



Department of Health and Human Services

Semiannual

Report to Congress

October 1, 2008–March 31, 2009



OIG

Office of Inspector General

OIG COMPONENTS

With more than 1,500 staff throughout the Nation, OIG plans and carries out audits, evaluations, investigations, and legal activities through the following four components:

OAS

Office of Audit Services – The Office of Audit Services (OAS) conducts financial and performance audits of departmental programs, operations, grantees, and contractors following Government Auditing Standards issued by the Government Accountability Office. Financial audits principally provide reasonable assurance about whether financial statements are presented fairly in all material respects; performance audits assess the achievement of objectives and identify the presence of systemic weaknesses giving rise to waste, fraud, or abuse. Recommendations address problems, such as improper payments and inefficient and ineffective use of resources. OAS performs audits or oversees the audit work of others through a nationwide network of auditors, information technology experts, and other professionals.

OEI

Office of Evaluation and Inspections – The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations, conducted by a nationwide staff of evaluators and other professionals, focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

OI

Office of Investigations – The Office of Investigations (OI) conducts and coordinates investigations of fraud and misconduct related to the Department's programs, operations, and beneficiaries. With investigators working in all 50 States, OI leverages its resources by actively coordinating with the Department of Justice and other law enforcement authorities. OI identifies systemic weaknesses that leave Department programs vulnerable to fraud and recovers damages and penalties through civil and administrative proceedings.

OCIG

Office of Counsel to the Inspector General – The Office of Counsel to the Inspector General (OCIG) provides legal advice and representation to OIG on matters relating to Medicare, Medicaid, and other HHS programs and operations, administrative law issues, criminal procedure, and internal OIG management. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. Finally, OCIG renders advisory opinions, issues fraud alerts, and provides other guidance to the health care industry concerning the Federal anti-kickback statute and OIG sanctions.

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Top Management Challenges

Each year, based on its work and observations, OIG identifies the most significant management and performance challenges facing HHS in the coming year. OIG provides the Department with this assessment, which is included in the Department's annual Agency Financial Report (AFR) to Congress. The FY 2008 top management challenges are listed below:

Top Management Challenges
1. Medicare Part D Oversight
2. Medicare Integrity
3. Medicaid and State Children's Health Insurance Program Integrity
4. Quality of Care
5. Emergency Preparedness and Response
6. Oversight of Food, Drugs, and Medical Devices
7. Grants Management
8. Integrity of Information Systems and the Implementation of Health Information Technology
9. Ethics Program Oversight and Enforcement

Message From the Inspector General



This report, which is submitted to Congress pursuant to the Inspector General Act of 1978, as amended, summarizes the activities of the Office of Inspector General (OIG) for the 6-month period ending March 31, 2009.

This has been an exceedingly busy and productive period for our Office in that each of our key components, often working collaboratively in a cross-disciplinary fashion, has achieved significant results on behalf of the Department of Health and Human Services (HHS) beneficiaries and American taxpayers. For example, our investigators and attorneys were instrumental in the Government's \$1.4 billion settlement with a pharmaceutical manufacturer for illegally promoting a drug for uses not approved by the Food and Drug Administration (FDA). Our Office completed significant evaluations of vulnerabilities in the oversight of Medicare Part D and in the way that the FDA and the National Institutes of Health address conflict-of-interest and ethics issues. We also performed major audit work to establish payment error rates in the Temporary Assistance for Needy Families Program (TANF), as requested by the Office of Management and Budget, and examined Medicare payment issues, such as identifying overpayments associated with hospital transfers.

This reporting period also has witnessed a significant restructuring of the governmentwide Inspector General (IG) corps, as well as major expansion of oversight responsibilities for many of the larger Offices of Inspector General. The Inspector General Reform Act of 2008, enacted in October, established a new Council to help IGs develop a strengthened system for governmentwide accountability and oversight.

This enhancement of OIG operations comes at an especially important time for the oversight community and for our Office in particular. In February, the Congress passed and the President signed into law the American Recovery and Reinvestment Act of 2009 (ARRA), which provides new funding for many existing as well as new program activities for Government agencies, including HHS. New funding for Medicaid, health information technology, medical research, and the expansion of the public health safety net requires greater resources to protect public monies. The ARRA established a Recovery Act Accountability and Transparency Board (the Board) consisting of a number of Inspectors General, including HHS/OIG. The Board is responsible for coordinating and conducting oversight of Federal spending under the ARRA to prevent waste, fraud, and abuse. As we do with all the programs administered by HHS, we look forward to fulfilling our responsibilities under the ARRA and appreciate the dedicated funding that Congress has furnished to our Office, and to the Board, to carry out our important work.

