

Semiannual

Report to Congress



April 1, 2009 – September 30, 2009



Department of Health and Human Services
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 and Human Services (HHS), for the 6 month period ending September 30, 2009.

Our office has witnessed an unprecedented level of activity as we have integrated emerging responsibilities linked to governmentwide projects, congressional initiatives, and public health emergencies with our ongoing audit, investigative, and evaluation activities across a broad spectrum of HHS programs. By capitalizing on collaboration among OIG components, this has been a period of considerable achievement.

We continue our mandated work pursuant to the American Recovery and Reinvestment Act of 2009 (Recovery Act). The leadership demonstrated by our Office of Audit Services has assisted the Department in appropriately meeting its spending goals and has contributed significantly to the Recovery Act Accountability and Transparency Board's governmentwide efforts to help prevent fraud, waste, and abuse and ensure transparency. Our health care integrity work is informed by OIG's "Five Principles" strategy to combat fraud, waste, and abuse and covers enrollment, payment, compliance, oversight, and response issues. Led by our Office of Counsel, we have used this strategy to inform Congress about our work and recommendations to strengthen program integrity. Many of our recommendations have been incorporated into health care reform initiatives.

We also continue to work with our law enforcement partners to pursue bad actors who bilk scarce resources from Medicare and Medicaid. Relying upon our Office of Investigations, which has spearheaded Medicare Fraud Strike Forces in conjunction with the Department of Justice (DOJ) since 2007, we have been able to effectively target broad-based fraud schemes. Strike Force operations in Miami, Los Angeles, Houston, and Detroit have resulted in nearly 200 convictions and millions of dollars in restitution. Building upon the success of the Strike Force model, we are working closely with the Department and DOJ on a new initiative, announced in May, known as the Health Care Fraud Prevention and Enforcement Action Team (HEAT). Integral to fraud prevention and enforcement, HEAT will enhance the Government's ability to detect fraud by increasing its reliance on data, technology, and analysis. In addition, OIG's public health oversight continues to address the Department's critical challenges in ensuring public health and safety. Our Office of Evaluation and Inspections and Office of Audit Services have issued reports on State and local pandemic influenza preparedness and on the Food and Drug Administration's responsibility for overseeing food safety.

As we address an expanding mission to protect HHS's vital health and human services 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.

A handwritten signature in black ink that reads "Daniel R. Levinson". The signature is written in a cursive, flowing style.

Daniel R. Levinson
Inspector General

Highlights

Summary of Accomplishments

For fiscal year (FY) 2009, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) reported savings and expected recoveries of \$20.97 billion: \$16.48 billion in implemented recommendations to put funds to better use; \$492 million in audit receivables; and \$4 billion in investigative receivables, which includes \$1 billion in non-HHS receivables resulting from OIG work (e.g., the States' share of Medicaid restitution).

Also for this FY, OIG reported exclusions of 2,556 individuals and entities from participation in Federal health care programs; 671 criminal actions against individuals or entities that engaged in crimes against departmental programs; and 394 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:

Medicare Fraud Strike Force Operations Lead to Sentencing of Seven Miami-Area Residents in Medicare Infusion Fraud Scheme

Seven employees of a Miami infusion clinic were ordered to pay \$19.8 million in restitution and sentenced to prison terms ranging from 37 to 97 months. In their guilty pleas, the individuals admitted to activities including manipulating patients' blood samples to generate false medical records, ordering and administering medications to treat conditions that were falsely documented with fraudulent test results, and billing Medicare for services that were medically unnecessary or never provided. (Details on p. 45.)

State and Local Pandemic Influenza Preparedness

During this semiannual period, we issued two reports related to States' and localities' pandemic influenza preparedness. Our key findings include the following:

- In one review, we found that although the majority of selected localities had begun planning to distribute and dispense vaccines and antiviral drugs, more needs to be done to improve localities' ability to respond to an influenza pandemic. Specifically, we found that in their preparedness plans, selected localities had not addressed most of the vaccine and antiviral drug distribution and dispensing preparedness items identified in HHS guidance. Further, although all of the selected localities conducted exercises related to vaccine and antiviral drug distribution and dispensing, most did not create after-action reports and improvement plans for these exercises. (OEI-04-08-00260) (Details on p. 55.)

- In the other review, we found that although the selected States and localities that we reviewed are making progress in preparing for a medical surge, more needs to be done to improve States' and localities' ability to respond to an influenza pandemic. Specifically, we found that fewer than half of the selected localities had started to recruit the medical volunteers required to respond to a medical surge and that none of the States reviewed had implemented electronic systems to manage volunteers. Moreover, although all of the selected localities had acquired limited medical equipment for a pandemic, only three of the five States reviewed had electronic systems to track beds and equipment. We also found that most of the selected localities had not identified guidelines for altering triage, admission, and patient care during a pandemic. (OEI-02-08-00210) (Details on p. 54.)

Pfizer, Inc., Enters Into Settlement for Marketing and Promotion Practices

Pfizer, Inc., (Pfizer) entered into a \$1 billion civil FCA settlement with the United States in connection with Pfizer's marketing and promotion practices associated with the anti-inflammatory drug Bextra and several other drugs. The settlement agreement is part of a global criminal, civil, and administrative settlement with Pfizer and its subsidiary, Pharmacia and Upjohn Company, Inc., which also includes a comprehensive 5-year corporate integrity agreement between Pfizer and OIG. (Details on p. 49.)

Medicaid Personal Care Claims Made by Providers in New York City

We estimated that New York State improperly claimed \$275.3 million in Federal Medicaid reimbursement for some personal care claims submitted by providers in New York City during calendar years 2004 through 2006. The improper claims occurred because the State did not adequately monitor New York City's personal care services program for compliance with Federal and State requirements. We recommended that the State refund \$275.3 million, work with the Centers for Medicare & Medicaid Services (CMS) to resolve two Consumer Directed Personal Assistance Program (CDPAP) claims, improve its monitoring of New York City's personal care services program, and promulgate specific regulations related to CDPAP claims. The State disagreed with our first recommendation and with several of our findings. (A-02-07-01054) (Details on p. 27).

Barriers to the Food and Drug Administration's Response to Food Emergencies

In two reviews, we addressed the Food and Drug Administration's (FDA) responsibilities for overseeing the safety of food in both the human and pet food supply. These reviews described difficulties identifying and removing contaminated products from store shelves. Both reviews found that additional statutory authority and guidance to the industry would strengthen FDA's effectiveness and its ability to respond to a contamination of human and pet food.

- In one review, we found that in the event of a food emergency, FDA would likely have difficulty tracing food products through the food supply chain. We were

able to trace only 5 of the 40 products reviewed through each stage of the food supply chain. For 31 of the 40 products, we could identify the facilities that likely handled the products, and for the remaining 4 products, we could not identify the facilities. Furthermore, 59 percent of the facilities reviewed did not meet FDA's requirements to maintain records about their sources, recipients, and transporters, and 25 percent were not aware of these requirements. We recommended, among other things, that FDA consider seeking additional statutory authority to strengthen its lot-specific information requirements and to request facilities' records at any time. We also recommended that FDA work with the industry to develop needed guidance and that FDA address issues related to mixing raw food products from a large number of farms. FDA agreed to consider these recommendations. (OEI-02-06-00210) (Details on p. 57.)

- In the second review, which was conducted in response to a request from the Senate Committee on Agriculture, Nutrition, and Forestry, we found that FDA did not have statutory authority to require pet food manufacturers or importers to initiate recalls of contaminated food or to assess penalties for recall violations. Furthermore, FDA's existing regulations were issued as nonbinding recall guidance for firms. We found that FDA's lack of authority, coupled with its sometimes lax adherence to its recall guidance and internal procedures, limited FDA's ability to ensure that contaminated pet food was promptly removed from retailers' shelves. Our report contained detailed recommendations for strengthening FDA's recall authority and improving its monitoring of recalls. FDA agreed or agreed in principle with all of our recommendations. (A-01-07-01503) (Details on p. 58.)

Nursing Home Executive Agrees to Permanent Exclusion

The President and Chairman of the Board of Pleasant Care Corporation (Pleasant Care), Emmanuel Bernabe, agreed to be permanently excluded from Federal health care programs following an investigation of substandard care at nursing homes formerly operated by Pleasant Care. OIG alleged that Bernabe, through his management and oversight of Pleasant Care, caused services to be furnished to Pleasant Care residents that substantially departed from the professional standard of care. For example, Pleasant Care failed to maintain adequate staffing levels, properly administer medication, provide adequate hydration and nutrition, and prevent accidents. (Details on p. 42).

Walgreen Enters Into \$1 Million Settlement for Employing Excluded Pharmacist

Walgreen Louisiana Co. (Walgreen) agreed to pay \$1,053,774 to settle its liability under the OIG's CMPL authority for allegedly employing an individual that Walgreen knew or should have known was excluded from participation in Federal health care programs. Walgreen submitted claims to Medicare, Medicaid, and TRICARE for prescriptions filled by the excluded pharmacist, as reported by Walgreen under OIG's Provider Self-Disclosure Protocol. (Details on p. 41).

Evaluation and Management Services Included in Eye and Ocular Adnexa Global Surgery Fees

We estimated that Medicare paid \$97.6 million for evaluation and management (E&M) services that were included in eye global surgery fees but not provided during the global surgery periods in calendar year 2005. Global surgery fees include payment for a surgical service and the related preoperative and postoperative E&M services provided during the global surgery period, which extends from the day before the surgery to 90 days after the surgery. We recommended that CMS consider adjusting the estimated number of E&M services to better reflect the number of E&M services actually being provided to beneficiaries or using the financial results of the audit, in conjunction with other information, during the annual update of the physician fee schedule. CMS believed that it would be prudent to conduct further analysis before proposing any changes in the number of E&M services. (A-05-07-00077) (Details on p. 7.)

Medicare Hospice Care for Beneficiaries in Nursing Facilities: Compliance With Medicare Coverage Requirements

Our medical record review determined the extent to which hospice claims for beneficiaries in nursing facilities in 2006 met Medicare coverage requirements. We found that 82 percent of sampled hospice claims for beneficiaries in nursing facilities did not meet at least one Medicare coverage requirement. We found that 33 percent of claims did not meet election requirements and that 63 percent of claims did not meet plan-of-care requirements. For 31 percent of claims, hospices provided fewer services than outlined in beneficiaries' plans of care. For 4 percent of claims, the certifications were missing or did not meet one or more Federal requirements. We recommended that CMS educate hospices about the coverage requirements and their importance in ensuring quality of care, provide tools and guidance to hospices to help them meet the coverage requirements, and strengthen its monitoring practices regarding hospice claims. (OEI-02-06-00221) (OEI-02-06-00223) (Details on p. 6.)

Power Wheelchairs in the Medicare Program: Supplier Acquisition Costs and Services

Our review compared Medicare payments for power wheelchairs with suppliers' acquisition costs and determined the number and type of services that suppliers performed in conjunction with providing power wheelchairs to Medicare beneficiaries. We found that in the first half of 2007, Medicare allowed an average of \$4,018 for standard power wheelchairs that cost suppliers an average of \$1,048. During the same timeframe, Medicare allowed an average of \$11,507 for complex rehabilitation packages that cost suppliers an average of \$5,880. Suppliers of standard power wheelchairs reported performing an average of five services per chair, while suppliers of complex rehabilitation power wheelchair packages reported performing an average of seven services, such as assembling and delivering the power wheelchair and educating the beneficiary about its use. We found that suppliers performed most services prior to and during, rather than after, the wheelchairs' delivery. We recommended that CMS determine whether Medicare's fee schedule amounts for standard and complex

rehabilitation power wheelchairs should be adjusted by using information from the Competitive Bidding Program, seek legislation to ensure that fee schedule amounts are reasonable and responsive to market changes, or exercise its authority to set payment limits when payments are grossly higher than acquisition costs. (OEI-04-07-00400) (Details on p. 12.)

Former Major League Baseball Player To Pay Close to \$800,000 for Evading Child Support Obligations While Residing in the South Pacific

Troy Lee Neel was ordered to pay \$778,917 and sentenced to 5 years' probation for evading child support obligations. A former major league baseball player, Neel failed to pay \$5,000 a month in child support; fled the country; and purchased a small island in the South Pacific, where he ran a resort. The case involved a 6-year multiagency international investigation. (Details on p. 65).

Background

At all levels, OIG works in close cooperation with 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 governmentwide 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 that 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 often steps 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 in this Semiannual Report lists cost savings estimates that apply to the entire fiscal year as a result of administrative, regulatory, and legislative actions that were taken based on OIG recommendations made in prior periods. Appendix B 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 the semiannual reports to Congress, OIG annually publishes the "Compendium of Unimplemented Recommendations" that 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>.

Table of Contents

Centers for Medicare & Medicaid Services.....	1
Medicare Part A and Part B Reports.....	2
Hospitals: Oxaliplatin Claims Billed by Hospitals.....	2
Hospitals: Interrupted Stays at Inpatient Rehabilitation Facilities.....	2
Hospitals: A Pennsylvania Hospital’s Reported Wage Data.....	3
Hospitals: High-Dollar Payments for Inpatient Services.....	3
Home Health Services: Medicare and Medicaid Home Health Payments for Skilled Nursing and Home Health Aide Services.....	4
Hospice Care: Compliance With Coverage Requirements for Beneficiaries in Nursing Facilities.....	5
Hospice Care: Services Provided to Beneficiaries Residing in Nursing Facilities.....	5
End-Stage Renal Disease: Separately Billed Laboratory Tests for Medicare Beneficiaries.....	6
High-Dollar Payments: Medicare Part B Claims.....	6
Physicians: Evaluation and Management Services Included in Eye and Ocular Adnexa Global Surgery Fees.....	7
Physicians: Place-of-Service Coding.....	8
Physicians: Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services.....	8
Chiropractors: Inappropriate Medicare Payments for Chiropractic Services.....	9
Imaging Services: Medicare Part B Billing for Ultrasound.....	10
Laboratories: Variation in the Clinical Laboratory Fee Schedule.....	10
Ambulance Services: Transportation Provided to Beneficiaries in Skilled Nursing Stays Covered Under Medicare Part A.....	11
Durable Medical Equipment: Independent Contractor’s Review of Durable Medical Equipment Claims From the Fiscal Year 2008 Comprehensive Error Rate Testing Program.....	12
Durable Medical Equipment: Supplier Acquisition Costs and Services for Power Wheelchairs.....	12
Durable Medical Equipment: Miscoded Claims for Power Wheelchairs.....	14
Durable Medical Equipment: Part B Services During Non-Part A Nursing Home Stays.....	14
Durable Medical Equipment: Comparison of Prices for Negative Pressure Wound Therapy Pumps.....	15
Durable Medical Equipment: Inappropriate Medicare Payments for Pressure Reducing Support Surfaces.....	16
Prescription Drugs: Aberrant Claim Patterns for Inhalation Drugs in South Florida.....	17
Prescription Drugs: Part B Payment and Policy for Chemotherapy Administration.....	18
Prescription Drugs: Beneficiary Utilization of Albuterol and Levalbuterol Under Medicare Part B.....	18
Contractor Operations: Termination Claims for Postretirement Benefit Costs.....	19
Contractor Operations: Medicare Contractor Processes for Reviewing Pennsylvania Hospitals’ Wage Data.....	20

Contractor Operations: Contractor Pension Costs Claimed for Medicare Reimbursement	20
Contractor Operations: Contractor’s Postretirement Benefit Assets	21
Medicare Part C Reports	21
Medicare Advantage Organization’s Adjusted Community Rate Proposal Modifications.....	21
Duplicate Capitation Payments.....	22
Medicare Part D Reports	22
Dual-Eligible Demonstration Project.....	22
Accuracy of Part D Plans’ Drug Prices on the Medicare Prescription Drug Plan Finder	23
Effect of the Part D Coverage Gap on Medicare Beneficiaries Without Financial Assistance in 2006.....	24
Reconciliation Payments for 2006 and 2007.....	24
Payments for Beneficiaries in Part A Skilled Nursing Facility Stays in 2006.....	26
Medicaid Related Reports.....	26
Hospitals: Inpatient Hospital Claims Billed as Family Planning Services in New York State	26
Hospitals: Medicaid Participation Eligibility for One Indiana State-Owned Psychiatric Hospital.....	27
Home Care: Medicaid Personal Care Claims Made by Providers in New York City	27
Medicaid Home, Community, and Nursing Home Care: Targeted Case Management Services in Pennsylvania.....	28
Nursing Homes: Long-Term Care, Managed Care Program Costs Claimed by Utah.....	28
Prescription Drugs: Accuracy of Drug Categorizations for Medicaid Rebates.....	29
Prescription Drugs: Medicaid Outpatient Drug Expenditures	30
Laboratories: Potential Improper Medicaid Payments for Outpatient Clinical Diagnostic Laboratory Services for Dual-Eligible Beneficiaries.....	31
Excluded Services: Medicaid Services to Incarcerated Juveniles in Georgia	31
Family Planning: Services Claimed Twice in Michigan.....	32
Medicaid Administration: Calculations of Additional Medicaid Funds Under the American Recovery and Reinvestment Act	32
Medicaid Administration: Fraud and Abuse Safeguards for State Medicaid Nonemergency Medical Transportation Services	33
Medicaid Administration: Managed Care Encounter Data Collection and Use.....	33
Medicaid Administration: Indirect Costs Submitted by the New York State Department of Health on Behalf of the Office of Mental Retardation and Developmental Disabilities	34
Medicaid Administration: West Virginia’s Retroactive Claims for Medicaid School-Based Services.....	35
Medicaid Administration: Hurricane Katrina-Related Uncompensated Care Claims	35
Medicare and Medicaid Information Systems and Data Security Reports.....	36
Information Systems: Usefulness of Medicaid Statistical Information System Data for Detecting Medicaid Fraud, Waste, and Abuse	36

Inaccurate Data in the Provider Enrollment, Chain, and Ownership System Individual Global Extract File.....	37
Other CMS Related Reports.....	38
Nursing Home Corporations Under Quality of Care Corporate Integrity Agreements	38
Emergency Health Services Furnished to Undocumented Aliens Covered by Section 1011 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003	39
Medicare and Medicaid Related Outreach.....	39
Advisory Opinions	39
Provider Self-Disclosure Protocol	40
Office of Inspector General Administrative Sanctions.....	41
Program Exclusions.....	42
Civil Monetary Penalties Law.....	43
Patient Dumping.....	43
Criminal and Civil Enforcement.....	44
Special Assistant United States Attorney Program	45
Health Care Fraud Prevention and Enforcement Action Team	45
Laboratories	46
Hospitals	47
Clinics	47
Nursing Homes.....	48
Durable Medical Equipment Suppliers.....	48
Prescription Drugs.....	48
Practitioners	49
Medicaid Fraud Control Units	50
Joint Investigations	50
Public Health and Human Services Programs and Departmentwide Issues	53
Public Health Related Reports	54
Emergency Preparedness: State and Local Pandemic Influenza Preparedness for Medical Surge.....	54
Local Pandemic Influenza Preparedness: Vaccine and Antiviral Drug Distribution and Dispensing	55
Vermont's Pandemic Influenza Expenditures	56
Traceability in the Food Supply Chain	57
Food and Drug Administration's Monitoring of Pet Food Recalls.....	58
Health Resources and Services Administration Grant Closeout Procedures.....	58
Indian Health Service Contract Health Services Program: Overpayments and Potential Savings	59
Indian Health Service Cost Statement for Fiscal Year 2005.....	59

Followup of Procurements Made by the National Institutes of Health for the Department of Defense.....	60
Superfund Financial Activities at the National Institute of Environmental Health Sciences	60
Public Health Related Legal Actions and Investigations	61
Health Education Assistance Loan Defaults.....	61
Public Health Related Investigations	62
Human Services Related Reports	63
Title IV-E Adoption Assistance Payments in Florida.....	63
Title IV-E Training Costs in Missouri.....	63
Office of Community Services' Corrective Actions Resulting From a Government Accountability Office Review.....	64
Child Support Enforcement	64
Child Support Task Forces.....	64
Child Support Investigations.....	64
Departmentwide Issues.....	65
Department of Health and Human Services Employee Travel Cards: Usage and Internal Controls.....	65
Non-Federal Audits	66
Resolving Recommendations	67
Legislative and Regulatory Review	67
Employee Fraud and Misconduct.....	68
Appendix A: Fiscal Year 2009 Savings Achieved Through Implementation of Recommendations in Audits and Evaluations.....	69
Appendix B: Resolving Recommendations.....	75
Table 1: Reports With Questioned Costs.....	75
Table 2: Funds Recommended To Be Put to Better Use	76
End Notes to Tables 1 and 2	77
Appendix C: Reporting Requirements of the Inspector General Act of 1978, as Amended	83
Appendix D: Status of Public Proposals for New and Modified Safe Harbors to the Anti-Kickback Statute.....	85
Appendix E: Summary of Sanctions Authorities.....	87
Program Exclusions.....	87
Patient Dumping.....	87
Civil Monetary Penalties Law.....	88
Anti-Kickback Statute and Civil False Claims Act Enforcement Authorities	88

Appendix F: Acronyms and Abbreviations..... 91

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) 2008, Medicare served an estimated 45 million enrollees at a cost of more than \$460.9 billion.¹ 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 2008, the enrollment for Medicaid was estimated at 48.2 million beneficiaries; total Federal and State outlays were approximately \$352 billion, of which the Federal share was \$201.4 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. In FY 2008, CHIP served 7.4 million beneficiaries at a Federal cost of \$6.9 billion.

OIG's focus on these health care programs reflects the spending of the Department of Health and 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

¹ The \$460.9 billion figure represents total outlays for Medicare health care and program administrative overhead (the latter being in the \$6 billion range for FY 2008). 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.

HHS to combat waste, fraud, and abuse in the Medicare and Medicaid programs. HCFAC funding constitutes a 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 provides OIG \$31.25 million in FY 2009, to remain available through FY 2011, for activities that ensure the proper expenditure of Medicaid funds.

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 Reports

Hospitals: Oxaliplatin Claims Billed by Hospitals

For the 88 payments that we reviewed, 10 hospitals billed a Medicare contractor for the incorrect number of service units of oxaliplatin, a chemotherapy drug used to treat colorectal cancer. As a result, the hospitals received overpayments totaling \$2.2 million during calendar years (CY) 2004 and 2005. These overpayments occurred primarily because the hospitals did not update their systems following a change in Medicare billing guidance.

We recommended that the contractor recover the \$2.2 million in overpayments to hospitals. The contractor agreed with our finding and recommendation and said that it had recouped all of the outstanding provider overpayments. (A-05-09-00010)

Hospitals: Interrupted Stays at Inpatient Rehabilitation Facilities

Inpatient rehabilitation facilities (IRF) did not always bill correctly for interrupted stays with discharge dates during CYs 2004 and 2005. Our nationwide computer match showed that 448 IRFs billed incorrectly for 986 interrupted stays during that period. If a Medicare inpatient is discharged from an IRF and returns to the same IRF within 3 consecutive calendar days, the IRF should combine the interrupted stay into a single claim and receive a single discharge payment.

We determined that the correct value of the stays was \$17.5 million, rather than the \$21.7 million that the IRFs billed. As a result, Medicare made net overpayments of \$4.2 million to the IRFs. The payment errors occurred because the IRFs did not have the necessary controls to identify or correctly bill interrupted stays. Additionally, until April 2005, CMS's Common Working File did not have an edit designed to identify all interrupted stays billed as two or more claims. After its adoption, the new Common

Working File edit effectively detected incorrectly billed interrupted stays and prevented overpayments to IRFs.

We recommended that CMS direct its fiscal intermediaries to recover the \$4.2 million in net overpayments that our review identified. CMS concurred with our recommendation. (A-01-08-00502)

Hospitals: A Pennsylvania Hospital's Reported Wage Data

We found that a Pennsylvania hospital did not fully comply with Medicare requirements for reporting wage data in its FY 2006 Medicare cost report. Under the acute-care hospital inpatient prospective payment system, CMS adjusts the Medicare base rate paid to participating hospitals by the wage index applicable to the area in which each hospital is located. CMS updates the wage indexes annually based on hospitals' wage data reported 4 years earlier.

