need further instructions on the appropriate use of these modifiers when they provide upgraded items to beneficiaries. [OEI-02-07-00421](#).

### **Medical Equipment and Supplies: Equipment Claims With the KX Modifier**

The KX modifier was not effective in ensuring that suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that submitted claims to a DME regional carrier (carrier) during 2006 had the required supporting documentation on file. Of the 100 items in our sample, suppliers did not have the required documentation on file for 54. As a result, the carrier made unallowable payments totaling \$4,600 for the 54 sampled items. Based on our sample results, we estimated that the carrier paid about \$127 million to suppliers that did not have the required documentation on file to support the DMEPOS items with calendar year 2006 dates of service.

These errors occurred because the carrier's electronic edits could determine only whether the required KX modifier was on the claim.

We recommended that the Medicare administrative contractor (MAC) that replaced the carrier (1) recover \$4,400 (\$150 was repaid during fieldwork) in payments for specific DMEPOS items claimed for which the suppliers did not have the required documentation, (2) review other payments for DMEPOS related to our unallowable sample items and recover any other unallowable payments, (3) notify CMS of the 23 suppliers that did not meet the supplier standard for maintaining proof of delivery so that CMS can take appropriate action, and (4) develop a corrective action plan to improve the effectiveness of the KX modifier and potentially save an estimated \$127 million. The MAC acknowledged the facts presented in the report and listed actions that it intended to take in response to our recommendations.

[A-04-08-04020](#).

## Part B Prescription Drugs:

### Comparison of Average Sales Prices to Average Manufacturer Prices and Widely Available Market Prices for Part B Prescription Drugs: Impact on Medicare Reimbursement

From April 2006 through February 2010, we issued 17 reports related to our continuing work comparing average sales prices (ASP) with average manufacturer prices (AMP) and widely available market prices (WAMP) for Medicare Part B prescription drugs. The Social Security Act, § 1847A(d)(2)(B), mandates that OIG perform these comparisons. For instances in which the ASP for a drug exceeds the AMP or WAMP by a certain threshold (currently 5 percent), section 1847A(d)(3) provides that the Secretary of HHS may disregard the ASP pricing methodology for that drug and that the Secretary of HHS substitute the payment amount for the drug code with the lesser of the WAMP (if any) or 103 percent of the drug's AMP.

In December 2007, the Medicare, Medicaid, and SCHIP Extension Act of 2007 (the Extension Act) amended the Social Security Act, § 1847A(b), and changed the way that CMS calculates volume-weighted ASPs, effective April 1, 2008. Analyzing CMS's Healthcare Common Procedure Coding System (HCPCS) codes for drugs covered under Medicare Part B, we identified in both of the previous comparisons and those issued during this semiannual period instances in which drug codes met the threshold for price adjustments. We determined that such adjustments, if implemented by the Secretary of HHS, would save Medicare millions of dollars in Part B drug costs.

During this semiannual reporting period, we issued an overview of our reviews for the first four quarters of 2008 (based on individual reports for each quarter of 2008<sup>2</sup>) and two reports of our reviews of the first two quarters of 2009.

- *Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2008* – In 2008, ASPs for 80 HCPCS codes exceeded AMPs by at least 5 percent in one or more quarters. If reimbursement amounts for these 80 codes had been lowered to 103 percent of the AMPs for the applicable quarter(s), Medicare expenditures would have been reduced by an estimated \$21.9 million from the third quarter of 2008 through the second quarter of 2009.

Of the 80 HCPCS codes that were eligible for price adjustment in 2008, over 40 percent met the 5-percent threshold during multiple quarters. According to manufacturers associated with drugs that met the threshold in every quarter, ASPs can exceed AMPs as a result of many factors, including the way in which AMPs are weighted, the types of sales included in ASPs and AMPs, differential pricing arrangements among purchasers, and errors in the calculation of AMPs. Because some drug products had missing or unavailable AMPs, between 12 and 14 percent of HCPCS codes were excluded from our pricing comparison in each quarter.

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<sup>2</sup> (1) [OEI-03-08-00530](#), (2) [OEI-03-09-00050](#), (3) [OEI-03-09-00150](#), and (4) [OEI-03-09-00340](#).

Manufacturers for almost 60 percent of drug products without AMPs had Medicaid rebate agreements in 2008 and were therefore generally required to submit AMP data.

Consistent with statutory requirements, we recommend that CMS (1) develop a process to adjust payment amounts based on the results of OIG's pricing comparisons, (2) lower Medicare reimbursement amounts for drugs that meet the 5-percent threshold, and (3) ensure that drug manufacturers are submitting the required AMP data in a timely manner. CMS concurred with our first recommendation but does not currently concur with our second recommendation. CMS outlined steps it has already taken to address our third recommendation and expressed support for adequate enforcement action against noncompliant manufacturers. [OEI-03-09-00350](#).

- *Comparison of First-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2009* – We identified a total of 23 HCPCS codes with ASPs that exceeded AMPs by at least 5 percent in the first quarter of 2009. If reimbursement amounts for these 23 codes had been based on 103 percent of the AMPs, Medicare expenditures would have been reduced by \$3.7 million during the third quarter of 2009. [OEI-03-09-00490](#).
- *Comparison of Second-Quarter 2009 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2009* – We identified a total of 24 HCPCS codes with ASPs that exceeded AMPs by at least 5 percent in the second quarter of 2009. If reimbursement amounts for these 24 codes had been based on 103 percent of the AMPs, Medicare expenditures would have been reduced by \$3.1 million during the fourth quarter of 2009. [OEI-03-09-00640](#).

### **Average Sales Prices: Manufacturer Reporting and CMS Oversight**

We found that for each quarter under review, over 40 percent of manufacturers submitted ASPs late. However, at least 95 percent of manufacturers submitted ASP data to CMS within 10 days after the deadline. Further, no more than 2 percent of manufacturer submissions each quarter were more than 30 days late.

CMS continues to cover a limited number of outpatient prescription drugs under its Part B benefit. Since January 2005, CMS has been paying for most Part B-covered drugs using a reimbursement methodology based on ASP. ASP is defined as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. Pursuant to the Social Security Act, § 1927, manufacturers with a Medicaid drug rebate agreement in effect must, among other things, provide CMS with pricing information, including the ASPs for their Part B-covered drugs.

Manufacturers that report ASPs are required to submit them to CMS no later than 30 days after the close of the previous quarter. As a result, there is a two-quarter lag between the time when sales reflected in the ASP occur and the time when these sales become the basis for Medicare payment amounts.

We found that CMS implemented several oversight procedures related to payment for Part B-covered drugs; however, CMS's methods still may inhibit efficiency and result in potential errors. For example, CMS relies on an inefficient manual processes for collecting ASP data. Also, almost one-fifth of labeler codes with ASP submissions were associated with manufacturers that were not required to provide these prices under the Medicaid drug rebate requirements. In fact, the Medicare payment amounts for some drugs were based solely on submissions from manufacturers that did not have rebate agreements in effect. If these manufacturers chose not to report ASPs, CMS would be unable to calculate ASP-based Medicare payment amounts for these drugs.

We recommended that CMS develop an automated system for the collection of ASP data. We also recommended that CMS seek a legislative change to directly require all manufacturers of Part B-covered drugs to submit ASPs. In comments on the draft report, CMS concurred with our recommendation to develop an automated system for the collection of ASP data; CMS did not concur with our recommendation to seek a legislative change to directly require all manufacturers of Part B-covered drugs to submit ASPs. However, CMS said that it will consider this recommendation as it continues to monitor the effects of current payment policies. [OEI-03-08-00480](#).

## **Medicare Contractors:**

### **Independent Review of Claims From the Fiscal Year 2008 Comprehensive Error Rate Testing Program**

An independent medical review contractor complied with its CMS contract in performing medical reviews of a subsample of claims from FY 2008 Comprehensive Error Rate Testing (CERT) samples. To help determine the annual Medicare error rate, CMS's CERT contractor conducts medical reviews of a sample of paid claims. CMS requires the CERT contractor to make medical review decisions in accordance with CMS's written policies.

The medical review contractor's results may not have provided CMS with assurance that the CERT contractor's FY 2008 FI and carrier error rates were accurate. The medical review found 116 erroneous claims that the CERT contractor had not initially determined to be in error. We were unable to quantify the statistical effect of the medical review contractor's results on the FY 2008 FI and carrier error rates. However, the medical review contractor identified enough incorrect determinations by the CERT contractor to warrant further CMS corrective action to improve the Medicare error rate process.

We recommended that CMS (1) clarify documentation policies to reduce the number of differences in professional judgment, (2) require the CERT contractor to obtain physician orders to support the medical necessity for diagnostic tests in accordance with Medicare requirements, and (3) require the CERT contractor to develop a corrective action plan to reduce the number of incorrect determinations. CMS concurred with our findings and

recommendations and outlined the steps it had taken to implement our recommendations. [A-01-09-00511](#).

### **Recovery Audit Contractors' Fraud Referrals**

We found that between March 2005 and March 2008, recovery audit contractors (RAC) referred two cases of potential fraud to CMS. However, CMS reported that it received no potential fraud referrals from RACs during this period.

RACs are contracted by CMS and are responsible for identifying improper payments of Medicare Part A and Part B claims. They are not responsible for reviewing claims for fraudulent activity; however, they are responsible for referring to CMS any cases of potential fraud that are identified during their reviews. A 3-year RAC demonstration project conducted from March 2005 through March 2008 was designed to detect and correct past improper payments in the Medicare fee-for-service (FFS) program and provide information to CMS and to the Medicare claims-processing contractors that could help protect the Medicare trust funds by preventing future improper payments. We also found that during the demonstration project, RACs received no formal training from CMS regarding the identification and referral of potential fraud. However, CMS did provide permanent RACs with a presentation about fraud. CMS is planning to provide the permanent RACs with further education and training on the identification and referral of potential fraud, although no date or agenda has been determined.

Having a RAC staff that is trained and knowledgeable about fraud will increase awareness and detection of potential fraud during the claims review process. Therefore, we recommended the following to CMS: (1) conduct followup to determine the outcomes of the two referrals made during the demonstration project, (2) implement a system to track fraud referrals, and (3) require RACs to receive mandatory training on the identification and referral of fraud.

CMS concurred with all three of our recommendations. In regard to our first recommendation, CMS stated that it researched the two cases identified by the RAC for potential referral and determined that they should be referred to OIG for further development. CMS is forwarding these two cases to OIG. Regarding our second recommendation, CMS stated that it is developing a system to track the RAC claims review process. Finally, in response to our third recommendation, CMS stated that it has already provided two training sessions to the RACs and is in discussions with OIG and the Department of Justice on additional training. [OEI-03-09-00130](#).

### **Contractor Information Security Program Evaluations**

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires that each Medicare contractor have its information security program evaluated annually by an independent entity. To comply with this provision, CMS contracted with a certified public accounting firm to evaluate information security programs at the MACs, FIs, and carriers. CMS also contracted with another firm to perform technical assessments at Medicare data centers.

The accounting firm's reviews of the Medicare contractor information security program evaluations were adequate in scope and sufficiency. We could not determine the extent and sufficiency of the work done for the data center technical assessments because of several issues with the working papers.

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 gaps have been adequately supported, identified, and included in the technical assessment reports. CMS concurred with our recommendation. [A-18-07-30290](#).

## Medicare Part C (Medicare Advantage)

### Beneficiary Appeals in Medicare Advantage

We found that Medicare Advantage Organizations (MAO) decided most organization determinations in favor of beneficiaries; they denied few. Of those denials, called "adverse determinations," few were appealed by beneficiaries, and upon appeal, MAOs overturned more than half of their own denials.

MAOs must have a procedure to determine whether a beneficiary is entitled to receive health services and the amount, if any, a beneficiary is required to pay for the services. The outcome is called an "organization determination." MAOs also must offer beneficiaries the right to appeal an adverse determination. Further, the Secretary of HHS must contract with an Independent Review Entity (IRE) to review second-level appeals in cases in which MAOs have returned decisions that are adverse to beneficiaries' initial appeals. CMS oversees MAO compliance through audits.

We also found that MAOs decided 23 percent of adverse expedited determinations, and 18 percent of appeals, late. At the second level of appeal, an IRE overturned about one in five adverse MAO decisions. It overturned 25 percent of adverse expedited service reconsiderations, compared with 16 percent of standard service reconsiderations. CMS identified many MA contracts that failed to meet appeals-related audit elements.

Our review raises questions and concerns. We found that beneficiaries appealed fewer than 1 in 10 adverse determinations. Although no rate of appeal is expected or correct, further study could examine factors that might explain the rate and could also identify differences between denials that beneficiaries appeal and those they do not. Also of particular concern are the problems with timeliness in processing adverse expedited determinations and the higher IRE overturn rate of expedited cases. Because expedited cases concern time-sensitive care, it is important that such care be delivered with minimal delays. [OEI-01-08-00280](#).

## **Beneficiaries Remain Vulnerable to Sales Agents' Marketing of Medicare Advantage Plans**

Each of the six selected plan sponsors we reviewed did not follow at least one of the marketing regulations concerning sales agent compensation and qualifications. These marketing regulations are critical to protecting Medicare beneficiaries because they address sales agents' financial motivation and their qualifications to market MA plans.

In July 2008, the Medicare Improvements for Patients and Providers Act of 2008, which prohibited or limited certain marketing activities by plan sponsors or sales agents, was enacted. Later in 2008, CMS promulgated regulations implementing these prohibitions and limitations, including specific regulations concerning sales agent compensation and qualifications. Five of the selected plan sponsors in our review that employ independent sales agents had compensation practices that resulted in inappropriate financial incentives for sales agents and field marketing organizations (FMO). FMOs typically provide sales agents with enrollment leads and marketing assistance. In addition, five of the six selected plan sponsors did not ensure that all of their sales agents were qualified under CMS's regulations. We also found that the number and types of beneficiaries' complaints remained unchanged after implementation of sales agent marketing regulations.

We recommended that CMS (1) take appropriate actions regarding the specific instances of noncompliance documented in this report, (2) audit plan sponsors and include an assessment of the vulnerabilities identified in this report, (3) issue additional regulations concerning FMO payments, (4) issue regulations requiring plan sponsors to contact all new enrollees to ensure that they understand plan rules, and (5) issue guidance clarifying that plan sponsors should terminate unlicensed sales agents immediately upon discovery.

CMS concurred with our first recommendation. CMS concurred in part with our second recommendation, stating that it would conduct audits or other oversight activities of plan sponsors posing the greatest risk to Medicare beneficiaries. As such, we have amended the wording of the recommendation. CMS did not concur with our final three recommendations. We continue to recommend that CMS issue additional regulations and guidance to protect Medicare beneficiaries from inappropriate sales agent marketing. However, we have modified the wording of two of our recommendations to reflect alternative approaches that are consistent with CMS's comments.

[OEI-05-09-00070](#).

## **Medicare Part D (Prescription Drug Program)**

### **Demonstration Project for Dually Eligible Beneficiaries**

Massachusetts complied with certain provisions of the "Reimbursement of State Costs for Provision of Part D Drugs" Medicare demonstration application when claiming drug costs for full-benefit, dually eligible beneficiaries (fully eligible for both Medicare and Medicaid). The demonstration project reimbursed States for drug costs and related

administrative costs incurred during the transition to Medicare Part D. However, we found that the State submitted claims for some drug costs to both the Medicaid program and the Medicare demonstration project. When we initiated our audit in November 2008, the State had not adjusted its Medicaid Forms CMS-64 to reflect \$15.2 million (\$7.6 million Federal share) in drug costs for which the State was reimbursed through the Medicare demonstration project in August and December 2006 and in June 2007 for the quarter ended March 31, 2006.

During our audit, the State adjusted its Forms CMS-64 for the quarters ended December 31, 2008, and March 31, 2009, to account for almost all of the \$7.6 million in drug costs reimbursed through the Medicare demonstration project. State officials told us that they planned to adjust the Form CMS-64 for the quarter ended June 30, 2009, for the remaining \$17,000.