As we address a very large and expanding mission to protect the vital health and human service programs of HHS, I would once again like to express my appreciation to the 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 the first half of fiscal year (FY) 2009, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) reported expected recoveries of more than \$274.8 million in audit receivables and \$2.2 billion in investigative receivables, including \$551.7 million in non-HHS receivables resulting from OIG work (e.g., the States' share of Medicaid restitution).

For this semiannual period, OIG reported exclusions of 1,415 individuals and entities for fraud or abuse involving Federal health care programs and/or their beneficiaries; 293 criminal actions against individuals or entities that engaged in crimes against departmental programs; and 243 civil actions, which included False Claims Act and unjust enrichment lawsuits filed in Federal district court, Civil Monetary Penalties Law settlements, and administrative recoveries related to provider self-disclosure matters.

The following are highlights of some of the many significant OIG efforts during this semiannual period:

Pharmaceutical and Medical Supply Manufacturers Settle Fraud Cases and Enter Corporate Integrity Agreements

OIG's efforts to investigate allegations of the pharmaceutical and medical device manufacturers' noncompliance with Federal laws led to the resolution of cases during this reporting period involving manufacturers that market pharmaceuticals and medical supplies prescribed to Medicare and Medicaid beneficiaries. Details of two of these cases follow:

■ **Eli Lilly and Company** (Lilly), a drug manufacturer, agreed to plead guilty and pay approximately \$1.4 billion to the Federal Government and participating States for promoting its antipsychotic drug Zyprexa for uses not approved by the Food and Drug Administration (FDA) and not covered by Medicaid or other Federal programs. In its plea agreement, Lilly admitted to promoting Zyprexa in elderly populations for unapproved uses, such as treatment for dementia, including Alzheimer's dementia. (Details on p. 37.)

■ **Bayer HealthCare LLC** (Bayer), a manufacturer of diabetic supplies, agreed to pay \$97.5 million plus interest to settle allegations that it paid kickbacks to several durable medical equipment (DME) mail order suppliers and diabetic supply distributors, leading them to submit false claims to Medicare. Bayer allegedly paid kickbacks to the suppliers and distributors to convert Medicare beneficiaries to Bayer's products from diabetic supplies manufactured by its competitors or to provide Medicare beneficiaries with Bayer diabetic supplies. (Details on p. 38.)

Both manufacturers entered into 5-year corporate integrity agreements (CIA) with OIG that included provisions to increase the accountability of the companies' Boards of Directors and management.

Skilled Nursing Facility Grant Park Care Center To Pay \$2 Million To Settle False Claims Act Allegations

The owners and operators of Grant Park Care Center, a 296-bed skilled nursing facility (SNF) in the District of Columbia (D.C.), agreed to pay the United States and D.C. \$2 million to settle allegations regarding fraudulent billings to Medicare and Medicaid between 1998 and 2007. The allegations involved providing compromised care to residents, reducing staffing levels to inadequate levels, and seeking reimbursement for services that were not provided or were of a quality that failed to meet professionally recognized standards of health care. Grant Park Care Center and its management company, Grant Park Management, LLC, entered into a 5-year CIA with OIG that required them to establish a detailed compliance program and retain an independent monitor to assess their quality assurance and quality improvement systems. (Details on p. 41.)

Miami Physician Sentenced to 30 Years in Prison for Role in HIV Infusion Fraud Scheme

Miami physician Ana Alvarez-Jacinto was sentenced to 30 years in prison and ordered to pay more than \$8.2 million in joint and several restitution in connection with her role in an HIV infusion fraud scheme. At the Saint Jude Rehab Center, Inc., clinic, HIV-positive Medicare patients were paid cash kickbacks in exchange for allowing Alvarez-Jacinto and her co-conspirators to prescribe unnecessary infusion treatments. The case was brought by the Medicare Fraud Strike Force, a multiagency team of prosecutors and investigators that uses real-time analysis of Medicare billing data to assist in the identification, investigation, and prosecution of individuals and companies that have committed DME and infusion therapy fraud. (Details on p. 36.)

Administrative Law Judge Affirms OIG's Exclusion of Three Former Pharmaceutical Executives

Administrative Law Judge (ALJ) Carolyn Cozad Hughes issued a decision on January 9, 2009, affirming OIG's decision to exclude three former Purdue Frederick executives—Michael Friedman, Paul Goldenheim, M.D., and Howard Udell—from participation in Federal health care programs for a period of 15 years. The exclusions were based on the executives' convictions for wrongful failure to "prevent or correct" fraudulent misbranding and distribution of OxyContin, a powerful narcotic. In sustaining the exclusions, ALJ Hughes found that the executives' fraud-related conduct "endangered the health and safety of program beneficiaries and others" and caused "astronomical" losses to Government programs. (Details on p. 33.)