We found that the hospital overstated its wage data by \$1.1 million and 1,977 hours. Our correction of the hospital's errors decreased the average hourly wage rate approximately 0.83 percent. Because the hospital did not revise the wage data in its cost report before CMS computed the FY 2009 wage indexes, the FY 2009 wage index for the hospital's statistical area was overstated, resulting in overpayments of the hospitals that use this wage index.

We recommended that the hospital implement review and reconciliation procedures to ensure that the wage data reported in future Medicare cost reports are accurate, supportable, and in compliance with Medicare requirements. The hospital stated that it would do so. (A-03-08-00019)

Hospitals: High-Dollar Payments for Inpatient Services

During the semiannual period, we issued two reports on high-dollar payments that fiscal intermediaries (intermediaries) 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 intermediaries to, among other functions, process and pay Medicare Part A (inpatient) claims submitted by providers.

The results of our audits follow.

■ **Intermediary for Illinois, Indiana, Kentucky, and Ohio** – Of the 303 high-dollar payments that the intermediary made to hospitals for inpatient services for CYs 2004 through 2006, 264 payments included net overpayments totaling \$7.4 million. At the start of our audit, hospitals had refunded overpayments totaling \$2.8 million for 4 claims but had not refunded net overpayments totaling \$4.7 million for 260 claims. Contrary to Federal guidance, hospitals had reported an inaccurate number of billing units for blood-clotting factor, incorrect diagnosis and procedure codes, and excessive charges that resulted in inappropriate payments.

We recommended that the intermediary (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 high-dollar payments for inpatient services. The intermediary agreed with our recommendations. (A-05-08-00028)

■ **Intermediary for All States Except New York** – Of the 249 high-dollar payments that another intermediary made to hospitals for inpatient services for CYs 2004 through 2006, 221 payments included net overpayments totaling \$3.9 million. The hospitals, which had not refunded this amount as of the start of our audit, received the overpayments by reporting the same types of incorrect information as noted above.

We recommended that the intermediary (1) recover the \$3.9 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 high-dollar payments for inpatient services. In comments on our draft report, the contractor described corrective actions that it had taken or planned to take to implement our recommendations. (A-05-08-00061)

Home Health Services: Medicare and Medicaid Home Health Payments for Skilled Nursing and Home Health Aide Services

Payment policies for home health services create vulnerabilities that may lead to both Medicare and Medicaid paying for the same skilled nursing and home health aide services. The claims information available to Medicaid payers does not enable them to ensure the appropriateness of payments.

Medicare pays home health providers through the prospective payment system (PPS) for services provided during episodes of care. For Medicaid services, we limited our review to fee-for-service claims. Medicaid is the payer of last resort; therefore, Medicaid should pay for home health services only if Medicare or another payer does not pay for them. During the period reviewed, we identified Medicaid payments amounting to \$3.3 million for 68,765 skilled nursing and home health aide claims potentially coverable by Medicare. We reviewed a sample of beneficiaries' case records to determine whether the Medicaid payments were appropriate based on Medicaid and Medicare policies. A companion report entitled "Duplicate Medicaid and Medicare Home Health Payments: Medical Supplies and Therapeutic Services" (OEI-07-06-00640) describes the extent to which both Medicare and Medicaid paid home health providers for the same medical supplies and therapeutic services.

We found that Medicaid paid nearly \$2 million for skilled nursing and home health aide services that were also vulnerable to being paid by Medicare in four of five States. Problems with coordination of care between providers and a lack of clarity in the Medicare coverage policy regarding billing for unskilled and skilled nursing services contributed to vulnerabilities. Claims data do not contain sufficient information to determine the appropriateness of Medicare coverage, limiting States' abilities to prevent Medicaid payments for services covered by Medicare.

From our findings, we concluded that CMS could consider methods to better integrate Medicare and Medicaid claims processing to prevent duplicate payments without relying on medical review and provide greater clarity in the CMS “Medicare Benefit Policy Manual” to explain that unskilled services provided during a skilled nursing visit paid under the PPS are included in the PPS payment. (OEI-07-06-00641)

Hospice Care: Compliance With Coverage Requirements for Beneficiaries in Nursing Facilities

We found that 82 percent of hospice claims for beneficiaries in nursing facilities (NF) did not meet at least one Medicare coverage requirement. Medicare paid approximately \$1.8 billion for these claims. More specifically, 33 percent of claims did not meet election requirements, and 63 percent did not meet plan of care requirements. For 31 percent of claims, hospices provided fewer services than outlined in beneficiaries’ plans of care. For 4 percent of claims, the certifications were missing or did not meet one or more Federal requirements.

The Medicare hospice benefit allows a beneficiary with a terminal illness to forego curative treatment for the illness and instead receive palliative care, which is the relief of pain and other uncomfortable symptoms. Based on the findings in this report, we recommended that CMS educate hospices about the coverage requirements and their importance in ensuring quality of care. We also recommended that CMS provide tools and guidance to help hospices meet the coverage requirements and that it strengthen its monitoring practices regarding hospice claims. CMS concurred with our recommendations and stated that it has educated providers about the requirements of the new Conditions of Participation (CoP), issued June 5, 2008, and has issued new Hospice Program Interpretive Guidance; a tool used by providers and State Survey agencies to determine compliance with the CoPs. We continue to recommend that CMS strengthen its monitoring practices regarding hospice claims.

This report is one in a series of four reports conducted by OIG that examine the hospice benefit for NF residents. It is based on data from a medical record review of a stratified random sample of hospice claims for beneficiaries in NFs in 2006. (OEI-02-06-00221)

Hospice Care: Services Provided to Beneficiaries Residing in Nursing Facilities

In 2006, 31 percent of Medicare hospice beneficiaries resided in NFs. Medicare paid \$2.59 billion for their hospice care, at an average of \$960 per week for each beneficiary. Hospices most commonly provided nursing, home health aide, and medical social services. They furnished an average of 4.2 visits per week per beneficiary for these three services combined. They also commonly provided drugs.

Medicare spending on hospice care and the number of beneficiaries receiving it have increased significantly in recent years. Previous OIG work has raised questions about the hospice benefit for NF residents. However, little subsequent research has been done to

examine hospice care for these beneficiaries and almost no beneficiary-specific data exist.

This memorandum report found that hospices provided nursing services to beneficiaries for 96 percent of claims, home health aide services for 73 percent of claims, and medical social services for 68 percent of claims. Drugs were provided to beneficiaries for 96 percent of claims. In addition, nursing services were provided at an average of 1.7 times per week, home health aide services at an average of 2.2 times per week, and medical social services at an average of 1.7 times per month.

This memorandum report is one in a series of four reports prepared by OIG that examine the hospice benefit for NF residents. It is based on data from a medical record review of a stratified random sample of hospice claims for beneficiaries in NFs in 2006. The report also uses claims data for all Medicare beneficiaries who received hospice care in 2006. This report contained no recommendations. (OEI-02-06-00223)

End Stage Renal Disease: Separately Billed Laboratory Tests for Medicare Beneficiaries

Medicare claims paid by an intermediary for laboratory tests that dialysis facilities provided to end stage renal disease (ESRD) beneficiaries did not always comply with Medicare ESRD payment requirements. Under the composite rate method of paying for dialysis services provided to ESRD beneficiaries, CMS specifies the laboratory tests that are included in the composite rate and the frequencies at which the tests are reimbursable as part of that rate. For 270 of the 360 beneficiary quarters that we sampled, dialysis facilities incorrectly billed and were reimbursed \$11,000 for ESRD-related laboratory tests. Based on our sample results, we estimated that the intermediary overpaid dialysis facilities \$3.9 million for laboratory tests provided to ESRD beneficiaries during CYs 2004–2006.

We recommended that the intermediary coordinate with CMS and other involved Medicare contractors to (1) conduct postpayment medical record reviews of claims submitted by dialysis facilities that separately billed ESRD laboratory tests to identify and recover overpayments estimated at \$3.9 million and (2) educate dialysis facilities about Medicare ESRD billing requirements related to the types of errors identified in our review. The intermediary agreed with our recommendations but noted that it no longer has jurisdiction over 2 of the 12 contracts covered by our review. We modified our recommendations accordingly and provided a copy of our report to the other contractor. (A-01-07-00522)

High-Dollar Payments: Medicare Part B Claims

In our review of high-dollar payments that a carrier made for services claimed under Medicare Part B, we defined high-dollar payments as those that were \$10,000 or more each. CMS contracts with carriers to, among other things, process and pay Medicare Part B claims submitted by physicians and medical suppliers.

Of the 100 sampled high-dollar Part B payments that a carrier made for services supplied during CYs 2004 through 2006, 23 payments included net overpayments totaling \$118,000. At the start of our audit, \$96,000 for 20 payments had not been refunded. Based on the sample results for our 3-year audit period, we estimated that the contractor made 402 overpayments totaling \$2.06 million to physicians and suppliers in Illinois, Michigan, Minnesota, and Wisconsin for Part B services.

We recommended that the carrier (1) recover the \$96,000 in identified overpayments, (2) review the 1,647 remaining high-dollar payments with potential overpayments estimated at \$1.9 million (\$2.06 million less \$118,000 overpaid) and work with the suppliers that claimed these services to recover any overpayments, (3) consider reviewing high-dollar payments made for services supplied after CY 2006 and recover any additional overpayments, and (4) improve internal controls related to manual claim processing. The carrier described corrective actions that it had taken or planned to take to implement our recommendations. (A-05-08-00022)

Physicians: Evaluation and Management Services Included in Eye and Ocular Adnexa Global Surgery Fees

In this CMS-requested review, we found that eye global surgery fees often did not reflect the number of evaluation and management (E&M) services that physicians provided to Medicare beneficiaries during global surgery periods. Global surgery fees include payment for a surgical service and the related preoperative and postoperative E&M services provided during the global surgery period. The period for major surgeries includes the day before the surgery, the day of the surgery, and the 90 days immediately following the day of the surgery. In determining a global surgery fee, CMS estimates the number of E&M services that a physician provides to a typical beneficiary during the global surgery period.

Of the 300 global surgeries that we sampled, 240 did not reflect the number of E&M services actually provided. Based on our sample results, we estimated that Medicare paid \$97.6 million for E&M services that were included in eye global surgery fees but not provided during the global surgery periods in CY 2005. The global surgery fees did not reflect the number of E&M services provided to beneficiaries because CMS had not adjusted or recently adjusted the relative value units for most of the sampled surgeries.

We recommended that CMS consider (1) adjusting the estimated number of E&M services within eye global surgery fees to reflect the number of E&M services actually being provided to beneficiaries, which may reduce payments by an estimated \$97.6 million, or (2) using the financial results of this audit, in conjunction with other information, during the annual update of the physician fee schedule. CMS acknowledged the merit of our findings but believed that it would be prudent to conduct further analysis before proposing any changes in the number of E&M services assigned to eye surgeries. (A-05-07-00077)

Physicians: Place-of-Service Coding

Based on our sample results, we estimated that carriers nationwide overpaid physicians \$20.2 million for incorrectly coded services provided during the 2-year period that ended December 31, 2006. The overpayments occurred because physicians did not always correctly code the office place of service on Medicare claims submitted to and paid by Part B carriers. The correct place-of-service code ensures that Medicare does not incorrectly reimburse the physician for the overhead portion of the payment if the service was performed outside the physician's office. For 129 of the 150 services that we sampled, physicians incorrectly coded the claims by using the office place-of-service code for services that were actually performed in outpatient hospitals or ambulatory surgical centers, resulting in approximately \$7,000 in overpayments.

We recommended that CMS instruct its Part B carriers to (1) recover the \$7,000 in overpayments for the sampled services, (2) review our information on the 857,761 nonsampled services to identify services estimated at \$20.2 million that were potentially billed with incorrect place-of-service codes and work with the physicians who provided the services to recover any overpayments, (3) strengthen their education process and reemphasize to physicians and their billing agents the importance of correctly coding the place of service and the need for internal controls to prevent Medicare billings with incorrect place-of-service codes, and (4) work with fiscal intermediaries and program safeguard contractors to develop a data match that will identify physician services at high risk for place-of-service miscoding and recover any identified overpayments. CMS concurred with our recommendations and described the actions that it planned to take to implement them. (A-01-08-00528)

Physicians: Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services

In the first 3 months of 2007, when Medicare allowed physicians more than 24 hours of services in a day, nonphysicians performed half of the services and 21 percent of these services were performed by unqualified nonphysicians. Medicare Part B pays for services that are billed by physicians but are performed by nonphysicians under the "incident to" rule. Little is known about Medicare services performed "incident to" the professional services of a physician because physicians are not required to identify them on their Medicare claims.

To identify the services not personally performed by physicians, we sampled claims from physicians for whom Medicare allowed more than 24 hours of services in a single day in the first 3 months of 2007. Some of the services that were performed by unqualified nonphysicians were invasive services, involving entry into the body by incision or insertion of an instrument. Our primary criteria for determining whether nonphysicians were qualified to perform the services were State laws and regulations.

We recommended that CMS revise the "incident to" rule. The rule should require that physicians who do not personally perform the services they bill to Medicare ensure that no persons except (1) licensed physicians personally perform the services or

(2) nonphysicians who have the necessary training, certification, and/or licensure, pursuant to State laws, State regulations, and Medicare regulations, personally perform the services under the direct supervision of licensed physicians. Further, CMS should require physicians who bill services to Medicare that they do not personally perform to identify the services on their Medicare claims by using a service code modifier. The modifier would enable CMS to monitor claims to ensure that physicians are billing for services performed by nonphysicians with appropriate qualifications. Finally, CMS should take appropriate action to address the claims for services that we detected that (1) were billed by physicians and performed by nonphysicians that were, by definition, not “incident to” services and (2) were for rehabilitation therapy services performed by nonphysicians who did not have the training of a therapist.

CMS concurred with two of our three recommendations. CMS did not concur with our recommendation to create a service code modifier to identify physicians’ claims for services that physicians do not personally perform. We continue to recommend that CMS have the ability to identify and monitor these claims. CMS stated it would study the operational issues involved in implementing the recommendation.

(OEI-09-06-00430)

Chiropractors: Inappropriate Medicare Payments for Chiropractic Services

In 2006, Medicare inappropriately paid a total net \$178 million (out of \$466 million) for chiropractic claims for services that medical reviewers determined to be maintenance therapy, miscoded, or undocumented. These claims represent 47 percent of chiropractic claims associated with beneficiaries receiving more than 12 chiropractic services within a year from the same chiropractor. OIG studies published in 1986, 1998, and 1999 found that significant vulnerabilities existed in connection with chiropractic claims, particularly concerning Medicare payments for maintenance therapy. Each of these studies recommended frequency edits or caps on the number of chiropractic claims allowed. In 2005, OIG conducted an additional study that found that 40 percent of allowed chiropractic claims in 2001 were for maintenance therapy and that when chiropractors provide more than 12 services per year to a beneficiary, the likelihood that some of those services were maintenance therapy increased greatly.

This study found that efforts to stop payments for maintenance therapy have been largely ineffective. Efforts to require a new modifier, educate chiropractors, and implement frequency-based controls or medical reviews have not been successful as carriers continue to report high error rates. To appropriately identify active/corrective treatment and thereby distinguish it from maintenance therapy, it is useful to identify the start of a new treatment episode. Because claims data do not indicate when a treatment episode began, the expectation of functional improvement can be determined only from a complete medical review of the treatment episode. We noted that the Comprehensive Error Rate Testing (CERT) paid claims error rate used by CMS is based on a review of a single claim, which limits its ability to detect maintenance therapy and may underestimate errors in claims made for chiropractic services. Finally, we found that chiropractors often do not comply with the “Medicare Benefit Policy Manual” documentation requirements.

Based on these findings, we recommended that CMS (1) implement and enforce policies to prevent future payments for maintenance therapy by implementing a new modifier for chiropractic claims to indicate the start of a new episode and/or a cap on allowed chiropractic claims; (2) review treatment episodes that include all claims from the initial visit to the sampled claim to strengthen the ability of the CERT to detect errors in chiropractic claims; (3) ensure that chiropractic claims are not paid unless documentation requirements are met; and (4) take appropriate action regarding the undocumented, medically unnecessary, and miscoded claims identified in our sample.

CMS agreed with the second recommendation and described actions it would take to address the fourth recommendation. CMS did not indicate agreement or disagreement with the first and third recommendations, but did describe its medical review process as it relates to documentation requirements and indicated no change in future practice to prevent claims without required documentation from being paid in error.
(OEI-07-07-00390)

Imaging Services: Medicare Part B Billing for Ultrasound

We found that in 2007, 20 high-use counties accounted for 16 percent of Part B spending on ultrasound services despite having only 6 percent of Medicare beneficiaries. We also found that 3.2 million claims, or nearly one in five nationwide, had characteristics that raise concern about whether the claims were appropriate. These claims represent \$403 million in Part B charges.

Medicare Part B covers ultrasound services provided in ambulatory settings, such as doctors' offices and testing centers. In 2007, Part B covered about 17 million ultrasound services at a cost of over \$2 billion. Previous OIG work has raised concern about the growth in other types of imaging covered under Part B and found that high geographic concentrations of suppliers or services may indicate weaknesses in Medicare's program safeguards. In this review, we found that average per-beneficiary spending on ultrasound in high-use counties was over three times that for beneficiaries in the rest of the country. We also found that certain suppliers billed for a large number of ultrasound claims with questionable characteristics.

We recommended that CMS monitor ultrasound claims data to detect questionable claims and review them prior to payment. We also recommended that CMS take action when suppliers bill for high numbers of questionable claims, including reviewing their claims to ensure that they are legitimate prior to payment and taking steps to revoke the Medicare billing numbers of suppliers that submit fraudulent claims. CMS concurred with both of our recommendations and described actions it would take to address them.
(OEI-01-08-00100)

Laboratories: Variation in the Clinical Laboratory Fee Schedule

In 2007, 97 percent of lab tests had at least one carrier rate that varied from the national limit amount (NLA). However, 83 percent of all carrier rates were at the NLA and 89 percent of laboratory test claims were paid at the NLA.

Medicare Part B payments for laboratory tests are determined by fee schedules originally established by carriers in 1985. These carrier fee schedules are collectively known as the Clinical Laboratory Fee Schedule. Each laboratory test has a congressionally mandated NLA that caps payments at a percentage of the median carrier rate. Currently, the NLA for laboratory tests is 74 percent of the median carrier rate for each laboratory test.

In establishing the Clinical Laboratory Fee Schedule in 1985, carriers used laboratory charge data that may not have reflected laboratory tests' costs. Since then, methods used to update carrier rates have incrementally added to the variation in carrier rates. As a result, carrier rates in 2007 were inconsistent both across carriers and within each carrier. The variation did not appear to reflect geographic differences in cost.

Carriers pay different rates for the same laboratory test, so Medicare payments also vary. Medicare paid over \$3.4 billion for laboratory tests in 2007. Medicare payments would have been \$3.5 billion if all tests had been paid at the NLA or \$2.4 billion if the NLA had been reduced to 50 percent of the median carrier rate. Setting all carrier rates at 73 percent of the median carrier rate would have eliminated variation without a change in overall Medicare payments.

Based on these findings, we recommended that CMS seek legislative authority to establish a new process for setting accurate and reasonable payment rates for laboratory tests.

In its comments to our report, CMS stated that it did not concur with our recommendation to seek legislation that would allow it to set accurate and reasonable payment rates for lab tests. However, CMS stated that it would consider the recommendation and that it was committed to improving payment policies for lab tests and to refining methodologies for establishing new payment rates. CMS explained that the President's budget for fiscal year 2010 does not include any proposals to amend the payment methodology for clinical laboratory tests. We encourage CMS to pursue legislation that would allow it to set accurate and reasonable payment rates for lab tests. (OEI-05-08-00400)

Ambulance Services: Transportation Provided to Beneficiaries in Skilled Nursing Stays Covered Under Medicare Part A

Based on our sample results, we estimated that Medicare Part B carriers made a total of \$12.7 million in potential overpayments to ambulance suppliers for transportation provided to beneficiaries in Part A SNF stays in CY 2006. Medicare Part A pays SNFs through prospective, per diem, case-mix adjusted rates that cover virtually all of their costs for furnishing services. Under this prospective payment system, some ambulance transportation provided by outside suppliers to SNF residents is included in the SNFs' Part A payments and is subject to consolidated billing. Therefore, Medicare Part B payments that suppliers receive for such transportation are overpayments.

Of the 114 claims that we reviewed, 61 claims totaling \$27,000 were incorrectly billed to Medicare Part B. As a result, Medicare paid twice for the ambulance transportation:

once to the SNF under the Part A prospective payment system and again to the ambulance supplier under Part B.

We recommended that CMS instruct its carriers to recover the \$27,000 in overpayments for the 61 incorrectly billed claims that we identified and review the claims that we did not review, which represent \$12.7 million in potential overpayments; provide additional guidance for suppliers and SNFs on its Web site and instruct its carriers and fiscal intermediaries to provide guidance to suppliers and SNFs to ensure compliance with consolidated billing requirements; and either establish additional edits in its Common Working File to prevent and detect Part B overpayments for ambulance transportation or instruct its carriers to develop a postpayment data match and recover any identified overpayments. CMS concurred with our recommendations. (A-01-08-00505)

Durable Medical Equipment: Independent Contractor's Review of Durable Medical Equipment Claims From the Fiscal Year 2008 Comprehensive Error Rate Testing Program

This audit, conducted at the request of the Senate Committee on Finance, found that an independent medical review contractor complied with its CMS contract in performing medical reviews of a subsample of claims from the FY 2008 durable medical equipment (DME) sample. However, the contractor's results did not provide assurance that the FY 2008 DME error rate was accurate. The CERT program was established to produce a Medicare fee-for-service error rate, which CMS must submit to Congress annually. To determine the error rate for FY 2008, CMS's CERT contractor conducted medical record reviews of a random sample of paid claims. The medical review contractor reviewed the CERT contractor's payment determinations.

The medical review contractor found that 175 of the 250 sampled claims were in error, significantly exceeding the 23 errors found by the CERT contractor. After further review, the CERT contractor agreed with 17 of the medical review contractor's additional error determinations (for a total of 40 error determinations) but disagreed with the remaining 135 error determinations. Most of the medical review contractor's error determinations were based on insufficient documentation to establish medical necessity.

We recommended that CMS require the CERT contractor to (1) develop a corrective action plan to reduce its number of incorrect determinations and (2) perform a complex medical review by obtaining and reviewing all medical records from all relevant suppliers to support the medical necessity of DME items. CMS concurred with our findings and recommendations and outlined the steps that it had taken to begin implementing our recommendations. (A-01-09-00500)

Durable Medical Equipment: Supplier Acquisition Costs and Services for Power Wheelchairs

Medicare and its beneficiaries paid almost four times the average amount paid by suppliers to acquire standard power wheelchairs during the first half of 2007. Suppliers purchased standard power wheelchairs for an average of \$1,048 and reported performing

an average of five services in conjunction with supplying them. Because Medicare allowed an average of \$4,018 for standard power wheelchairs, Medicare and its beneficiaries paid suppliers an average of \$2,970 beyond the suppliers' acquisition cost to perform an average of five services and cover supplier business costs. The beneficiaries' average copayments covered 77 percent of the suppliers' average acquisition cost for standard power wheelchairs. Medicare and its beneficiaries paid almost two times the average amount paid by suppliers to acquire complex rehabilitation power wheelchair packages during the first half of 2007. Suppliers purchased complex rehabilitation power wheelchair packages for an average of \$5,880 and reported performing an average of seven services in conjunction with supplying them. Because Medicare allowed an average of \$11,507 for complex rehabilitation power wheelchair packages, Medicare and its beneficiaries paid suppliers an average of \$5,627 beyond the suppliers' acquisition cost to perform an average of seven services and cover supplier business costs.