We recommended that the State refund \$17,000 to the Federal Government and make future refunds to the Medicaid program in a timely fashion. The State agreed with our recommendations. [A-01-09-00601](#).

### **Potential Part D Fraud and Abuse Identified by Medicare Drug Integrity Contractors**

Of the 4,194 potential fraud and abuse incidents that Medicare Drug Integrity Contractors (MEDIC) identified in FY 2008, 87 percent were identified through external sources, such as complaints. The remaining 13 percent were identified proactively, including through data analysis. Of the 1,320 investigations that MEDICs conducted in FY 2008, 96 percent involved incidents identified through external sources. Before implementing the Part D benefit, CMS developed a strategy to help combat Part D fraud and abuse. A key aspect of the strategy was MEDICs' use of innovative data analysis techniques. Beginning in FY 2007, CMS awarded contracts to three regional MEDICs to address potential fraud and abuse in the Part D benefit.

Problems accessing and using data hindered MEDICs' ability to identify and investigate potential fraud and abuse incidents. MEDICs reported that they needed prescription drug event (PDE) data and Part B data to identify and investigate potential fraud and abuse. However, MEDICs did not receive access to PDE data until August 2007, nearly a year after their contracts began. Two MEDICs were not given access to Part B data until fall 2008, and the third MEDIC did not receive access to Part B data before its contract ended. Once they received access to PDE data, MEDICs found that important variables were not available or were stored incorrectly.

MEDICs' lack of authority to directly obtain information such as prescriptions and medical records from pharmacies, pharmacy benefit managers, and physicians hindered them in investigating potential fraud and abuse incidents. MEDICs may not have been aware of some potential fraud and abuse because plan sponsors are not required to refer them. Also, CMS did not give MEDICs approval to conduct audits of plan sponsors' compliance plans in FY 2008.

We recommended that CMS ensure that MEDICs have access to accurate and comprehensive data to assist in identifying and investigating potential fraud and abuse and conducting data analysis. We also recommended that CMS authorize MEDICs to directly obtain information that they need to identify and investigate potential fraud and abuse from entities such as pharmacies, pharmacy benefit managers, and physicians even if statutory or regulatory change is required to do so. We also recommended that CMS (1) require plan sponsors to report to MEDICs all potential fraud and abuse incidents that are referred to law enforcement agencies and (2) ensure that MEDICs have approval to conduct compliance plan audits for which they are responsible.

In response to our final report, CMS indicated that the MEDICs currently have access to prescription drug event data and Parts A and B claims data through the integrated data repository. By mid-2010, CMS anticipates providing benefit integrity contractors full user access to a data system, One PI, containing data on Part D, Part A, and Part B claims. CMS nonconcurred with our recommendation to seek statutory authority and make the regulatory changes necessary to allow CMS to obtain information from downstream entities and indicated that it goes against the structure of the Part D program. CMS concurs with OIG's recommendation that when referring fraud and abuse incidents to law enforcement, sponsors should also report that same information to the MEDICs. While CMS did not indicate concurrence or nonconcurrence in its final comments, it did indicate that MEDICs have approval to conduct compliance plan audits in FY 2010 for Medicare Advantage Organizations and plan sponsors. [OEI-03-08-00420](#).

### **Medicare Part D Plan Sponsor Electronic Prescribing Initiatives**

We found that plan sponsors have launched voluntary electronic prescribing (e-prescribing) initiatives to increase prescriber adoption of e-prescribing. At the time of our data collection in September 2008, about 20 percent of plan sponsors had an e-prescribing initiative and another 18 percent reported that they were planning one. Initiatives included at least one of the following: free or discounted software, hardware, training, Internet connectivity, or financial incentives. More than half of plan sponsors with an initiative reported average or high prescriber participation.

Finally, 75 percent of plan sponsors with an initiative could not report a quantifiable benefit because they did not measure outcomes. The remaining 25 percent reported that they measured for and saw a quantifiable benefit. These plan sponsors most commonly reported that the initiative resulted in an increase in generic substitutions and an increase in formulary compliance. [OEI-05-08-00322](#).

### **Electronic Prescribing Standards: Early Assessment Shows Partial Connectivity**

Nearly 80 percent of plan sponsors reported at least partial implementation of standards governing communication between plan sponsors and prescribers, but few reported complete implementation. Problems implementing the formulary and benefits standard, one of the plan-to-prescriber standards, limit complete plan-to-prescriber

connectivity. Plan sponsors reported incomplete implementation of the formulary and benefits standard because their systems are not fully compatible with the standard.

The MMA established the Medicare Part D e-prescribing program, which stipulates that plan sponsors must implement e-prescribing standards specified by the Secretary of HHS. On behalf of the Secretary, CMS established e-prescribing standards. These standards facilitate the communication of prescription information among prescribers (e.g., doctors), plan sponsors, and dispensers (e.g., pharmacies). Three of these standards enable communication between plans and prescribers of eligibility, medication history, and formulary and benefits information. A fourth standard address eligibility and co-payment information between plans and dispensers. We surveyed all plan sponsors for plan year 2008 between August and September 2008 to determine the extent of implementation of the standards.

Most plan sponsors had complete plan-to-dispenser connectivity. Only 5 percent of plan sponsors reported no plan-to-dispenser connectivity.

Based on these findings, we recommended that CMS ensure that plan sponsors fully implement the plan-to-prescriber and plan-to-dispenser standards. We also recommended that CMS collaborate with plan sponsors and industry representatives to address barriers to full implementation of the formulary and benefits standard.

CMS concurred with each of our recommendations. To address them, CMS will continue to educate plan sponsors about e-prescribing requirements. If necessary, CMS will also use available mechanisms to bring plan sponsors into compliance. CMS plans to continue collaboration with the National Council for Prescription Drug Programs to update and develop new e-prescribing standards. [OEI-05-08-00320](#).

### **Midyear Formulary Changes in Medicare Prescription Drug Plans**

All sponsors of Medicare PDPs made formulary changes in 2008. Most of the changes (64 percent) were positive and improved formularies by adding new drugs, reducing cost sharing, or removing utilization controls. Of the negative changes—which require CMS approval and restrict the formulary by removing drugs, increasing cost sharing, or adding utilization controls—62 percent promoted generic drug substitution.

Sponsors identify the list of drugs they cover in their formularies. CMS sets guidelines for when and how sponsors may make formulary changes. Sponsors must provide written notice to beneficiaries taking affected drugs before implementing negative changes. CMS also requires sponsors to post updated formularies on their Web sites at least monthly and to list formulary changes 60 days before they take effect.

We found that with few exceptions, sponsors met beneficiary notification requirements for formulary changes. We found, too, that CMS's monitoring processes detected most, though not all, noncompliance.

We concluded that sponsors and CMS are managing midyear formulary changes without major problems. Part D regulations require sponsors to promote cost-effective use of prescription drugs where medically appropriate, and it appears that sponsors

adhered to these rules. We made no recommendations to CMS. CMS generally agreed with our findings. [OEI-01-08-00540](#).

# Medicaid

## Hospitals

### Supplemental Rate Payments to a Massachusetts Hospital Company

Of the \$337 million that Massachusetts claimed in Medicaid supplemental rate payments to one hospital company during FYs 2004 and 2005, \$11.5 million (\$5.75 million Federal share) was not claimed in accordance with Federal and State plan requirements. We identified an additional \$5.6 million (\$2.8 million Federal share) in supplemental payments to a medical school affiliated with the company on which we were unable to express an opinion.

We recommended that the State (1) make a financial adjustment of \$11.5 million (\$5.75 million Federal share), (2) work with CMS to determine the appropriateness of \$5.6 million (\$2.8 million Federal share) in supplemental payments to the medical school, and (3) follow State plan requirements when submitting claims for supplemental payments. The State disagreed with \$8.5 million of our \$11.5 million finding but agreed to work with CMS in resolving our finding related to payments to the medical school.

[A-01-07-00013](#).

## Home- and Community-Based Services

### Connecticut's Community-Based Administrative Claims

In our review of community-based Medicaid administrative costs that Connecticut claimed for State FYs 2005 and 2006, we found that claims totaling \$19.8 million may not have fully complied with Federal requirements. The State claimed reimbursement from CMS for administrative case management activities provided by contracted organizations. Because the State made omissions and deviations from acceptable practices when calculating its claims and was unable to provide adequate documentation, we were unable to express an opinion on whether the claims should be allowed.

We recommended that the State work with CMS to determine what portion of the \$19.8 million was allowable under Federal requirements. The State agreed to do so.

[A-01-08-00003](#).

## Other Services, Equipment, and Supplies

### Claims for Family Planning Services in New York State

New York State improperly claimed enhanced 90-percent Federal reimbursement for Medicaid family planning services claims submitted by selected providers. Of the 105 claims in our sample, 50 qualified as family planning services and could be claimed

at the enhanced 90-percent Federal reimbursement rate. However, the remaining 55 could not be claimed as family planning services. Of those 55 claims, 51 were for services unrelated to family planning and 4 lacked documentation. Based on our sample results, we estimate that the State received \$3.8 million in unallowable Federal Medicaid reimbursement. This overpayment occurred because the selected providers incorrectly claimed services as family planning and the State's Medicaid Management Information System (MMIS) edit routines did not adequately identify claims unrelated to family planning.

We recommended that the State (1) refund \$3.8 million to the Federal Government and (2) consider the results of this review in its evaluation of our previous recommendations to ensure that providers bill as family planning only those services directly related to family planning and ensure that MMIS edits identify claims that are ineligible for enhanced 90-percent Federal reimbursement. The State agreed with our recommendations and described corrective actions that it planned to take.

[A-02-09-01015](#).

### **Missouri School District Administrative Claims**

Of the \$15.3 million (Federal share) that Missouri claimed in Medicaid administrative costs for the St. Louis Public and Springfield school districts for FYs 2004 through 2006, \$4.2 million was unallowable for Federal reimbursement because the State did not correctly calculate and claim administrative costs for the School District Administrative Claiming (SDAC) program. In addition, because of errors identified during our review of the St. Louis and Springfield school districts, the other Missouri school districts received \$16.3 million in unallowable Medicaid payments for FYs 2004 through 2006. We set aside for CMS adjudication \$1.5 million for administrative costs claimed for the St. Louis Public and Springfield school districts and \$3.9 million for administrative costs claimed for all other Missouri school districts. The SDAC program permits children to receive health-related services, generally without having to leave school. States may be reimbursed for the administrative activities that directly support identifying and enrolling potentially eligible children in Medicaid.

We recommended that Missouri (1) refund \$20.5 million to the Federal Government for unallowable SDAC expenditures; (2) work with CMS to determine what portion of the school district administrative costs claimed for the quarter ending December 2004 was allowable; (3) review all school district Medicaid administrative claims that the State paid after March 2006 to determine whether it included nonresponses in the sample and, if so, recalculate the administrative claims and refund to the Federal Government the amount overpaid; and (4) strengthen policies and procedures to ensure that SDAC expenditures submitted for Federal reimbursement are accurate and reasonable.

Missouri partly agreed and partly disagreed with our recommendations. Nothing in the State's comments caused us to change our findings or recommendations.

[A-07-08-03107](#).

# Prescription Drugs

## Outlier Average Manufacturer Prices in the Federal Upper Limit Program

We found that about 20 percent of AMPs reported for the 242 outlier drugs were inaccurate. When the new AMP-based Federal upper limit (FUL) provisions are implemented, CMS will exclude the lowest AMP from the FUL calculation if it is more than 60 percent below the second-lowest AMP to ensure that at least two drug products are available at or below the FUL amount. In January 2008, the lowest AMPs for 242 FUL drugs met this criterion. This study examined the accuracy of the AMP data submitted by manufacturers that would be used in the new FUL calculation, pending the lifting of the Federal court's injunction on its implementation.

Inaccuracies in the reported data resulted in part from discrepancies in the unit of AMP submission that created the appearance of outliers. Furthermore, some outlier AMPs are not accurate and would no longer be outliers if revised data were used. Also, several outlier drug products are no longer sold by manufacturers and therefore should not be included in FUL calculations.

OIG supports CMS's continuing efforts to ensure the integrity of future FUL amounts based on AMPs and further recommended that CMS (1) examine the units of AMP submission for all FUL drugs before establishing FUL amounts, (2) direct manufacturers to periodically examine their monthly AMP calculations to ensure accurate reporting of data, and (3) continue directing manufacturers to report termination dates for discontinued drug products as soon as they are known.

CMS concurred with our first and third recommendations but did not explicitly concur or not concur with our second recommendation. CMS believes it would not be beneficial to instruct manufacturers to reexamine their AMPs without more information from OIG about the causes of the inaccurate AMPs. OIG will provide details about inaccurate AMPs directly to CMS, along with any explanations voluntarily offered by manufacturers for their AMP revisions. [OEI-03-07-00740](#).

## Rebates for Brand-Name Drugs With Multiple Versions

Our review found that of the top 150 brand-name drugs for CY 2007 ranked by Medicaid reimbursement, 114 had more than 1 version. For 65 of the 114, the prices of the earliest versions of the drugs exceeded their inflation-adjusted prices when the new versions entered the market. We calculated that for CYs 1993–2007, States could have collected about \$2.5 billion in additional rebates for the 65 brand-name drugs if the baseline AMPs of the new versions had been adjusted (i.e., reduced) to reflect price increases in excess of inflation for the earliest versions.

For a manufacturer's covered outpatient drug to be eligible for Federal Medicaid funding, the manufacturer must enter into a rebate agreement that is administered by CMS and pay quarterly rebates to the States. Federal law requires manufacturers to pay an additional rebate when the AMP for a brand-name drug increases more than inflation.

We did not evaluate the drug manufacturers' bases for developing the new versions of existing drugs identified in our review. Because the Medicaid drug rebate program calculates rebates separately for each version of a drug, manufacturers could develop new versions of existing brand-name drugs solely to avoid paying additional rebates when they substantially increase prices. Without some modification to the rebate law, the risk that manufacturers will take advantage of this potential loophole may increase over time.

We recommended that CMS continue to seek legislative authority to modify the present rebate formula calculation to ensure that manufacturers cannot circumvent paying additional rebates by bringing new versions of existing brand-name drugs to market. CMS concurred with our findings and recommendation. [A-06-09-00033](#).

## Medicaid Administration

### State Claims Under the American Recovery and Reinvestment Act of 2009

During the semiannual period, we conducted audits of four States' Medicaid claims associated with the increased Federal medical assistance percentage (FMAP) under the American Recovery and Reinvestment Act of 2009, P.L. No. 111-5 (Recovery Act). The Recovery Act provides, among other initiatives, fiscal relief to States to protect and maintain State Medicaid programs in a period of economic downturn. For the recession adjustment period (October 1, 2008, through December 31, 2010), the Recovery Act provides an estimated \$87 billion in additional Medicaid funding based on temporary increases in States' FMAPs. The Federal Government pays its share of a State's medical assistance expenditures under Medicaid based on the FMAP, which varies depending on the State's relative per capita income.

Our audits found that the four States' claims associated with the temporarily increased FMAP were computed using the Medicaid expenditure base specified in the Recovery Act. These claims totaled \$174 million in Alabama, \$817 million in Florida, \$276 million in Maryland, and \$273 million in Missouri. In all four States, expenditures were supported by accounting records and policies and procedures were in place to segregate Medicaid expenditures that qualified for the temporarily increased FMAP and to ensure that those Medicaid expenditures that did not qualify were not claimed for reimbursement at the temporarily increased FMAP.

Our reports on Alabama, Florida, and Maryland contained no recommendations. Our report on Missouri recommended that the State document its policies and procedures for claiming the temporary increase in the FMAP. Missouri concurred and said that it would update its written procedures. [A-04-09-06111](#), [A-04-09-06110](#), [A-03-09-00203](#), and [A-07-09-02762](#).