Deficiencies in Oversight of Medicare Part D Plan Sponsors

During this semiannual period, we issued reports on three reviews related to oversight of the Medicare Part D program, as follows:

- In our review of Medicare stand-alone prescription drug plan sponsors' fraud and abuse programs, we found that 24 of 86 sponsors had not identified any potential fraud and abuse incidents in the first 6 months of 2007. These sponsors, under contract with the Centers for Medicare & Medicare Services (CMS) to provide Part D drug coverage to Medicare beneficiaries, are required to have a comprehensive and effective program to detect and deter fraud and abuse. The most prevalent type of potential fraud and abuse identified was inappropriate billing, such as submitting claims for drugs not provided. Further, not all plan sponsors that identified potential fraud and abuse incidents conducted inquiries, initiated corrective actions, or made referrals for further investigation. (OEI-03-07-00380) (Details on p. 6.)
- In a follow-up to a 2006 OIG report on sponsors' compliance plans for preventing and detecting waste, fraud, and abuse, we found that in 2007, CMS had conducted only one audit of a sponsor's compliance plan and had not verified sponsors' compliance plan self-assessments. (OEI-03-08-00230) (Details on p. 5.)
- In our review of CMS's audits of Medicare Part D bids, we found that one-quarter of all bid audits completed for plan years 2006 and 2007 identified at least one material finding. We also found that although bid amounts are the basis for payment to sponsors, bid audits are not designed to result in adjustments to bid amounts. As of April 2008, only 4 percent of the required financial audits of plan year 2006 had begun. (OEI-05-07-00560) (Details on p. 7.)

Among our recommendations was that CMS review Part D plan sponsors to determine why certain sponsors have especially high or low volumes of potential fraud and abuse and whether sponsors that have identified potential fraud and abuse have initiated inquiries and corrective actions and have made referrals for further investigation. We also recommend that CMS modify the bid audit process to hold plan sponsors more accountable for material findings identified in bid audits and conduct the required number of financial audits in a timely manner.

Results of Supplier Appeals Demonstrate Weakness in Appeals Process

During this semiannual period, we updated a March 2007 OIG report on South Florida medical suppliers, focusing on the 491 suppliers that we identified during 1,581 unannounced visits as failing to meet Medicare standards and that had their billing privileges revoked by CMS. Nearly half of them appealed the revocations and received hearings. At the time we issued our October 2008 report, of the 243 suppliers that appealed and received hearings, 91 percent had their billing privileges reinstated. We found that without criteria regarding the types of evidence necessary to reinstate the billing privileges of suppliers, hearing officers reinstated the suppliers' billing privileges based on a variety of evidence. Following a review of reinstated suppliers by CMS's

contractor, two-thirds of the reinstated billing numbers were revoked or inactivated, and some individuals connected to reinstated suppliers have been indicted. CMS agreed with our recommendation to strengthen the appeal process by developing criteria regarding the types of evidence required for hearing officers to reinstate suppliers' billing privileges. (OEI-03-07-00540) (Details on p. 19.)

Prevalence of Adverse Events and the Efforts To Reduce Them

During this semiannual period, we issued four reports related to “adverse events” and “never events.” Adverse events are events that harm patients as a result of medical care, such as infection associated with use of a catheter; the term “never events” refers to a specific list of serious events, such as surgery on the wrong patient, that the National Quality Forum (NQF) has deemed “should never occur in a healthcare setting.” The Tax Relief and Health Care Act of 2006 mandated that OIG report to Congress regarding the incidence of never events among Medicare beneficiaries, payment by Medicare or beneficiaries for services in connection with such events, and CMS's processes to identify never events and deny payment. Our key findings included the following:

- Reducing the incidence of adverse events in hospitals is a high priority within the industry, and new policies, such as Medicare's nonpayment for care associated with adverse events and public disclosure of adverse events, strengthen hospitals' incentives to develop safer practices.
- As of December 2008, there was no national adverse event reporting system or Federal standards regarding State adverse event reporting systems. We found variations among the 26 States that had adverse event reporting systems, making their data unsuitable for use in the aggregate to identify national incidence and trends.
- Using physician reviewers, we found that during a 1-week period in August 2008, 15 percent of hospitalized Medicare beneficiaries in two selected counties experienced an adverse event during their hospital stays. Although not nationally representative, these results substantiate concerns about the incidence of adverse events in hospitals and the importance of safety initiatives to reduce occurrences.
- Comparing beneficiaries of Medicare Advantage Special Needs Plans (SNP) with beneficiaries of Medicare Advantage Prescription Drug Plans (MA-PD) in 2006, we determined that both groups of beneficiaries were similarly exposed to potentially inappropriate drug pairs. Severe and serious potential drug-drug interactions accounted for 17 percent of all potential drug-drug interactions for SNP and other MA-PD beneficiaries. (OEI-06-07-00470; OEI-06-07-00471; OEI-06-08-00220; OEI-05-07-00490) (Details on p.11.)