We collected documentation of the prices suppliers paid to purchase a sample of standard and complex rehabilitation power wheelchairs that Medicare beneficiaries received in the first half of 2007. We also collected documentation of the services performed prior to, during, and over an average of 9 months after the delivery of the power wheelchairs.

Medicare's average allowed amount for standard power wheelchairs in the first half of 2007 (\$4,018) was 383 percent of suppliers' average acquisition cost. In comparison, Medicare's payment under the Competitive Bidding Acquisition Program (\$3,073) would have been 293 percent of suppliers' average acquisition cost. Although Medicare's fee schedule amount was reduced to \$3,641 to offset the Competitive Bidding Acquisition Program's delay, the 2009 fee schedule amount exceeds the average competitively bid price by \$568.

Medicare's fee schedule amounts include reimbursement for the acquisition cost of the power wheelchair and also for supplier services, such as assembling and delivering the power wheelchair and educating the beneficiary about its use. We found that suppliers performed most services prior to and during, rather than after, the wheelchairs' delivery. Suppliers of complex rehabilitation power wheelchair packages reported performing twice as many services as suppliers of standard power wheelchairs at times other than the day of delivery. Suppliers reported performing required services most of the time, as well as other services as needed.

We recommended that CMS determine whether Medicare's standard and complex rehabilitation power wheelchair fee schedule amounts should be adjusted by using information from the Competitive Bidding Program, seeking legislation to ensure that fee schedule amounts are reasonable and responsive to market changes, or using its inherent reasonableness authority. CMS concurred with our recommendation and noted that the report provided valuable insight on suppliers' average acquisition costs for standard and complex rehabilitation power wheelchairs. (OEI-04-07-00400)

Durable Medical Equipment: Miscoded Claims for Power Wheelchairs

Eight percent of Medicare standard and complex rehabilitation power wheelchair claims from the first half of 2007 were miscoded. The suppliers billed Medicare for these claims using procedure codes that did not match the power wheelchairs' model information.

We discovered the coding errors identified in this report while reviewing power wheelchair model information on manufacturer invoices as part of a separate evaluation to determine suppliers' costs to purchase these chairs. Power wheelchairs are assigned to procedure codes based on the manufacturers' model information. However, the supplier is not required to include the model information on the claim when requesting Medicare reimbursement.

Three percent of standard and complex rehabilitation power wheelchair claims were upcoded and 4 percent were downcoded. One percent of claims were miscoded but had insufficient model information to categorize as either upcoded or downcoded. Complex rehabilitation power wheelchair claims were miscoded more often than standard power wheelchair claims (23 percent and 7 percent, respectively). Complex rehabilitation power wheelchair claims were also upcoded more often than standard power wheelchair claims (12 percent and 3 percent, respectively). In the first half of 2007, suppliers submitted over 13 times more standard than complex rehabilitation power wheelchair claims. Therefore, the greater number of standard power wheelchair claims strongly influenced the combined error rates.

Our analysis indicates that suppliers may need further education to determine the correct power wheelchair procedure codes to bill Medicare, and that opportunities exist to improve CMS's review of power wheelchair claims. This report contained no recommendations. (OEI-04-07-00403)

Durable Medical Equipment: Part B Services During Non-Part A Nursing Home Stays

This report presents findings based on our review of Part B DME payments during non-Part A nursing home stays in 2006. This report stems from the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), which mandates OIG to monitor Medicare Part B payments during non-Part A nursing home stays.

We found that \$30 million was inappropriately allowed for DME during non-Part A SNF stays, most of which were also certified by Medicaid. Also, we found that nearly \$11.9 million more was inappropriately allowed by Part B during Medicaid NF stays and distinct part nursing home stays providing primarily skilled care. Further, CMS and States reported that they do not maintain a primary level of care designation for nursing homes that could facilitate accurate claim submission by suppliers and proper claim adjudication by payment contractors.

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. However, Part B does not pay for DME unless the nursing home qualifies as a beneficiary's home. Because most nursing homes provide primarily skilled care or rehabilitation, they are excluded from qualifying as a beneficiary's home. Only a small number of nursing homes certified only for Medicaid, called NFs, or distinct parts of nursing homes may qualify as a beneficiary's home. In contrast, the large number of SNFs and dually certified nursing homes—those certified for both Medicare and Medicaid—do not qualify as a beneficiary's home.

To identify inappropriate payments for DME, we used resident assessment data to determine all nursing home stays nationwide during 2006. We then analyzed related Medicare claims data for any DME payments during these stays.

To address these overpayments, we recommended that CMS routinely identify non-Part A beneficiary nursing home stays; recoup inappropriate payments identified in this report; identify patients entering nursing homes with rented DME; and implement a process to identify nursing homes that provide primarily skilled care and make this information available to claims processors, nursing homes, and suppliers. CMS concurred with the first two recommendations and agreed with the underlying objectives of the other recommendations but suggested alternative approaches using claims processing edits to address them. (OEI-06-07-00100)

Durable Medical Equipment: Comparison of Prices for Negative Pressure Wound Therapy Pumps

Suppliers paid an average of \$3,604 for new negative pressure wound therapy pump models, compared to Medicare's purchase price of \$17,165. Medicare reimbursed suppliers for these pumps based on this purchase price, which is more than four times the average price paid by suppliers. Medicare reimbursed suppliers \$1,716 for these pumps each month for the first 3 months. At this rate, suppliers recouped the average cost of a new pump in about 2 months. Moreover, if a beneficiary were to rent the pump for all of the 13 months allowed by Medicare, the beneficiary's coinsurance alone (\$3,599) would cover almost the entire average cost of a new pump. These pumps are portable or stationary devices used for the treatment of ulcers or wounds that have not responded to traditional wound treatment methods.

When Medicare first started covering pumps in 2001, it covered only one pump model, which was both manufactured and supplied by a single manufacturer. Since then, a number of manufacturers have introduced new pump models in the market and are charging substantially less for them.

Our review also found that suppliers purchased three-quarters of the pumps that they provided to beneficiaries, while the remaining one-quarter were leased, rented, or exchanged. Finally, we found that suppliers reported not communicating as required with almost one-quarter of beneficiaries' clinicians. In the absence of clinician input, suppliers cannot determine whether there is a continued medical need for a pump.

Suppliers generally reported meeting other requirements, such as providing delivery, education, as well as maintenance and repairs when needed.

Based on the findings of this report, we recommended that CMS reduce Medicare's reimbursement amount for pumps. CMS should consider the following methods to reduce the reimbursement amount: use its inherent reasonableness authority to reduce the reimbursement amount for pumps and include pumps in the second round of the Competitive Bidding Acquisition Program. In addition, CMS should continue to monitor the growth of the new pump market. Lastly, CMS should educate suppliers of new pump models on the importance of communication with beneficiaries' treating clinicians and follow up on the claims that we identified that may be inappropriate. CMS concurred with four of our recommendations and will consider the remaining recommendation about including pumps when designing the second round of the Competitive Bidding Acquisition Program. (OEI-02-07-00660)

Durable Medical Equipment: Inappropriate Medicare Payments for Pressure Reducing Support Surfaces

Based on a review of medical record documentation and supplier documentation, 86 percent of group 2 support surface claims for the first half of 2007 did not meet Medicare coverage criteria. This amounted to an estimated \$33 million in inappropriate payments during that time. We considered a claim as not meeting Medicare coverage criteria if it either (1) did not meet Medicare's clinical coverage requirements or (2) did not meet Medicare's supplier documentation requirements.

Pressure reducing support surfaces are used for the care or prevention of pressure ulcers. Pressure ulcers, also known as bed sores or decubitus ulcers, commonly occur among the elderly and among individuals with spinal cord injuries. Support surfaces are covered under Medicare Part B as DME. CMS categorizes support surfaces into three groups based on the complexity of their features. Group 2 support surfaces is the largest group.

Based on an independent medical review, we found that 80 percent of group 2 support surface claims did not meet Medicare's clinical coverage requirements. In addition, we found that 33 percent of claims did not meet supplier documentation requirements. Over three-quarters of the claims that did not meet supplier documentation requirements also did not meet Medicare's clinical coverage requirements.

More specifically, 38 percent of the claims were undocumented, 22 percent were medically unnecessary, 17 percent had insufficient documentation, and 3 percent had other billing errors. For the claims that did not meet supplier documentation requirements, the supplier delivered the support surface before obtaining the physician order, the supplier did not have a physician order, the supplier was missing the proof of delivery, or the physician order was not dated.

Last, we found that CMS contractors had limited safeguards in place to prevent improper payments for group 2 support surfaces. In particular, contractors' use of the KX modifier, which a supplier uses to indicate that a claim meets Medicare coverage criteria

and that adequate documentation exists, was not successful in flagging inappropriate claims. In addition, none of the CMS contractors conducted any widespread medical reviews of support surface claims. Moreover, only half of the CMS contractors responsible for supplier education conducted any educational activities in recent years that focused on group 2 support surfaces.

Based on the findings of this report, we recommended that CMS ensure that claims for group 2 support surfaces meet Medicare coverage criteria and are paid appropriately. Accordingly, CMS should (1) conduct prepayment and postpayment medical reviews of group 2 support surface claims;(2) educate suppliers and health care providers, such as home health agencies, about Medicare coverage criteria for support surfaces; (3) review the use of the KX modifier as a program safeguard; and (4) conduct additional statistical analyses to monitor payments for group 2 support surfaces. In addition, CMS should take appropriate action regarding the claims in our sample that were inappropriate. CMS concurred with our recommendations and stated that it will share our findings on inappropriate claims with its contractors for potential additional prepayment edits and prepayment medical review. (OEI-02-07-00420)

Prescription Drugs: Aberrant Claim Patterns for Inhalation Drugs in South Florida

Even though just 2 percent of Medicare beneficiaries live in South Florida, this area accounted for 17 percent of Medicare's total spending for inhalation drugs in 2007. In addition, the beneficiaries listed on 62 percent of South Florida inhalation drug claims did not have Medicare-billed office visits or other services in the past 3 years with the physicians who reportedly prescribed the drugs. Medicare Part B covers inhalation drugs when they are used in conjunction with DME. Beneficiaries typically obtain DME items, including inhalation drugs, through suppliers, which then submit claims to Medicare. CMS contractors established a local coverage determination (LCD) for inhalation drugs that set coverage limitations, such as the maximum milligrams per month that may be billed for certain inhalation drugs.

In our review, we found that Medicare spent an average of five times more per beneficiary on inhalation drugs in South Florida compared to the rest of the country, with the greatest spending differences attributable to the more expensive brand-name drugs levalbuterol and budesonide. In addition, three-fourths of South Florida beneficiaries receiving budesonide frequently exceeded coverage guidelines set in the LCD (for a 90-day period).

To address these issues, we recommended that CMS ensure that its contractors are enforcing the coverage guidelines for inhalation drugs, eliminate Medicare's vulnerability to potentially fraudulent or excessive inhalation drug claims in South Florida, and review cases where the DME supplier appears to be fraudulently billing Medicare for inhalation drugs and take appropriate action based on the review's results. CMS concurred with our three recommendations and stated that a "medically unlikely" edit for budesonide was implemented in September 2008. (OEI-03-08-00290)

Prescription Drugs: Part B Payment and Policy for Chemotherapy Administration

Although questionable claims for chemotherapy administration exceeded \$60 million from 2005 to 2007, Medicare data are insufficient to determine consistently whether such payments are appropriate. Medicare pays for certain drugs, including chemotherapy agents, under Part B and pays separately for the administration of covered drugs. Payment rates for the administration of chemotherapy agents are nearly twice those for administering other drugs. CMS does not specify which particular drugs qualify for the chemotherapy administration rate, leaving that decision to the carriers that it contracts with to process Part B claims.

Physicians sometimes legitimately bill Medicare for a drug administration service, but do not bill for the drug itself. Therefore, we cannot determine with certainty what portion was inappropriate of the \$16.9 million that Medicare paid for chemotherapy administration on days when no drug was billed or of the \$43.8 million paid on days when only nonqualifying drugs were billed. Furthermore, carriers have implemented inconsistent chemotherapy administration coding policies and review procedures, sometimes disagreeing on whether certain drugs qualify for billing with chemotherapy administration codes, which are reimbursed at a higher rate than the equivalent nonchemotherapy administration codes.

OIG recommended that CMS (1) establish a process to determine which specific drugs qualify for the chemotherapy administration payment rate, (2) instruct carriers that have not done so to consider a probe review of unmatched chemotherapy administration claims, and (3) ensure that drug administration claims are coded correctly and paid appropriately.

CMS concurred with our recommendation to instruct carriers that have not done so to consider a probe review of unmatched chemotherapy administration claims. CMS did not concur with our other two recommendations. Based on CMS's response to our recommendation to clearly define the criteria for qualifying drugs, we modified the language in a way that addressed practice variations. The remaining two recommendations, which suggested specific actions to help ensure that drug administration claims are coded correctly, were replaced with a broader recommendation that defers to CMS's judgment of actions. (OEI-09-08-00190)

Prescription Drugs: Beneficiary Utilization of Albuterol and Levalbuterol Under Medicare Part B

We found that utilization patterns among beneficiaries who were prescribed albuterol and levalbuterol fluctuated noticeably between 2003 and 2007—almost always shifting toward the drug that was most favorable for the supplier from a reimbursement perspective.

In 2003 and 2004, albuterol and levalbuterol were included in the same payment code and had the same Medicare payment amount, which was based on the median average

wholesale price of all versions of both drugs. Effective January 1, 2005, CMS established separate payment codes and payment amounts for these drugs. At the same time, under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Medicare reimbursement for an inhalation drug was set at 106 percent of the drug's average sales price (ASP). These changes increased the payment amount for levalbuterol but decreased the payment amount for albuterol. Effective July 1, 2007, CMS recombined albuterol and levalbuterol into a single code and began to base payment on the volume-weighted ASP for both drugs. However, as of April 1, 2008, CMS again reestablished separate payment codes and payment amounts for these two drugs.

Medicare reimbursement favored albuterol in 2003 and 2004 (from a supplier's reimbursement perspective), and nearly all beneficiaries (97 percent) received that drug. However, as a result of payment and coding changes that took effect on January 1, 2005, reimbursement became much more favorable for levalbuterol. Twenty-five percent of beneficiaries who were on albuterol in 2004 were changed to levalbuterol between January 1, 2005, and June 30, 2007. Physicians in our sample typically cited clinical reasons for changing beneficiaries from albuterol to levalbuterol during this time. Despite the move to ASP, average per-beneficiary spending on albuterol and levalbuterol actually increased above pre-MMA levels. Between January 1 and June 30, 2007, Medicare paid an average of \$600 per beneficiary for both albuterol and levalbuterol, or \$94 more per beneficiary than in the first half of 2003.

However, a July 1, 2007, payment and coding change made albuterol more favorable from a supplier's perspective; two-thirds of beneficiaries in our sample were changed from levalbuterol to albuterol between July 1 and December 31, 2007. Physicians in our sample typically cited financial reasons for changing beneficiaries from levalbuterol to albuterol in the second half of 2007.

When Congress and CMS make reimbursement and coding decisions, it is important that they take into consideration that new policies may affect what drug a beneficiary is prescribed and, in some cases, limit access to a potentially more effective product or drive utilization to a more expensive product that offers no clinical advantage. (OEI-03-07-00440)

Contractor Operations: Termination Claims for Postretirement Benefit Costs

Our reviews of three terminated contractors found that they did not always claim allowable postretirement benefit (PRB) costs for Medicare reimbursement. Medicare pays a portion of contractors' PRB costs. In claiming these costs, contractors must follow cost reimbursement principles and the provisions of their Medicare contracts. Our findings follow.

■ **Kansas contractor** – The contractor's entire termination claim of \$11.2 million for PRB costs was unallowable for Medicare reimbursement. The contractor based its claim on a retroactive change in accounting practice without CMS approval. Therefore, and pursuant to the Medicare contracts, none of the costs claimed were allowable for Medicare reimbursement. We recommended that the contractor withdraw its

\$11.2 million termination claim. The contractor disagreed with our finding and recommendation. After reviewing the contractor's comments, we maintain that the contractor should withdraw the full claim amount. (A-07-09-00310)

■ **Maryland contractor** – The contractor's entire termination claim of \$1.5 million for PRB costs was unallowable for Medicare reimbursement. The contractor based its claim on a retroactive change in accounting practice without CMS approval. Therefore, and pursuant to the Medicare contracts, none of the costs claimed were allowable for Medicare reimbursement. We recommended that the contractor withdraw its \$1.5 million termination claim. The contractor disagreed with our recommendation. After reviewing the contractor's comments, we maintain that the contractor should withdraw the full claim amount. (A-07-09-00299)

■ **Utah contractor** – The contractor's entire termination claim of \$1.4 million in PRB costs for Part A and Part B contracts was unallowable for Medicare reimbursement. The claim was calculated based on a retroactive change in accounting practice without CMS approval. Therefore, and pursuant to the Medicare contracts, none of the costs claimed were allowable. We recommended that the contractor withdraw its \$1.4 million termination claim. The contractor did not concur with our recommendation. The contractor also stated that its recalculated termination claim was approximately \$83,000 less than we reported in our draft report. After reviewing the contractor's comments and additional documentation, we revised our finding and recommendation to reflect the recalculated termination claim amount. We maintain that the contractor should withdraw the full claim amount. (A-07-08-00278)

Contractor Operations: Medicare Contractor Processes for Reviewing Pennsylvania Hospitals' Wage Data

As a result of a congressional request, we reviewed two Medicare contractors and found that the first contractor followed CMS requirements when reviewing a Pennsylvania hospital's wage data that CMS used to calculate the FYs 2004 through 2009 wage indexes. Both contractors followed CMS requirements when reviewing 20 other Pennsylvania hospitals' wage data that CMS used to calculate the FY 2009 wage indexes. Both contractors completed their reviews within established timeframes and provided documentation to support their adjustments to the hospitals' wage data.

Because we found no evidence of disparate treatment based on the Medicare contractor that reviewed the wage data or a hospital's geographic location, we made no recommendations. (A-03-08-00020)

Contractor Operations: Contractor Pension Costs Claimed for Medicare Reimbursement

A Medicare contractor in Puerto Rico claimed \$2.9 million of unallowable Medicare pension costs for FYs 1988 through 2006, primarily because the contractor calculated pension expense using a standard intended for financial reporting. Medicare reimburses a portion of the annual contributions that contractors make to their pension plans. In

claiming costs, contractors must follow cost reimbursement principles contained in the Federal Acquisition Regulation, Cost Accounting Standards, and Medicare contracts. The contractor claimed \$7 million in pension costs, but we calculated the allowable pension costs to be \$4.1 million.

We recommended that the contractor reduce its Final Administrative Cost Proposal pension costs by \$2.9 million or refund this amount to CMS and ensure that future pension cost claims are in accordance with the Medicare contracts. The contractor stated that it was not in a position to concur with our recommendations because its Medicare contract had been terminated. We maintain that our finding and recommendations are valid. (A-07-08-00268)

Contractor Operations: Contractor's Postretirement Benefit Assets

We found that a Medicare contractor understated its Medicare segment PRB assets as of January 1, 2006, by \$2.4 million. In claiming costs for PRB plans, contractors must follow cost reimbursement principles contained in the Federal Acquisition Regulation and applicable Cost Accounting Standards, as required by the Medicare contracts. As part of a change in its accounting practice, the contractor was required to identify and update the Medicare segment's PRB assets. However, the contractor made errors in its update computations. In addition, the contractor did not make adjustments for participants who transferred into and out of the Medicare segment.

We recommended that the contractor increase the Medicare segment PRB assets by \$2.4 million as of January 1, 2006, and make adjustments for participant transfers in future updates. The contractor disagreed with the amount of our recommended increase but agreed to make adjustments for participant transfers in future updates. After reviewing the contractor's comments and additional information, we revised our recommended asset increase to \$2.4 million, not the higher amount reflected in our draft report. (A-07-08-00280)

Medicare Part C Reports

Medicare Advantage Organization's Adjusted Community Rate Proposal Modifications

An MA organization's proposed uses of a \$41 million estimated MMA payment increase in contract year 2004 for three plans were not always supported and allowable under the MMA. MA organizations assume responsibility for providing all Medicare-covered services, except hospice care, in return for a predetermined capitated payment. The organization's proposed uses of \$4.7 million for one of its three plans were not allowable because, contrary to CMS instructions, these funds related to mandatory supplemental benefits. In addition, because of a clerical error, the organization overstated by an estimated \$95,000 its proposed use of the payment increase to enhance benefits for another plan. The organization's proposed uses of approximately \$36 million were allowable.

We recommended that the organization follow CMS instructions and guidance when preparing future proposals (now referred to as “bids”) and ensure that amounts included in the proposals are allowable. The organization did not agree with our recommendation. The organization did not provide any additional information that would cause us to change our finding or recommendation. (A-06-06-00093)

Duplicate Capitation Payments

We found that of the 218 million capitation payments totaling approximately \$158 billion that CMS made for Medicare Part C enrollees from January 2006 through March 2008, only 373 payments totaling \$301,000 were duplicate payments for 1 month of health care coverage. CMS may make only one capitation payment per month for each individual enrolled in an MA plan or a Programs of All-Inclusive Care for the Elderly plan. Although CMS had correctly paid organizations for the vast majority of plan enrollees, the validation process that CMS used to ensure the accuracy of payments did not identify and prevent all improper payments.

We recommended that CMS (1) recoup the \$301,000 in improper payments; (2) determine whether enhancements to its validation process would be cost effective and, if so, implement the enhancements; and (3) periodically review, on a postpayment basis, payments made to organizations to detect and recover any duplicate payments. CMS concurred with our recommendations and described the corrective actions that it was taking or planned to take. (A-07-08-01052)

Medicare Part D Reports

Dual-Eligible Demonstration Project

New Jersey complied with certain provisions of the Medicare demonstration application when claiming drug costs for full-benefit dually eligible beneficiaries (fully eligible for both Medicare and Medicaid). The demonstration project permitted Medicare to fully reimburse States for full-benefit dually eligible beneficiaries’ Part D drugs to the extent that the costs were not recoverable from a Medicare Part D plan. However, New Jersey claimed some drug and administrative costs to both the Medicaid program and the Medicare demonstration project. For the \$79 million that the State was reimbursed through the Medicare demonstration project and that it included on its Medicaid Forms CMS-64, the State did not adjust its Forms CMS-64 to reflect \$11.3 million (\$5.8 million Federal share) for some demonstration project costs. According to State officials, New Jersey did not adjust its Forms CMS-64 to account for some of its drug costs and most of its administrative costs paid through the Medicare demonstration project because of a clerical oversight.

We recommended that the State refund \$5.8 million to the Federal Government for improper Medicaid drug claim payments (\$5.2 million) and administrative cost payments (\$600,000). We did not make any procedural recommendations because the demonstration project has ended. The State said that it would adjust its expenditure reports in accordance with our recommendation. (A-02-08-01007)

Accuracy of Part D Plans' Drug Prices on the Medicare Prescription Drug Plan Finder

A comparison of selected Part D plans' retail prices posted on the Medicare Prescription Drug Plan Finder (Plan Finder) for 10 drugs commonly used by seniors to actual drug costs on corresponding prescription drug event claims revealed that Plan Finder prices generally exceeded actual drug costs, frequently by large amounts. Overall, we found that drug price data in Plan Finder did not accurately reflect actual drug costs on Part D claims because the prices frequently overestimated the drug costs charged when beneficiaries had their prescriptions filled at the pharmacy.