### California's Payment Error Rate Measurement Universes

California was unable to reconcile the FY 2007 Payment Error Rate Measurement (PERM) universes to the quarterly Forms CMS-64 and CMS-21. CMS developed the

PERM program to comply with Federal requirements for measuring improper payments made in the FFS, managed care, and eligibility components of the Medicaid and State Children's Health Insurance programs in FY 2007 and future years. The Office of Management and Budget (OMB) requires CMS to include the PERM results in its annual accountability report.

We could not determine whether California's managed care and FFS universes were complete and accurate because we were unable to reconcile these universes to Forms CMS-64 and CMS-21. CMS regional officials stated that they had reconciled the forms to the accounting records that the State used to support the forms. However, those accounting records did not include detailed claim information. State officials said that they could not reconcile the forms to the managed care or FFS universes, and the California State Auditor found that Form CMS-64 was not traceable to individual claims.

We recommended that CMS (1) instruct the State to reconcile its PERM universes to Forms CMS-64 and CMS-21 and ensure that its universes are complete and accurate, (2) instruct the State to implement a payment system that produces readily available information, and (3) annually reconcile various expenditures on Forms CMS-64 and CMS-21 to detailed claim information. CMS did not agree with our first two recommendations and did not specifically address our third recommendation. Without reconciling the PERM universe to Forms CMS-64 and CMS-21, CMS is unable to show that it has complied with the requirements to produce a statistically valid estimate of improper payments. [A-06-08-00050](#).

# Legal Activities and Investigative Outcomes Related to Centers for Medicare & Medicaid Services Programs

## Medicare- and Medicaid-Related Outreach

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

### Advisory Opinions

In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), OIG, in consultation with 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. From October 1, 2009, through March 31, 2010, OIG received 23 advisory opinion requests and issued 3 advisory opinions. OIG advisory opinions are available at <http://oig.hhs.gov/fraud/advisoryopinions.asp>.

### Provider Self-Disclosure Protocol

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.

In addition, OIG issued an Open Letter to Health Care Providers in 2006 to promote the use of the self-disclosure protocol to resolve civil monetary penalty (CMP) liability under the physician self-referral and anti-kickback statutes for financial arrangements

between hospitals and physicians. The self-disclosure guidelines are available on the OIG Web site at <http://www.oig.hhs.gov/fraud/selfdisclosure.asp>.

On April 15, 2008, OIG published another Open Letter to Health Care Providers. The letter sets forth certain refinements to the October 1998 Self-Disclosure Protocol. To improve the self-disclosure process, OIG, among other steps, streamlined its internal self-disclosure procedures. In addition, OIG explained that it will generally not require a self-disclosing entity to enter into a CIA or certification of compliance agreement (CCA) when a resolution has been negotiated pursuant to the protocol. A CIA is an agreement between the provider and OIG that is entered into in exchange for OIG's agreement not to seek an exclusion of that provider from participation in Medicare, Medicaid, and other Federal health care programs. CIAs are monitored by OIG and require providers to enhance existing compliance programs or establish new ones. The compliance programs are designed, in part, to prevent a recurrence of the underlying fraudulent conduct. OIG may also negotiate a CCA in lieu of a comprehensive CIA, under appropriate circumstances. The CCA requires that the provider maintain its existing compliance program and agree to certain compliance obligations that mirror those found in a comprehensive CIA.

OIG published its most recent Open Letter to Health Care Providers on March 24, 2009, that narrowed the scope of the self-disclosure protocol in regard to violations of the physician self-referral ("Stark") law and explained that OIG will no longer accept disclosure of a matter that involves only liability under the physician self-referral law in the absence of a colorable anti-kickback statute violation. The Open Letter also established a minimum settlement amount for anti-kickback disclosures of \$50,000.

The self-disclosure guidelines are available on the OIG Web site at <http://www.oig.hhs.gov/fraud/selfdisclosure.asp>.

During this reporting period, self-disclosure cases resulted in \$27.1 million in HHS receivables. The following are examples:

- **Michigan** – Meijer, Inc., agreed to pay \$3 million to resolve its liability under the FCA. Meijer self-disclosed to OIG and the United States Attorney's Office that between 1997 and 2006 it employed four pharmacists who were excluded from participating in Federal health care programs.
- **New York** – Oswego Hospital (Oswego) agreed to pay \$2,134,037 to settle its liability under the CMP provisions applicable to physician self referrals and kickbacks and applicable under New York State statutes. As reported under OIG's Provider Self-Disclosure Protocol, Oswego initially disclosed a physician recruitment arrangement that failed to meet the applicable Stark Law exception. Following the disclosure, Oswego submitted five more reports detailing financial arrangements with more than 20 physicians between 1999 and 2007. The reports disclosed several violations of law that involved failure to meet requirements of exceptions for recruitment arrangements, office leases, and professional service arrangements. Another violation involved the provision of discounted employee benefit plan premiums to nonemployed physicians. OIG contended that many of the arrangements also

created liability under the anti-kickback statute. Because Oswego self-disclosed its violations and cooperated throughout the investigation, no CIA was imposed.

- **Ohio** – Medina General Hospital (Medina) agreed to pay \$240,298 for allegedly violating the Civil Monetary Penalties Law (CMPL) provisions applicable to kickbacks and physician self-referrals. Medina self-disclosed that it failed to meet Stark Law requirements in its financial relationships with a family practice physician, occupational health services physicians, and a cardiologist. Specifically, the financial relationships were during periods when there were no written service agreements and payments were not made consistent with the contracts.
- **North Carolina** – The Neurological Institute, P.A., formerly known as Neurology Consultants of the Carolinas, P.A. (Institute), agreed to pay \$181,851 to resolve its CMPL liability. The Institute disclosed to OIG that from October 1, 2003, through June 30, 2006, it improperly submitted claims to Medicare and Medicaid for (1) a physician’s services (or an item or service incident to a physician’s service) when the individual who furnished the service was not a physician, (2) services provided by Dr. T. Hemanth Rao when the services were not actually provided by Dr. Rao, and (3) services provided based on codes that the Institute knew or should have known would result in greater payments than were appropriate.
- **New York** – Margaretville Memorial Hospital and Margaretville Nursing Home, Inc., (collectively, “Margaretville”) agreed to pay \$80,000 to resolve its liability under the CMPL. Pursuant to the OIG Provider Self-Disclosure Protocol, Margaretville reported that from January 1, 2006, through April 30, 2008, it inappropriately billed Medicare Part D and State health care plans for drugs provided by Margaretville Hospital to Margaretville Nursing Home residents when the drugs were already paid for as part of the beneficiaries’ Medicare Part A coverage. After the self-disclosure, OIG conducted an investigation that revealed, among other things, a lack of specific billing protocols or training, a lack of internal controls over the pharmaceutical billings in question, and minimal adherence to the compliance program in place at the hospital and at the nursing home.

## Office of Inspector General Administrative Sanctions

OIG has the authority to impose administrative sanctions for fraud or abuse or other activities that pose a risk to Federal health care programs and their beneficiaries (see Appendix E 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 CMPs for submitting false or fraudulent claims to a Federal health care program or for violating the anti-kickback statute, the Stark Law, or the “patient dumping” provision of the Social Security Act.

During this reporting period, OIG administered 1,963 sanctions in the form of program exclusions or administrative actions for alleged fraud or abuse or other activities that posed a risk to Federal health care programs and their beneficiaries. Details and examples follow.

## Program Exclusions

During this semiannual reporting period, OIG excluded 1,935 individuals and entities from Medicare, Medicaid, and other Federal health care programs. Most of the exclusions resulted from convictions for crimes relating to Medicare or Medicaid, for patient abuse or neglect, or as a result of license revocation. For example:

- **Ohio** – Chiropractor Gregory Dew was excluded for a minimum of 60 years based on his conviction for rape, corruption of a minor, and gross sexual imposition. The Ohio State Chiropractic Board permanently revoked his license, and the State Medical Board of Ohio permanently revoked his license to practice as a physician assistant. In addition, the Ohio Department of Job and Family Services terminated his Medicaid Provider Agreement. Dew was sentenced to 43 years' incarceration.
- **California** – Haroutyun Gulderyan, owner of an independent diagnostic testing facility, was excluded for a minimum of 45 years based on his health-care-related conviction. Over a 4-year period, Gulderyan was involved in a fraud scheme that caused Medicare to pay for tests that were unnecessary or were never performed. As part of the scheme, individuals known as "cappers" were paid cash to recruit Medicare patients to receive services at medical clinics and diagnostic testing facilities owned and operated by Gulderyan and his co-conspirators. Gulderyan was sentenced to 24 months' incarceration and ordered to pay \$11,011,523 in joint and several restitution.
- **Oregon** – Mohammed Salah Mohammed, a medical doctor, was excluded indefinitely based on the Oregon Medical Board's revocation of his license to practice medicine. His license to practice was revoked based on allegations that he engaged in a series of unprofessional interactions with sexual overtones with several female patients and a hospital nurse. He also allegedly falsified a patient's medical record.
- **Virginia** – Midwife Kristina Zittle was excluded for an indefinite period based on the suspension of her license to practice midwifery by the Virginia Board of Medicine. The Board found that Zittle provided negligent care to two patients during the course of their home births. She allegedly made numerous clinical and professional misjudgments, which resulted in the infants being stillborn.
- **Nebraska** – Pharmacist Randall Paulsen was excluded for an indefinite period based on the revocation of his license by the Nebraska Department of Health and Human Services, Division of Public Health. The State revoked his license based on code of ethics violations. Paulsen exchanged free prescription drugs for sexual favors with two female customers over a 4- to 6-year period. In addition, he failed to maintain complete and accurate records of his controlled substance inventory.

## 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 \$5.1 million in CMPs and assessments. The following are among the CMP actions resolved during this reporting period:

- **Florida** – Dr. Robert Diaz agreed to pay \$65,000 and enter into a 3-year period of exclusion to resolve his liability under the CMPL for receiving kickbacks from medical device manufacturers. Diaz’s liability arises from his solicitation and receipt of remuneration in the form of consulting payments from Biomet Orthopedics, Inc. (Biomet), and Zimmer, Inc. (Zimmer), in exchange for using their orthopedic hip and knee products. OIG alleged that the compensation paid under consulting agreements with Biomet and Zimmer were received, in part, in return for Diaz ordering, or causing to order, Biomet and Zimmer orthopedic products, respectively, to be paid for, in whole or in part, by Federal health care programs.
- **California** – Michael Bakst, former Executive Director of Community Memorial Hospital (CMH), agreed to pay \$64,000 to resolve his liability under the CMPL and the CMP provisions of the Stark Law. From May 29, 2002, through September 23, 2003, Bakst allegedly orchestrated a scheme involving CMH remunerating doctors and cardiac surgeons for referrals to CMH. In December 2007, CMH agreed to pay the United States over \$1.5 million to resolve CMH’s liability for more than 17 different arrangements with physicians and physician family members that allegedly violated the Stark Law and the False Claims Act.

## Criminal and Civil Enforcement

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 FCA. A description of these enforcement authorities can be found in Appendix E.

The successful resolution of false claims often involves the combined investigative efforts and resources of OIG, the Federal Bureau of Investigation (FBI), Medicaid Fraud Control Units (MFCU), and other law enforcement agencies. OIG is responsible for assisting DOJ in bringing and settling cases under the FCA. Many providers elect to settle their cases prior to litigation. As part of their settlements, providers often agree to enter into corporate integrity agreements (CIA) with OIG to avoid exclusions from Medicare, Medicaid, and other Federal health care programs. Such agreements are monitored by OIG and require the providers to enhance existing compliance programs or establish new ones. The compliance programs are designed, in part, to prevent a recurrence of the underlying fraudulent conduct.

During this semiannual reporting period, the Government’s enforcement efforts resulted in 242 criminal actions and 158 civil actions against individuals or entities that engaged in health-care-related offenses. These efforts resulted in \$2.3 billion in HHS and \$188.7 million in non-HHS investigative receivables, including civil and administrative settlements or civil judgments related to Medicare; Medicaid; and other Federal, State,

and private health care programs. Some of the notable enforcement actions are described below. Summaries are organized by the sector of the health care industry involved or by the nature of the offense.

### **Special Assistant United States Attorney Program**

DOJ and OIG launched a program in which OIG attorneys serve as Special Assistant United States Attorneys. OIG attorneys are detailed full-time to DOJ's Criminal Division, Fraud Section, for temporary assignments, such as with the Medicare Fraud Strike Force described below; 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 fighting fraud. Under this program, OIG attorneys have successfully litigated important criminal cases relating to DME, infusion therapy, physical therapy, and other types of Medicare and Medicaid fraud.

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

On May 20, 2009, Secretary of HHS 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. A key component of HEAT task force efforts is expansion of Medicare Fraud Strike Force operations. Strike Forces began in March 2007 and are operating in seven major cities—Miami, FL; Los Angeles, CA; Detroit, MI; Houston, TX; Brooklyn, NY; Baton Rouge, LA; and Tampa, FL. The Strike Force teams coordinate law enforcement operations with other Federal, State, and local law enforcement entities.

These teams have a proven record of success analyzing real-time data to quickly identify and prosecute fraud almost as it occurs.

During this reporting period, Strike Force efforts have resulted in the filing of charges against 119 individuals or entities, 42 convictions, and \$16 million in investigative receivables. Examples of Strike Force efforts during this reporting period follow:

- **Michigan** – Two managers at separate infusion therapy clinics have been sentenced to more than 75 months' incarceration and ordered to pay a combined \$1,870,996 in restitution for conspiracy to commit health care fraud. Dulce Briceno, manager and part owner of Xpress Center Inc. (XPC), was sentenced to 63 months' incarceration and ordered to pay \$1,789,234 in restitution after pleading guilty to conspiracy to commit health care fraud. Briceno, along with other owners of the infusion therapy clinic, recruited and paid patients \$50 per visit to purport to have received legitimate services at XPC. XPC then billed Medicare for beneficiary medications (primarily Cosyntropin and Interferon) and services that were medically unnecessary and/or not provided. Arturo Apolinar, manager of AR Group Services, was sentenced to 1 year and 1 day of incarceration and ordered to pay \$81,762 in restitution for health care fraud. Apolinar obtained a doctor's provider enrollment information, without the doctor's knowledge, to apply for and obtain a Medicare provider number. He

then used this information to submit false claims to the Medicare program for infusion therapy services that were never provided.

In addition to the sentences for Briceno and Apolinar, one of the beneficiary patients involved in the XPC scheme, Darrell Brown, pleaded guilty to conspiracy to commit health care fraud and was ordered to pay \$173,732 in restitution. Brown visited the clinic three times per week, was paid \$50 per visit, and provided his Medicare card and signed medical forms, which were used to bill the Medicare program for injections and/or infusion treatment that he did not receive.

- **California** – Gevork Kartashyan and Eliza Shubaralyan, owners of CHH Medical Supply, were each sentenced to 2 years' incarceration and ordered to pay \$400,000 in restitution, jointly and severally, for health care fraud. Kartashyan and Shubaralyan, who are married, billed Medicare nearly \$1 million for medically unnecessary power wheelchairs and wheelchair accessories. During trial, elderly Medicare beneficiaries testified that Kartashyan and Shubaralyan recruited them to visit Los Angeles-area medical clinics, where they turned over their Medicare numbers and other personal identifying information in exchange for promised vitamins, diabetic shoes, and other items that were never received. The clinics used this information to create fraudulent power wheelchair prescriptions that could be sold to DME company owners, who then billed Medicare for the wheelchairs. Many of the beneficiaries did not know they were getting a power wheelchair until it was delivered by CHH Medical Supply. All of the beneficiaries testified that they did not need or use the power wheelchairs. Five physicians testified that they never authorized or approved the power wheelchair prescriptions written under their names.
- **Florida** – Miriam Hernandez, owner of M&A Medical Services Plus, Inc. (M&A), was sentenced to 32 months' incarceration and ordered to pay \$760,197 in restitution after pleading guilty to health care fraud. M&A billed Medicare for services and products that it never provided.
- **Florida** – Yessenia D'Oleo, owner of Radiant Medical Supply, Inc. (Radiant Medical), was sentenced to 12 months and 1 day of incarceration and ordered to pay restitution of \$415,270 for health care fraud. From August 2007 through November 2007, Radiant Medical, a DME provider, submitted claims to Medicare for enteral formula, infusion supplies, ostomy pouches, and other DME that was neither prescribed by the referring physicians nor received by the beneficiaries. Radiant Medical also submitted claims to Medicare for deceased beneficiaries.