Handling of Conflicts of Interest and Ethics Issues at the Food and Drug Administration and the National Institutes of Health

Adding to our previous work related to conflicts of interest in HHS programs, we issued reports on ethics issues at the National Institutes of Health (NIH) and FDA during this semiannual period, as follows:

■ **FDA** – In our review of disclosure of financial interests to FDA, we found that the agency did not have complete information about the financial interests of clinical investigators associated with the 118 marketing applications approved by the agency in FY 2007. FDA regulations require sponsors to disclose in their marketing applications the financial interests of the primary clinical investigators who contributed data to “covered clinical studies.” We recommended that FDA ensure that sponsors submit complete financial information for all clinical investigators, such as maintaining a full list of clinical investigators, checking that sponsors have submitted all required attachments to financial forms, updating guidance to sponsors, and adding a review of financial information to the onsite inspection protocol. FDA generally agreed with our recommendations but did not agree with our recommendation to require sponsors to submit financial information for clinical investigators during the pretrial application process.

■ **NIH** – Of the allegations related to conflicts of interest and ethics violations received by NIH between January 1, 2006, and June 30, 2007, we found that the most common allegations involved employees’ failure to complete ethics training or ethics forms. NIH employees are responsible for reporting allegations of noncriminal misconduct to the appropriate supervisor, to a higher level management official within the organization, or to the NIH Office of Management Assessment. We also found that the majority of NIH Institutes did not have written procedures for handling allegations related to conflict-of-interest statutes and ethics regulations or uniform procedures for conferring about such allegations with other NIH offices. We recommended that NIH develop a formal, written policy for the various ethics offices regarding the handling of allegations of conflicts of interest and ethics violations; and ensure that documentation is maintained on the resolution of allegations. NIH concurred with our recommendations. (OEI-05-07-00730; OEI-03-07-00220) (Details on pp. 47 and 50.)

Compliance With Medicare’s Postacute Care Transfer Policy

In our nationwide review, we estimated that Medicare overpaid \$24.8 million to hospitals that improperly coded claims as discharges to home rather than transfers to postacute care for the 3 years that ended September 30, 2005. Under the postacute care transfer policy, Medicare pays more for inpatient discharges to home than it does for transfers to certain postacute care settings, such as skilled nursing facilities (SNF). Most of the overpayments occurred before CMS had implemented a system edit to detect transfers improperly coded as discharges to home. We recommended that CMS review the claims for the audit period, recover the overpayments, determine why the system edit did not detect all overpayments, and amend the edit as appropriate. CMS agreed with our recommendations. (A-04-07-03035) (Details on p. 18.)

Improper Temporary Assistance for Needy Families Payments

In our reviews of Temporary Assistance for Needy Families (TANF) basic assistance payments for the year that ended March 31, 2007, we found that four States—Idaho, Minnesota, Pennsylvania, and Vermont—collectively claimed an estimated \$30.5 million in improper payments. TANF is a block grant program that provides funding to States to help families move from public assistance to self-sufficiency; TANF’s basic assistance includes benefits designed to meet a family’s ongoing basic needs. The errors pertained to recipient eligibility, payment calculations, and documentation. The estimated error rates ranged by State from 5.5 percent to 16.5 percent of the Federal dollars expended. These reviews, part of an eight-State series, were requested by the Administration for Children and Families and the Office of Management and Budget to determine the FY 2008 national TANF error rate. The four States agreed with our recommendations, which focused on State compliance with requirements, recipient eligibility, and payment calculations. (A-06-07-00104; A-07-07-01045; A-03-07-00552; A-01-07-02504) (Details on p. 52.)

Departmental Financial Statement Audit

In an audit of the FY 2008 HHS financial statements, independent external auditors provided an unqualified opinion. This is the 10th consecutive year that the statements were deemed reliable and fairly presented. However, the report on internal controls noted two material weaknesses—one pertaining to financial reporting systems, analyses, and oversight and the other to financial management information systems. (A-17-08-00001) (Details on p. 58.)

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

Centers for Medicare & Medicaid Services

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

- Medicare, which provides health insurance for people 65 years of age or older, people younger than 65 years old with certain disabilities, and people of any age with end stage renal disease. In fiscal year (FY) 2008, Medicare served an estimated 45 million enrollees at a cost of more than \$460.9 billion. 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 State Children's Health Insurance Program (SCHIP), 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, SCHIP 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), P.L. No. 104-191, which established the Health Care Fraud and Abuse Control program (HCFAC) under the direction of the Attorney General and the Secretary of HHS to combat waste, fraud, and abuse in the Medicare and Medicaid programs. HCFAC funding constitutes a 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), P.L. No. 109–171, which provides OIG annual funding of \$25 million in FYs 2006–2010 to undertake fraud and abuse control activities related to the Medicaid program.