CMS created Plan Finder, located on the [Medicare.gov](http://www.Medicare.gov) Web site, as a tool to help beneficiaries compare and select Part D plans. Plans' drug prices are a significant factor to beneficiaries selecting a plan. Plan Finder indicates in its plan drug details section that "drug costs displayed are only estimates" and that "actual costs at the pharmacy may vary slightly." However, our review revealed that Plan Finder drug prices were a median of 28 percent (or \$18) higher than actual drug costs for the 10 drugs included in our review. Drug prices posted on Plan Finder exceeded actual drug costs for 92 percent of the claims in our review and were less than actual drug costs for 7 percent of claims. Plan Finder prices equaled actual drug costs for 1 percent of the claims reviewed. Percentage differences between Plan Finder prices and actual costs were generally greater for the generic drugs in our review, while dollar differences were greater for the brand-name drugs reviewed.

OIG recommended that CMS ensure that plans' drug prices displayed on Plan Finder accurately reflect actual drug costs on Part D claims. As an immediate measure, OIG also recommended that CMS add a disclaimer to the Plan Finder plan search results screen indicating that drug cost estimates may differ more than "slightly" from actual drug costs. CMS concurred with our first recommendation but did not concur with our second recommendation. However, CMS indicated that it will revise language on the Plan Finder Web site to advise beneficiaries that if they do not select a specific pharmacy when conducting a Plan Finder search, the drug prices displayed may be different from point-of-sale drug costs at their pharmacies.

In addition, CMS stated that OIG's methodology is flawed and OIG's findings are false and misleading because we conducted a general search rather than a pharmacy-specific search in Plan Finder. OIG does not agree. By choosing to conduct a general search, we employed the same method that beneficiaries using Plan Finder were advised to employ to find the least expensive plan for their needs. Both CMS and AARP (formerly the American Association of Retired Persons) recommended conducting a general search rather than a pharmacy-specific search to improve a beneficiary's ability to find the least expensive plan. Our findings generate concerns about the accuracy of the plan and drug cost information provided to beneficiaries who choose to conduct a general search rather than a pharmacy-specific search in Plan Finder. (OEI-03-07-00600)

Effect of the Part D Coverage Gap on Medicare Beneficiaries Without Financial Assistance in 2006

Seven percent of Part D beneficiaries entered the coverage gap and did not receive financial assistance with prescription drug costs in 2006. During the coverage gap, drug-purchasing behavior changed for almost all these beneficiaries. Medicare Part D provides an optional drug benefit to Medicare beneficiaries. During the coverage year, the financial responsibilities of beneficiaries, plan sponsors, and CMS vary during four distinct coverage phases: annual deductible, initial coverage, coverage gap, and catastrophic coverage. Some research suggests that beneficiaries who entered the Medicare Part D coverage gap may have changed their prescription drug use behaviors because they were responsible for 100 percent of their drug costs during the coverage gap.

Sixty-nine percent of beneficiaries decreased the average number of drugs they purchased during the coverage gap. This decrease could have represented a strategy that beneficiaries used to reduce their financial burden during the coverage gap, or it could have represented appropriate reductions due to changes in beneficiaries' health status. In addition, the greater the average number of drugs per month that beneficiaries purchased before entering the coverage gap, the more they reduced the average number of drugs per month that they purchased during the coverage gap. Beneficiaries who purchased an average of at least nine drugs per month had the largest decrease at 18 percent.

Based on these findings, we recommended that CMS support outreach and education activities targeted at beneficiaries who make more prescription drug purchases before entering the coverage gap. To do this, CMS could encourage plan sponsors to augment current outreach and beneficiary education efforts and supplement plans' outreach and education efforts by working directly with beneficiaries to explore cost-saving strategies. In addition, CMS should target low income subsidy outreach to beneficiaries who entered the coverage gap in previous years without financial assistance. CMS concurred with one of our two recommendations. CMS did not agree with our first recommendation. We continue to believe that targeting beneficiaries with more prescription drug purchases before the coverage gap for outreach and education will assist these beneficiaries in identifying cost-saving strategies. CMS concurred with our second recommendation. However, the actions CMS stated it would take may not fully address our recommendation to use drug utilization data to identify potential beneficiaries for the subsidy. (OEI-05-07-00610)

Reconciliation Payments for 2006 and 2007

Part D sponsors owe a net total of \$18 million to Medicare for the 2007 Part D payment reconciliation, which is significantly less than the net total of \$4.4 billion that sponsors owed for 2006. Despite this improvement, sponsors continue to submit inaccurate bids and make large unexpected profits.

CMS makes monthly prospective payments to sponsors for providing prescription drug coverage to Medicare beneficiaries. These payments are based on estimates that sponsors provide in their bids prior to the beginning of the plan year. After the close of the plan year, CMS reconciles these payments with the sponsors' actual costs to determine whether sponsors owe money to Medicare or Medicare owes money to sponsors.

More specifically, sponsors owe Medicare a net total of \$600 million because of unexpected profits or losses that triggered risk sharing for 2007. Many of these sponsors overestimated the costs of providing the benefit in their bids. As a result, Medicare payments to sponsors and beneficiary premiums were higher than necessary. Medicare recoups a portion of these higher payments. However, beneficiaries do not directly recoup any of the money that they paid in higher premiums. At the same time, sponsors will receive a net total of \$406 million from Medicare for the low-income cost-sharing subsidy and a net total of \$186 million for the reinsurance subsidy because they underestimated these costs in their bids.

Further, sponsors continue to make large unexpected profits. Based on our calculations, the 179 sponsors that had profits large enough to trigger risk sharing made at least \$1.02 billion in unexpected profits in 2007. These sponsors owe a portion of these unexpected profits to Medicare based on the risk-sharing requirements. In addition, sponsors included an estimated \$1.07 billion of expected profits in their bids.

Finally, for 2006, CMS collected almost all of the funds that sponsors owed to Medicare in November and December 2007. However, we reported that CMS has not collected a total of \$14 million from five sponsors for 2006.

Based on these findings, we recommended that CMS (1) ensure that sponsors' bids more accurately reflect their costs of providing the benefit to Medicare beneficiaries, (2) hold sponsors more accountable for inaccuracies in the bids, (3) determine whether changes to the risk corridors are appropriate, (4) determine whether alternative methodologies would better align payments with sponsors' costs for the low-income cost-sharing and reinsurance subsidies, and (5) follow up with the sponsors that owe funds for 2006. CMS concurred with three of our recommendations and did not state whether it concurred with the other two recommendations. CMS noted in its July 17, 2009, letter to OIG that there was no longer \$14 million outstanding. It indicated that immediately following reconciliation, plan sponsors owed approximately \$4.4 billion for 2006 and collected virtually all of this money soon after reconciling the plan year; leaving as outstanding approximately \$14 million or .03 percent of the original amount owed. CMS reported that it has since collected amounts owed due to the 2006 reconciliation from all sponsors that are solvent. With respect to a plan sponsor that owed \$7.9 million, CMS noted that it performed a reopening after the plan's submission of added data, and it was determined that the sponsor only owed \$7.6 million. CMS stated that it had collected \$7.6 million on April 30, 2009, and \$252,000 from another of the applicable sponsors, which represented the total amounts owed by those sponsors for 2006. The remaining sponsors are insolvent and owe minimal amounts. CMS noted that it has filed the appropriate documents with the applicable bankruptcy courts.

(OEI-02-08-00460)

Payments for Beneficiaries in Part A Skilled Nursing Facility Stays in 2006

Medicare Part D paid for 1.2 million prescription drugs events, amounting to \$75 million, for beneficiaries in Part A SNF stays in 2006. The majority of these payments were most likely inappropriate.

Medicare Part D covers most prescription drugs; however, it excludes drugs that are covered under Medicare Parts A or B. Specifically, Part D excludes drugs for beneficiaries in Part A SNF stays if the drugs were for use in the facility or to facilitate the beneficiaries' discharge. These drugs are covered under Part A, except for a few drugs that are covered under Part B. CMS has identified duplicate payments by Medicare Parts A and D as a potential vulnerability.

Sixty percent of the drugs Part D paid for while beneficiaries were in Part A SNF stays in 2006 were dispensed by long-term care pharmacies. These pharmacies dispense drugs for use in long-term care settings, including SNFs. Because these drugs were most likely dispensed for use in the facility during a Part A SNF stay, Part D payments for them, which amounted to \$41.3 million, were most likely inappropriate. The remaining 40 percent of drugs paid for by Part D for beneficiaries in Part A SNF stays were dispensed by retail and other types of pharmacies. If these drugs were for use in the facility or were to facilitate the beneficiaries' discharge, then Part D payments were also inappropriate. Nearly every SNF and half of all pharmacies had beneficiaries who had a drug paid for by Part D during their Part A SNF stay. At the same time, a small number of SNFs and pharmacies were responsible for a large percentage of these Part D payments.

Based on these findings, we recommended that CMS ensure that Part D payments for drugs for beneficiaries in Part A SNF stays are appropriate. More specifically, CMS should provide additional guidance about when Parts A and D may pay for drugs for beneficiaries preparing for discharge; educate SNFs, pharmacies, and Part D sponsors that drugs covered under Parts A or B for beneficiaries in SNF stays are not eligible for coverage under Part D; implement retrospective reviews to prevent inappropriate Part D payments for drugs for this population; and follow up with the SNFs and pharmacies that were responsible for a large percentage of Part D payments for beneficiaries in Part A SNF stays. CMS concurred with the three recommendations in our draft report. However, it raised several concerns, and in response, we clarified the language in the report and added a recommendation that CMS provide additional guidance that clarifies the circumstances under which Parts A and D may pay for drugs for beneficiaries preparing for discharge. (OEI-02-07-00230)

Medicaid Related Reports

Hospitals: Inpatient Hospital Claims Billed as Family Planning Services in New York State

New York State improperly claimed enhanced 90-percent Federal reimbursement for inpatient family planning claims submitted by hospitals. Of the 173 claims in our

sample, 3 qualified as family planning services and could be claimed at the enhanced 90-percent Federal reimbursement rate. However, the remaining 170 claims could not be claimed as family planning services or could be claimed only in part as family planning services. Based on our sample results, we estimated that the State received \$2.6 million in unallowable Federal Medicaid reimbursement.

This overpayment occurred because (1) providers incorrectly claimed services as family planning, (2) the State's Medicaid Management Information System (MMIS) edit routines did not adequately identify claims unrelated to family planning, (3) the State did not have procedures to allocate the costs of inpatient hospital claims partially related to family planning, and (4) providers did not properly complete sterilization consent forms.

We recommended that the State (1) refund \$2.6 million to the Federal Government, (2) reemphasize to providers that only services directly related to family planning should be billed as family planning, (3) ensure that MMIS edit routines properly identify claims that are ineligible for enhanced 90-percent Federal reimbursement, (4) develop procedures to properly allocate the cost of inpatient hospital stays partially related to family planning, (5) reinforce guidance to hospitals regarding Medicaid sterilizations, and (6) determine the amount of Federal Medicaid funds improperly reimbursed for claims unrelated to family planning subsequent to our audit period and refund that amount to the Federal Government. The State generally agreed with our recommendations and described actions that it will take in response. (A-02-06-01007)

Hospitals: Medicaid Participation Eligibility for One Indiana State-Owned Psychiatric Hospital

During the period July 1, 1996, through June 30, 2007, Indiana paid \$26.2 million (\$16.3 million Federal share) to a hospital that was not eligible to receive Medicaid payments for inpatient psychiatric services. The hospital did not meet Federal Medicaid eligibility requirements because it did not demonstrate compliance with two special Medicare Conditions of Participation requirements.

We recommended that the State (1) refund \$16.3 million to the Federal Government for Medicaid inpatient psychiatric service payments made to the hospital from July 1, 1996, through June 30, 2007; (2) identify and refund the Federal share of additional unallowable Medicaid payments to the hospital for inpatient psychiatric services provided after June 30, 2007; and (3) ensure that Medicaid payments for inpatient psychiatric services are made only to eligible hospitals. The State disagreed with the finding and first recommendation and did not address the other recommendations. After reviewing the State's comments, we maintain that our finding and recommendations are valid. (A-05-07-00076)

Home Care: Medicaid Personal Care Claims Made by Providers in New York City

New York State improperly claimed Federal Medicaid reimbursement for some personal care claims submitted by providers in New York City during CYs 2004 through 2006.

Of the 100 claims in our random sample, 80 claims complied with Federal and State requirements, but 18 claims did not. We could not determine whether the two remaining claims, which involved services under the State's Consumer Directed Personal Assistance Program (CDPAP), complied with Federal and State requirements. Based on our sample results, we estimated that the State improperly claimed \$275.3 million in Federal Medicaid reimbursement during the audit period.

We recommended that the State (1) refund \$275.3 million to the Federal Government, (2) work with CMS to resolve the two CDPAP claims, (3) improve its monitoring of New York City's personal care services program to ensure compliance with Federal and State requirements, and (4) promulgate specific regulations related to claims submitted under the CDPAP. The State disagreed with our first recommendation and agreed with our remaining recommendations. The State also disagreed with many elements of our findings. After reviewing the State's comments and additional documentation, we revised our findings and statistical estimates to reflect the \$275.3 million improper claim, not the higher amount reflected in our draft report. (A-02-07-01054)

Medicaid Home, Community, and Nursing Home Care: Targeted Case Management Services in Pennsylvania

Pennsylvania's claims for targeted case management (TCM) services did not always comply with Federal and State requirements. Federal law authorizes State Medicaid agencies to provide case management services to Medicaid beneficiaries. These services are referred to as TCM when they are furnished to specific populations in a State. Based on our review of 375 claims in 100 sampled beneficiary-months, 36 claims included in 15 beneficiary-months were unallowable because the services were unsupported by case records or insufficiently documented. As a result, we estimated that during CYs 2003 through 2005, the State claimed \$11.9 million (\$6.5 million Federal share) in unallowable TCM costs.

We recommended that the State (1) refund to the Federal Government the \$6.5 million for unallowable TCM services, (2) review TCM claims submitted subsequent to our audit period and report any necessary adjustments, and (3) ensure that future TCM services claimed under the Medicaid program are properly documented in accordance with Federal and State requirements. The State partly agreed and partly disagreed with our findings. Based on additional documentation provided by the State, we revised our report and recommendations to reflect that we are questioning 15 sampled beneficiary-months with 36 errors. (A-03-06-00202)

Nursing Homes: Long-Term Care, Managed Care Program Costs Claimed by Utah

Utah did not ensure that payments made under nonrisk contracts for long-term care services were equal to or less than the upper payment limits. Under a nonrisk contract, the contractor (1) is not at financial risk for changes in utilization or for service costs incurred that are equal to or less than the upper payment limits specified in Federal regulations and (2) may be reimbursed by the State for the incurred costs, subject to

specified limits. Because the State could not ensure that the costs claimed for long-term care services were equal to or less than the upper payment limits, we were unable to express an opinion on the \$27.4 million of Federal reimbursement that the State received for the costs of long-term care services for the period July 1, 2000, through December 31, 2005. Therefore, we set aside these costs for adjudication by CMS.

We recommended that the State work with CMS to (1) resolve the allowability of \$27.4 million in Federal reimbursement for long-term care services and (2) review claims subsequent to our audit period through the end of the program in 2007 and return to CMS any overpayments identified subject to the upper payment limits. The State did not concur with our findings or recommendations. After reviewing the State's comments, we slightly modified our second recommendation. However, the State did not provide information that caused us to change our findings or remaining recommendation. (A-07-08-02719)

Prescription Drugs: Accuracy of Drug Categorizations for Medicaid Rebates

We found that manufacturers typically categorize their drugs in the average manufacturer price (AMP) file in the same manner as national compendia. However, our manual review of drug categorizations identified (1) a potential problem with Medicaid payment for drugs that do not have Food and Drug Administration (FDA) approval and (2) instances in which certain drugs appear to have been categorized incorrectly in the AMP file, thus resulting in a loss of rebates for States.

For Federal payments to be available for covered outpatient drugs provided under Medicaid, drug manufacturers must pay quarterly rebates to State Medicaid agencies and provide CMS with the AMP for each national drug code (NDC) they market. In addition, for Medicaid Federal payment to be available, most covered outpatient drugs must be approved by FDA for safety and effectiveness, with certain exceptions.

Drugs with matching drug categorizations accounted for 90 percent of NDCs and 97 percent of Medicaid expenditures under review. However, a manual review of 75 high-expenditure nonmatching NDCs revealed that over 40 percent of the NDCs that underwent manual review were associated with unapproved drugs.

Based on the findings of this report, we recommended that CMS (1) work closely with FDA to identify drugs not approved for safety and effectiveness by FDA and therefore potentially ineligible for Medicaid Federal financial participation; (2) work with manufacturers to determine the correct categorizations of the drugs identified in this report as potentially miscategorized in the AMP file; and (3) continue to explore and undertake a range of efforts to ensure that drug manufacturers are submitting the required AMP data in a timely manner, including collaborating with OIG on administrative remedies for noncompliance.

In its response to our final report, CMS concurred with our three recommendations. Further, CMS did note that it reaffirms its intention to continue working to improve each of the three areas identified by OIG. (OEI-03-08-00300)

Prescription Drugs: Medicaid Outpatient Drug Expenditures

In separate reviews of Medicaid outpatient prescription drug expenditures, we found that three States had claimed Federal reimbursement for expenditures that did not fully comply with Federal requirements. Medicaid generally covers outpatient drugs if the drug manufacturers have rebate agreements with CMS and pay rebates to the States. Under the Medicaid drug rebate program, CMS provides the States with a quarterly Medicaid drug tape, which lists all covered outpatient drugs, indicates each drug's termination date if applicable, and specifies whether FDA has determined the drug to be less than effective. CMS guidance instructs the States to use the tape to verify coverage of the drugs for which they claim reimbursement.

Our specific findings were as follows:

■ **California** – For FYs 2004 and 2005, California claimed \$24 million (Federal share) for unallowable Medicaid expenditures, which included \$21 million in unsupported drug expenditures and \$3 million in drug expenditures that were not eligible for Medicaid coverage because the drugs were dispensed after their termination dates. In addition, the State claimed \$10.9 million (Federal share) for drug products not listed on the quarterly drug tapes for which the State did not provide conclusive evidence that the drugs were eligible for Medicaid coverage.

We recommended that the State (1) refund \$24 million (Federal share) to the Federal Government for unallowable drug expenditures, (2) work with CMS to resolve \$10.9 million (Federal share) in expenditures for drug products that were not listed on the quarterly tapes and that may not have been eligible for Medicaid coverage, and (3) strengthen and establish internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements. The State agreed to work with CMS to resolve the issues regarding drugs not listed on the quarterly drug tapes and disagreed with our internal control recommendations related to maintaining documentation and retaining funding codes. The State did not provide any new information to cause us to modify our recommendations. (A-09-07-00039)

■ **Michigan** – Michigan claimed Medicaid reimbursement for \$106,000 (Federal share) in FY 2005 for outpatient expenditures for drug products that were not eligible for Medicaid coverage because they were dispensed after their termination dates or less than effective. In addition, the State claimed \$2.9 million (Federal share) for drug products that were not listed on the CMS quarterly drug tapes. Because the State did not verify whether the drugs missing from the tapes were eligible for Medicaid coverage, these drug expenditures may not be allowable for Medicaid reimbursement.

We recommended that the State (1) refund \$106,000 to the Federal Government for drug expenditures that were not eligible for Medicaid coverage, (2) work with CMS to resolve \$2.9 million in payments for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid reimbursement, and (3) strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements. The State concurred with our first and second recommendations and

described corrective actions that it had taken to strengthen its internal controls.
(A-05-08-00048)

■ **New York** – New York State claimed Medicaid reimbursement for \$1.2 million (Federal share) in FYs 2004 and 2005 for outpatient expenditures for drug products that were not eligible for Medicaid coverage because they were dispensed after their termination dates, less than effective, or inadequately documented. In addition, the State claimed \$16.2 million (Federal share) for drug products that were not listed on the CMS quarterly drug tapes. Because the State did not verify whether the drugs missing from the tapes were eligible for Medicaid coverage, these drug expenditures may not be allowable for Medicaid reimbursement.

We recommended that the State (1) refund \$1.2 million to the Federal Government for drug expenditures that were not eligible for Medicaid coverage, (2) work with CMS to resolve \$16.2 million in payments for drugs that were not listed on the quarterly drug tapes and that may not have been eligible for Medicaid reimbursement, and (3) strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements. The State generally agreed with our recommendations. (A-02-07-01028)

Laboratories: Potential Improper Medicaid Payments for Outpatient Clinical Diagnostic Laboratory Services for Dual-Eligible Beneficiaries

We determined that Medicaid programs in 8 of 11 selected States spent a total of \$1.3 million in potential improper payments for clinical diagnostic laboratory services that were provided on an assignment-related basis to dual eligibles in FY 2005 and 2006. Dual eligibles are beneficiaries who are enrolled in Medicare Part A and/or Part B and also entitled to some Medicaid benefits. Over half of the potential improper payments we identified corresponded to five Current Procedural Terminology codes. One of these codes accounted for almost 30 percent of the potential improper payments we identified. State Medicaid programs should not pay for any portion of outpatient clinical diagnostic laboratory services that were provided on an assignment-related basis to dual eligibles who are enrolled in Medicare Part B.

This memorandum report had no recommendations. Our results demonstrated that opportunities exist to educate State Medicaid programs that they should not pay for any portion of outpatient clinical diagnostic laboratory services provided to dual-eligible beneficiaries. CMS did not have any comments on this memorandum report.
(OEI-04-07-00340)

Excluded Services: Medicaid Services to Incarcerated Juveniles in Georgia

For Federal FYs 2003 and 2004, the Georgia Medicaid agency inappropriately claimed \$3.8 million (\$2.3 million Federal share) in costs relating to non-inpatient medical services provided to juvenile inmates of public institutions because neither the Georgia Department of Juvenile Justice (DJJ) nor the Medicaid agency had adequate controls to ensure that those services were excluded from Federal financial participation.

We recommended that the Medicaid agency refund the \$2.3 million overpayment, identify and refund overpayments made subsequent to our audit, and establish monitoring procedures to ensure the accuracy of Medicaid eligibility status codes. The Medicaid agency requested that we delay the release of our report until April 2009 to give it “the opportunity to review each claim considered ‘erroneously reimbursed.’” We delayed issuance of our report; however, neither DJJ nor the Medicaid agency provided additional support for their assertion that juveniles voluntarily residing at the institutions were included in our overpayment calculation. (A-04-06-00026)

Family Planning: Services Claimed Twice in Michigan

For FYs 2006 and 2007, Michigan claimed and received \$1.1 million (\$1 million Federal share) in unallowable reimbursement for family planning services that it claimed more than once. Our review showed that some services were claimed twice on behalf of the same beneficiaries on the same dates of service. The State reported the claims twice because the computer system that it used to report family planning services inappropriately compiled the same claim data from a report that identified family planning services for all places of service and another report that identified services only at family planning clinics.

We recommended that the State refund \$1 million to the Federal Government for the unallowable duplicate Medicaid costs claimed from October 2005 through September 2007 and review family planning services claimed during the period January 2001 through September 2005 and for the period after September 2007 and refund to the Federal Government any Federal reimbursement for additional costs claimed more than once. The State concurred with our recommendations. (A-05-08-00064)

Medicaid Administration: Calculations of Additional Medicaid Funds Under the American Recovery and Reinvestment Act

In two reviews during this semiannual period, we evaluated HHS’s compliance with certain provisions of the Recovery Act, which provides 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 \$87 billion in additional Medicaid funding based on temporary increases in States’ Federal medical assistance percentages (FMAP). The Federal Government pays its share of States’ medical assistance expenditures based on the FMAP, which varies depending on each State’s relative per capita income.