## Pharmaceutical Companies

- **Massachusetts** – As an update to the summary of the global criminal, civil, and administrative resolution with Pfizer, Inc. (Pfizer), from the previous *Semiannual Report to Congress* (April 1, 2009 through September 30, 2009), Pharmacia & Upjohn Company, Inc. (Pharmacia), a subsidiary of Pfizer, was sentenced and ordered to pay criminal fines and forfeiture of \$1.3 billion. As noted in the last *Semiannual Report*, the global resolution with the United States addressed Pfizer's and Pharmacia's

marketing and promotion practices associated with the anti-inflammatory drug Bextra and several other drugs. Pfizer also entered into a comprehensive 5-year CIA with OIG.

- **New Hampshire** – Mylan Pharmaceuticals, Inc. (Mylan), and UDL Laboratories, Inc. (UDL), agreed to pay \$118 million plus interest to resolve allegations that the companies submitted false claims to the Medicaid program by underpaying rebates due to the States under the Medicaid Drug Rebate Program. The amounts of the rebates are determined in part by whether a drug is considered an “innovator” drug or a “noninnovator” drug. The rebate that must be paid for innovator drugs is higher than the rebate for noninnovator drugs. Mylan and UDL allegedly sold innovator drugs that were manufactured by other companies and classified the drugs as noninnovator drugs for Medicaid rebate purposes. As a result of the improper classification of the drugs, the companies underpaid their rebate obligations under the Medicaid Rebate Program.
- **Massachusetts** – Omnicare, Inc., a provider of pharmacy services to long-term-care (LTC) facilities, agreed to pay \$98 million plus interest to resolve its FCA liability for allegedly engaging with several parties in kickback schemes that resulted in false or fraudulent claims being submitted to Medicare Part D and Medicaid. One of the kickback schemes involved generic drug manufacturer IVAX Pharmaceuticals, Inc., and IVAX Corporation (collectively, “IVAX”). IVAX also entered into a settlement agreement with the Government, under which it agreed to pay \$14 million plus interest to resolve its FCA liability for a kickback violation involving an \$8 million payment to induce Omnicare to purchase \$50 million in drugs from IVAX. As a result of the kickback, Omnicare submitted false or fraudulent claims to Medicaid from January 2000 through June 2004. Omnicare’s settlement also resolved liability related to kickback schemes it had with SNFs Mariner Health Care, Inc., and SavaSeniorCare Administrative Services, LLC, and with pharmaceutical manufacturer Johnson & Johnson. The settlement with Omnicare resolves allegations made in five separate *qui tam* complaints. Omnicare also entered into a 5-year Amended and Restated CIA, which consolidates the terms set out in Omnicare’s pre-existing CIA and First Amendment to the CIA effective in November 2006 and October 2007, respectively. IVAX also entered into a 5-year CIA.
- **Massachusetts** – As part of a global criminal, civil, and administrative settlement, Biovail Corporation (Biovail) agreed to pay \$24,775,172 to resolve its liability related to the marketing and promotion of the drug Cardizem, L.A., an extended-release version of a heart medication to control high blood pressure. From 2003 to 2004, Biovail Pharmaceuticals, Inc. (BPI), a U.S. subsidiary of Canada-based Biovail, allegedly paid physicians and other medical prescribers up to \$1,000 each to induce them to recommend and/or write prescriptions for Cardizem, L.A., thereby causing false and/or fraudulent claims for payment to be submitted to Medicaid. Under the civil resolution, Biovail agreed to pay \$2,528,782 plus interest to settle its potential FCA liability. Under the criminal resolution, BPI pleaded guilty to conspiracy and kickback charges and was ordered to pay an assessment of \$2,800 and a criminal fine

of \$22,243,590 (total \$22,246,390). In addition to the monetary settlement, Biovail agreed to enter a 5-year CIA with OIG.

## Hospitals

- **Texas** – South Texas Health System (STHS) agreed to pay \$27.5 million and enter into a 5-year CIA to resolve its liability for violations of the Stark Law, anti-kickback statute, and the FCA. STHS allegedly engaged in improper financial relationships, including medical directorships and leases, with seven doctors during various periods from January 1, 1999, to December 31, 2006. STHS submitted claims to Medicare and Medicaid for services rendered to patients referred by these doctors to its hospitals.
- **New Jersey** – The University of Medicine and Dentistry of New Jersey (UMDNJ) agreed to pay \$8,333,212 to resolve its civil liability under the FCA, the Stark Law, other statutory liability laws, and certain common law causes of action. UMDNJ, the State of New Jersey’s Health Sciences University, operates eight medical schools and two acute-care hospitals. In 2005, UMDNJ entered into a Deferred Prosecution Agreement (DPA) with the United States Attorneys’ Office. The DPA required UMDNJ to install a Federal monitor to oversee its business operations. While conducting his duties, the monitor discovered that local cardiologists were being paid for “no show” jobs in exchange for referring cardiology patients to UMDNJ’s acute-care hospitals. The contracts with these cardiologists purportedly required them to perform academic and clinical duties, when, in fact, they were being hired to refer patients to UMDNJ’s cardiology program. To date, 10 cardiologists involved in the scheme have entered into settlements with the United States.

In addition, UMDNJ entered into a 5-year CIA under which it must maintain and/or revise as necessary its Code of Conduct and Policies and Procedures; provide annual training to its employees, medical staff, and agents; submit Implementation and Annual Reports to OIG; and hire an Independent Review Organization to conduct Focus Arrangements Reviews, Claims Reviews, and an Unallowable Costs Review.

- **Michigan** – SCCI Hospitals of America, Inc., which operates a chain of long-term acute-care hospitals (LTACH), agreed to pay \$830,166 to resolve its liability under the FCA. Between October 1, 2004, and September 2, 2005, SCCI allegedly (1) improperly admitted patients to its Michigan facility who did not meet LTACH criteria, (2) held and treated patients who no longer needed hospitalization in order to increase Medicare reimbursement, (3) requested referring physicians to modify original orders to circumvent medical-necessity requirements, (4) inappropriately discharged patients who were not well enough for discharge, and (5) upcoded diagnosis-related group (DRG) classifications.

## Clinics

- **Florida** – Caridad Perez was sentenced to 78 months’ incarceration and ordered to pay \$14,051,221 in restitution for her participation in a health care fraud conspiracy.

While an employee at an infusion clinic, Perez recruited and paid cash kickbacks to Medicare beneficiaries in exchange for allowing their Medicare numbers to be billed at numerous Miami-based infusion therapy clinics for medically unnecessary and nonrendered infusion therapy medication.

- **California** – Vardges Egiazarian was sentenced to 78 months’ incarceration and ordered to pay restitution of \$1,558,620 for health care fraud. Egiazarian, who operated three health care clinics, submitted claims to Medicare for office visits, physical therapy, and/or other procedures and diagnostic tests that were not needed and/or not rendered. Egiazarian and others entered into illegal relationships with physicians and laboratories to establish medical practices using the providers’ names and operated the practices as if they were run by the providers when, in fact, they were not. Once established, Egiazarian, acting alone or with others, controlled the practices and often paid physicians a relatively small flat fee to bill Medicare under their provider numbers. Kickbacks were given to “cappers” who recruited patients to come to the clinics in return for “freebies,” such as DME and cash payments. Egiazarian also used false identification documents to establish bank accounts using aliases to launder fraud proceeds.

## Home Health

**Michigan** – Visiting-physicians practices VPA, PC, and VPA of Texas, PLLC (collectively, VPA), agreed to pay \$9.5 million and enter into a 5-year CIA to resolve allegations under the FCA for submitting claims for unnecessary services to Medicare, TRICARE, and the Michigan Medicaid program. VPA allegedly improperly billed for unnecessary home visits and care plan oversight services, unnecessary tests and procedures, and more complex evaluation and management services than were actually provided.

## Practitioners

- **New York** – Podiatrist Steven Ginsberg was sentenced to 36 months’ incarceration and ordered to pay \$5,434,143 in restitution for health care fraud and making false statements. Ginsberg systematically billed Medicare for routine foot care not covered by Medicare and billed for services not rendered, such as costly nerve conduction tests and abscess drainages. Ginsberg also billed several private insurance companies for surgeries that were never performed. In addition to his sentencing, Ginsberg surrendered his license to practice podiatry in the State of New York.
- **West Virginia** – Dr. John Sharp was sentenced to 36 months’ incarceration and ordered to pay \$542,275 in restitution for health care fraud. From May 1998 to January 2006, Sharp defrauded the Medicare, Medicaid, and West Virginia Workers’ Compensation programs by billing for services that were not rendered and also causing the programs to pay higher rates of reimbursement than were warranted. The investigation found that Sharp was given notice on several occasions that his billing practices were improper, yet he continued the fraudulent billings.

- **Maryland** – Podiatrist Leon Booker agreed to pay \$100,629 to resolve his liability under the FCA. An OIG investigation determined that from January 1, 2005, to March 30, 2008, Booker falsely submitted claims for payment to Medicare and Medicaid by billing for Evaluation and Management (E&M) services even though no significant, separately identifiable E&M service was performed. Booker also billed for multiple procedures on the same day even though he performed no distinct and separate procedure on that day.

### **Durable Medical Equipment Suppliers**

**Louisiana** – Positive Home Oxygen, L.L.C. (Positive), its owner, Jeffrey McElveen, and the company's medical director, Dr. Robert Cleveland, were sentenced related to a DME fraud scheme. Positive was ordered to pay \$809,169 in restitution and was permanently excluded from the Medicare program. McElveen was sentenced to 18 months' incarceration and ordered to pay \$200,000 in restitution, and Cleveland was sentenced to 3 months' home detention and ordered to pay \$200,000 in restitution. Investigators determined that McElveen and his company fraudulently billed Medicare for providing motorized wheelchairs to beneficiaries who did not qualify for the chairs. Cleveland signed certificates of medical necessity for the chairs in exchange for referrals to his practice and cash.

### **Transportation Companies**

**Maine** – Ambulance Service, Inc. (ASI) and Northern Maine Medical Center (NMMC) agreed to pay a total settlement amount of \$1,032,000 to resolve their liability under the FCA. ASI also entered into a 5-year CIA with OIG. The settlement resolves ASI's and NMMC's liability for allegedly submitting improper Advanced Life Support transport claims to Medicare and Medicaid between January 1, 2003, and December 31, 2005. Investigators found that an ASI employee was improperly billing and coding for ASI's services in 2003 and 2004. In 2005, NMMC took over the billing and coding functions for ASI, and in doing so, hired the same ASI biller who had been improperly billing and coding. OIG concluded that ASI and NMMC failed to adequately supervise the employee or ensure that she was properly trained. As a result of the investigation, NMMC terminated the employee.

### **Medicaid Employee Fraud**

**Minnesota** – Kim Austen was sentenced to 42 months' incarceration and ordered to pay \$903,896 in restitution to the Minnesota Department of Human Services (DHS) after her guilty plea to health care fraud. An investigation revealed that Austen, a unit supervisor at DHS, embezzled State and Federal Medicaid funds between August 5, 2003, and September 10, 2008. Austen created a fictitious vendor number in the State's electronic accounting system under the name of her boyfriend. Using this vendor number, Austen caused 23 paper checks and/or warrants to be manually drafted with her boyfriend as the payee. The payments were taken from an expense account set aside to make advance payments to Medicaid providers. Austen was authorized to approve these

types of payments as part of her responsibilities at DHS. Austen picked up the checks drafted to her boyfriend directly from the Minnesota Department of Finance and deposited them into two personal bank accounts, a joint savings account in her and her boyfriend's names and a checking account in her name only.

### **Prescription Drugs**

**Pennsylvania** – Robert Mark Reilly was sentenced to 60 months' incarceration and ordered to pay \$250,828 in restitution for conspiracy to commit mail, wire, and health care fraud. Reilly was responsible for financial arrangements in a conspiracy in which he and numerous individuals based in Canada solicited and received money from thousands of elderly American victims on the false promise of receiving free Government grants or discount prescription drug coverage through an insurance plan purportedly affiliated with Medicare. The investigation revealed that telemarketers contacted Medicare beneficiaries to get them to enroll in a bogus discount drug benefit program. Some beneficiaries were told that they would lose their Medicare benefit if they did not enroll. The telemarketers were able to persuade some Medicare beneficiaries to provide their bank account information, after which Reilly and his co-conspirators withdrew money from the victims' bank accounts.

### **Neuromonitoring Services**

**Colorado** – Surgical Concepts, LLC (Surgical Concepts), agreed to pay \$242,528 to settle its liabilities under the FCA. From January 1, 2006, through December 31, 2007, Surgical Concepts submitted claims to Medicare, TRICARE, and the Federal Employees Health Benefits Program for physician time and effort reviewing neurological test data before surgery and providing real-time intraoperative neuromonitoring services. However, the test results were not reviewed by a physician before surgery, and no physician provided real-time monitoring services during surgery. Instead, a physician conducted a "post-hoc" review of the data in the days or weeks after the surgeries.

### **Identity Theft**

**Iowa** – Dr. Douglas Dvorak was sentenced to 85 months' incarceration and ordered to pay \$71,375 in restitution for mail fraud, aggravated identity theft, and money laundering. Dvorak obtained names and dates of birth of Medicaid beneficiaries (primarily children) through family members and friends and used this information to bill the maximum number of chiropractic manipulation services allowed by Medicaid for each beneficiary per year. In one example in 2006, Dvorak billed the annual maximum chiropractic services (24) on nearly consecutive days for premature twin newborns who were patients in a neonatal intensive care unit at the time of the purported services. According to his friends and family members who provided the names and dates of birth to Dvorak, this information was provided as potential referrals and not as part of a criminal scheme. The beneficiaries had never heard of Dvorak or received chiropractic services from him or any other chiropractor.

## Medicaid Fraud Control Units

MFCUs are key partners in the fight against fraud, waste, and abuse in State Medicaid programs. In FY 2009, HHS awarded \$189.9 million in Federal grant funds to 50 State MFCUs, which employed a total of 1,835 individuals.

Collectively, in FY 2009, MFCUs reported 26,744 investigations, of which 17,090 were related to Medicaid fraud and 9,654 were related to patient abuse and neglect, including patient funds cases. The cases resulted in 1,539 individuals being indicted or criminally charged, including 960 for fraud and 579 for patient abuse and neglect, including patient funds cases. In total, 1,331 convictions were reported in FY 2009, of which 19 were related to Medicaid fraud and 512 were related to patient abuse and neglect, including patient funds cases.