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

Reports Related to CMS's Programs

Medicare-Related Reports

High-Dollar Medicare Inpatient Claims

During the semiannual period, we issued two reports on high-dollar payments made by fiscal intermediaries (intermediaries) to hospitals for inpatient services claimed under Medicare Part A. We defined high-dollar Part A claims 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. CMS guidance requires that hospital claims be completed accurately to be processed correctly.

The results of these audits are as follows:

■ **Intermediary for Wisconsin and Michigan** – In our review of the intermediary's high-dollar payments made to hospitals in Wisconsin and Michigan for inpatient service claims processed during calendar years (CY) 2004 and 2005, we found that the intermediary had overpaid hospitals \$1.6 million for 107 high-dollar claims. After adjustments and refunds, 105 payments totaling \$1.3 million remained outstanding at the start of our audit fieldwork. The overpayments occurred because the hospitals' claims contained inaccurate data and insufficient documentation, hospitals misunderstood how to report charges, and the claim-processing systems used by the intermediary did not have sufficient edits in place to detect and prevent overpayments.

We recommended that the intermediary recover the identified overpayments, use the results of this audit in its provider education activities, and consider implementing controls to identify and review all high-dollar payments for inpatient services. The intermediary agreed. (A-05-07-00069)

■ **Intermediary for Florida** – In our review of the intermediary's high-dollar payments made to hospitals in Florida for inpatient service claims processed during CYs 2004 and 2005, we found that the intermediary had overpaid hospitals \$1.7 million for 125 high-dollar claims. The overpayments resulted mostly from the hospitals' clerical errors, conversion of the pharmacy system from dispensing units to billing units, or outdated billing systems; in addition, the intermediary's claim-processing system did not have sufficient edits in place to detect and prevent the overpayments.

We recommended that the intermediary recover the \$1.7 million in identified overpayments, use the results of this audit in its provider education activities, and consider implementing controls to identify and review all payments greater than \$200,000 for inpatient services. The intermediary agreed to initiate recovery procedures for the overpayments that we identified and stated that it was redesigning its education

materials to strengthen their effectiveness and that it would work with CMS to implement an edit for payments greater than \$200,000. (A-04-07-06020)

High-Dollar Medicare Outpatient Claims

During the semiannual period, we issued three reports on high-dollar payments made by intermediaries to hospitals for outpatient services claimed under Medicare Part B. We defined high-dollar outpatient Part B claims as those that were \$50,000 or more each. CMS contracts with intermediaries to, among other functions, process and pay Medicare institutional Part B claims submitted by providers. Providers are required to use the appropriate procedure codes on their claims and to report units of service as the number of times that a service or procedure was performed.

In January 2006, CMS required intermediaries to suspend high-dollar outpatient claims pending a determination of their legitimacy. However, this control was not yet in place during our audit periods.

The results of these audits are as follows:

■ **Intermediary for Connecticut, Delaware, and New York** – In our review of the intermediary’s high-dollar payments made to hospitals in Connecticut, Delaware, and New York for outpatient service claims processed in CYs 2003–05, we found that the intermediary had overpaid hospitals \$14.6 million for 38 claims. Of the 166 payments in our review, 128 were appropriate; however, 38 resulted in overpayments because hospitals provided incorrect claim-related data or did not have documentation supporting the services billed. Prior to our fieldwork, hospitals refunded \$13.5 million for 17 of the 38 overpayments. Twenty-one overpayments totaling \$1.1 million remained outstanding at the start of our fieldwork.

We recommended that the intermediary inform us of the status of the recovery of the \$1.1 million in overpayments and use the results of this audit in its provider education activities. The intermediary agreed. (A-02-07-01039)

■ **Intermediary for Florida** – In our review of the 40 high-dollar Medicare Part B payments that the intermediary made to hospitals in Florida for outpatient services in CYs 2004–2005, we identified 17 with overpayments totaling \$1.5 million. The hospitals received these overpayments by billing excessive units of service.

We recommended that the intermediary recover the \$1.5 million in identified overpayments. The intermediary stated that it had adjusted the identified outpatient claims and initiated its standard overpayment recovery procedures to recover the overpayments. (A-04-08-06008)

■ **Intermediary for North Carolina** – In our review of the 39 high-dollar payments that the intermediary made to hospitals for outpatient services for CYs 2004–2005, we

identified 22 with overpayments totaling \$1.8 million. The hospitals received these overpayments by billing excessive units of service.

We recommended that the intermediary recover the \$1.8 million in identified overpayments. In its comments, the intermediary provided information on actions that it was taking to recoup the overpayments. (A-04-08-06010)

Provider Relationships and the Use of Magnetic Resonance Under the Medicare Physician Fee Schedule

In our review of magnetic resonance (MR) services paid under the Medicare Physician Fee Schedule (MPFS) in 2005, we determined that when doctors who ordered MR services and the parties involved in providing them were connected through a medical practice or business relationship, those services were provided differently than other services. MR enables doctors to diagnose and treat patients by providing detailed images of tissues and blood vessels deep inside the body.