- The first report found that the Office of the Assistant Secretary for Planning and Evaluation (ASPE) calculated the temporary FMAP increases for the first two quarters of FY 2009 for the 50 States and the District of Columbia in accordance with the Recovery Act. ASPE provided these FMAP increases to CMS for use in determining the amount of Federal funds to award to States through the Medicaid grant process. This report contained no recommendations. (A-09-09-00075)

■ The second report found that for the first two quarters of FY 2009, CMS calculated the additional Medicaid funding awarded under the Recovery Act in accordance with the Social Security Act and the Recovery Act. To calculate the additional funding for each State and the District of Columbia, CMS used the State-reported actual or estimated expenditures, deducted the expenditures identified in section 5001(e) of the Recovery Act (to which the increased FMAPs do not apply) if the State reported the expenditures, and multiplied the remaining expenditures by the correct percentage-point increase in the FMAP provided by ASPE. Based on its calculations, CMS made available to States approximately \$15.2 billion in additional funding for the first two quarters of FY 2009. This report contained no recommendations. (A-09-09-00080)

Medicaid Administration: Fraud and Abuse Safeguards for State Medicaid Nonemergency Medical Transportation Services

OIG found that States concentrate their Medicaid nonemergency medical transportation (NEMT) safeguard activities on screening providers, requiring prior approval for services, and implementing methods to prevent and detect improper payments. Depending upon the State, responsibility for conducting these activities lies with the State Medicaid agency itself, other State agencies, contracted transportation brokers, or some combination of these entities. The 29 States that use brokers to administer their NEMT benefit reported using multiple techniques to monitor their brokers, including complaint investigation, periodic contract renewal, and broker reporting requirements.

Federal regulations require each State to ensure that Medicaid beneficiaries have necessary transportation to and from medical providers and to describe, in their State plans, the methods that the State will use to meet this requirement. Federal regulations also require that each State Medicaid agency establish an integrity program for identifying and investigating suspected fraud and abuse cases and referring them to law enforcement. If a State detects evidence of potential fraud and abuse, it must refer those cases to the State Medicaid Fraud Control Unit (MFCU) or other appropriate law enforcement agency, such as a local district attorney, for investigation.

OIG also found that State MFCUs investigated a combined total of 509 NEMT fraud and abuse cases from 2004 to 2006, with the most common types involving billing for services not rendered, unspecified overbilling, and upcoding. Of the 509 cases reported by State MFCUs, 73 percent were closed and the remaining 27 percent were open at the time the State MFCUs submitted data to OIG during the second half of 2007. Among the closed cases, 40 percent were dismissed because the allegations were unsubstantiated after investigation and another 18 percent were investigated and closed without prosecution. Twelve percent of closed cases resulted in criminal convictions, and parties agreed to settlements in another 10 percent of closed cases. This memorandum report contained no recommendations. (OEI-06-07-00320)

Medicaid Administration: Managed Care Encounter Data Collection and Use

We found that all 40 States with capitated Medicaid managed care collect encounter data from managed care organizations (MCO); however, the usefulness of the Medicaid

Statistical Information System (MSIS) is limited because CMS does not enforce encounter data requirements. The Balanced Budget Act of 1997 (BBA) requires that Medicaid claims submitted to CMS “on or after January 1, 1999, provide for electronic transmission of claims data in the format specified by the Secretary [of Health and Human Services] and consistent with the MSIS (including detailed individual enrollee encounter data and other information that the Secretary may find necessary).”

As the only national database of Medicaid claims and beneficiary eligibility information, the MSIS is used by CMS to manage, analyze, and disseminate information on Medicaid beneficiaries, services, and payments. The MSIS is also widely used for research and policy analysis by both public and private organizations, and may also be used for detecting fraud, waste, and abuse. The MSIS must include encounter data to be representative of Medicaid beneficiaries because over 65 percent of Medicaid beneficiaries receive all or part of their health care services through Medicaid managed care.

State Medicaid agency staff in 39 of the 40 States with capitated Medicaid managed care reported using the encounter data that they collect to manage their Medicaid managed care programs. To ensure the successful collection of encounter data from MCOs, most States have established reporting requirements that dictate the format, frequency, and/or validation expectations of the data. States have also established incentives and/or sanctions related to encounter data reporting.

State Medicaid agency staff indicated that they would welcome information about how other States are using the data and additional guidance from CMS regarding encounter data. However, although all States with Medicaid managed care are collecting encounter data from MCOs, CMS accepted MSIS submissions without encounter data from 15 States. The usefulness of the MSIS is limited by the absence of encounter data and CMS staff indicated that encounter data are needed to measure what Medicaid is paying for.

We recommended that CMS clarify and enforce existing Federal requirements that States include encounter data in their MSIS submissions. CMS concurred with these two recommendations. We also recommended that CMS seek legislative authority to impose sanctions against States that fail to meet the MSIS reporting requirements for encounter data, to which CMS responded that it did not concur at that time. CMS stated that it wants to pursue efforts that address our first two recommendations before considering seeking sanction authority. (OEI-07-06-00540)

Medicaid Administration: Indirect Costs Submitted by the New York State Department of Health on Behalf of the Office of Mental Retardation and Developmental Disabilities

The New York Office of Mental Retardation and Developmental Disabilities (OMRDD) did not maintain documentation to support its indirect administrative cost rate calculations. In addition, the New York State Department of Health (DOH) did not review OMRDD’s administrative costs before claiming them on the Form CMS-64.

As a result, \$8.1 million (\$4 million Federal share) of the \$9.7 million (\$4.8 million Federal share) in indirect administrative costs that DOH claimed from January 1, 2003, through June 30, 2006, was unallowable. OMRDD provides services to individuals, both Medicaid and non-Medicaid beneficiaries, with mental retardation and developmental disabilities under a cooperative agreement with DOH, which administers the State's Medicaid program. DOH reports the total of OMRDD's direct and indirect Medicaid administration costs for Federal Medicaid reimbursement.

We recommended that DOH refund \$4 million to the Federal Government and verify that Medicaid indirect costs billed by OMRDD are adequately supported. DOH concurred with our finding and recommendations. (A-02-06-01028)

Medicaid Administration: West Virginia's Retroactive Claims for Medicaid School-Based Services

The State did not fully comply with Federal requirements for an exemption to the 2-year limit for filing retroactive claims for Medicaid school-based services. A portion of the State's retroactive claim, \$4.1 million (Federal share), fell outside the required 2-year filing period because it related to expenditures made by the State in the quarters ending December 31, 2000, through June 30, 2001. Of this amount, \$2.3 million (Federal share) related to new cost components that were not in the original rates used to calculate the claims for school-based services and did not reflect the settlement of previously identified costs. As a result, the \$2.3 million (Federal share) was not exempt from the 2-year time limit and was therefore unallowable. The remaining \$1.8 million (Federal share) met the requirements for an exemption because it reflected the settlement of previously identified salary and fringe benefit costs.

We recommended that the State refund \$2.3 million (Federal share) for costs claimed after the 2-year filing limit that were not exempt and ensure that future claims comply with the limit. The State did not concur with our finding or recommendation. However, nothing in the State's comments gave us cause to modify our recommendation. (A-03-06-00201)

Medicaid Administration: Hurricane Katrina Related Uncompensated Care Claims

Under the Social Security Act, § 1115, CMS authorized certain States to operate an uncompensated care pool (UCCP) to reimburse providers for medically necessary services provided to Hurricane Katrina evacuees and affected individuals and to Hurricane Rita evacuees without other coverage. We evaluated UCCP reimbursement in two States.

■ **Alabama** – For services supplied through January 31, 2006, by five providers that received high UCCP reimbursement, the State generally claimed reimbursement in accordance with the approved section 1115 demonstration and UCCP plan. However, we found that nine claims totaling \$27,000 were unallowable because the individuals who received the services were not from an area affected by Hurricane Katrina or Rita,

had health care coverage under other programs, or did not provide addresses that could be used to establish eligibility. One other claim totaling \$16,000 was allowable as a UCCP claim, but the State inappropriately used this claim in its Medicaid disproportionate share hospital (DSH) calculation.

We recommended that the State (1) refund \$27,000; (2) consider reviewing the claims that were not included in our sample and, if appropriate, make a refund to CMS; and (3) determine the effect of incorrectly including a claim reimbursed under the UCCP in the hospital-specific DSH calculation and make an appropriate adjustment on its quarterly claim. The State concurred with our first recommendation and did not address our second recommendation. With respect to our third recommendation, the State said that the hospital would have received only a small payment from the inclusion of the UCCP claim in the DSH calculation. We revised our third recommendation in response to the State's comments. (A-04-08-03040)

■ **Louisiana** – Louisiana did not always claim reimbursement for services provided by a hospital in accordance with Federal and State laws and regulations or with the approved provisions of the UCCP plan. Of the \$8.3 million in costs claimed as of December 31, 2006, for services provided by the hospital, \$7.7 million was unallowable. The State claimed the unallowable costs because it (1) did not have procedures to ensure that it claimed uncompensated care costs only for services covered under the Medicaid plan, (2) did not instruct the hospital to analyze its uncompensated care claims to determine whether payments had been received from other sources, (3) relied on the hospital to verify that the costs claimed were based on actual inpatient days, and (4) did not have procedures to ensure that it identified all duplicate claims.

We recommended that the State refund to CMS the \$7.7 million in unallowable costs claimed. Because the State's authorization to obtain Federal reimbursement for hurricane-related uncompensated care has ended, we made no procedural recommendations. The State disagreed with our findings and recommendation. Nothing in the State's comments caused us to revise our report. (A-06-08-00023)

Medicare and Medicaid Information Systems and Data Security Reports

Information Systems: Usefulness of Medicaid Statistical Information System Data for Detecting Medicaid Fraud, Waste, and Abuse

We determined that Medicaid Statistical Information System (MSIS) data were not timely, accurate, or comprehensive for detection of fraud, waste, and abuse. The MSIS is the only source of nationwide Medicaid claims and beneficiary eligibility information. CMS collects MSIS data directly from States to, among other things, assist in detecting fraud, waste, and abuse in the Medicaid program. Timely, accurate, and comprehensive MSIS data can assist HHS in meeting Health Care Fraud Prevention and Enforcement Action Team (HEAT) objectives to combat health care fraud.

We analyzed State submission and CMS release of FYs 2004 through 2006 quarterly MSIS files; CMS's disclosure and documentation of MSIS error tolerance adjustments; and the data elements captured by MSIS to determine its usefulness for detecting fraud, waste, and abuse. We determined that during FYs 2004 through 2006, MSIS data were an average of 1½ years old when they were released to all users. In addition, CMS did not fully disclose or document information about the accuracy of MSIS data. Furthermore, as of June 2009, the MSIS had not captured many of the data elements that can assist in fraud, waste, and abuse detection.

Our results indicate opportunities for States and CMS to reduce the timeframes for file submission and validation, respectively. Further, there are opportunities for CMS to improve the documentation and disclosure of error tolerance adjustments and expand current State Medicaid data collection and reporting to further assist in fraud, waste, and abuse detection and meet HEAT objectives. This report was issued directly in final form because it contained no recommendations. (OEI-04-07-00240)

Inaccurate Data in the Provider Enrollment, Chain, and Ownership System Individual Global Extract File

During data collection for an upcoming study entitled "Reassignment of Medicare Benefits" (OEI-07-08-00180), we identified inaccurate data in the Provider Enrollment, Chain, and Ownership System (PECOS) Individual Global Extract File (the Extract). The Extract is designed to provide a point-in-time snapshot of all PECOS data on active providers and their active reassignments of benefits (reassignments). The inaccurate data we identified limited the usefulness of the Extract, requiring us to search the PECOS database for the individual records of 497 Medicare providers in our study sample to verify the accuracy of the Extract data. CMS staff investigated and confirmed the errors that we identified and indicated that they would conduct further research to determine the exact cause of errors in the Extract. CMS staff also indicated that they would add information regarding the inaccurate data to their tracking log for PECOS and prioritize identifying solutions in a future release of PECOS, although they did not indicate when the solutions would be implemented.

We found two types of errors. One type of error resulted in records of terminated reassignments being retained in the Extract, which should have contained only records of reassignments that were active on the date the Extract was created. We found that 3.2 percent of the records present in the Extract were affected by this type of error. The second type of error we identified occurred when the date that the reassignment record was created in PECOS populated the effective date field in the Extract, rather than the date the reassignment took effect.

To limit the impact of the inaccurate data, CMS may want to alert all users of the Extract of the extent and nature of data inaccuracies in the Extract until a corrected version of PECOS is released. When correcting the processing errors, CMS may also want to explore whether other inaccuracies exist in the Extract, such as the Organizational Global Extract file containing similar inaccuracies, other date fields populating incorrectly, and records of disenrolled providers remaining in the Extract. (OEI-07-08-00181)

Other CMS Related Reports

Nursing Home Corporations Under Quality of Care Corporate Integrity Agreements

OIG found that all 15 corporations included in this review enhanced quality of care structures and processes while under their corporate integrity agreements (CIA) and cited positive effects of the CIAs. All 15 corporations had written policies and procedures regarding quality of care, codes of conduct, and training required by their CIAs; monitored their quality of care using standardized data and internal self-assessment tools and by tracking complaints; and created or expanded their compliance infrastructures to integrate quality of care. This review included all nursing homes that were placed under CIAs between June 2000 and December 2005.

Under quality of care CIAs, nursing home corporations with identified quality of care problems consent to certain requirements in exchange for an agreement by OIG not to exclude them from participation in Federal health care programs. A nursing home quality of care CIA is a contract that is typically entered into for 3 to 5 years and requires implementation of quality of care structures and processes and monitoring by an independent quality monitor.

Despite some initial resistance from 3 corporations, OIG found that all 15 corporations were ultimately responsive to quality monitors' guidance and corporate representatives reported that they valued the input. OIG's review of quality monitoring reports and corporate annual reports confirmed the monitors' opinions that the 15 corporations were largely responsive to their guidance. Corporate representatives cited several benefits of quality monitoring; for example, monitors offered new ideas and fresh ways of thinking about quality of care structures and processes.

Representatives of all 15 corporations described challenges they encountered when implementing the CIA requirements. Corporations with multiple nursing homes encountered challenges in ensuring consistency in quality of care systems across all layers of their organizations and across geographic regions. For example, an analysis of Quality Assessment and Assurance (QAA) committee minutes indicated that nursing homes' implementation of quality of care systems was inconsistent. Other challenges involved organizational disruptions, such as sales and purchases of nursing homes or corporate level reorganizations, staff resistance to implementation, use of staff time to implement the CIA requirements, and costs associated with CIAs.

Based on these findings, areas that OIG will explore for its oversight of future CIAs include: responding swiftly to noncompliant corporations and those that fail to address quality problems, including in the CIAs specific requirements for documentation of nursing home QAA activities, and sharing lessons learned by corporations and quality monitors with other corporations placed under subsequent CIAs. (OEI-06-06-00570)

Emergency Health Services Furnished to Undocumented Aliens Covered by Section 1011 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Of the 31 sampled claims submitted by a Florida hospital for services provided under section 1011 of the MMA for the period May 10 through September 30, 2005, 24 claims totaling \$93,000 were either partially or completely unallowable for section 1011 program reimbursement. As a result, the hospital received \$67,000 in unallowable payments. Section 1011 of the MMA provided \$250 million per year for FYs 2005 through 2008 for payments to eligible providers for emergency health services provided to undocumented aliens and other specified aliens pursuant to Emergency Medical Treatment and Labor Act of 1986 (EMTALA) requirements.

We recommended that the hospital (1) refund to its program contractor \$67,000 for services that did not meet section 1011 reimbursement requirements; (2) review the remaining claims for our audit period totaling \$82,000 and claims for subsequent periods and submit adjustments for any claims that did not meet section 1011 reimbursement requirements; (3) follow its existing policies and procedures to ensure that future section 1011 program claims meet section 1011 reimbursement requirements; and (4) develop and implement procedures to ensure that section 1011 program claims are for covered services up to the point of stabilization rather than through the patients' entire hospital stays.

The hospital did not directly address our first three recommendations. Regarding the fourth recommendation, the hospital said that it had modified its internal processes and would ensure that all future claims are not billed past the point of stabilization. Nothing in the hospital's comments caused us to revise our findings or recommendations.
(A-04-06-07007)

Medicare and Medicaid Related Outreach

As part of OIG's ongoing efforts to promote the highest level of ethical and lawful conduct by the health care industry, we have continued to 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 HIPAA, OIG, in consultation with the Department of Justice (DOJ), issues advisory opinions to outside parties regarding the interpretation and applicability of certain statutes relating to Federal health care programs. This authority allows OIG to provide case-specific formal guidance regarding the application of the anti-kickback statute and safe harbor provisions and other OIG health care fraud and abuse sanctions. For the period April 1 through September 30, 2009, OIG received 22 advisory opinion requests and issued 15 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 guidelines, entitled “Provider Self-Disclosure Protocol,” give providers an opportunity to minimize the potential costs and disruption that a full-scale OIG audit or investigation may 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.

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 corporate integrity agreement (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 another Open Letter to Health Care Providers on March 24, 2009, that narrowed the scope of the self-disclosure protocol regarding 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 \$12.7 million in HHS receivables. The following are examples:

■ **Louisiana** – Walgreen Louisiana Co. (Walgreen) agreed to pay \$1,053,774 to settle its liability under OIG’s Civil Monetary Penalties Law (CMPL) authority for allegedly employing an individual who Walgreen knew or should have known was excluded from participation in Federal health care programs. As reported under OIG’s Provider Self-Disclosure Protocol, Walgreen submitted to Medicare, Medicaid, and TRICARE claims for prescriptions filled by an excluded pharmacist who had applied for his job using his middle name, thereby allegedly obscuring his excluded status. However, if Walgreen had checked his pharmacy license, as it is required to do, it would have uncovered his first name, under which he was excluded. The State of Louisiana was a party to the settlement agreement and released its administrative claims.

■ **New Mexico** – The University of New Mexico Health Sciences Center and UNM Medical Group, Inc., the billing agent for professional services rendered by physicians and other medical providers associated with the University of New Mexico Health Sciences Center (collectively, UNMHSC), agreed to pay \$200,000 to settle its potential FCA liability for employing two excluded individuals. Specifically, as disclosed under OIG’s Provider Self-Disclosure Protocol, UNMHSC employed an excluded individual in an administrative position between March 2001 and February 2004 and employed an excluded physician between August 2004 and August 2005. As part of the settlement agreement, UNMHSC signed a certification relating to its practices designed to prevent hiring, contracting, or employing any excluded individuals.

■ **Pennsylvania** – St. Mary Medical Center (SMMC) agreed to pay \$172,617 to resolve its CMPL liability for billing for items and services provided by an excluded emergency department nurse employee. SMMC self-disclosed that it had employed an excluded individual as an emergency department nurse from June 20, 2005, until December 17, 2007. Prior to hiring this individual in 2004, SMMC completed a preemployment screening that accurately reflected that the individual was not excluded at that time. The individual subsequently was excluded on June 20, 2005. SMMC disclosed that its CMPL liability began on October 22, 2005, the date that it should have known that the individual was excluded, based upon an annual screening completed by a third-party contractor. SMMC terminated the individual’s employment on December 17, 2007.

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 physician self-referral statute, or the “patient dumping” provision of the Social Security Act.

During this reporting period, OIG administered 1,166 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 reporting period, OIG excluded 1,141 individuals and entities from participating in 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. Examples follow:

- **California** – The president and chairman of the board of Pleasant Care Corporation (Pleasant Care), Emmanuel Bernabe, agreed to be permanently excluded from Federal health care programs following an investigation of substandard care at nursing homes formerly operated by Pleasant Care. Until March 2007, Pleasant Care was the second largest nursing home chain in California, operating more than 29 facilities in 14 counties. The exclusion of Bernabe is the result of an OIG investigation of allegations of substandard care provided at Pleasant Care-operated nursing facilities between 2003 and 2007. OIG alleged that Bernabe, through his management and oversight of Pleasant Care, caused services to be furnished to Pleasant Care residents that substantially departed from the professional standard of care. The alleged failures put residents at risk for harm and included the failure to maintain adequate staffing levels, properly administer medication, provide adequate hydration and nutrition, and prevent accidents.
- **Alabama** – Pediatrician Michael Sharpe was excluded indefinitely based on his voluntary surrender of his license to practice medicine while under investigation for allegations of sexual misconduct involving a minor.
- **Multi-State** – Eleven individuals were excluded for various periods, ranging from 5 to 40 years, based on their convictions in a conspiracy scheme that involved the purchase and sale of counterfeit, misbranded, or illegally imported drugs not intended or approved for distribution in the United States. In addition, OIG continues to review other potential exclusion cases associated with this fraud scheme. The names and periods of exclusion of those already excluded as part of this investigation include Michael Carlow and Julio Cruz, 40 years; Noah Salcedo-Smith and Christopher Lamoreaux, 35 years; Alexander Nassar, 30 years; Paul Kriger, 25 years; Salvatore Esposito, 20 years; Frank Ianneillo, 15 years; and Douglas Albers, Richard Rounsborg, and Robert Spence, 5 years. Defendants convicted in this fraud scheme have been sentenced to various periods of incarceration and/or home detention and ordered to pay restitution amounts ranging from approximately \$680,000 to over \$4 million.
- **California** – Kyon Maung Teo, a dentist and owner of a dental practice, and his wife and office manager, Kin Thor Pang, were excluded for a minimum of 30 years based on

their health-care-related convictions in a \$4.5 million Medi-Cal fraud scheme. From November 1999 to December 2003, Teo and Pang submitted false claims to Medi-Cal for dental procedures that were medically unnecessary or were not performed. In State court, Teo and Pang pleaded no contest and agreed to pay \$3 million, half of which will cover the cost of the investigation and the costs of the victims' corrective dental treatment. Teo and Pang were also sentenced to 1 year and 360 days of incarceration, respectively.

■ **California** – Alberto Miguel Otiniano, a certified nursing assistant, was excluded for a minimum of 15 years based on his conviction related to patient abuse. Otiniano sexually assaulted three patients, one of whom was on pain medication and in and out of consciousness at the time of the assault. Otiniano was sentenced to 6 years of incarceration and his license to practice as a certified nursing assistant was revoked by the California Department of Public Health.

■ **New York** – Patricia Villegas, an unlicensed esthetician, was excluded for a minimum of 15 years based on her health-care-related conviction. A New York State jury trial showed that Villegas caused serious injury to two of her clients when she injected a silicone-type substance into their faces. Villegas's actions caused deformities, impairment, and permanent scarring to her clients' faces, requiring them to undergo multiple reconstructive surgeries. Villegas was sentenced to 5 years of incarceration.

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 \$5.2 million in CMPs and assessments. The following are among the CMP actions resolved during this reporting period:

■ **Nevada** – West Valley Imaging Limited Partnership; William L. Boren, M.D.; Luke S. Cesaretti, M.D.; and Sundant Limited Partnership (collectively, West Valley) agreed to pay \$2 million plus interest and to enter into a 5-year integrity agreement for allegedly violating the CMPL. West Valley allegedly performed radiology tests and exams that were not ordered by Medicare beneficiaries' treating physicians. The integrity agreement requires an annual independent review organization (IRO) claims review and a quarterly IRO review of paid claims submitted by West Valley to determine whether West Valley complied with applicable rules and procedures relating to obtaining and maintaining treating physician orders for all diagnostic services provided to Medicare beneficiaries.

Patient Dumping

Some of the CMP cases that OIG resolved between April 1 and September 30, 2009, were pursued under EMTALA, a statute designed to ensure patient access to appropriate emergency medical services. The following are examples of settlements under this statute:

■ **Florida** – Palms West Hospital paid \$50,000 to resolve allegations that it refused to accept requests to transfer two individuals at emergency departments at nearby hospitals. In both instances, the individuals had unstable emergency medical conditions that the transferring hospital could not stabilize. The first instance involved a 38-year-old woman with a suspected ectopic pregnancy. The obstetrician/gynecologist refused to accept the transfer of this patient because he felt that the patient should be taken to a hospital closer to the transferring hospital. The second instance involved a 60-year-old man with a fracture/dislocation of his shoulder. The on-call physician at Palms West Hospital refused to accept the transfer.