### Joint Investigations

- **Tennessee** – FORBA Holdings, LLC (FORBA), agreed to pay \$24 million plus interest and enter into a 5-year quality-of-care CIA to resolve its liability for violations of the FCA. FORBA manages a chain of 68 pediatric dental clinics in 22 States and the District of Columbia commonly known as “Small Smiles Centers.” The settlement resolves allegations that FORBA caused false claims to be submitted to Medicaid programs for dental services performed on low-income children insured by Medicaid. The investigation revealed that, among other things, FORBA allegedly caused the submission of claims for reimbursement for dental services that were either not medically necessary or did not meet professionally recognized standards of care. The services billed to the Medicaid programs included performing pulpotomies (baby root canals), placing crowns, administering anesthesia, performing extractions, and providing fillings and/or sealants. The investigation involved the OIG, the FBI, and the National Association of Medicaid Fraud Control Units (NAMFCU).
- **Florida** – Sachin Amin, owner and managing pharmacist of The Rx Shop, was sentenced to 18 months’ incarceration and ordered to pay \$738,000 in restitution after pleading guilty to submitting false claims to Medicare and Medicaid. From 2005 through 2007, Amin submitted false claims for prescription medications that were never dispensed. The investigation involved OIG, the FBI, the Defense Criminal Investigative Service, the Office of Personnel Management, the Drug Enforcement Agency, the Florida Department of Law Enforcement, and the Florida MFCU.
- **South Carolina** – Lalendra DeSilva and Carolina Pennington, co-owners of the DME company Helex, Inc. (Helex), were sentenced for conspiracy to commit income tax fraud. DeSilva was sentenced to 30 months’ incarceration and ordered to pay \$201,984 in restitution, of which \$112,000 is owed to the Medicaid program. Pennington was sentenced to 1 year and 1 day of incarceration and ordered to pay \$86,123 in restitution. The investigation revealed that Helex billed Medicaid for volume ventilators that beneficiaries never received. DeSilva and Pennington

bought a \$415,000 home in cash without filing tax returns during Helex's first 2 years in operation. The investigation involved OIG, the Internal Revenue Service (IRS), and the South Carolina MFCU.

- **Georgia** - Dr. Randy Lentz and physical therapist Scott Bowlin were sentenced after their guilty pleas to conspiracy to commit health care fraud. Lentz was sentenced to 34 months' incarceration and ordered to pay \$248,755 in restitution, and Bowlin was sentenced to 19 months' incarceration and ordered to pay \$19,839 in restitution. Lentz owned and operated a gym in Jesup which was in financial difficulty. To keep the gym in operation, Lentz and Bowlin devised a scheme to bill Medicare and Medicaid for physical therapy services that were not provided; their alleged patients were simply working out in the gym. The investigation involved OIG, the FBI, and the Georgia MFCU.
- **Rhode Island** – Drs. Frank Lafazia and James Gallo entered into a settlement and release agreement with the Rhode Island MFCU. Lafazia and Gallo agreed to pay \$40,300 and \$34,700, respectively, to settle allegations that they charged patients between \$100 and \$175 in cash for office visits in order to obtain prescriptions for Suboxone, despite the fact that the patients were enrolled in Medicare and/or Medicaid. The investigation determined that the physicians told beneficiaries that if they did not pay cash for each office visit, which typically lasted only a few minutes, they would not receive a prescription for Suboxone, which is used to help treat Opioid drug addiction. Lafazia and Gallo also required Suboxone patients to sign agreements that stated the physicians would not bill any Suboxone-related visits to Medicare or Medicaid, despite the fact that both physicians billed Medicare and Medicaid for services such as laboratory tests related to Suboxone treatment and office visits unrelated to Suboxone treatment. There was no technical loss to the Medicare or Medicaid programs, and both physicians agreed to fully refund the beneficiaries who paid money out of pocket for the Suboxone prescriptions. The settlement amount also included expenses incurred in the joint OIG-Rhode Island MCFU investigation.

## Other CMS-Related Reports

### Financial Statement Audit

The CMS FY 2009 financial statements received an unqualified audit opinion, which means that the statements were fairly presented in accordance with generally accepted accounting principles. However, auditors identified a material weakness in CMS's information systems controls. The weakness is related primarily to CMS's oversight of information security, access to financial systems, and control over application configuration management. (*CMS Financial Report, Fiscal Year 2009*. Audit Opinion Section. Daniel R. Levinson, Inspector General, *Report on the Financial Statement Audit of the Centers for Medicare & Medicaid Services for Fiscal Year 2009*. OAS-17-09-02009 (pp. 86, 96, 102) [Report](#) )

# Public Health, Human Services, and Departmentwide Issues

## Public Health Reports

### **Ethics Program for Special Government Employees on Federal Advisory Committees**

We found that CDC had a systemic lack of effective oversight of the ethics program for Special Government Employees (SGE) on Federal advisory committees (committees). Committees play an influential role in decisionmaking for the Federal Government. At CDC, committees address important public health topics. For example, in 2007, one committee recommended routine vaccination of young females in the United States to prevent cervical cancer. In 2009, this same committee recommended that H1N1 influenza vaccination efforts focus on five target groups in the United States.

To protect the committees' integrity and credibility, SGEs with conflicts of interest must not inappropriately influence their committees' work. Before permitting SGEs to participate in committee meetings, CDC must ensure that SGEs disclose complete financial information on a Confidential Financial Disclosure Report and identify and resolve all SGEs' conflicts of interest. Finally, CDC must provide ethics training to SGEs and monitor their compliance with ethics requirements during committee meetings. We reviewed Confidential Financial Disclosure Reports and related documents for 246 SGEs serving on 17 CDC committees in 2007.

We found that CDC and its SGEs on committees did not comply with a number of ethics requirements in 2007. That is, for almost all SGEs, CDC did not ensure that Confidential Financial Disclosure Reports were complete in 2007, and most of these forms contained multiple omissions. CDC did not identify or resolve conflicts of interest for 64 percent of SGEs in 2007. More than one-fourth of SGEs had unidentified and unresolved potential conflicts of interest on file. CDC also did not ensure that 41 percent of SGEs received required ethics training in 2007. Finally, 15 percent of SGEs did not comply with ethics requirements during committee meetings in 2007. These SGEs participated in meetings without having a current, certified Confidential Financial Disclosure Report on file, or they voted on committee matters in which they were prohibited from participating because of a documented conflict of interest.

We recommended that CDC ensure that SGEs' Confidential Financial Disclosure Reports are complete and identify and resolve all SGEs' conflicts of interest before permitting them to participate in committee meetings. Further, CDC should require SGEs to disclose their involvement in grants and other interests that could pose conflicts, which are not disclosed on the Confidential Financial Disclosure Report. CDC should also increase collaboration among CDC officials and with the HHS Office of the General Counsel to ensure that SGEs' conflicts of interest are identified and resolved. Also, CDC

should ensure that SGEs and CDC employees receive ethics training. CDC should monitor and track SGE compliance with ethics requirements.

CDC concurred with all seven of our recommendations. CDC indicated that since the time of our review, it has begun or plans to implement improvements that coincide with our recommendations. [OEI-04-07-00260](#).

### **CHEMPACK Project: Nerve Agent Antidote Storage**

We found that CDC's procedures did not ensure that nerve agent antidotes stockpiled in States to respond to a nerve agent release were stored to ensure the highest level of quality. While this finding is specific to the CHEMPACK project, it raises concerns about whether a similar vulnerability exists with other CDC assets, i.e., non-CHEMPACK drugs in the \$3.5 billion Strategic National Stockpile, because all assets share the same quality system and similar Shelf Life Extension Program (SLEP) procedures.

In 2004, CDC established the CHEMPACK project as part of the Strategic National Stockpile to assist States in protecting communities against the potentially deadly effects of chemical agents that attack the human nervous system (i.e., nerve agents). While nerve agent antidotes in the CHEMPACK Project (CHEMPACK drugs) are part of the Strategic National Stockpile, they are not placed with other federally stockpiled drugs. Through this voluntary project, CDC has put more than 1,900 containers of CHEMPACK drugs in multiple locations in participating States, enabling States to quickly respond to a nerve agent release. Each container is stocked with CHEMPACK drugs to treat 454 or 1,000 people, depending on the container's configuration.

As a holder of CHEMPACK drugs, CDC is subject to current good manufacturing practices (CGMP) provisions in the Food, Drug, and Cosmetic Act (FDCA). The FDA considers CGMP provisions of the FDCA to be met if drugs are stored under conditions required by their FDA-approved labels. FDA also requires entities that perform activities regulated by CGMP to establish and maintain a system to ensure the quality of their products. CDC participates in SLEP for CHEMPACK drugs. SLEP defers drug replacement costs by extending expiration dates.

We found that almost one-quarter of CHEMPACK containers did not have at least three daily temperature readings in accordance with CDC procedures. We also found that CDC's storage requirements for CHEMPACK drugs were not consistent with FDA's requirements and that 9 percent of CHEMPACK containers with at least three daily temperature readings were not stored according to FDA's requirements for at least 1 month. Also, CDC did not consistently implement quality system procedures. We found that CDC's procedures allowed CHEMPACK drugs to inappropriately receive extended expiration dates under SLEP.

We recommended that CDC (1) seek FDA guidance on whether CHEMPACK drugs that have received extended expiration dates under SLEP are appropriate for use, (2) revise its CHEMPACK project SLEP procedures to comply with FDA requirements, (3) revise its CHEMPACK drug storage temperature requirements to comply with FDA

requirements, and (4) ensure that the CHEMPACK project's quality system meets CGMP requirements for drug storage.

CDC concurred with all four of our recommendations and noted several actions it has taken or plans to take. For example, CDC has retroactively calculated mean kinetic temperature for the same period as our evaluation and identified three CHEMPACK containers that FDA suggests may require more testing to ensure potency. However, it is unclear from CDC's comments how it accounted for CHEMPACK containers that were missing temperature readings and documentation of temperature-recording device calibrations. CDC also said that our report did not evaluate the overall Strategic National Stockpile program and that the report should not imply that problems exist with Strategic National Stockpile non-CHEMPACK assets. Nevertheless, CDC has begun to assess how best to start an independent review of its quality system and other procedures for CHEMPACK containers, and the rest of the Strategic National Stockpile assets, to ensure compliance with FDA requirements. [OEI-04-08-00040](#).

### **Compliance With Appropriations Laws and Acquisition Regulations**

Our audit, initiated in response to a congressional request, found that a CDC service contract and eight sampled task orders awarded to a small business referred to as "Contractor A" did not always comply with appropriations laws and acquisition regulations with respect to personal service contracts and contract funding. By using contractor personnel for personal services, CDC violated the Federal Acquisition Regulation, which states that obtaining personal services by contract circumvents civil service laws. CDC also violated the bona fide needs statute by extending periods of performance beyond 1 year and expending \$1.1 million of annual appropriations outside their 1-year period of availability. CDC complied with appropriations laws and acquisition regulations with respect to competition, inherently governmental functions, and pricing.

We recommended that CDC (1) identify any active contracts or task orders being administered as personal service contracts and take action to correct their administration, (2) develop and implement policies and procedures to prevent CDC officials from administering task orders as personal service contracts, (3) determine whether the \$1.1 million expended outside the 1-year period of availability violated the Anti-Deficiency Act and take action to correct any such violations, and (4) develop and implement policies and procedures to ensure compliance with appropriations statutes and acquisition regulations regarding obligating and expending funds.

CDC disagreed that it administered the task orders awarded to Contractor A as personal service contracts and did not directly address our first recommendation. Nevertheless, CDC described actions that it had taken or planned to take in response to our second recommendation. CDC agreed with our last two recommendations. We maintain that CDC should identify any contracts or task orders being administered as personal service contracts and take corrective action. [A-04-08-01059](#).

## Food Facility Registry

We found that 7 percent of selected domestic food facilities failed to register or failed to cancel their registration with FDA, as required. We also found that 48 percent of selected facilities failed to provide accurate information when they registered or failed to provide accurate information after the facilities' information changed, as required. For each of these facilities, FDA was missing information or had inaccurate information, which could hinder its ability to identify food facilities that might be linked to an outbreak of foodborne illness.

In December 2003, FDA began requiring facilities that manufacture, process, pack, or hold food for consumption in the United States to register with FDA so that the agency would have sufficient and reliable information about them. This enables FDA to quickly find facilities during an outbreak of foodborne illness or for inspection.

We also found that FDA's regulations do not ensure that the registry contains information that might be needed in an emergency. In many cases, facilities failed to provide information that could be useful to FDA in an emergency because providing certain information in the FDA registry is optional. We found that 52 percent of the managers of the selected food facilities reported that they were unaware of registry requirements.

Our review raises questions about the accuracy and utility of the registry. We recommended that FDA develop strategies to ensure that the information in the registry is accurate, including seeking statutory authority to require food facilities to reregister routinely. FDA should also consider seeking statutory authority to impose civil penalties through administrative proceedings against facilities that fail to register or fail to provide accurate information. FDA also should consider making some of the optional fields in the registry mandatory. FDA should work with the food industry to conduct more education and outreach to inform food facilities about registry requirements. FDA generally agreed with our recommendations, noting that the study confirms problems the agency has encountered, as well as the need for additional statutory authority. [OEI-02-08-00060](#).

## Adverse Event Reporting for Medical Devices

We found that the Center for Devices and Radiological Health (CDRH), within FDA, does not use adverse event reports systematically to detect and address safety concerns about medical devices.

The adverse event reporting system provides CDRH and manufacturers with a means to identify and monitor adverse events involving medical devices. Regulations require that manufacturers and user facilities submit reports to FDA within specific timeframes after an adverse event occurs. These events include deaths, serious injuries, malfunctions, and events that require remedial action to prevent an unreasonable risk of substantial harm to the public.

We found that CDRH has not documented followup on adverse events, nor does it consistently read adverse event reports for the first time in a timely manner. CDRH rarely acts when manufacturers and user facilities submit reports late. We also found that the inability to obtain complete and usable information in adverse event reports hinders analysts' review of reports and that CDRH makes limited use of annual reports. Overall, FDA received twice as many adverse event reports for medical devices in 2007 as in 2003; however, the number of some types of adverse event reports, such as 5-day reports, decreased. We also found that manufacturers submitted most adverse event reports on time, but that many 5-day manufacturer and user facility reports were late.

We recommended that FDA develop a protocol for reviewing adverse event reports that addresses the following needs: documenting followup on adverse events, ensuring and documenting that CDRH is meeting its own guidelines for reviewing high-priority adverse event reports, following up with manufacturers that routinely submit reports late or with incomplete information, and improving outreach strategies to reduce user facility underreporting. We also recommended that FDA seek legislative authority to eliminate the regulation requiring user facilities to submit annual reports.

FDA agreed with both of our recommendations. In response to our first recommendation, FDA said that CDRH will develop a review protocol that addresses the needs that our report identified. Because FDA said that a change in statutory authority would be needed to eliminate the requirement to submit annual reports, we revised our second recommendation accordingly. [OEI-01-08-00110](#).

### **Implementation of the Core Medical Services Requirement in the Ryan White Program**

Almost all recipients of grants under Parts A, B, and C of the Ryan White Act complied with the core medical services requirement. In 2007, 96 percent of Part A grantees complied with the requirement, and in 2008, 98 percent allocated their grant funds in compliance with the requirement. All Part B and Part C grantees were in compliance with the requirement based on grantee-provided 2007 expenditure and 2008 allocation reports.

The reauthorization of the Ryan White program in 2006 (P.L. No. 109-415) changed how Ryan White funds may be used, emphasizing life-saving and life-extending services for people living with HIV/AIDS. A key change made by the law included providing more funds for direct health care services for Ryan White clients and establishing a requirement that certain grantees spend at least 75 percent of awarded grant funds on core medical services unless they receive a waiver. Examples of core medical services include outpatient health services, home health care, mental health services, and medications. Section 703 of the law repealed the Ryan White program effective October 1, 2009, unless it is reauthorized. On October 30, 2009, President Obama signed the Ryan White HIV/AIDS Treatment Extension act of 2009, reauthorizing the program through September 30, 2013.

We conducted structured interviews with and collected expenditure and allocation information from all Part A, all Part B, and a random sample of 90 of the 363 Part C Ryan White grantees funded in 2007 in the 50 States, the District of Columbia, and Puerto Rico. We also conducted interviews with all 42 HRSA project officers responsible for overseeing Parts A, B, and C Ryan White grants.

We found that grantees were spending a high proportion of their grant funding on core medical services before implementation of the requirement. Even though grantee expenditures on core medical services changed little from 2006 to 2007, the core medical services requirement affected support services and administrative processes for some grantees. When asked, 71 of the 121 grantees interviewed made suggestions for Congress to consider during the next reauthorization. Although grantees generally found HRSA guidance on the core medical services requirement helpful, 71 percent of grantees reported that project officer turnover in recent years created program management difficulties. We also found that project officer oversight issues continue to cause vulnerabilities in the program.