We found that MR services paid under the MPFS were similarly ordered, performed, and billed regardless of whether they were ordered by high users (doctors whose allowed charges for the MR services they ordered placed them in the 95th percentile among all doctors who ordered MR services). For example, all MR services shared the same likelihood of being ordered by physicians within a small number of specialties and shared the same likelihood of being provided by the same entity receiving payment from Medicare. However, one-quarter of MR services paid under the MPFS featured connections between the doctors who ordered services and the parties involved in providing them. These services were more likely to have been ordered by high users of MR and differed from other services by which specialties ordered, performed, billed, and received Medicare payment for them. They also were more likely to have been billed as the technical component only and to have had payment reassigned.

We concluded that the complexity and limited transparency with which MR services are provided warranted continued attention to ensure that services are reasonable, necessary, and compliant with Medicare statutes and regulations. Although the report did not have recommendations, CMS agreed with our findings and conclusion and outlined regulatory steps it had taken to address overutilization of diagnostic testing services. (OEI-01-06-00261)

CMS's Oversight of Prescription Drug Plan Sponsors' Compliance Plans

We reviewed CMS's oversight of PDP sponsors' compliance plans in a followup to a 2006 OIG report and found that CMS conducted only one audit of a PDP sponsor's compliance plan in 2007. Part D sponsors, which provide prescription drug coverage to Part D beneficiaries under prescription drug plans, are required to have compliance plans addressing elements contained in regulations at 42 CFR § 423.504(b)(4)(vi) and requirements in Chapter 9 of CMS's "Prescription Drug Benefit Manual"—both focused on preventing and detecting fraud, waste, and abuse in the Part D program. The one audit

that CMS had conducted was a focused audit; none of CMS's 17 routine audits included a compliance plan review. In response to a prior OIG report issued in December 2006, CMS stated that it would conduct routine audits of Part D sponsors' compliance plans and follow up with sponsors that we had identified as having compliance plan deficiencies. However, our follow-up review of 2007 found that CMS conducted one focused audit of a sponsor's compliance plan in 2007. In April 2008, CMS reported to OIG that it planned to initiate audits of compliance plans in the summer of 2008; however, as of early August 2008, none had been conducted. We also found that although sponsors completed a compliance plan self-assessment, CMS did not verify the sponsors' responses.

Further, CMS instructed all PDP sponsors to complete a compliance plan self-assessment, but OIG found that CMS did not verify sponsors' responses. The self-assessment was based on regulatory requirements and recommendations in Chapter 9 of the "Prescription Drug Benefit Manual"; however, not all of the compliance plan requirements were included in the self-assessment. CMS followed up with 23 PDP sponsors that attested that they had not implemented one or more of the compliance plan requirements in the self-assessment. However, CMS did not request supporting documentation to confirm that these PDP sponsors corrected their compliance plans.

We recommended that CMS conduct audits to verify Part D sponsors' compliance with all the elements and requirements contained in regulations and in the guidance Chapter 9 of the "Prescription Drug Benefit Manual" and consider assessing the extent to which sponsors have also implemented specific recommendations described in Chapter 9 of the manual. CMS stated that it agreed with our recommendation and would begin audits of Part D sponsors' compliance plans in the near future. (OEI-03-08-00230)

Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse

Our review of Medicare stand-alone prescription drug plan sponsors' identification of potential fraud and abuse found that 24 of 86 sponsors had not identified any potential fraud and abuse incidents in the first 6 months of 2007. Stand-alone prescription drug plan sponsors contract with CMS to provide Part D drug coverage to Medicare beneficiaries. Sponsors are required to have a comprehensive and effective program to detect and deter fraud. Potential fraud and abuse may be identified during internal claim reviews or through complaints or referrals from external sources, such as CMS, Medicare Drug Integrity Contractors (MEDIC), law enforcement agencies, beneficiaries, and pharmacy providers.

Among our findings:

- Of the 62 sponsors that identified incidents, 7 accounted for 90 percent of all incidents identified, 47 conducted inquiries, 32 initiated corrective actions, and 33 referred incidents to other entities for further investigation. Overall, 17 plan sponsors initiated all three actions, 21 initiated two actions, 19 initiated one action, and 5 did not initiate any.

- The most prevalent type of potential fraud and abuse incident identified was inappropriate billing, such as claims submitted for drugs not provided.