■ **Florida** – Plantation General Hospital paid \$40,000 to resolve allegations that it failed to provide an appropriate medical screening examination, stabilizing treatment, and/or an appropriate transfer to a 22-year-old pregnant woman who presented to its ED. The woman told the ED staff that her doctor said she could deliver any time and that she was leaking fluid and having contractions. A nurse called the woman's doctor and told him that the patient appeared stable (without having examined the patient). The nurse then reported to the woman that she had to go to another hospital, about a half hour away, to deliver her child. When the woman expressed worry about whether she could get to the other hospital in time and requested ambulance transport, the nurse told her that she could not help her and that she must go to the other hospital. A friend drove the woman at very high speeds to the other hospital where she delivered shortly after arrival.

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 integrity agreements 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 FY 2009, the Government's enforcement efforts resulted in 515 criminal actions and 387 civil actions against individuals or entities that engaged in health-care-related offenses. These efforts resulted in \$3 billion in HHS and \$985.7 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 6-month 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 Health and Human Services 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 existing programs, as well as investing in new resources and technologies, to prevent and combat fraud, waste, and abuse. As a key component of its efforts, the HEAT taskforce utilizes and supports the joint HHS-DOJ Medicare Fraud Strike Force teams in South Florida and Los Angeles, operating since 2007 and 2008, respectively, and Detroit and Houston, created in 2009. These teams have a proven record of success analyzing real-time data to quickly identify and prosecute fraud almost as it occurs. The Strike Force teams coordinate law enforcement operations with other Federal, State, and local law enforcement entities.

During this reporting period, Strike Force efforts have resulted in the filing of charges against 138 individuals or entities, 44 convictions, and \$40.7 million in investigative receivables. Examples of Strike Force efforts during this reporting period follow:

■ **Florida** – Seven Miami-area residents were sentenced to prison terms ranging from 37 to 97 months and ordered to pay restitution amounts ranging from \$747,433 to \$12,464,499, for a total of \$19,816,398, in connection with a Medicare fraud scheme involving human immunodeficiency virus (HIV) infusion services. The seven defendants pleaded guilty to conspiracy to commit health care fraud. All seven co-conspirators worked at Midway Medical Center, Inc. (Midway), a Miami clinic that purportedly provided injection and infusion treatments to patients with HIV. Most of the services allegedly provided to patients at Midway were billed to the Medicare program as treatments for a diagnosis of thrombocytopenia, a disorder involving a low count of platelets in the blood. None of the patients at Midway actually had low blood platelet counts. Midway laboratory technician Alexis Dagnesses admitted to manipulating patients' blood samples to make it appear that the patients had low blood platelet counts

before the blood was sent to a laboratory for analysis. Roberto Rodriguez and Carmen Del Cueto, part-owners and practicing physicians at Midway, admitted to prescribing medications designed to treat thrombocytopenia despite knowing that the laboratory results had been falsified and that the patients did not actually have that condition. Rodriguez, Del Cueto, and Carlos Garrido, also a part-owner and practicing physician at Midway, admitted to routinely billing Medicare for services that were medically unnecessary and, in many instances, never provided. Midway part-owner and operator Marcia Garcia admitted to conspiring with physicians in these fraudulent activities. Midway medical assistants Gonzalo Nodarse and Alexis Carrazana admitted to making false entries in medical records indicating that they had provided medications on particular dates and in particular dosages to patients when, in fact, they had not provided medications.

■ **California** – Melkon Gabrielyan was sentenced to 54 months’ incarceration and ordered to pay \$807,000 in restitution pursuant to his guilty plea to health care fraud and aggravated identity theft. As the owner and operator of durable medical equipment company, TA Medical Supply, Gabrielyan admitted that beginning in January 2004, he fraudulently billed Medicare for durable medical equipment purportedly supplied to beneficiaries. Gabrielyan submitted claims to Medicare for items such as orthotic braces and power wheelchairs that were not delivered, were not prescribed by the physicians listed on the claims, or were not medically necessary. In addition, Gabrielyan acknowledged that he knowingly and willfully stole the identity of a Medicare beneficiary for the purpose of submitting false claims.

■ **Florida** – Pedro Gonzalez and William Sosa were each sentenced to 33 months of imprisonment and ordered to pay joint and several restitution of \$714,208 after pleading guilty to health care fraud and conspiracy to commit health care fraud. Gonzalez and Sosa controlled and operated P & W Medical Equipments, Inc. (P & W Medical), a DME provider, from June 2002 through October 2004. During that time, P & W Medical billed Medicare for orthotic devices that were neither prescribed by physicians nor received by beneficiaries.

Laboratories

■ **New York** – Quest Diagnostics Incorporated (Quest) and its wholly owned subsidiary, Nichols Institute Diagnostics (NID), entered a \$302 million global criminal and civil settlement to resolve allegations raised in a qui tam complaint concerning various types of diagnostic test kits that NID manufactured, marketed, and sold to laboratories throughout the country between May 1, 2000, and April 30, 2006. As part of the criminal resolution, NID pleaded guilty to a felony misbranding violation of the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) relating to NID’s Nichols Advantage Intact Parathyroid Hormone Immunoassay, a test used by laboratories throughout the country to measure parathyroid hormone (PTH) levels in patients. As part of the plea, NID agreed pay a criminal fine of \$40 million. Quest also entered into a nonprosecution agreement with the United States. As part of the civil settlement, Quest, as the parent company of NID, agreed to pay \$262 million plus interest to resolve FCA allegations relating to the Advantage Intact PTH assay and four other assays manufactured by NID that allegedly

provided inaccurate and unreliable results. Quest has also agreed to pay various State Medicaid programs approximately \$6.2 million to resolve similar civil claims. Quest entered a 5-year CIA that requires it to hire two independent review entities. Quest's board of directors (board) is required to hire a compliance expert to determine how compliance concerns are communicated to senior management and the board. The company is required to retain an independent review organization to review Quest's compliance with FDA Quality System Regulation and labeling requirements.

Hospitals

■ **Texas** – The Methodist Hospital (Methodist) agreed to pay the Government \$9,990,000 plus interest to resolve its liability under the FCA and other statutes for the submission of false claims to Medicare and TRICARE. The Government alleged that from January 1, 2001, through August 7, 2003, Methodist artificially inflated its cost-to-charge ratio through its cost reports, triggering payments exceeding those to which it was entitled.

■ **Ohio** – Regency Hospital Company, LLC; Regency Hospital of North Central Ohio, LLC; Regency Hospital of Odessa, LLLP; and Regency Hospital of Northwest Arkansas, LLC (collectively, Regency), agreed to pay \$9.8 million plus interest to resolve their potential FCA liability. Regency Hospital Company, LLC, owns and operates 23 long-term acute care hospitals (LTACH) in 10 States, including Regency Hospital of North Central Ohio, LLC (doing business as Regency Hospital of Akron and Regency Hospital of Ravenna); Regency Hospital of Odessa, LLP; and Regency Hospital of Northwest Arkansas, LLC (doing business as Regency Hospital of Springdale). The United States contended that Regency violated the FCA by falsely certifying that the average length of stay was greater than 25 days and, as a result, the LTACHs were reimbursed at the higher LTACH diagnosis-related group (DRG) rate when they were only entitled to be reimbursed at the acute care hospital DRG rate. Regency Hospital Company, LLC, also agreed to enter into a 5-year CIA.

Clinics

■ **Florida** – Jorge Ramirez was sentenced to 70 months of incarceration and ordered to pay \$4,028,994 in restitution following his guilty plea to health care fraud. Ramirez was the owner of the Rehabilitation Institute & Science Clinic (RISC), a clinic that purportedly provided Medicare beneficiaries with Imiglucerase, Rituximab, Octreotide, and other infusion medications used to treat HIV/AIDS, non-Hodgkin's lymphoma, and Gaucher's disease. From March 31 through November 7, 2005, Ramirez, on behalf of RISC, caused the submission of false and fraudulent claims for these drugs to Medicare.

■ **Georgia** – Alain Amador was sentenced to 52 months of incarceration and ordered to pay \$3,928,552 in restitution following his guilty plea to conspiracy to commit health care fraud. Amador and his co-conspirators set up a series of medical clinics that existed in name only. Amador, who has a nursing degree, was instrumental in leasing space in the names of the companies, opening bank accounts, incorporating the companies, and obtaining Medicare billing numbers for them. The co-conspirators also improperly

obtained identity information of actual doctors and Medicare patients. The fraudulent information was used to bill Medicare for infusion therapy services that were not rendered.

Nursing Homes

■ **Texas** – Regency Nursing and Rehabilitation Centers, Inc. (Regency), agreed to pay \$4 million plus interest to resolve its potential FCA liability for violations allegedly committed at 10 of its nursing facilities located in south, central, and east Texas. The allegations included submitting claims to Medicare and Medicaid for skilled services that were not medically necessary and/or were for patients that did not qualify for the claimed services. In addition, the Government alleged that Regency falsely certified on its cost reports that all services had been provided in accordance with all applicable laws and regulations.

Durable Medical Equipment Suppliers

■ **Florida** – A durable medical equipment company, Nationwide Medical, Inc. (Nationwide), and Howard Siegel agreed to pay the Government \$2 million for allegedly violating the anti-kickback statute. Between September 30, 2004, and June 25, 2007, Nationwide and Howard Siegel, President and Chief Executive Officer of Nationwide, allegedly entered into professional services agreements (PSA) with sleep labs and other health care providers (collectively, “sleep labs”) in multiple States. Under the PSAs, Nationwide provided continuous positive airway pressure (CPAP) devices and associated equipment to the sleep labs and paid the sleep labs a “set-up fee” each time a sleep lab provided Nationwide’s device and equipment to a patient. Nationwide submitted claims for reimbursement to Medicare for the delivery of the CPAP device and associated equipment, as well as for the monthly rental of the CPAP device and replacement supplies. Nationwide also entered into a 5-year CIA.

■ **Texas** – Aniekan Jonathan Ekwere, owner of Coastal Medical Supply, was sentenced to 18 months of incarceration and ordered to pay \$702,963 in restitution for health care fraud and conspiracy to commit health care fraud. Through his durable medical equipment company, Ekwere submitted claims to Medicare and Medicaid for reimbursement of motorized wheelchairs. In most cases, Ekwere provided Medicare and Medicaid recipients in both Texas and Louisiana either with less expensive scooters or nothing at all. As part of his scheme, Ekwere paid Jude Akpan, an employee of one of Texas’s largest not-for-profit hospital systems, for fraudulent prescriptions, certificates of medical necessity, and Medicare patient information. Akpan was sentenced to 5 years’ probation and ordered to pay restitution of \$19,221, joint and several with Ekwere, for receiving illegal kickbacks.

Prescription Drugs

■ **Kentucky** – Verlon Lane Pierce, a pharmacist, was sentenced to 6 months of home incarceration on charges of health care fraud and the sale of prescription drug samples. In addition, Pierce paid the United States \$850,000 as a criminal forfeiture of proceeds

from the criminal activity. He also paid the United States \$495,606 in an FCA settlement, making the combined criminal and civil recovery \$1,345,606. During his guilty plea, Pierce admitted that from January 1, 2001, through December 1, 2004, he defrauded health care benefit programs, including Medicaid, by unlawfully billing those programs for pharmaceutical drug samples provided to patients. Pierce also admitted he unlawfully purchased, sold, and traded prescription drug samples. Pierce's activities occurred in connection with his business, Medicine Arts Pharmacy.

■ **South Carolina** – The Medicine Dropper, Inc., and its pharmacist owners, John Frank Weeks and Derrelyn B. Weeks (collectively, Medicine Dropper), agreed to pay the United States \$500,000 plus interest to resolve allegations of violating the Controlled Substances Act (CSA), which was enacted as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, and applicable regulations and to settle allegations of violating the FCA for submitting false claims to Medicaid for prescriptions for three Medicaid recipients. The Government alleged that Medicine Dropper filled invalid Ketamine prescriptions and filled prescriptions that were not for a legitimate medical purpose. As part of the resolution of this matter, Medicine Dropper agreed to adopt reasonable and customary policies to prevent the use of its pharmacy for “doctor shopping,” fill prescriptions using the correct Drug Enforcement Administration number for the physician, ensure that all required elements of the prescription are present prior to dispensing, and no longer dispense Ketamine products.

■ **Massachusetts** – Pfizer, Inc. (Pfizer), entered into a \$1 billion civil FCA settlement with the United States in connection with Pfizer's marketing and promotion practices associated with the anti-inflammatory drug Bextra and several other drugs. The settlement agreement is part of a global criminal, civil, and administrative settlement with Pfizer and its subsidiary, Pharmacia and Upjohn Company, Inc., which also includes a comprehensive 5-year corporate integrity agreement between Pfizer and OIG.

The civil settlement agreement resolved allegations against Pfizer brought by relators in nine separate FCA qui tam cases. The relators generally alleged that Pfizer promoted Bextra and other drugs for uses that were not approved by FDA and that Pfizer provided illegal remuneration to health care professionals in connection with the promotion of the drugs. The civil settlement resolved allegations that Pfizer engaged in the improper marketing and promotion practices for the drugs at issue at various times between 2001 and 2008.

The CIA entered into between the OIG and Pfizer contains several provisions designed to promote corporate and individual accountability, increased transparency, and extensive monitoring of field and headquarters activities of Pfizer. The CIA also requires that Pfizer proactively identify potential risks associated with promoting individual products and that it implement a plan to mitigate the identified risks.

Practitioners

■ **Missouri** – Dr. Bic Stafford and Family Foot & Ankle Care, Ltd. (FFA), agreed to pay \$425,000 to resolve their liability under the FCA. From January 2003 to October 2008,

Stafford and FFA allegedly submitted claims to Medicare for complex podiatric surgical procedures when, in fact, only routine foot care was provided. As part of the settlement, Dr. Stafford agreed to be excluded from Federal health care programs for 5 years and FFA agreed to be permanently excluded.

Medicaid Fraud Control Units

MFCUs are key partners in the fight against fraud, waste, and abuse in State Medicaid programs. State MFCUs operate in 49 States and the District of Columbia pursuant to the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977 with the objective of strengthening the Government's capability to detect, prosecute, and punish Medicaid fraud. MFCUs investigate and prosecute, or refer for prosecution, providers charged with defrauding the Medicaid program or abusing, neglecting, or financially exploiting beneficiaries in Medicaid-sponsored facilities.

Since 1979, OIG has been responsible for administering the Medicaid fraud control grant program and providing oversight and guidance to State MFCUs. This involves administering Federal financial grants to MFCUs, assessing the performance of MFCUs, and partnering with MFCUs in conducting joint investigations and performing other outreach work. During FY 2008, OIG provided oversight for and administration of approximately \$184 million in Federal grants distributed to the 50 MFCUs.

Joint Investigations

■ **Indiana** – Dennis Lennartz was sentenced to 43 months of incarceration and ordered to pay \$964,852 in restitution for his guilty plea to health care fraud. The investigation revealed that Lennartz received payments from Medicaid by having his business partner bill for transportation services purportedly provided to Medicaid beneficiaries from August 2006 through December 2008. Lennartz had obtained approximately 160 Medicaid numbers of nursing home patients with developmental disabilities and used these numbers to submit the false claims to Medicaid. Lennartz, who was previously convicted of health care fraud, hid his involvement in the scheme by having the Medicaid provider number registered to one of his former employees. The investigation involved OIG, the FBI, and the Indiana MFCU.

■ **Texas** – Brothers Mazen and Wesam Abdallah were each sentenced to 30 months' imprisonment and were ordered to pay \$637,425 in joint and several restitution for their involvement in a scheme to defraud Medicare and Medicaid. After a 5-week trial in which more than 50 witnesses testified, a jury convicted both brothers of conspiracy to commit health care fraud and convicted Wesam Abdallah of additional charges of health care fraud and an anti-kickback violation. The Abdallahs owned and operated Americare Medical Service (Americare), an ambulance company that specialized in transporting dialysis patients to and from their treatments. Many of their patients did not qualify for transportation and either had no prescriptions or used prescriptions on which the doctors' signatures were either photocopied or procured by tricking doctors into signing the prescriptions. In addition, the Abdallahs recruited patients using public transportation manifests that they had purchased and by paying kickbacks to patients. Defendants Ayad

Fallah and Murad Almasri, who owned and operated Americare before selling it to Mazen Abdallah, were previously sentenced pursuant to their guilty pleas to conspiracy. Fallah and Almasri were each sentenced to time served and ordered to pay \$1,660,113 in joint and several restitution. A third previous owner of Americare was also charged but remains a fugitive. The investigation involved OIG, the FBI, the Internal Revenue Service (IRS), and the Texas MFCU.

■ **Rhode Island** – Carmine DeTomasio, a pharmacist and co-owner of Prime Drug, Inc. (Prime Drug), was sentenced to 1 year and 1 day of incarceration and ordered to pay \$404,125 in joint and several restitution for illegally buying and selling pharmaceuticals and defrauding health care insurers. DeTomasio's codefendant, Louis Romanelli, was sentenced to 30 months of imprisonment for his role in the scheme. DeTomasio supplied Romanelli with the drug Vicodin, which Romanelli then sold on the street. Prime Drug also purchased HIV/AIDS drugs and controlled prescription drugs from beneficiaries through Romanelli at one-third the cost of the purchase price from a legitimate drug wholesaler. Upon receiving the prescription drugs from Romanelli, Prime Drug repackaged them for redistribution to Medicare Part D and Medicaid beneficiaries at the full reimbursement rate. Additionally, DeTomasio also submitted false reimbursement claims to health insurance carriers for prescription drugs that the store had not dispensed. Further implicated in connection with the scheme was former North Providence Police officer Paul Vittorio, who had warned Romanelli that he might be under investigation and suggested that Romanelli move his operation. Vittorio also admitted trying to influence the testimony of a grand jury witness. Vittorio was sentenced to 5 months of imprisonment and ordered to pay a fine of \$17,627 for misprision of a felony, tampering with a witness, and making false statements. This investigation involved OIG, FDA, the Rhode Island MFCU, the U.S. Postal Inspection Service, the IRS, and the Drug Enforcement Administration.

■ **Maryland** – Chesapeake Youth Center (CYC), a former residential treatment center for adolescents, agreed to pay \$259,120 to resolve its potential FCA liability. The United States alleged that from January through July 2005, CYC submitted or caused to be submitted claims to Medicaid for inpatient adolescent psychiatric services that were not provided or were substandard or worthless. The investigation involved OIG, the Maryland MFCU, and the Civil Division of DOJ.

Public Health and Human Services Programs and Departmentwide Issues

Based on our available resources each fiscal year (FY), we allocate about 20 percent of our appropriations to reviews of the Department of Health and Human Services' (HHS) approximately 300 public health and human services programs and to departmentwide issues that affect more than one program. However, a portion of these resources is used for mandatory reviews, including financial statement audits conducted pursuant to section 405(b) of the Government Management Reform Act of 1994 (GMRA), the Chief Financial Officers Act of 1990 (CFO Act), and information systems reviews required by the Federal Information Security Management Act of 2002 (FISMA).

This chapter summarizes the Office of Inspector General's (OIG) reports related to public health and human services programs and departmentwide issues. It also provides statistics related to and examples of OIG actions and investigations related to public health and human services programs, describes actions taken on OIG's recommendations, and offers examples of OIG's review and clearance of regulations and guidance related to the Department's programs.

This chapter describes OIG's work related to the following areas:

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

- The Centers for Disease Control and Prevention (CDC) operates a system of health surveillance to monitor and prevent disease outbreaks, including those that would result from acts of bioterrorism; implements disease-prevention strategies; and maintains national health statistics.
- The Food and Drug Administration (FDA) is responsible for ensuring the safety of the Nation's food, drugs, medical devices, biologics, cosmetics, and animal food and drugs; and for ensuring the efficacy of the Nation's drugs, medical devices, biologics, and animal drugs.
- The Health Resources and Services Administration (HRSA) maintains a safety net of health services for people who have low incomes, are uninsured, or live in rural areas or urban neighborhoods where health care is scarce.
- The Indian Health Service (IHS) provides or funds health care services for 1.9 million American Indians and Alaska Natives.

- The National Institutes of Health (NIH) supports medical and scientific research examining the causes of and treatments for diseases such as cancer and HIV/AIDS.
- The Substance Abuse and Mental Health Services Administration (SAMHSA) funds services to assist people with or at risk for mental and substance abuse disorders.

Human services programs. Several HHS agencies support human services to assist vulnerable individuals of all ages, including the following:

- The Administration for Children and Families (ACF) operates more than 60 programs that promote the economic and social well-being of children, families, and communities, including Temporary Assistance for Needy Families (TANF), the national child support enforcement system, the Head Start program for preschool children, and programs relating to foster care and adoption services.
- The Administration on Aging (AoA) supports programs that provide services such as meals, transportation, and caregiver support to older Americans at home and in the community through a nationwide network of services for the aging.

Departmentwide issues. Certain OIG work cuts across HHS programs, including financial accounting, information systems management, and oversight of grants and contracts. Such work may relate to functions carried out by HHS's Program Support Center (PSC), which provides a wide range of administrative support to operating and staff divisions within the Department.

Public Health Related Reports

Emergency Preparedness: State and Local Pandemic Influenza Preparedness for Medical Surge

We found that although the selected States and localities that we reviewed are making progress in preparing for a medical surge, more needs to be done to improve States' and localities' ability to respond to an influenza pandemic.

A pandemic will affect much of the country at the same time, so medical resources such as hospital beds, medical equipment, and personnel will likely be scarce. The ability to rapidly respond to an increased demand for medical resources is often referred to as a medical surge. The recent public health emergency caused by an outbreak of human cases of H1N1 influenza has highlighted the need for States and localities to be prepared for a medical surge.

We found that all of the 10 selected localities that we reviewed had established partnerships to prepare for a medical surge; however, there was variation in the degree to

which coordination between partners occurred. We also found that fewer than half of the selected localities had started to recruit medical volunteers, and none of the five States that we reviewed had implemented an electronic system to manage these volunteers. Similarly, all 10 localities had acquired limited medical equipment for a pandemic, but only three of the five States had electronic systems to track available beds and equipment. In addition, most of the selected localities were in the early stages of planning for alternate care sites, and most had not identified guidelines for altering triage, admission, and patient care during a pandemic. Finally, although all of the selected localities conducted medical surge exercises, none consistently documented the lessons learned from these exercises.

Based on the findings of this report, we recommend that the Assistant Secretary for Preparedness and Response (ASPR), in collaboration with CDC (1) work with States and localities to improve their efforts within each of the five components of medical surge that we reviewed, (2) ensure that States and localities document the lessons learned from preparedness exercises that address medical surge, (3) address the issue of legal protections for medical professionals and volunteers who respond to public health emergencies, (4) facilitate the sharing of information and emerging practices among States and localities, and (5) provide training and technical assistance to States and localities on key issues. ASPR concurred with all five of our recommendations. CDC did not formally comment, but did provide technical comments. (OEI-02-08-00210)

Local Pandemic Influenza Preparedness: Vaccine and Antiviral Drug Distribution and Dispensing

We found that although the majority of selected localities had begun planning to distribute and dispense vaccines and antiviral drugs, more needs to be done to improve localities' ability to respond to an influenza pandemic.

In June 2009, the World Health Organization raised the pandemic influenza alert level to Phase 6 and declared the start of the 2009 H1N1 influenza pandemic. To assist States and localities in planning for an influenza pandemic, HHS provides guidance regarding vaccine and antiviral drug distribution and dispensing. HHS also recommends that States and localities exercise their pandemic influenza vaccine and antiviral drug distribution and dispensing plans and collaborate with community partners to develop and exercise these plans. Although the Office of the Assistant Secretary for Preparedness and Response (ASPR) annually reviews State-level pandemic influenza (pan flu) planning, it does not directly assess local pan flu planning. Therefore, based on HHS guidance documents and input from CDC and ASPR, we reviewed 89 preparedness items within eight planning areas (components) to determine the extent to which 10 selected localities had prepared to distribute and dispense pan flu vaccines and antiviral drugs.