HRSA concurred with our findings. Regarding the finding that turnover among project officers affects oversight of grantees, HRSA said that it has lost a number of experienced project officers in recent years and is hiring new staff members. HRSA noted that in response to the complex requirements of the Ryan White Act, its reauthorization (P.L. No. 111-87), and the influx of new project officers, training would intensify. [OEI-07-08-00240](#).

### **Ryan White Title II Funding in Maryland**

Maryland complied with many, but not all, Federal requirements in administering funds provided under Title II of the Ryan White CARE Act. Title II grants fund the purchase of medications through AIDS Drug Assistance Programs and other health care and support services for people with HIV/AIDS.

From April 1, 2003, through March 31, 2006, Maryland complied with the Title II payer-of-last-resort requirement that funds not be used to pay for drugs that are eligible for coverage by other Federal, State, or private health insurance and with the requirement that funds be used only for eligible clients. However, from April 1, 2000, through March 31, 2006, the State did not comply with the Federal requirement that reported expenditures include only drugs that the State actually purchased. Specifically, the State claimed \$1.8 million in unallowable Title II expenditures for drugs that it authorized but never purchased.

We recommended that the State refund \$1.8 million to the Federal Government for reported expenditures for drugs that it authorized but never purchased. The State concurred with our finding and said that it would refund the \$1.8 million. [A-03-08-00551](#).

## **Fiscal Year 2005 Cost Statement for the Indian Health Service's Phoenix-Area Office**

We found that the \$25.8 million of obligations reported in Indian Health Service's (IHS) FY 2005 cost statement for the Phoenix-area office included \$66,000 for unallowable depreciation and \$2 million for unsupported salaries, fringe benefits, and related obligations on which we could not express an opinion. Based on our review of judgmentally selected obligations totaling \$5.6 million and our limited review of IHS's internal controls, we concluded that the remaining \$23.7 million reported in the cost statement was allowable.

We recommended that IHS (1) adjust its next cost statement for the Phoenix-area office for \$66,000 of unallowable depreciation that was reported in the FY 2005 cost statement; (2) review the Phoenix-area office's cost statements before and after FY 2005 and adjust its next cost statement for unallowable depreciation that was reported; (3) strengthen its policies and procedures to ensure that depreciation is not reported for items that are fully depreciated; (4) work with CMS to determine how much of the \$2 million for salaries, fringe benefits, and related obligations reported in the Phoenix-area office's FY 2005 cost statement was allowable and adjust its next cost statement for obligations that are determined to be unallowable; and (5) develop and implement policies and procedures to ensure that estimates used to allocate obligations in cost statements are supported with cost information that is current, accurate, and in sufficient detail. IHS partly agreed and partly disagreed with our recommendations. ([A-09-07-00086](#)).

## **How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health**

In this review of the National Institutes of Health (NIH) grantee institutions' identification, management, and oversight of financial conflicts of interest, we found a number of vulnerabilities. The most common type of financial conflict of interest among researchers is equity ownership (including stock and stock options) in companies in which the researchers' financial interests could significantly affect the grant research. Other financial conflicts of interest among researchers involved inventing technology, consulting, or holding positions with outside companies. Examples of our findings follow.

- Ninety percent of the grantee institutions rely solely on the researchers' discretion to determine which of their significant financial interests are related to their research and are therefore required to be reported.
- Because nearly half of the institutions do not require researchers to provide specific amounts of equity or compensation on financial disclosure forms, specific financial interests of NIH-funded researchers are often unknown.
- When researchers submit information on their financial interests, the institutions do not routinely verify it.

- Some institutions lack documentation to support their oversight of financial conflicts of interest.
- Most do not have policies and procedures that address subgrantee compliance with Federal regulations in regard to financial conflicts of interest.
- Conflicts were not reported by the institutions to NIH in a consistent format.
- Institutions are not required to report to NIH any financial interests that they have with outside companies.
- Institutions often require researchers to disclose conflicts in research publications; however, grantee institutions rarely reduce or eliminate financial conflicts of interest.

As in a previous OIG report, we recommended that NIH ask grantee institutions to provide it with details of the nature of all reported financial conflicts of interest and how they are managed, reduced, or eliminated. We also recommended that NIH (1) require the institutions to collect information on all significant financial interests held by researchers and not just those deemed by researchers to be reasonably affected by the research, (2) collect information on specific amounts of equity and compensation from researchers, (3) develop and disseminate guidance on methods to verify researchers' financial interests, (4) ensure that the institutions are providing adequate oversight of subgrantee compliance with the Federal financial conflict-of-interest regulations, (5) ensure that the institutions are maintaining proper documentation as outlined in the Federal financial conflict-of-interest regulations, (6) ensure that the institutions are taking appropriate actions against researchers who do not follow the institutions' financial conflict-of-interest policies and procedures, (7) increase oversight of the institutions to ensure that financial conflicts of interest are reported and managed appropriately, and (8) develop regulations that address institutional financial conflicts of interest.

Overall, NIH did not say whether it concurs with our recommendations. NIH highlighted a number of initiatives designed to improve NIH oversight of and promote grantee compliance with Federal regulations. OIG recognizes NIH's continued efforts in increasing oversight of grantee institutions. However, vulnerabilities continue to exist at the institutions in their identification, management, and oversight of financial conflicts of interest. [OEI-03-07-00700](#).

### **Internal Controls for Awarding American Recovery and Reinvestment Act Funds**

Our review found that NIH's internal controls for awarding Recovery Act funds to grantees, as described by management, were suitably designed to provide reasonable assurance that the specified internal control objectives would be achieved if the controls were satisfactorily complied with and applied. Because we did not take steps to determine the effectiveness of the internal controls, we expressed no opinion on the operating effectiveness of any aspects of NIH's internal controls for awarding Recovery Act funds, individually or in the aggregate. [A-05-09-00064](#).

# Public-Health-Related Legal Actions and Investigations

## Office of Inspector General Administrative Sanctions

OIG excludes from participation in Federal health care programs individuals who fail to repay HHS-secured educational loans and investigates specific allegations of fraud, waste, and abuse affecting public health and human services programs. These investigations are often complex and can include allegations of misuse or theft of grant funds, conflict of interest, and kickbacks. The following sections provide descriptions and data related to these efforts.

### Health Education Assistance Loan Program

Under the Health Education Assistance Loan (HEAL) program, HRSA guarantees commercial loans to students seeking education in health-related fields. The students are allowed to defer repayment of the loans until after they have graduated and begun to earn income. Although the Department's Program Support Center (PSC) takes steps to ensure repayment, some loan recipients do not resolve their indebtedness.

After PSC has exhausted efforts to secure repayment of a debt, it declares an individual in default. Thereafter, the Social Security Act permits exclusion from Medicare, Medicaid, and all other Federal health care programs for nonpayment of these loans. Exclusion means that the individual may not receive reimbursement under these programs for professional services rendered nor can any other provider receive reimbursement for services ordered or prescribed by the individual. OIG is responsible for excluding individuals who have defaulted on HEAL loans from participation in Federal health care programs.

During the semiannual period, we conducted an evaluation of and excluded individuals from the HEAL program. The results of this work are below.

### HEAL Exclusions

During the period covered by this report, six individuals and related entities were excluded as a result of PSC referral of their cases to OIG. Individuals who have been excluded as a result of default may enter into settlement agreements whereby the exclusions are stayed while they pay specified amounts each month to satisfy their debts. If they default on these settlement agreements, they may be excluded until the entire debts are repaid and they may not appeal the exclusions. After being excluded for nonpayment of their HEAL debts, 2,274 individuals have chosen to enter into settlement agreements or completely repay their debts. That figure includes the 35 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 \$169.3 million. Of that amount, \$4.5 million is attributable to this reporting period.

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

- Colorado – Medical Doctor Pamela Simons - \$841,445
- California – Chiropractor David Eckel - \$141,140
- North Carolina - Medical Doctor Alan Mitchell - \$137,111
- New York – Chiropractor Eric Obadia - \$107,091

### **Employed HEAL Program Defaulters**

Our evaluation of the HEAL program found that 312 of the 486 HEAL defaulters who earned income in FY 2008 made no payments on their loans during that time. These 312 HEAL defaulters earned \$13.4 million and owed \$47.5 million on their loans in FY 2008. Ninety-eight of these defaulters (31 percent) earned \$50,000 or more. These 98 defaulters were responsible for nearly \$15 million of the \$47.5 million owed. We also found that 174 HEAL defaulters earned \$9.6 million and owed \$22.5 million on their loans in FY 2008. The median income for these defaulters was \$47,331. However, 78 (45 percent) paid less than \$2,000 each and, of these, 24 paid less than \$500 each toward their loans in FY 2008. The amount these defaulters paid totaled \$659,135 in FY 2008, or just 3 percent of their total loan balance during that time.

Because a portion of HEAL defaulters earned income that seemingly would enable them to make payments but made only minimal or no payments on their outstanding loans, we recommended that HRSA work with PSC to (1) use the information we provided on these HEAL defaulters to assist with collection efforts and (2) consider obtaining wage data from Federal or State sources to enable HRSA and PSC to target future collection efforts on defaulters who have income. HRSA concurred with our recommendations. [OEI-03-09-00100](#).

### **Public-Health-Related Investigations**

OIG investigates cases involving the misuse of public health agency funds as well as the improper possession, use, and transfer of biological agents and toxins, called “select agents,” that the Department has determined to pose a severe threat to public health. The following is an example of a case involving violations of the select agent regulations:

**Wisconsin** - A university in Wisconsin agreed to pay \$40,000 to resolve its liability under the select agent regulations. The university self-reported to the CDC Division of Select Agents and Toxins (DSAT) that it failed to obtain prior approval from DSAT for restricted experiments conducted between September 2004 and December 2007.

## **Human-Services-Related Reports**

### **Administration for Children & Families’ Resolution of Audit Recommendations**

We found that during FYs 2006–2008, the Administration for Children & Families (ACF) resolved 10,979 of the 14,180 audit recommendations that were pending during the period. However, ACF did not resolve 7,531 of the 10,979 recommendations within the

required 6-month period. As of September 30, 2008, ACF had not resolved 2,086 audit recommendations that were past due for resolution. The dollar amounts associated with these recommendations totaled \$94.6 million. OMB Circular A-50 requires prompt resolution and corrective actions on audit recommendations. Resolution must be made within a maximum of 6 months after the issuance of a final report. Because ACF did not resolve all audit recommendations in a timely manner, it did not have reasonable assurance that it was exercising proper stewardship over Federal dollars.

We recommended that ACF (1) resolve all audit recommendations within the required 6-month audit resolution period and (2) resolve the 2,086 outstanding audit recommendations that were past due as of September 30, 2008. ACF did not directly address our recommendations. After reviewing ACF's written comments, we reviewed our records and maintain that the stewardship report as of September 30, 2008, is accurate. Moreover, ACF's submission of required documentation after our audit period does not negate the validity of our findings and recommendations as of September 30, 2008. [A-07-09-03118](#).

### **Pennsylvania's Foster Care Claims on Behalf of Children Who Exceeded the Maximum Eligible Age**

From October 1997 through September 2002, Pennsylvania improperly claimed Title IV-E foster care maintenance and associated administrative costs for some children over the age of 19. ACF provides the Federal share of States' costs, including maintenance (room and board) costs and administrative and training costs, for children in foster care who meet Title IV-E requirements. The State, as required, did not file any Title IV-E claims for services provided to 63 of 100 sampled children after they reached the age of 19. However, the State filed unallowable Title IV-E claims on behalf of the 37 remaining sampled children for services provided after they turned 19. Based on our sample results, we estimated that the State improperly claimed at least \$1.6 million (Federal share) in Title IV-E maintenance and associated administrative costs on behalf of children aged 19 or older in the 65 counties reviewed.

We recommended that the State (1) refund to the Federal Government \$1.6 million, including \$1 million in unallowable maintenance costs and \$639,000 in unallowable administrative costs, for October 1997 through September 2002; (2) work with ACF to identify and resolve any unallowable claims for maintenance costs for children aged 19 or older made after September 2002 and refund the appropriate amount; and (3) work with the counties to establish controls to identify and prevent claims for Title IV-E reimbursement for children aged 19 or older.

The State disagreed with our finding and recommendations. The State questioned our authority to conduct the audit and stated that our recommendations were without merit and contrary to law. We maintain the validity of our recommendations, as well as our conclusion that the State did not always comply with Federal Title IV-E age requirements. [A-03-08-00553](#).

## **California's Foster Care Claims for Payments Made by Los Angeles County**

In this ACF-requested review, which covered October 1, 2000, through November 30, 2001, we found that California improperly claimed Federal Title IV-E reimbursement for Los Angeles County payments to foster homes of relative caregivers. Contrary to ACF rules, 87 of the 100 relative homes in our sample had not been approved based on State foster family home licensing standards. There was no assurance that the 13 remaining homes had been approved based on State licensing standards because the case file documentation was missing or substantially incomplete. Based on our sample results, we estimated that the State improperly claimed \$88.8 million (\$45.5 million Federal share) for county payments to relative homes.

These deficiencies occurred because the State disagreed that the licensing standards used for nonrelative homes were required for relative homes and the State had not instructed the county to discontinue claiming payments for approved relative homes to which those standards had not been applied. The standards applied to relative homes were less restrictive than those applied to nonrelative homes in such areas as criminal background checks of caregivers and sleeping arrangements for children and adults.

We recommended that the State refund to the Federal Government \$45.5 million in unallowable foster care payments to relative homes. The State said that it did not believe that any payments were made in error and that any process concerns that resulted in a lack of documentation had been corrected. However, the State did not provide any information that would cause us to change our finding or recommendation.

[A-09-06-00023](#).

## **Title IV-E Long-Term Training Costs in Missouri**

Of the \$3 million (Federal share) in Title IV-E long-term training costs that Missouri claimed at the enhanced 75-percent Federal financial participation (FFP) rate from July 1, 2002, through June 30, 2006, \$301,000 was unallowable. Federal regulations authorize ACF to pay an enhanced 75-percent FFP rate for certain State training costs related to Title IV-E foster care and adoption assistance. The unallowable costs claimed included indirect costs that were not authorized for reimbursement at the enhanced rate, inadequately documented costs, and indirect costs that were claimed on an incorrect cost base. In addition, \$1 million was potentially unallowable because the costs were not properly allocated to all benefiting programs as required by Federal regulations. The remaining \$1.7 million claimed was allowable.

We recommended that the State adjust its next quarterly claim to reduce Federal reimbursement claimed for Title IV-E training by \$301,000 (Federal share), work with ACF to determine an appropriate methodology to allocate \$1.5 million (\$1 million Federal share) in long-term training costs and make appropriate financial adjustments and revisions to the cost allocation plan as necessary, and strengthen its policies and procedures to ensure that it claims Federal reimbursement for Title IV-E training in accordance with Federal requirements and contractual provisions. The State generally

disagreed with the first two recommendations and agreed with the third. We maintain that our findings and recommendations are valid. [A-07-09-03120](#).

## Health and Safety at Head Start Grantees

As part of a series of reviews requested by ACF's Office of Head Start, we assessed four Head Start grantees' compliance with Federal and State regulations on ensuring the health and safety of children in their care. The major objectives of the Head Start program include promoting school readiness and enhancing the social and cognitive development of low-income children by providing health, educational, nutritional, and social services. In FY 2009, Congress appropriated \$7.1 billion to fund the Head Start program's regular operations. The Recovery Act provides an additional \$2.1 billion for the program during FYs 2009 and 2010.