We recommended that CMS do the following:

- review Part D plan sponsors to determine why certain sponsors identified especially high or low volumes of potential fraud and abuse,
- determine whether the Part D plan sponsors that identified potential fraud and abuse initiated inquiries and corrective actions and made referrals for further investigation as recommended by CMS,
- require Part D plan sponsors to maintain and routinely report information related to the results of sponsors' fraud and abuse programs, and
- use this required information to help determine the effectiveness of sponsors' fraud and abuse programs.

In response to our first recommendation, CMS described its intentions to follow up with its MEDICs, revise reporting requirements, and provide guidance to PDP sponsors on incident tracking. CMS also concurred with our second recommendation but did not indicate whether it concurred with our third or fourth recommendations.
(OEI-03-07-00380)

CMS's Audits of Medicare Part D Bids

In our review of CMS's audits of Medicare Part D bids, we found that one-quarter of all bid audits completed for plan years 2006 and 2007 identified at least one material finding. Bid amounts are the basis for payments to Part D plan sponsors. Bid audits are in-depth reviews of the actuarial assumptions used to calculate a bid; CMS uses them in its oversight of Medicare Part D bidding. CMS intends also to supplement its oversight with information gathered from financial audits, which verify the accuracy of plan sponsors' financial data.

Our findings included the following:

- The largest number of bid audits with material findings identified findings involving nonpharmacy costs and methodology errors.
- CMS has not adjusted plan sponsors' bid amounts based on bid audit material findings. Instead, it used bid audits to influence the submission, review, and audit of future bid amounts.
- As of April 2008, only 4 percent of the required financial audits of plan year 2006 had begun. Without financial audits, CMS will not be able to ensure the accuracy of the base period data used as the foundation of the bid amount.

We recommended that CMS modify the bid audit process to hold plan sponsors more accountable for material findings identified in bid audits and conduct the required number of financial audits in a timely manner. CMS agreed with the second recommendation and stated that it would carefully consider the first. However, CMS also expressed concerns with how the bid audit findings were presented in the report and cited financial challenges in carrying out the audit requirements. (OEI-05-07-00560)

Comparing Medicare Part D and Medicaid Pharmacy Reimbursement Amounts for Selected Drugs

In our comparison of Part D and Medicaid pharmacy reimbursement for 40 single-source and 39 multiple-source drugs in the third and fourth quarters of 2006, we found that Part D and Medicaid pharmacy reimbursement amounts for most of the single-source drugs that we reviewed were similar. However, Medicaid reimbursement amounts for the multiple-source drugs that we reviewed were typically higher than the Part D amounts. Our study compared only the amount reimbursed to pharmacies by Part D and Medicaid; it did not compare total program expenditures, nor did it examine the impact of rebates or post-point-of-sale price concessions.

For the five States selected for our review, we found that the Medicaid and Part D ingredient cost reimbursement amounts were similar for single-source drugs. In all five States, the average Medicaid ingredient costs exceeded the average Part D ingredient costs for most multiple-source drugs under review. In addition, Medicaid dispensing fees were substantially higher than average Part D dispensing fees for both the single-source and multiple-source drugs under review.

Congress took action to reduce multiple-source drug prices in the Medicaid program through provisions in the Deficit Reduction Act of 2005. These provisions would have expanded the number of drugs subject to Federal upper limits and reduced the Federal upper limit amounts for these multiple-source drugs. These provisions would have also granted States access to average manufacturer price (AMP) data, which, in turn, would have allowed States to base Medicaid drug reimbursement on AMPs. However, a Federal judge issued a preliminary injunction to prevent the implementation of AMP-based Federal upper limits and AMP-based Medicaid reimbursement amounts. In addition, because of the Medicare Improvements for Patients and Providers Act of 2008, CMS is prohibited from establishing Federal upper limit amounts based on AMPs or sharing AMP data with States prior to October 1, 2009. As a result, Federal upper limits and Medicaid reimbursement amounts are still based on published prices, which previous OIG work has found to result in inflated payments for multiple-source drugs. CMS agreed with the methodology and concurred with the findings in the report. (OEI-03-07-00350)

Medicare Payments on Behalf of Deceased Enrollees

In a review of Medicare payments to MA organizations on behalf of deceased enrollees, we found that CMS paid approximately \$4.4 million for coverage periods after the

enrollees' months of death. MA organizations provide managed care to enrollees under Medicare Part C. Pursuant to Federal regulations, after an enrollee dies, the last allowable payment is for the month in which the enrollee died. CMS made improper payments for 2,657 of the approximately 1.7 million deceased enrollees (far less than 1 percent of the enrollees who died) between January 1, 2003, and April 30, 2007. Although CMS had correctly stopped payments for the vast majority of the deceased enrollees, its systems did not identify and prevent all improper payments.