We found that selected localities had not addressed in their planning documents most of the distribution and dispensing components and preparedness items identified in HHS pan flu guidance that we reviewed. Across the eight components, localities' planning documents generally were not actionable. That is, plans did not generally identify the organization or individuals responsible for carrying out specific actions; identify the

sources of personnel that would be necessary to staff distribution and dispensing positions; and/or include valid, detailed formal agreements with partnering agencies. In addition, although all selected localities conducted at least one exercise related to vaccine and antiviral drug distribution and dispensing, most did not consistently create After Action Reports and Improvement Plans for these exercises. Finally, all selected localities collaborated with different types of community partners to develop and exercise their plans to distribute and dispense vaccines and antiviral drugs during an influenza pandemic.

We recommended that CDC work with States to improve local pan flu vaccine and antiviral drug distribution and dispensing preparedness by (1) determining why localities appear to be in the early stages of planning, (2) prioritizing the planning areas where States should focus any carryover or future funding, and (3) placing special emphasis on ensuring that localities develop actionable plans. Further, CDC should coordinate with States to ensure that localities consistently document exercises with After Action Reports and Improvement Plans to enhance their pan flu vaccine and antiviral drug distribution and dispensing preparedness. Finally, CDC should facilitate the sharing of pan flu planning and response information and emerging promising practices. CDC agreed with two of the three recommendations. Specifically, CDC agreed to work with States to encourage localities to develop After Action Reports and Improvement Plans for their preparedness exercises. Additionally, CDC agreed that States and localities should use the “Lessons Learned Information Sharing” Web site to share planning resources. CDC did not indicate whether it agreed with the first recommendation, but noted that it plans to use some of OIG’s suggested actions to address this recommendation.

(OEI-04-08-00260)

Vermont’s Pandemic Influenza Expenditures

As of June 30, 2008, Vermont had not spent \$1 million, or 44 percent, of the \$2.36 million in pan flu funding that it received from CDC for award phases I through III. CDC provides funding to States, territories, and certain large cities through cooperative agreements to improve preparedness and response capabilities for bioterrorism and other public health emergencies. Beginning in 2005, Congress appropriated funds in three phases specifically to upgrade capabilities to prepare for and respond to pan flu.

The State attributed its unspent funds to delays in receiving supplemental guidance and funding from CDC for award phases I and II and to Vermont’s legislative and administrative procedures, which caused delays in bringing new positions online. Of the \$1.32 million that the State charged to the award, more than \$5,000 was not allowable. Specifically, \$4,753 should have been charged to another CDC award, and \$686 was not supported by the required documentation.

We recommended that the State amend the final pan flu financial status reports to reverse the \$4,753 incorrectly charged to the pan flu award and to refund the \$686 that lacked required documentation. The State agreed with our findings and recommendation.

(A-01-08-01500)

Traceability in the Food Supply Chain

We were able to trace 5 of 40 products in our review through each stage of the food supply chain. The facilities that handled these products in our review were able to provide information about the specific product that we purchased or were able to link that product to lot-specific information in their records. For 31 of the 40 products, we could identify the facilities that likely handled the products. For the remaining four products, we could not identify the facilities that likely handled the products.

Beginning in 2005, FDA required certain food facilities to maintain records identifying the sources, recipients, and transporters of food products. The purpose of these records is to enable FDA to trace an article of food through each stage of the food supply chain (from a retail shelf back to a farm) if FDA has a reasonable belief that a food product is adulterated and presents a serious health threat. Traceability is the ability to follow the movement of a food product through the stages of production, processing, and distribution. Traceability is often used to identify the sources of food contamination and the recipients of contaminated food in product recalls and seizures.

Several factors limited our ability to trace the specific food products through each stage of the food supply chain: (1) processors, packers, and manufacturers did not always maintain lot-specific information, as required; (2) other types of facilities commonly did not maintain lot-specific information because it is not required; (3) retailers received products not labeled with lot-specific information; and (4) products from a large number of farms were mixed. Additionally, 59 percent of the food facilities did not meet FDA's requirements to maintain records about their sources, recipients, and transporters. Finally, 25 percent of the food facilities were not aware of FDA's records requirements.

Based on these findings, we recommended that FDA improve the traceability of food products by seeking statutory authority, if necessary, to strengthen its existing records requirements regarding lot-specific information. We also recommended that FDA consider seeking additional statutory authority, such as the ability to require each facility that handles a food product to maintain records about every facility or farm that previously handled the product. We also recommended that FDA work with the food industry to develop guidance on traceability and that FDA address issues related to mixing raw food products from a large number of farms. To increase compliance with the records requirements, we recommended that FDA seek statutory authority to request facilities' records at any time, as opposed to its current authority to request records only when FDA has a reasonable belief that an article of food presents a serious health threat. We also recommended that FDA should include a component in its food facility inspections that verifies whether facilities are complying with its records requirements. Finally, we recommended that FDA conduct education and outreach activities to inform the food industry about its records requirements. FDA stated that it will consider our recommendations on seeking statutory authority and mixing food from a large number of farms, and described its efforts in response to our recommendations to work with the food industry and to conduct education and outreach activities. (OEI-02-06-00210)

Food and Drug Administration's Monitoring of Pet Food Recalls

In this review, conducted at the request of the Senate Committee on Agriculture, Nutrition, and Forestry, we evaluated FDA's authority and procedures with respect to pet food recalls. From March 16 to April 26, 2007, firms initiated and FDA oversaw 16 Class I (highly hazardous) recalls of pet food contaminated with melamine. Three recalls by one manufacturer accounted for approximately 89 percent of the products in the 16 recalls. Our review focused on three recalls by that manufacturer and one small recall each by an import firm and an import broker.

We found that FDA did not have statutory authority to require manufacturers or importers to initiate pet food recalls or to assess penalties for recall violations. Furthermore, FDA issued its regulations as nonbinding recall guidance for firms. Several bills proposed in the 110th session of Congress would have provided FDA with authority to mandate recalls and to dictate and enforce the terms of a recall.

FDA had developed procedures for monitoring recalls and assessing a firm's recall effectiveness. However, FDA did not always follow its procedures in overseeing three of the five recalls that we reviewed. Furthermore, FDA's procedures were not always adequate for monitoring large recalls. FDA's lack of authority, coupled with its sometimes lax adherence to its recall guidance and internal procedures and the inadequacy of some of those procedures, limited FDA's ability to ensure that contaminated pet food was promptly removed from retailers' shelves.

Our report contained detailed recommendations for strengthening FDA's recall authority and improving its effectiveness in monitoring food recalls. FDA agreed or agreed in principle with all of our recommendations. (A-01-07-01503)

Health Resources and Services Administration Grant Closeout Procedures

We found that the 3,184 HRSA grants identified by the HHS Division of Payment Management (DPM) as eligible for closeout as of December 31, 2006, which had unexpended balances totaling more than \$173 million, remained open in the payment system for several reasons. DPM is responsible for closing grants after receiving instructions from the Administration for Children and Families or the HHS Division of Financial Operations. HRSA is responsible for initiating closeout of grants.

As a general rule, grants must be closed within 180 days after the end of the grant period (the cutoff date). However, the grants remained open after the cutoff dates because of staffing shortages; differences among the grant award, expenditure, and drawdown amounts in the payment system; or a lack of grant closeout procedures. Also, HRSA and the Division of Financial Operations did not adhere to or lacked follow-up procedures to determine whether DPM had actually closed grants for which closeout was initiated.

We recommended that HRSA use the information in this report to ensure that grants are closed in a timely manner and to eliminate the backlog of grants eligible for closeout. In

response, HRSA described actions that it had taken or planned to take to implement our recommendation. (A-02-07-02008)

Indian Health Service Contract Health Services Program: Overpayments and Potential Savings

IHS and tribes paid above the Medicare rate for 22 percent of hospital claims. As a result, IHS and tribes overpaid \$1 million for hospital claims between January and March 2008.

Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and its implementing regulations, all Medicare-participating hospitals must accept reimbursement no greater than the Medicare rate as payment in full for patients eligible for Contract Health Services (CHS). Nonhospital providers, including physicians, are not covered by the MMA provision.

If IHS and tribal payments for nonhospital claims had been capped at the Medicare rate, they could have saved as much as \$13 million between January and March 2008. Savings from claims over the Medicare rate could have paid for approximately 41,000 additional nonhospital claims between January and March 2008 that might otherwise have been deferred or denied. IHS and tribes paid above Medicare rates for 71 percent of nonhospital claims, most of which were for physician services.

We recommended that IHS and tribes take appropriate action regarding overpaid CHS hospital claims. IHS should also direct its fiscal intermediary to ensure that all future CHS claims are paid at or below the Medicare rate. IHS should provide technical assistance to tribes to ensure proper payments of hospital claims. Lastly, IHS should seek legislative authority to cap payments for CHS nonhospital services. (OEI-05-08-00410)

Indian Health Service Cost Statement for Fiscal Year 2005

We found that the \$173.9 million of obligations reported in the IHS Headquarters FY 2005 Medicare cost statement included \$3.4 million of unallowable obligations for the section 103 scholarship program, \$10 million of obligations for the sections 104 and 112 scholarship programs on which we could not express an opinion, and \$350,000 of unallowable obligations related to construction. Federal regulations and CMS guidance establish standards for the allowability and allocability of costs included in Medicare cost statements.

We recommended that IHS (1) adjust a future Headquarters cost statement for \$3.4 million of unallowable section 103 scholarship obligations, (2) review the Headquarters cost statements before and after FY 2005 and adjust a future cost statement for section 103 scholarship obligations, (3) discontinue reporting section 103 scholarship obligations in its Headquarters cost statements, (4) work with CMS to determine the appropriate credits to offset \$10 million of sections 104 and 112 scholarship obligations and adjust a future cost statement for these credits, (5) ensure that it identifies and reports appropriate credits in its cost statements for sections 104 and 112 scholarships for which

the recipients had not fulfilled their service obligations, (6) adjust a future Headquarters cost statement for \$350,000 of unallowable obligations related to construction, and (7) ensure that it does not include obligations reimbursed by other governmental entities in Headquarters cost statements.

IHS disagreed that the section 103 scholarship obligations were unallowable under Medicare and did not explicitly address our recommendation to adjust a future Headquarters cost statement for \$3.4 million. IHS disagreed with our second and third recommendations, did not explicitly address our fourth and fifth recommendations, and agreed with our sixth and seventh recommendations. Nothing in IHS's comments caused us to revise our findings or recommendations. (A-09-07-00054)

Followup of Procurements Made by the National Institutes of Health for the Department of Defense

As required by the John Warner National Defense Authorization Act for Fiscal Year 2007, § 817, as amended, we conducted a follow-up review of procurements made by the NIH Information Technology Acquisition and Assessment Center (the Center) on behalf of the Department of Defense (DoD).

We found that the Center's compliance with acquisition requirements had significantly improved. However, the Center did not fully implement our prior recommendations related to the use of operations and maintenance (O&M) funds instead of research, development, test, and evaluation (RDT&E) funds and the use of funds for equipment and services that were provided after the period of performance for which the funds were obligated. We also found that between FYs 2002 and 2007, the Center paid for some equipment and services that were provided after the period of performance and that the Center did not always maintain adequate documentation on competition, award decisions, and contractor monitoring. In addition, the Center exercised a task order option that may not have filled an existing need of the Government.

We recommended, among other things, that the Center (1) request that DoD provide a final decision on the use of \$1.2 million of O&M funds instead of RDT&E funds for three task orders identified in our previous review that remain unresolved, (2) work with DoD to resolve funds (\$1.4 million identified in our previous review and \$3.7 million identified in our current review) that were used for equipment and services provided after the period of performance for which the funds were obligated, and (3) determine whether options to task orders fill an existing need of the Government before awarding the options. NIH concurred with our recommendations and stated that for those areas under its control, it had taken action or was planning corrective measures in conjunction with DoD. (A-03-08-03000)

Superfund Financial Activities at the National Institute of Environmental Health Sciences

In our review of Superfund financial transactions at the National Institute of Environmental Health Sciences (NIEHS) for FY 2008, we found that the transactions

were allowable, allocable, and reasonable in accordance with applicable laws and regulations. NIEHS receives Superfund funding to train people who handle hazardous waste and manage hazardous waste facilities and to conduct research on the effects of hazardous substances on human health. We conducted this audit pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), which requires the inspector general of a Federal organization with Superfund responsibilities to audit all uses of the Superfund. Our report contained no recommendations. (A-04-09-01062)

Public Health Related Legal Actions and Investigations

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 paragraphs provide descriptions and statistics related to these efforts.

Health Education Assistance Loan Defaults

OIG excludes from participation in Federal health care programs individuals who have defaulted on loans obtained through the Health Education Assistance Loan (HEAL) program. Through the HEAL program, HRSA guarantees commercial loans to students seeking education in health-related fields of study. The students are allowed to defer repayment of the loans until after they have graduated and begun to earn income. Although the Department's PSC takes steps to ensure repayment, some loan recipients do not resolve their indebtedness.

After the PSC has exhausted efforts to secure repayment of a debt, it declares an individual in default. Thereafter, the Social Security Act permits, and in some instances mandates, 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. During the period covered by this report, 13 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. Some health professionals, upon being notified of their exclusion, immediately repay their HEAL debts.

After being excluded for nonpayment of their HEAL debts, 2,239 individuals have chosen to enter into settlement agreements or completely repay their debts. That figure

includes the 51 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 \$164.8 million. Of that amount, \$4.9 million is attributable to this reporting period.

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

- **Georgia** – Chiropractor Ronald G. Knight - \$277,707
- **California** – Podiatrist Susan Kirkpatrick - \$190,066
- **Georgia** – Dentist Cheryl Coggins - \$178,040
- **U.S. Virgin Islands** – Podiatrist Ian Cook - \$169,754
- **Indiana** – Dentist David Price - \$141,733
- **Washington** – Osteopath Ralph A. Mitchell - \$120,804

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 are examples of cases involving improper use of grant funds resolved during this reporting period:

- **Maine** – Robert L. Newell, the former Governor of the Passamaquoddy Tribe, Indian Township, was sentenced to 60 months in prison and ordered to pay \$1,741,876 in joint and several restitution for conspiring to defraud the United States and other offenses he committed while serving as tribal governor from 2002 to 2006. Newell’s co-conspirator, James J. Parisi, Jr., was sentenced to 12 months and 1 day in prison and held responsible for \$1,602,516, a portion of the joint restitution figure, for crimes he committed while serving as the Director of Finance at the Passamaquoddy Tribe, Indian Township Reservation, from 2003 to 2006. Newell and Parisi misapplied approximately \$1.74 million in restricted Federal funds awarded to Indian Township for its tribal programs, including funds awarded to the tribe’s Indian Health Center for a substance abuse and HIV prevention program.
- **Puerto Rico** – The Inter-American University of Puerto Rico (IAUPR) agreed to pay \$611,117 plus interest to resolve its civil and administrative liability in connection with its misappropriation and improper use of HRSA grant funds for grant years 2000 through 2004. A non-profit private educational institution, IAUPR received grant funds from HRSA for a Health Careers Opportunity Program (HCOP). The HCOP grant funds were intended to be used by IAUPR to increase the participation of disadvantaged students in the health care field. Instead, as reported under OIG’s Provider Self-Disclosure Protocol, the Director of IAUPR’s HCOP program allegedly diverted a portion of the HCOP funds

from the grants for her own personal use. In addition, the Director allegedly made other improper grant disbursements as a result of her failure to document the eligibility of a handful of students participating in the HCOP program. In conjunction with the settlement agreement, the HHS Office of Grants agreed to provide IAUPR with a suspension and debarment release as part of a separate administrative agreement.

Human Services Related Reports

Title IV-E Adoption Assistance Payments in Florida

Based on our sample results, we estimated that Florida claimed unallowable adoption assistance payments totaling \$4.4 million (Federal share) for the period October 2004 through September 2007. Of the 200 payments in our sample, 18 were unallowable because State records did not demonstrate that the payments met Federal reimbursement requirements. Although the State had internal controls that prevented most unallowable payments, controls over eligibility documentation were not sufficient to detect documentation errors in all cases. The State recently took steps to improve these controls.

We recommended that the State refund \$4.4 million to the Federal Government, review payments claimed after the audit period on behalf of the 18 children identified in our review to ensure compliance with Federal requirements and repay any unallowable amounts, and use the results of this audit in staff education and quality assurance reviews. The State did not specifically address our first recommendation; however, it provided information on steps that it planned to take to implement our second and third recommendations. (A-04-08-03523)

Title IV-E Training Costs in Missouri

We found that none of the \$10.2 million (\$7.7 million Federal share) in Title IV-E (foster care and adoption assistance) training costs that Missouri allocated from its social services cost pool from July 2002 through June 2006 were allowable for Federal reimbursement at the enhanced 75-percent Federal financial participation rate. Of the \$7.7 million Federal share, \$2.6 million was unallowable because the cost pool did not consist entirely of allowable training costs reimbursable at the enhanced rate. In addition, contrary to Federal regulations, none of the costs included in the cost pool were included in the State's approved training plan. We set aside an additional \$3.3 million for adjudication by ACF and accepted the remaining \$1.8 million.

We recommended that Missouri (1) adjust its next "Title IV-E Foster Care and Adoption Assistance Financial Report" to reduce Federal reimbursement claimed for Title IV-E training by \$2.6 million and (2) work with ACF to determine what portion of the \$3.3 million Federal share was not allocable to Title IV-E and make financial adjustments as necessary. Missouri did not agree with our findings or recommendations. Nothing in the State's comments caused us to revise our report. (A-07-08-03114)

Office of Community Services' Corrective Actions Resulting From a Government Accountability Office Review

We initiated a review at ACF's Office of Community Services (OCS) in response to the \$1 billion that the American Recovery and Reinvestment Act of 2009 (Recovery Act) appropriated for the Community Services Block Grant (CSBG) program. CSBG program funds are intended to reduce poverty, revitalize low-income communities, and help low-income families become self-sufficient. In a June 2006 report, the Government Accountability Office (GAO) identified deficiencies in OCS's management of and internal controls over the CSBG program. To correct these deficiencies, GAO made nine recommendations.

During our follow-up audit, we found that OCS had implemented the six GAO recommendations that we reviewed. Specifically, OCS conducted a risk-based assessment of State CSBG programs and established policies and procedures to help ensure that OCS's onsite monitoring was focused on the States with the highest risk. In addition, OCS developed written policies and procedures in the areas that GAO identified. Because OCS had implemented GAO's recommendations, we made no recommendations. (A-01-09-02502)

Child Support Enforcement

Congress annually appropriates funds to OIG for the purpose of detecting, investigating, and prosecuting 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 both 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 48 convictions and court-ordered restitution and settlements of \$3.4 million during this semiannual period. Examples of OIG's enforcement results for failure to pay child support include the following:

■ **Texas** – Troy Lee Neel, the most egregious child support evader in the State’s history, was sentenced to 5 years’ probation and ordered to pay \$778,916 in restitution for foreign travel to evade legal child support obligations. As part of a 1998 divorce decree, Neel was ordered to pay \$5,000 per month for his two children, both of whom have serious medical conditions. Neel was a former professional major league baseball player whose annual salary was over \$2 million. After leaving the baseball profession, Neel lived on a resort island in the Republic of Vanuatu in the South Pacific that he had purchased for \$1.5 million. The U.S. State Department refused to issue Neel a new passport once his old one expired, and, in December 2008, Neel was arrested in a California airport after arriving on a flight from Australia. Neel’s guilty plea and sentencing were the culmination of a 6-year, multi-agency international investigation.

■ **Iowa** – Robert Ray Davis was sentenced to 21 months of incarceration and 1 year of supervised release, and was ordered to pay restitution of \$117,655, for failure to pay child support for two of his three children. In a May 2000 divorce decree, Davis was ordered to pay \$1,379 per month for the support of his two minor children; the third child was emancipated at the time of the decree.

■ **Ohio** – David Pandorf was sentenced to 5 years’ probation and ordered to pay \$45,987 in restitution for failure to pay child support. Pandorf’s guilty plea had been entered into the Southern District of Florida after the case was transferred from the Southern District of Ohio. Pandorf had been licensed and registered in the State of Florida as a yacht broker and had approximately \$126,000 credited into his bank account from January 2007 through May 2008, while making only one \$400 child support payment. Pandorf is also a convicted felon who had previously served time in Federal prison on State and Federal drug-related charges.

Departmentwide Issues

Department of Health and Human Services Employee Travel Cards: Usage and Internal Controls

Based on a review of 2007 HHS travel card transactions, 6 percent constituted misuse. Of the 6 percent, 4 percent were for personal purchases while the cardholder was not on official travel, including airfare to attend a relative’s funeral and lodging for a personal trip following official travel. One percent of the transactions were for personal purchases while the cardholder was on official travel. Lastly, 1 percent of the transactions were for local travel expenses. The travel card may not be used for expenses within the local travel area, with the exception of expenses for authorized rental cars.

Federal regulations require an employee who travels more than five times per year to obtain a travel card. Travel cardholders are personally liable for transactions made with their travel cards. Pursuant to the Federal Travel Regulation and the “HHS Travel Manual,” official travel expenses include transportation, lodging, meals, and incidentals associated with official temporary duty travel. Misuse is defined in part as the use of a Federal charge card for other than the official Government purpose for which it is

intended. Travel card program administrators are responsible for reviewing and monitoring cardholder activities, including occurrences of misuse.

We also found that of the transactions that did not match electronic voucher data, 27 percent constituted misuse, projecting to \$1.4 million. Travel card program guidance is lacking in some areas, and training does not meet Office of Management and Budget (OMB) requirements. Furthermore, program administrators may not identify all misuse. Finally, less than one-third of sampled transactions that constituted misuse were associated with follow-up actions.

Based on these findings, we recommended that the Assistant Secretary for Administration and Management (ASAM) improve travel card program guidance, travel card program training, and methods used to identify misuse. In its comments to the draft report, ASAM accepted the report recommendations and described actions it has taken or will take to address them. (OEI-07-07-00480)

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 1,339 reports that covered \$1.5 trillion in audited costs. Federal dollars covered by these audits totaled \$463 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.

Reports issued:	
Without changes or with minor changes	1,235
With major changes	84
With significant inadequacies	20
Total	1,339

The 1,339 reports included 5,265 recommendations for improving management operations. In addition, these audit reports provided information for 101 special memoranda that identified concerns for increased monitoring by management.

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 B.

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.

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** – Former NIH employee Delores Stroud was sentenced to 6 months of home detention and ordered to pay \$43,065 in restitution for theft of Government property. Stroud used her Government-issued Visa card to make unauthorized personal purchases for various items, including a Nintendo Wii console, Wii video games and accessories, a University of Phoenix class ring, televisions, and cameras.

Appendix A: Fiscal Year 2009 Savings Achieved Through Implementation of Recommendations in Audits and Evaluations

After laws involving the Department of Health and Human Services (HHS) programs have been enacted, the Office of Inspector General (OIG) analyzes them to identify provisions that were supported by recommendations arising from OIG work. A similar process occurs with respect to administrative changes recommended by OIG and implemented by HHS management through regulations or other directives. For administrative changes, the savings estimates are developed by the relevant HHS operating or staff division or by OIG. For legislative savings, we use estimates prepared by the Congressional Budget Office (CBO). As part of the process of informing Congress of the potential impact of legislation under consideration, CBO projects the annual Federal costs and savings that are expected to result from enacting the legislation.

The savings estimates described annually in this appendix represent funds that will be available for better use as a result of actions taken, such as reductions in budget outlays; deobligations of funds, reductions in costs incurred; preaward grant reductions; and reductions and/or withdrawal of the Federal portion of interest subsidy costs of loans or loan guarantees, insurance, or bonds. Savings of this kind often reflect not only OIG's recommendations, but also the contributions of others, such as HHS operating divisions and the Department of Justice.

Total savings attributed to fiscal year (FY) 2009 as a result of legislative and administrative actions related to OIG recommendations totaled \$16,484.7 million (\$16.48 billion).