Our reviews found that the four grantees complied with many, but not all, Federal Head Start and State health and safety regulations. The grantees' failure to consistently comply with these regulations jeopardized the health and safety of children in their care. Specifically:

- **Grantee A in Connecticut** – As of May 2009, the files on 6 of the grantee's 127 Head Start employees did not contain all required documentation of preemployment checks, and the grantee's three childcare facilities did not fully protect children from unsafe materials and equipment and did not always provide a secure environment for children. For example, at one facility, potentially dangerous items, including a butcher knife, a steak knife, and a pair of full-sized office scissors, were accessible to children in an unlocked classroom drawer.

We recommended that the grantee develop and consistently implement procedures to ensure that (1) all employee files contain all required documentation, (2) all unsafe materials and equipment are stored in locked areas out of the reach of children and all necessary repairs are addressed in a timely manner, and (3) all facilities are secure. In response, the grantee described its completed and ongoing actions to address the deficiencies that we identified. [A-01-09-02505](#).

- **Grantee B in Connecticut** – As of June 2009, the files on 21 of the grantee's 72 Head Start employees lacked required documentation of child abuse and neglect registry checks, criminal record checks, and/or fingerprint cards. In addition, the grantee's two facilities did not always provide a safe and secure environment. For example, toxic chemicals, such as paint and cleaning supplies, were accessible to children in an unlocked closet at one facility.

We recommended that the grantee develop and consistently implement procedures to ensure that all employee files contain evidence of child abuse and neglect checks, criminal background checks, and fingerprint cards; all unsafe materials are stored in locked areas out of the reach of children and other unsafe conditions are addressed; and all facilities are secure. In response, the grantee described its completed and continuing actions to address the identified deficiencies.

[A-01-09-02508](#).

- **Grantee A in Georgia** – As of August 2009, 10 of the grantee’s 12 childcare facilities that we reviewed did not adequately protect children from unsafe materials and equipment. For example, a classroom at one facility had a broken window, and another window had sharp metal trim that was accessible to children on the playground.

We recommended that the grantee consistently follow its procedures to ensure that all necessary repairs are addressed in a timely manner and that all unsafe materials and equipment are stored in locked areas out of the reach of children. In response, the grantee described its corrective actions. [A-04-09-03528](#).

- **Grantee B in Georgia** – As of August 2009, the files on 2 of the grantee’s 232 employees did not contain evidence of criminal record checks, and the grantee’s 14 childcare facilities did not meet all Federal Head Start and State regulations on protecting children from unsafe materials and equipment. At one facility, for example, poison ivy was growing on the playground fence, and fire ant mounds were present on the playground.

We recommended that the grantee consistently follow its procedures to ensure that (1) all employee criminal record checks are completed and employee files contain evidence of the checks; (2) all electrical outlets are covered with protective caps, fire extinguishers are inspected annually, and first-aid kits are complete and current; (3) all unsafe materials and equipment are stored in locked areas out of the reach of children; and (4) all necessary repairs are completed. The grantee agreed with our recommendations and described its actions to address the deficiencies that we identified. [A-04-09-03531](#).

## Child Support Enforcement

### Child Support Intergovernmental Collaboration

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); 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.

## Child Support Investigations

OIG investigations of child support cases, nationwide, resulted in 36 convictions and court-ordered restitution and settlements of \$2.9 million during this semiannual period. Examples of OIG's enforcement results for failure to pay child support include the following:

- **Tennessee** – Dwayne Rudd was sentenced to 5 years' probation and ordered to pay \$577,500 in restitution for failure to pay child support. The Judge told Rudd that if he fails to make payments while on probation, he will be sentenced to 2 years in prison. Rudd is a former professional football player who played for the Cleveland Browns, Minnesota Vikings, Tampa Bay Buccaneers, and Oakland Raiders over the course of his 7-year career in the National Football League.
- **New Hampshire** – Virginia Attorney Peter Mitrano was sentenced to 2 years' incarceration to be followed by 1 year of probation, and he was ordered to pay \$517,406 in restitution for failure to pay child support. Mitrano was indicted in August 2008 after failing to pay child support for his three children, as ordered in 2002.
- **Virginia** – Robert Cahill was sentenced to 2 years' incarceration to be followed by 1 year of supervised release, and he was ordered to pay \$72,732 in restitution for failure to pay child support for his two children. At his plea hearing, Cahill told the magistrate that he was injured in the first Persian Gulf War. He subsequently told pretrial services that he was injured, received the Purple Heart Award, and received a large cash settlement from the Government for his injuries. However, the investigation revealed that Cahill was discharged from the Navy 8 months before the Persian Gulf War, was never injured, and never received a settlement from the Government.
- **South Dakota** – Matthew Olshove was sentenced to 5 years of supervised release and 6 months at a halfway house. He was ordered to pay \$39,256 in restitution after pleading guilty to failure to pay child support. Olshove's mother, Dorothy, was sentenced to 1 year of probation and fined \$1,000 after her guilty plea to obstruction of justice. The investigation revealed that Matthew Olshove failed to pay child support for his children and that his mother harbored him at her house, preventing his arrest during several attempts made by law enforcement. Dorothy Olshove, who was indicted by a Federal grand jury, was arrested June 24, 2009; her son was arrested 12 hours later.
- **Georgia** – Doni Wagoner was sentenced to 5 years' probation and ordered to pay \$30,204 in restitution for failure to pay child support. As part of a divorce decree in 1994, Wagoner was ordered to pay monthly child support payments to the custodial parent of his mentally disabled child. However, Wagoner made only sporadic payments.

## Misuse of Administration for Children & Families Grant Funds

OIG also investigates cases involving the misuse of ACF grant funds. The following is an example:

**Utah** – Douglas Frownfelter was sentenced to 1 year and 1 day in prison and ordered to pay \$24,596 in restitution for theft of Government funds. Frownfelter, a law enforcement officer at the time the crime occurred, received monthly adoption assistance payments of \$559 per month between February 2003 and September 2006 to which he was not entitled. His adopted son resided with the mother while Frownfelter continued to receive adoption subsidy payments.

## Departmentwide Issues

### Processes for Performing Limited Data-Quality Reviews

The Recovery Act created the Recovery Accountability and Transparency Board (Recovery Board) to provide transparency in the use of Recovery Act funds and to prevent and detect fraud, waste, and mismanagement. To help meet its mandate, the Recovery Board asked that the 29 Inspectors General (IG) of Federal agencies receiving Recovery Act funds determine whether the agencies had processes in place to perform limited data-quality reviews of recipient-reported information and to notify recipients of the need to make appropriate and timely changes. We issued a summary of the IGs' reports, as well as a report on HHS's process for performing limited data-quality reviews of recipients' information.

- Our summary found that 20 IGs had issued 21 reports as of November 3, 2009. Because many of the IGs' assessments were conducted before the recipients reported and corrected data, the objective of the IGs' assessments did not include determining whether the agencies' processes were effective. However, most of the 20 IGs said that they intended to evaluate the effectiveness of agency processes in future reviews. Fifteen of the 20 IGs assessed agency processes for reviewing information reported by both grantees and contractors. The five other IGs advised the Recovery Board that they assessed agency processes only for grantees because the final OMB guidance for contractors was not available until September 30, 2009. [A-09-10-01002](#).
- Our review found that HHS had designed a process to (1) perform limited data-quality reviews intended to identify material omissions and/or significant errors in information reported by recipients (grantees and contractors) of Recovery Act funds and (2) notify recipients of the need to make appropriate and timely changes. This report contained no recommendations. [A-09-09-00113](#).

### Departmental Financial Statement Audit

The Chief Financial Officers Act of 1990, as amended, requires OIG or an independent external auditor, as determined by OIG, to audit the HHS financial statements in accordance with applicable standards. Independent external auditors provided an unqualified opinion on the FY 2009 HHS financial statements. This means that for the

11<sup>th</sup> consecutive year, the statements were reliable and fairly presented. However, the report on internal controls noted two material weaknesses:

- **Financial Reporting Systems, Analyses, and Oversight** – HHS continued to have internal control weaknesses in its financial management systems, financial analyses and oversight, and corrective actions. The lack of an integrated financial management system, substantial manual procedures, and untimely or inadequate reconciliations and account analyses hindered HHS’s ability to produce financial statements. Also, management had not implemented corrective action on some longstanding internal control deficiencies.
- **Financial Management Information Systems** – Weaknesses in both the design and the operation of key general controls were noted in the areas of security management, access controls, configuration management, segregation of duties, and contingency planning. General controls are necessary to safeguard data, protect business application programs, and ensure continued computer operations in case of unexpected interruptions. In addition, weaknesses were noted in business process controls, interface controls, and data management system controls for specific financial applications.

Refer to: *Department of Health & Human Services Fiscal Year 2009 Agency Financial Report*. Section II. Daniel R. Levinson, Inspector General, *Report on the Financial Statement Audit of the Department of Health & Human Services for Fiscal Year 2009*. OAS-17-09-00001 (pp. II-7, II-14) [Report](#)

## Non-Federal Audits

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. In this semiannual period, OIG’s National External Audit Review Center reviewed 1,737 reports that covered \$1.65 trillion in audited costs. Federal dollars covered by these audits totaled \$449 billion, about \$199 billion of which was HHS money.

OIG’s oversight of non-Federal audit activity informs Department managers about the soundness of management of Federal programs and identifies any significant areas of internal control weakness, noncompliance, and questioned costs that require formal resolution by Federal officials. 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 selected reports. The non-Federal audit reports reviewed and issued during this reporting period are categorized in the following table.

<b>Reports issued:</b>	
Without changes or with minor changes	1,626
With major changes	99
With significant inadequacies	12
<b>Total</b>	<b>1,737</b>

The 1,737 reports included 5,359 recommendations for improving management operations. In addition, these audit reports provided information for 55 special memorandums that identified concerns for increased monitoring by management.

### **Employee Fraud and Misconduct**

Most people employed by HHS are dedicated, honest civil servants. Occasionally, however, employees violate their ethical and fiduciary responsibilities. OIG conducts or oversees investigations of serious allegations of wrongdoing by Department employees, as in the following example:

**Maryland** – Lekyla Whitaker, a former FDA employee, was sentenced to 1 year of incarceration, suspended, and ordered to pay \$3,290 in restitution after pleading guilty to theft over \$500. The investigation identified Whitaker’s involvement in the interception and misuse of other FDA employees’ Government-issued purchase cards and her misuse of Government FedEx accounts for personal mailings. Whitaker has since resigned from her position with FDA.

### **Legislative and Regulatory Review**

Pursuant to the IG Act, § 4(a)(2), OIG reviews existing and proposed legislation and regulations relating to HHS’s programs and operations and makes recommendations concerning their impact on economy and efficiency or the prevention and detection of fraud and abuse. Most audits and other reviews that OIG conducts are designed to test compliance with and/or assess the administration and oversight of existing laws and regulations. OIG’s reports of such reviews describe our findings, which include questioned costs, inefficiencies, vulnerabilities to fraud, inconsistencies, errors in application, or weaknesses in oversight or supporting systems. OIG’s corresponding recommendations advise HHS and the pertinent operating or staff divisions of the type of actions we believe are needed to effectively respond to the findings. Recommendations may be administrative, regulatory, legislative, or a combination.

The narratives in this *Semiannual Report to Congress* describe findings and recommendations from recently completed OIG reviews, many of which focus on existing laws and regulations. In our *Compendium of Unimplemented Office of Inspector General Recommendations*, which is published annually, we describe priority findings and

recommendations from past periods that remain to be implemented, along with pertinent citations of existing laws and regulations. In our annual *Work Plan*, which is published at the start of each fiscal year, we provide citations that pertain to ongoing or future reviews. All three publications are available on our Web site at <http://www.oig.hhs.gov/publications.asp>.

OIG also reviews proposed legislation and regulations related to HHS programs and operations. HHS routinely involves its operating and staff divisions, including the Office of Inspector General, in the review and development of HHS regulations through a well-established HHS process. Moreover, OIG's audits, evaluations, and investigations are sometimes cited in regulatory preambles as influencing HHS regulations. OIG also participates in a longstanding HHS process for developing and reviewing HHS's legislative proposals. In addition, OIG provides independent, objective technical assistance on a bipartisan, bicameral basis to congressional committees and members who request it.

### **Resolving Recommendations**

In accordance with the Inspector General Act of 1978 (IG Act), § 5, 5 U.S.C. App., tables indicating the dollar value of actions taken on OIG's recommendations in this semiannual period have been developed and are provided in Appendix A.

# Appendix A:

## Resolving Recommendations

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

**Table 1: Reports With Questioned Costs**

Questioned costs are those costs that are questioned by OIG 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.

Reports	Number of Reports	Dollar Value Questioned	Dollar Value Unsupported
<b>Section 1</b>			
For which no management decision had been made by the beginning of the reporting period <sup>1</sup>	169	\$1,479,636,000	\$65,265,000
Issued during the reporting period	88	\$145,064,000	\$6,436,000
<b>Total Section 1</b>	<b>257</b>	<b>\$1,624,700,000</b>	<b>\$71,701,000</b>
<b>Section 2</b>			
For which a management decision was made during the reporting period <sup>2, 3, 4</sup>			
Disallowed costs	152	\$667,251,000	\$24,066,000
Costs not disallowed	6	\$201,979,000	\$2,298,000
<b>Total Section 2</b>	<b>158</b>	<b>\$869,230,000</b>	<b>\$26,364,000</b>
<b>Section 3</b>			
For which no management decision had been made by the end of the reporting period			
<b>Total Section 1 Minus Total Section 2</b>	<b>99</b>	<b>\$755,470,000</b>	<b>\$45,337,000</b>

<b>Section 4</b>			
For which no management decision was made within 6 months of issuance <sup>5</sup>	65	\$633,880,000	\$38,901,000

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

Recommendations 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 recommendations. Implemented recommendations are reported in the fall edition of the *Semiannual Report*.

Reports	Number of Reports	Dollar Value
<b>Section 1</b>		
For which no management decision had been made by the beginning of the reporting period <sup>1</sup>	16	\$1,799,472,000
Issued during the reporting period	4	\$2,630,024,000
<b>Total Section 1</b>	<b>20</b>	<b>\$4,429,496,000</b>
<b>Section 2</b>		
For which a management decision was made during the reporting period		
Value of recommendations agreed to by management		
Based on proposed management action	6	\$373,361,000
Based on proposed legislative action		
Value of recommendations not agreed to by management	1	\$97,600,000
<b>Total Section 2</b>	<b>7</b>	<b>\$470,961,000</b>
<b>Section 3</b>		
For which no management decision had been made by the end of the reporting period <sup>2</sup>		
<b>Total Section 1</b>		
<b>Minus Total Section 2</b>	<b>13</b>	<b>\$3,958,535,000</b>

## End Notes to Tables 1 and 2

### Table 1 End Notes

<sup>1</sup> The opening balance was adjusted upward by \$ 70.9 million because of a reevaluation of previously issued recommendations.

<sup>2</sup> The following OIG audits with questioned cost recommendations were resolved as a result of a Department of Justice settlement of a False Claims Act case between the

Federal Government, New York State, and New York City: A-02-02-01030, *Review of Medicaid Speech Claims Made by School Health Providers in New York State*; A-02-03-01008, *Review of Medicaid Transportation Claims Made by School Health Providers in New York State*; A-02-02-01029, *Review of Medicaid Speech Claims Made by the New York City Department of Education*; A-02-03-01023, *Review of Medicaid Transportation Claims Made by the New York City Department of Education*; A-02-03-01029, *Review of Retroactive School Health Claims - New York City Department of Education*; and A-02-04-01021, *Review of Retroactive School Health Claims - New York State*. As a result of this settlement, CMS reduced its original disallowance of \$769,735,788 on the first four audits to \$291,260,251. CMS resolved an additional two audits this semiannual period by reporting management decisions in the amount of \$120,941,632 based on the negotiated settlement.

<sup>3</sup> During the period, revisions to previously reported management totaled \$694,000.

<sup>4</sup> Included are management decisions to disallow \$70.1 million in questioned costs that were identified by non-Federal auditors in audits of State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards conducted in accordance with 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.