OIG Recommendation	Implementing Action	Savings (millions)
CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)		
State-Enhanced Payments Under Medicaid Upper Payment Limit Requirements. The Centers for Medicare & Medicaid Services (CMS) should move as quickly as possible to issue regulatory changes to the upper payment limit (UPL) rules governing enhanced payments to local government providers. The recommendation related to findings in OIG report number A-03-00-00216.	On January 12, 2001, CMS issued revisions to the UPL regulations that, among other things, created new payment limits for local-government-owned providers. This final rule significantly affects a State's ability to reap windfall revenues by reducing the available funding pool from which to make enhanced payments to local-government-owned providers.	\$7,600

OIG Recommendation	Implementing Action	Savings (millions)
<p>Medicaid Enhanced Payments to Local Providers. Reconsider capping the aggregate UPL at 100 percent for all facilities, rather than the 150-percent allowance for non-State-owned Government hospitals. The recommendation related to findings in OIG report number A-03-00-00216.</p>	<p>CMS issued a final rule that modified the Medicaid UPL provisions to remove the 150-percent UPL for services furnished by non-State-owned or -operated hospitals. The rule became effective in the spring of 2002.</p>	<p>\$3,100</p>
<p>Payment Reform for Part B Drugs and Biologicals. Reexamine drug reimbursement methodologies based on average wholesale price (AWP) with the goal of reducing payments in both Medicare and Medicaid. The recommendation related to findings in the following OIG reports. OEI-03-96-00420 OEI-03-97-00290 OEI-03-00-00310 OEI-03-97-00293 A-06-00-00023 A-06-01-00053 A-06-02-00041</p>	<p>Sections 303 through 305 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) revised the current payment methodology for Part B-covered drugs and biologicals that were not paid on a cost or prospective payment basis. Under the MMA, most drugs were to be paid at 85 percent of the April 1, 2003, AWP effective January 1, 2004, through December 31, 2004, unless they met certain exceptions. Since January 1, 2005, most drug prices have been based on the average sales price or competitive acquisition instead of AWP.</p>	<p>\$1,500</p>
<p>Medicare Secondary Payer. Ensure sufficient resources and contractor training for retroactively examining paid claims to identify other payer sources and initiating recovery action on all related overpayments. The recommendation related to findings in the following OIG reports. A-02-98-01036 A-04-92-02057 A-09-89-00162 A-10-86-62005</p>	<p>Section 301 of the MMA clarifies the Secretary's authority to make certain reimbursable conditional payments and to take recovery actions against all responsible entities, including collection of damages, under Medicare Secondary Payer provisions. This section builds on other program improvements related to OIG's work that were implemented by the Balanced Budget Act (BBA), Omnibus Budget Reconciliation Act (OBRA) 1993, OBRA 1990, and OBRA 1989.</p>	<p>\$900</p>
<p>Clinical Diagnostic Laboratory Tests. Seek legislation to allow across-the-board adjustments in Medicare laboratory fee schedules, bringing them in line with the prices that laboratories charge physicians in a competitive marketplace, and periodically evaluate the national fee schedule levels. The recommendation related to findings in the following OIG reports. A-09-89-00031 A-09-93-00056</p>	<p>Section 628 of the MMA froze annual updates for FY 2004 through FY 2008. This action builds on prior legislative actions in the BBA, OBRA 1993, OBRA 1990, and legislation in 1984 that were also responsive to OIG's recommendations to curb excessive clinical laboratory test reimbursements by Medicare.</p>	<p>\$900</p>

OIG Recommendation	Implementing Action	Savings (millions)
<p>Payments for Durable Medical Equipment. Take steps to reduce payments for a variety of durable medical equipment (DME) and related supplies. The recommendation related to findings in the following OIG reports: OEI-03-01-00680 OEI-03-02-00700 OEI-07-96-00221 OEI-03-96-00230 OEI-03-94-0021 OEI-06-92-00861 OEI-06-92-00866</p>	<p>Section 302 of the MMA froze payments for certain DME items, including prosthetics and orthotics, effective January 1, 2004.</p>	<p>\$700</p>
<p>Medicare Home Health Payments. Reduce the Home Health Agency (HHA) update factor to account for the high error rate found in OIG's review. The annual update was defined as the home health market basket percentage increase. The recommendation related to findings in report number A-04-99-01194.</p>	<p>Section 701 of the MMA changed the updates of home health rates from fiscal year to calendar year beginning in 2004, with the update for the last three quarters of 2004 equal to the market basket increase minus 0.8 percent.</p>	<p>\$700</p>
<p>Payment for Services Furnished in Ambulatory Surgical Centers. Set rates that are consistent across sites and reflect only the costs necessary for the efficient delivery of health services and establish parity among ambulatory surgical centers (ASC) and outpatient departments. The recommendation related to findings in the following OIG reports. OEI-05-00-00340 OEI-09-88-01003 A-14-98-00400 A-14-89-00221</p>	<p>Section 626 of the MMA limited the ASC update starting April 1, 2004, then froze updates for a period beginning the last quarter of FY 2005, effectively reducing the payment advantage to ASCs for those procedure codes that are more highly paid in the surgical center compared to outpatient departments. Section 626 also mandated that CMS implement a new payment system that takes into account disparities in the costs of procedures performed in ASCs and the costs of procedures performed in hospital outpatient departments, which CMS implemented by regulation effective January 1, 2008.</p>	<p>\$400</p>
<p>Capped Rental Durable Medical Equipment. Eliminate the semiannual maintenance payment allowed for capped rental DME, pay only for repairs when needed, eliminate the 15-month rental option, and convert rentals to purchases after the 13th month. The recommendation related to findings in report number OEI-03-00-00410.</p>	<p>Section 5101 of the Deficit Reduction Act of 2005 (DRA) revised the payment rules for capped rental DME to require that ownership of the item transfer to the beneficiary after the 13th month and that Medicare pay for maintenance services on a cost-reimbursement basis.</p>	<p>\$200</p>

OIG Recommendation	Implementing Action	Savings (millions)
<p>Part B Drugs Average Sales Price. Adopt an alternate calculation of volume-weighted average sales price that is consistent with the results set forth in section 1847A(b)(3) of the Social Security Act. The recommendation related to findings in report number OEI-03-05-00310.</p>	<p>Section 112 of the Medicare, Medicaid, and State Children’s Health Insurance Program (SCHIP) Extension Act of 2007 establishes a revised calculation method for calculating volume weighted average sales prices for Medicare Part B drugs that comports with OIG’s recommendation.</p>	<p>\$200</p>
<p>Medicaid Third Party Liability. Determine whether legislation is needed to explicitly include pharmacy benefit management companies in the Medicaid definition of a third party, require third parties to match their eligibility files with Medicaid’s eligibility files, and allow Medicaid up to 3 years to recover payments from liable third parties. The recommendation related to findings in report number OEI-03-00-00030.</p>	<p>Section 6035 of the DRA made several changes to strengthen Medicaid’s third-party liability provisions, including clarification regarding pharmacy benefit managers. The section also includes requiring States to ensure that health insurers, as a condition of doing business in the State, provide requested coverage data; accept the State’s right of recovery; and agree, conditionally, not to deny a claim solely on the basis of date of submission of the claim when the claim is submitted by the State within a 3-year period beginning on the date on which the item or service was furnished.</p>	<p>\$170</p>
<p>Medicaid Drug Rebates—Sales to Repackagers Excluded From Best Price Determinations. Require drug manufacturers that excluded sales to health maintenance organizations (HMO) from their best price calculations to repay the rebates and evaluate the policy guidance relating to exclusion of sales to other (non-HMO) repackagers from best price determinations. Medicaid rebates were lost because sales to HMOs were improperly excluded from drug manufacturers’ best price determinations in FYs 1998 and 1999. The recommendation related to findings in report number A-06-00-00056.</p>	<p>CMS issued Medicaid Drug Rebate Program Release #47 in July 2000, reiterating that section 1927(c) of the Social Security Act requires that manufacturers include in the best price the lowest price available to, among other entities, any wholesaler, retailer, provider, and HMO. The release specifically stated that this includes sales to organized health care settings, such as HMOs.</p>	<p>\$81</p>
<p>Rebates for Physician-Administered Drugs. Encourage States to take actions to collect rebates on physician-administered drugs, especially single-source drugs. States should either use National Drug Codes (NDC) instead of procedure codes or link procedure codes to NDCs for single source drugs. The recommendation related to findings in report number OEI-03-02-00660.</p>	<p>Section 6002 of the DRA requires States to provide for the collection and submission of utilization data needed to secure rebates for physician-administered drugs and provide that the utilization data for single source and specified multiple-source physician-administered drugs be submitted using NDC numbers (unless the Secretary specifies an alternative coding system).</p>	<p>\$20</p>

ADMINISTRATION FOR CHILDREN AND FAMILIES		
OIG Recommendation	Implementing Action	Savings (millions)
<p>Availability of Health Insurance for Title IV-D Children. Connecticut should either implement policies and procedures to require noncustodial parents to pay all or part of the Medicaid costs for their dependent children or establish a Statewide health insurance plan that provides reasonably priced, comprehensive coverage for children, with costs paid by noncustodial parents. The recommendation related to findings in report number A-01-97-02506.</p>	<p>The Balanced Budget Act of 2006 established the Children’s Health Insurance program to enhance Medicaid coverage provided to children and to allow States to create insurance options for families that exceed Medicaid resource and income limits. Under Connecticut law, applicants include noncustodial parents ordered to provide health insurance.</p>	\$5.7
<p>Triennial Reviews of Child Support Orders and Medical Support by Parents. Ensure that more periodic reviews are initiated and take action to increase medical support by parents. OIG reviewed the effects of 1996 legislation that no longer required States to conduct periodic reviews and adjustments of child support orders (unless requested by a State agency or parent) and found that many States had, in effect, discontinued the reviews. The recommendations related to findings in report number OEI-05-98-00100.</p>	<p>Section 7302 of the DRA implemented our recommendation to increase periodic reviews by requiring States to adjust child support orders of families on the Temporary Assistance for Needy Families program every 3 years. CBO estimated net savings resulting from section 7302 beginning with \$7 million in FY 2009. Section 7307 of the DRA requires, for court orders that are issued or amended after enactment, that all States assess the ability of either or both parents to provide medical support for their children. CBO estimated savings from section 7307 would accrue beginning in FY 2007 and scored the FY 2009 savings as \$1 million.</p>	\$8

Appendix B: Resolving Recommendations

The following statistical Tables summarize OIG monetary recommendations and the Department's 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 the 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.

The 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 of its Semiannual Report. Superscripts indicate end notes.

Reports	Number of Reports	Dollar Value Questioned	Dollar Value Unsupported
Section 1			
For which no management decision had been made by the beginning of the reporting period ¹	163	\$1,283,456,000	\$75,198,000
Issued during the reporting period	109	\$479,991,000	\$52,443,000
Total Section 1	272	\$1,763,447,000	\$127,641,000
Section 2			
For which a management decision was made during the reporting period ^{2,3}			
Disallowed costs	129	\$217,583,000	\$59,645,000
Costs not disallowed	11	\$137,129,000	\$9,229,000
Total Section 2	140	\$354,712,000	\$68,874,000
Section 3			
For which no management decision had been made by the end of the reporting period			
Total Section 1 minus Total Section 2	132	\$1,408,735,000	\$58,767,000
Section 4			

For which no management decision was made within 6 months of issuance ⁴	64	\$966,393,000	\$96,639,000
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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 Appendix A.

Reports	Number of Reports	Dollar Value
Section 1		
For which no management decision had been made by the beginning of the reporting period ¹	11	\$1,920,259,000
Issued during the reporting period	3	\$97,618,000
Total Section 1	14	\$2,017,877,000
Section 2		
For which a management decision was made during the reporting period ²		
Value of recommendations agreed to by management		
Based on proposed management action	1	\$173,966,000
Based on proposed legislative action		
Value of recommendations not agreed to by management	1	\$45,763,000
Total Section 2	2	\$219,729,000
Section 3		
For which no management decision had been made by the end of the reporting period ³		
Total Section 1 minus Total Section 2	12	\$1,798,148,000

End Notes to Tables 1 and 2

Table 1 End Notes

¹ The opening balance was adjusted upward by \$36.4 million due to a reevaluation of previously issued recommendations.

² During the reporting period, revisions to previously reported management decisions included:

CIN: A-04-00-02171, REVIEW OF ALABAMA STATE MEDICAID AGENCY ENHANCED PAYMENTS TO PUBLIC HOSPITALS FOR FYS 1997 TO 2000. CMS subsequently determined that the State's upper payment limit calculation was consistent with its Medicaid State plan and reversed its original management decision to disallow \$236,983,528.

CIN: A-06-03-75545, STATE OF LOUISIANA. CMS subsequently increased its original disallowance for unallowable disproportionate share hospital payments by \$49,710,047.

CIN: A-02-04-01004, REVIEW OF MEDICAID DISPROPORTIONATE SHARE HOSPITAL PAYMENTS TO UNIVERSITY HOSPITAL, UNIVERSITY OF MEDICINE AND DENTISTRY OF NEW JERSEY: JULY 1, 1995, THROUGH JUNE 30, 2001. CMS reduced its original disallowance of \$85,697,689 by \$3,018,366 to reflect the actual amount of unallowable costs that had been paid to the State.

CIN: A-09-02-00085, REVIEW OF MEDICAL CLAIMS FOR OXYGEN EQUIPMENT AND SUPPLIES. CMS determined that it could not recoup its 2006 disallowance for CY 2000 and 2001 claims because 42 CFR 405.841 restricted its ability to reopen its initial determination on claims totaling \$1,745,219.

CIN: A-04-07-88264, STATE OF GEORGIA. CMS originally disallowed estimated questioned costs of \$2,186,893 in this nonfederal audit report. Subsequently CMS determined that actual unallowable costs totaled \$597,029 and reduced its original disallowance by \$1,589,864.

Not detailed are net reductions to previously issued management decisions totaling \$1.1 million.

³ Included are management decisions to disallow \$50.8 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, the OIG is responsible for ensuring that work performed by these non-Federal auditors complies with Federal audit standards; accordingly, the OIG tracks, resolves, and reports on recommendations in these audits.

⁴ Due to administrative delays, many of which are beyond management control, resolution of the following 64 audits was not completed within 6 months of issuance; 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-02-03-01029	REVIEW OF RETROACTIVE SCHOOL HEALTH CLAIMS - NEW YORK CITY DEPT. OF EDUCATION, OCT 2006, \$259,433,325
CIN: A-06-07-00039	REVIEW OF AMP CALCULATION - MANUFACTURER C, MAR 2008, \$101,000,000
CIN: A-02-04-01021	REVIEW OF RETROACTIVE SCHOOL HEALTH CLAIMS - REST OF NEW YORK STATE, OCT 2006, \$60,188,395
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-02-06-02000	RYAN WHITE - PAYER OF LAST RESORT, SEP 2008, \$24,340,789
CIN: A-05-07-00076	REVIEW OF INDIANA MEDICAID PAYMENTS TO INELIGIBLE PSYCHIATRIC HOSPITALS, MAR 2009, \$16,298,423
CIN: A-09-01-00098	AUDIT OF KERN MEDICAL CENTER DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR FY 1998, SEP 2002, \$14,165,950
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 & WHITE, MAY 2003, \$8,229,574
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 - FY 2004 – FY 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-09-01-00085	AUDIT OF UCSD MEDICAL CENTER DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR SFY 1998, SEP 2002, \$3,776,054
CIN: A-04-07-01046	FLORIDA/CDC - ALLOWABILITY OF COSTS CLAIMED FOR REIMBURSEMENT UNDER BIOTERRORISM AND EMERGENCY PREPAREDNESS PROGRAM GRANTS, 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-06-06-00105	AUDIT OF NEW MEXICO'S TITLE IV-E ADMINISTRATIVE AND TRAINING COSTS (STATE ISSUES), DEC 2008, \$1,138,499

CIN: A-05-07-00062 OHIO - TITLE IV-E FOSTER CARE PAYMENTS FOR DELINQUENT YOUTH, AUG 2008, \$689,720

CIN: A-04-07-03515 UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS - MISSISSIPPI, AUG 2008, \$674,578

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

CIN: A-05-06-00038 IN-UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS, 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-05-05-00033 MICHIGAN - UNDISTRIBUTED CHILD SUPPORT COLLECTIONS, 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-02-06-02005 UNDISTRIBUTABLE CHILD SUPPORT PAYMENTS - NEW JERSEY, FEB 2008, \$186,113

CIN: A-09-05-00077 REVIEW OF PACIFICARE'S USE OF ADDITIONAL CAPITATION UNDER THE MMA OF 2003, MAR 2006, \$135,000

CIN: A-02-06-02006 TITLE IV-E ADMINISTRATIVE AND TRAINING COSTS, NOV 2008, \$132,591

CIN: A-05-06-00029 AUDIT OF COST-BASED HMOS FOR OVERPAYMENTS MADE TO CAPITATED PROVIDERS, SEP 2006, \$132,075

CIN: A-05-06-00031 AUDIT OF COST-BASED HMOS FOR OVERPAYMENTS MADE TO CAPITATED PROVIDERS, SEP 2006, \$122,130

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

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-MI 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-05-05-00042 DUPLICATE MEDICARE PAYMENTS TO COST-BASED HEALTH MAINTENANCE ORGANIZATION PLAN- DEAN HEALTH PLANS, INC. FOR FYS 2000-2003, AUG 2005, \$91,710

CIN: A-05-01-00090 PAYMENTS TO AETNA U.S. HEALTHCARE PA FOR INSTITUTIONAL BENEFICIARIES, JUL 2002, \$87,516

CIN: A-05-05-00043 DUPLICATE MEDICARE PAYMENTS TO COST-BASED HEALTH MAINTENANCE ORGANIZATION PLAN - JOHN DEERE HEALTH PLANS, INC. FOR FYS 2000-2003, SEP 2005, \$78,799

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 NORTHEAST PENNSYLVANIA FOR INSTITUTIONAL BENEFICIARIES, MAY 2002, \$62,432
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, ARIZONA 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 INSTITUTIONALIZED BENEFICIARIES, MAY 2002, \$18,842
CIN: A-05-01-00095	PAYMENTS TO HUMANA OF ARIZONA FOR INSTITUTIONAL BENEFICIARIES, JUN 2002, \$18,645
CIN: A-07-03-00151	REVIEW OF MEDICARE PAYMENTS FOR BENEFICIARIES WITH INSTITUTIONAL 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 CINS :	64
TOTAL AMOUNT :	\$966,392,956

Table 2 End Notes

¹ The opening balance was adjusted downward by \$ 38.4 million.

² During the reporting period revisions to previously reported management decisions totaled \$18.8 million.

³ Due to administrative delays, many of which are beyond management control, resolution of the following 9 audits was not completed within 6 months of issuance; however, based upon discussions with management, resolution is expected before the end of 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-02-07-02014	OPEN AND INACTIVE GRANTS ON THE PAYMENT MANAGEMENT SYSTEM - CDC, FEB 2009, \$245,097,758
CIN: A-04-06-03508	UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS - FLORIDA, JAN 2008, \$7,881,447
CIN: A-05-05-00033	MICHIGAN-UNDISTRIBUTED CHILD SUPPORT COLLECTIONS, AUG 2006, \$4,397,133

CIN: A-06-00-00073 MANAGED CARE ADDTL BENEFITS -- NYLCARE HEALTH PLANS OF
THE SOUTHWEST -- CY 2000, MAR 2002, \$4,000,000
CIN: A-05-06-00038 INDIANA-UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS, 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 MINNESOTA - UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS,
SEP 2006, \$28,240

TOTAL CINS : 9
TOTAL AMOUNT : \$1,700,530,100

Appendix C: 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. 67
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 “Compendium of Unimplemented Office of Inspector General Recommendations” at http://www.oig.hhs.gov/publications.html .
(a)(4)	Matters referred to prosecutive authorities	p. 44
(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 B
(a)(9)	Statistical Table 2 – Funds Recommended To Be Put To Better Use	Appendix B
(a)(10)	Summary of previous audit reports without management decisions	Appendix B
(a)(11)	Description and explanation of revised management decisions	Appendix B
(a)(12)	Management decisions with which the Inspector General is in disagreement	None

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

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

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

In response to the 2008 annual solicitation, OIG received the following proposals related to safe harbors:

Proposal	OIG Response
Create a new safe harbor protecting the provision of free, subsidized, or reduced price language services (including oral interpretation and written translation) by hospitals and health systems to physicians and other health care providers and clinicians, and a corresponding regulatory exception to the physician self-referral law.	OIG is not adopting this suggestion with respect to application of the anti-kickback statute. These arrangements vary greatly and should be addressed on a case-by-case basis, such as under the advisory opinion procedures. Development of a physician self-referral law regulatory exception is beyond OIG's scope of authority.
Create a new safe harbor for incentive payments and shared-savings programs (gainsharing) coordinated with, or similar to, the Centers for Medicare & Medicaid Services' (CMS) proposal under the physician self-referral law. One proposal was to coordinate with CMS to develop a consistent, comprehensive safe harbor for such arrangements that would protect participants from sanctions under the physician self-	OIG is not adopting these suggestions at this time. OIG may develop an anti-kickback statute safe harbor for similar arrangements in the future. OIG has no authority to promulgate a safe harbor related to the civil monetary penalty for hospital payments to physicians to reduce or limit services to Medicare or Medicaid beneficiaries. OIG will continue to issue advisory opinions on these types of arrangements in response to requests.

Proposal	OIG Response
referral, civil monetary penalty, and anti-kickback laws.	
Create a new safe harbor to protect payments consisting of a portion of savings realized through participation in the 340B program ² by 340B-covered entities to State Medicaid plans to encourage patient referrals to the 340B-covered entities, or, alternatively, to modify the shared risk safe harbor to protect such arrangements.	OIG is not adopting these suggestions at this time. These suggestions require further study and some of them may be impractical given the statutory language of the shared risk safe harbors.
Revoke the Government Purchasing Organization (GPO) safe harbor, or, alternatively, modify the safe harbor to cap payments at 1 percent and include clarifying language that expressly prohibits any remuneration that is not directly related to the costs of negotiating a supply contract.	OIG is not adopting the suggestion to revoke the safe harbor. The GPO safe harbor is statutory. OIG is also not adopting the suggestions to modify the safe harbor at this time. The suggested modifications require further study and may be impractical given the statutory language of the GPO safe harbor.
Modify the safe harbor for electronic health records (EHR) arrangements to exclude laboratories from the category of protected EHR software donors and provide that donors cannot tie the donation of qualifying software to the acceptance and use of donor-specific interfaces, upgrades, or modifications.	OIG is not adopting these suggestions at this time because they require further study and experience with EHR arrangements. With respect to the first suggestion, in the preamble to the final rule, OIG expressed concern about potential abuses by laboratories and indicated that OIG would revisit protection for laboratory donors if abuses occurred. With respect to the second suggestion, OIG notes that the regulations already require interoperability and restrict donors from inhibiting the use, compatibility, or interoperability of donated items and services with other EHR systems.

² Public Health Service Act, § 340B.

Appendix E: 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 and 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 civil 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 F: Acronyms and Abbreviations

Following are lists of acronyms and abbreviations used in this publication.

Terms, Titles, and Organizations

ACF	Administration for Children and Families
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
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
ESRD	end-stage renal disease
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FMAP	Federal medical assistance percentage
FY	fiscal year
GAO	Government Accountability Office
HCFAC	Health Care Fraud and Abuse Control (program)
HCOP	Health Careers Opportunity Program

HEAL	Health Education Assistance Loan
HEAT	Health Care Fraud Prevention and Enforcement Action Team
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IRF	inpatient rehabilitation facility
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
MCO	managed care organization
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
O&M	operations and maintenance
OCSE	Office of Child Support Enforcement
OIG	Office of Inspector General
OCS	Office of Community Services
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
PTH	parathyroid hormone
QAA	Quality Assessment and Assurance
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

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.
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
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)