<sup>5</sup> Because of administrative delays, many of which were beyond management control, resolution of the following 65 audits was not completed within 6 months of issuance of the report; however, based upon discussions with management, resolution is expected before the end of the next semiannual reporting period:

CIN: A-06-07-00041	REVIEW OF AMP CALCULATION - MANUFACTURER A, MAR 2008, \$268,000,000
CIN: A-06-07-00039	REVIEW OF AMP CALCULATION - MANUFACTURER C, MAR 2008, \$101,000,000
CIN: A-03-07-00560	PENNSYLVANIA FOSTER CARE MAINTENANCE PAYMENTS, PHILADELPHIA, UNDER \$300, MAY 2008, \$56,513,439
CIN: A-09-02-00054	AUDIT OF STATE OF CALIFORNIA DISPROPORTIONATE SHARE HOSPITAL PROGRAM FOR FY 1998, MAY 2003, \$33,318,976
CIN: A-01-02-00006	REVIEW OF RATE SETTING METHODOLOGY FOR MEDICAID SCHOOL BASED HEALTH SERVICES - CONNECTICUT, MAY 2003, \$32,780,146
CIN: A-06-07-00040	REVIEW OF AMP CALCULATION - MANUFACTURER B, MAR 2008, \$27,700,000
CIN: A-09-01-00098	AUDIT OF KERN MEDICAL CENTER DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR FY 1998, SEP 2002, \$14,165,950
CIN: A-09-07-00054	ALLOWABILITY OF COSTS INCLUDED IN THE INDIAN HEALTH SERVICES'S HEADQUARTERS COST STATEMENT FOR FISCAL YEAR 2005, AUG 2009, \$13,710,824
CIN: A-03-06-00564	PENNSYLVANIA FOSTER CARE MAINTENANCE PAYMENT, PHILADELPHIA, OVER \$300/DAY, DEC 2007, \$11,693,989

CIN: A-03-05-00550 AUDIT OF PENNSYLVANIA FOSTER CARE MAINTENANCE PAYMENTS - CASTILLE SAMPLE, SEP 2007, \$11,611,822

CIN: A-06-02-00034 COST REPORTS AND MEDICARE FEE-FOR-SERVICE PAYMENTS - SCOTT AND WHITE, MAY 2003, \$8,229,574

CIN: A-03-08-03000 REVIEW OF PROCUREMENTS MADE BY THE NATIONAL INSTITUTES OF HEALTH FOR THE DEPARTMENT OF DEFENSE, MAY 2009, \$6,300,000

CIN: A-04-08-03521 AUDIT OF UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS IN TENNESSEE FOR THE PERIOD OCTOBER 1, 1998, TO DECEMBER 31, 2007, FEB 2009, \$5,768,243

CIN: A-01-06-00007 REVIEW OF RHODE ISLAND'S MEDICAID ADMINISTRATIVE COST CLAIMS - FYS 2004 AND 2005, MAR 2008, \$5,092,735

CIN: A-04-04-02003 MEDICARE OUTLIER PAYMENTS TO COMMUNITY MENTAL HEALTH CENTERS, APR 2006, \$4,762,036

CIN: A-07-07-01046 REVIEW OF PAYMENTS FOR DECEASED MEDICARE BENEFICIARIES ENROLLED IN MEDICARE ADVANTAGE ORGANIZATIONS AND MEDICARE ADVANTAGE PRESCRIPTION DRUG PLANS, MAR 2009, \$4,414,643

CIN: A-04-08-03523 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

CIN: A-09-01-00085 AUDIT OF UCSDMC DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR SFY 1998, SEP 2002, \$3,776,054

CIN: A-04-07-01046 ALLOWABILITY OF COSTS CLAIMED FOR REIMBURSEMENT UNDER CDC BIOTERRORISM AND EMERGENCY PREPAREDNESS PROGRAM GRANTS - FLORIDA, SEP 2008, \$3,633,671

CIN: A-06-04-00076 MEDICAL REVIEW OF SYNERGY'S PARTIAL HOSPITALIZATION SERVICES CLAIMS, MAR 2006, \$3,098,296

CIN: A-10-96-00001 REVIEW OF GROUP HEALTH'S GHCPs REPORTING OF ESRD, APR 1997, \$2,763,498

CIN: A-07-08-03114 REVIEW OF MISSOURI ACF TRAINING COSTS, AUG 2009, \$2,556,099

CIN: A-06-06-00105 AUDIT OF NEW MEXICO'S TITLE IV-E ADMINISTRATIVE TRAINING COSTS (STATE ISSUES), DEC 2008, \$1,138,499

CIN: A-09-08-01006 REVIEW OF WASHINGTON STATE'S PANDEMIC INFLUENZA EXPENDITURES FOR THE PERIOD AUGUST 31, 2005, THROUGH JUNE 30, 2008, JUL 2009, \$751,178

CIN: A-07-09-03119 MISSOURI CLAIM FOR TITLE IV-E TRAINING COSTS FOR SALARIES AND BENEFITS, JUL 2009, \$741,872

CIN: A-04-07-01047 ALLOWABILITY OF COSTS CLAIMED FOR REIMBURSEMENT UNDER CDC'S BIOTERRORISM AND EMERGENCY PREPAREDNESS GRANT PROGRAMS - ALABAMA, SEP 2008, \$570,400

CIN: A-07-09-03121 MISSOURI TITLE IV-E TRAINING COSTS FOR RTCS AND FOSTER CARE PARENTING, SEP 2009, \$569,663

CIN: A-05-06-00038 UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS - INDIANA, MAR 2007, \$461,430

CIN: A-04-04-02010 REVIEW OF COMPREHENSIVE OUTPATIENT REHABILITATION THERAPY SERVICES PROVIDED BY ABSOLUTE THERAPY INC., NOV 2006, \$414,712

CIN: A-06-06-00072 REVIEW OF COST FOR TEXAS MEDICAL FOUNDATION AUDITEE, MAY 2008, \$403,581

CIN: A-05-01-00096 PAYMENTS TO INTER VALLEY FOR INSTITUTIONAL BENEFICIARIES, MAY 2002, \$319,355

CIN: A-07-05-01013 PAYMENTS FOR MEDICARE PLUS CHOICE ORGANIZATION FOR INSTITUTIONAL BENEFICIARIES, OCT 2005, \$293,885

CIN: A-01-08-02502 REVIEW OF TITLE IV-E FOSTER CARE FOR CHILDREN AGE 19 OR OLDER IN MASSACHUSETTS, JUL 2009, \$272,810

CIN: A-05-05-00033 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-06-09-00006 TEXAS SUBRECIPIENT CDC BIOTERRORISM - EL PASO, SEP 2009, \$186,839

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 THROUGH 2008, JUL 2009, \$124,046

CIN: A-05-01-00091 PAYMENTS TO UNITED HC OF FLORIDA FOR INSTITUTIONAL BENEFICIARIES, SEP 2002, \$121,023

CIN: A-04-07-01045 COSTS CLAIMED FOR ESRD NETWORK 6 OPERATIONS, AUG 2009, \$116,728

CIN: A-05-05-00044 DUPLICATE MEDICARE PAYMENTS TO COST-BASED HEALTH MAINTENANCE ORGANIZATION PLAN - ARNETT HEALTH PLANS, INC., FOR FISCAL YEARS 2000 THROUGH 2003, SEP 2005, \$111,862

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, JUN 2002, \$100,692

CIN: A-05-02-00067 REVIEW OF MEDICARE FEE-FOR-SERVICE PAYMENTS AND COST REPORTS - WELBORN, JUN 2003, \$97,623

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 DRUGS (PDE-DEMO): BARON DRUGS, SEP 2009, \$79,489

CIN: A-02-06-01023 AUDIT OF QUALITY IMPROVEMENT ORGANIZATION - NEW YORK, MAR 2008, \$77,358

CIN: A-05-01-00089 ADDITIONAL BENEFITS REVIEW ON MANAGED CARE ORGANIZATION, OCT 2002, \$77,000

CIN: A-09-06-00039 MEDICARE INTEGRITY - AUDIT OF QUALITY IMPROVEMENT ORGANIZATION - WASHINGTON STATE, FEB 2008, \$73,636

CIN: A-06-07-00009 REVIEW OF CAREFLITE CONTRACT, JUN 2007, \$68,841

CIN: A-04-05-02000 AUDIT OF HHA THERAPY BILLINGS, SEP 2005, \$63,425

CIN: A-05-01-00086	PAYMENTS TO HMO OF NE PENNSYLVANIA FOR INSTITUTIONAL BENEFICIARIES, MAY 2002, \$62,432
CIN: A-01-08-00601	REVIEW OF COSTS CLAIMED BY RETIREE DRUG SUBSIDY PLAN SPONSOR BLUE CROSS BLUE SHIELD OF MASSACHUSETTS, INC., FOR PLAN YEAR ENDED DECEMBER 31, 2006, APR 2009, \$33,300
CIN: A-04-06-00023	REVIEW OF QUALITY IMPROVEMENT ORGANIZATIONS - TENNESSEE, JUL 2008, \$30,654
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
CIN: A-08-04-76779	COLORADO FOUNDATION FOR MEDICAL CARE, DEC 2003, \$18,925
CIN: A-05-01-00100	PAYMENTS TO FALLON HEALTH FOR INSTITUTIONAL 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 STATUS, JUN 2003, \$18,400
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: 65	
TOTAL AMOUNT : \$633,880,420	

## Table 2 End Notes

<sup>1</sup> The opening balance was adjusted upward by \$1.3 million.

<sup>2</sup> Management decisions were not made within 6 months on nine reports. Discussions with management are ongoing, and it is expected that the following audits will be resolved by the next semiannual reporting period:

CIN: A-06-07-00042	INDEXING THE REBATE FOR GENERIC DRUGS, OCT 2007, \$966,000,000
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	UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS - MICHIGAN, 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-05-06-00038	UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS - INDIANA, 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 -  
MINNESOTA, SEP 2006, \$28,240

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

TOTAL NUMBER OF REPORTS: 9  
TOTAL AMOUNT: \$1,455,450,106

## Appendix B: Reporting Requirements of the Inspector General Act of 1978, as Amended

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 of the Act	Requirement	Location
Section 4		
(a)(2)	Review of legislation and regulations	p. 60
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 <i>Compendium of Unimplemented Office of Inspector General Recommendations</i> : <a href="http://www.oig.hhs.gov/publications.html">http://www.oig.hhs.gov/publications.html</a> .
(a)(4)	Matters referred to prosecutive authorities	p. 33
(a)(5)	Summary of instances in which information was refused	None
(a)(6)	List of audit reports	Submitted to Secretary under separate cover
(a)(7)	Summary of significant reports	Throughout this report
(a)(8)	Statistical Table 1 – Reports With Questioned Costs	Appendix A
(a)(9)	Statistical Table 2 – Funds Recommended To Be Put to Better Use	Appendix A
(a)(10)	Summary of previous audit reports without management decisions	Appendix A
(a)(11)	Description and explanation of revised management decisions	Appendix A
(a)(12)	Management decisions with which the Inspector General is in disagreement	None

## **Appendix C:**

# **Summary of Sanctions 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 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.

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 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 presents 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 CMPL 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. § 320a-7b(b)).

### **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 CMPL 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 D:

## Acronyms and Abbreviations

Following are selected acronyms and abbreviations used in this publication.

### Terms, Titles, and Organizations

ACF	Administration for Children & Families
AHRQ	Agency for Healthcare Research and Quality
AMP	average manufacturer price
ARRA	American Recovery and Reinvestment Act
ASAM	Office of the Assistant Secretary for Administration and Management
ASP	average sales price
ASPE	Office of the Assistant Secretary for Planning and Evaluation
ASPR	Office of the Assistant Secretary for Preparedness and Response
CCA	certification of compliance agreement
CDC	Centers for Disease Control and Prevention
CDPAP	Consumer Directed Personal Assistance Program
CERT	Comprehensive Error Rate Testing (program)
CHIP	Children's Health Insurance Program
CHS	contract health services
CIA	corporate integrity agreement
CMP	civil monetary penalty
CMPL	Civil Monetary Penalties Law
CMS	Centers for Medicare & Medicaid Services
CoPs	Conditions of Participation
CPAP	continuous positive airway pressure
CSBG	Community Services Block Grant
CY	calendar year
DME	durable medical equipment
DMEPOS	durable medical equipment, prosthetics, orthotics, and supplies
DoD	Department of Defense
DOH	Department of Health
DOJ	Department of Justice
DPM	Division of Payment Management
DRG	diagnosis-related group
DSH	disproportionate share hospital
E&M	evaluation and management (services)
ED	emergency department
ENT	enteral nutrition therapy
ESA	erythropoiesis-stimulating agent
ESRD	end stage renal disease
FBI	Federal Bureau of Investigation

FDA	Food and Drug Administration
FFS	fee for service
FI	fiscal intermediary
FMAP	Federal medical assistance percentage
FMO	field marketing organization
FY	fiscal year
GAO	Government Accountability Office
HAC	hospital acquired conditions
HCFAC	Health Care Fraud and Abuse Control (program)
HCOP	Health Careers Opportunity Program
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
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IRF	inpatient rehabilitation facility
IRE	independent review entity
IRO	independent review organization
IRS	Internal Revenue Service
LCD	local coverage determination
LTC	long-term care
LTACH	long-term acute care hospital
MA	Medicare Advantage
MAO	Medicare Advantage organization
MAC	Medicare administrative contractor
MCO	managed care organization
MEDIC	Medicare drug integrity contractor
MFCU	Medicaid Fraud Control Unit
MMIS	Medicaid Management Information System
NDC	national drug code
NEMT	nonemergency medical transportation
NF	nursing facilities
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
NLA	national limit amount
NPSD	Network of Patient Safety Databases
O&M	operations and maintenance
OCSE	Office of Child Support Enforcement
OIG	Office of Inspector General
OCS	Office of Community Services
OPO	organ procurement organization
PDE	prescription drug event

PDP	private prescription drug plan
PECOS	Provider Enrollment, Chain, and Ownership System
P.L.	Public Law
PPS	prospective payment system
PRB	postretirement benefit
PSA	professional services agreement
PSC	Program Support Center
PSO	Patient Safety Organization
PTH	parathyroid hormone
QAA	Quality Assessment and Assurance
RAC	recovery audit contractor
RDT&E	research, development, test, and evaluation
SNF	skilled nursing facility
TCM	targeted case management
UCCP	uncompensated care pool
U.S.C.	United States Code
WAMP	widely available market price

## Public Laws

BBA	Balanced Budget Act of 1997, P.L. No. 105-33
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, P.L. No. 106-554
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act of 1980, P.L. No. 96-510
CFO Act	Chief Financial Officers Act of 1990, P.L. No. 101-576
CSA	Controlled Substances Act, Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, P.L. No. 91-513
DRA	Deficit Reduction Act of 2005, P.L. No. 109-171,
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
FDCA	Federal Food, Drug, and Cosmetic Act of 1938, P.L. No. 75-717
FISMA	Federal Information Security Management Act of 2002, P.L. No. 107-347
GMRA	Government Management Reform Act of 1994, P.L. No. 103-356
HIPAA	Health Insurance Portability and Accountability Act of 1996, P.L. No. 104-191
IG Act	Inspector General Act of 1978 (IG Act), as amended by P.L. No. 111-25, 5 U.S.C. App.
MIPPA	Medicare Improvements for Patient and Providers Act of 2008, P.L. No. 110-275
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173

Recovery Act	American Recovery and Reinvestment Act of 2009, P.L. No. 111-5
SCHIP	SCHIP Extension Act of 2007, P.L. No. 110-73
TRHCA	Tax Relief and Health Care Act of 2006, P.L. No. 109-432
Not Abbreviated	John Warner National Defense Authorization Act for Fiscal Year 2007, P.L. No. 109-364
Not Abbreviated	Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977, P.L. No. 95-142
Not Abbreviated	Supplemental Appropriations and Rescissions Act of 1980, P.L. 96-304