We recommended that CMS recoup the \$4.4 million in unallowable payments and implement system enhancements to prevent and detect improper payments in the future. CMS responded that it had already recovered \$3.5 million and would not recover the remainder because CMS stated that it has a time limit beyond which it does not adjust improper payments. CMS separately provided detailed descriptions of its procedures to prevent and detect improper payments. We revised our second recommendation after reviewing the procedures but continue to recommend that CMS recoup the full \$4.4 million. (A-07-07-01046)

Qualified Pension Plans of Terminated Medicare Contractors

Our reviews of two terminated Medicare contractors found that the contractors had not always complied with Federal requirements or the Medicare contracts' pension segmentation requirements. Medicare pays a portion of contractors' contributions to their pension plans. Because Medicare contracts specifically prohibit any profit (gain) from Medicare activities, contractors must credit to the Medicare program those pension gains (excess pension assets) that occur when a Medicare segment of its operations terminates. Our findings from these two reviews are as follows:

■ **Ohio contractor** – In our review of the contractor's calculations for the period March 1986 through June 2002, we determined that the contractor needed to refund the Federal Government \$14.9 million. The contractor did not correctly identify the initial allocation of pension plan assets to the Medicare segment or comply with the requirements for updating assets. As a result, the contractor understated the Medicare segment assets by \$2 million. In addition, the contractor did not comply with Federal requirements when determining Medicare's share of the Medicare segment excess pension assets as of the termination of the Medicare contracts. As a result, the contractor understated Medicare's share by \$7.5 million.

We recommended that the contractor increase the Medicare contractor segment pension assets as of June 30, 2002, by \$2 million; increase Medicare's share of the excess Medicare segment pension assets as of June 30, 2002, by \$7.5 million; and refund to the Federal Government \$14.9 million, which we calculated to be Medicare's share of the Medicare segment excess pension assets as of the termination of the Medicare contracts. The contractor did not address our recommendations in its comments. (A-07-07-00239)

■ **Maryland contractor** – We determined that the contractor overstated the excess Medicare segment pension assets as of December 31, 2005, by almost \$11,000. We also

determined that the contractor had understated Medicare's share of the Medicare segment excess pension assets by \$512,000 by not fully complying with Federal requirements in its calculation.

We recommended that the contractor decrease Medicare segment pension assets as of December 31, 2005, by \$10,793; increase Medicare's share of the excess Medicare segment pension assets as of December 31, 2005, by \$512,000; and refund to the Federal Government \$4,271,992, which we calculated to be Medicare's share of the Medicare segment excess pension assets as of the termination of the Medicare contracts. The contractor concurred with our first recommendation but disagreed with our second and third recommendations and with the applicability of some of our criteria. The contractor's comments did not provide additional information to cause us to change our findings or recommendations. (A-07-07-00243)

Medicare Capital Disproportionate Share Payments

In our review of \$1.6 billion in Medicare capital disproportionate share hospital (DSH) payments made between FYs 2000 and 2006, we found that \$21.9 million was paid to 397 hospitals that were not eligible for these payments. To receive Federal reimbursement of capital-related costs of inpatient hospital services, hospitals must be classified as urban and have 100 or more beds. The 397 hospitals were either rural or had fewer than 100 beds.

We recommended that CMS take the following steps:

- direct the intermediaries to recover \$21.9 million in capital DSH payments made to ineligible hospitals and
- determine whether capital DSH payments were made to ineligible hospitals for the period subsequent to our review, direct intermediaries to recover any unallowable payments, and conduct reviews on a recurring basis to determine whether capital DSH payments are being made to ineligible hospitals.

CMS agreed with our recommendations. (A-07-08-02735)

Trends in Nursing Home Deficiencies and Complaints

In our study of nursing home deficiencies and complaints, we found that in each of the CYs 2005–2007, over 91 percent of nursing homes surveyed were cited for deficiencies and a greater percentage of for-profit nursing homes were cited for deficiencies than were not-for-profit and government nursing homes. The most common deficiency categories cited were quality of care, resident assessment, and quality of life. Additionally, 17 percent of nursing homes surveyed in 2007 were cited for actual harm or immediate jeopardy deficiencies, and 3.6 percent were cited for substandard quality-of-care deficiencies—a slight increase since 2005. Lastly, the number of substantiated

complaints decreased nearly 3 percent since 2005. This report contained no recommendations. (OEI-02-08-00140)

Prevalence of Adverse Events in Hospitals and the Efforts To Reduce Them

During this semiannual period, we issued four reports related to “adverse events” and “never events.” Adverse events are events that harm patients as a result of medical care, such as infection associated with use of a catheter, and the term “never events” refer to a specific list of serious events, such as surgery on the wrong patient, that the National Quality Forum (NQF) has deemed “should never occur in a healthcare setting.” The Tax Relief and Health Care Act of 2006 mandated that OIG report to Congress regarding the incidence of never events among Medicare beneficiaries, payment by Medicare or beneficiaries for services in connection with such events, and CMS’s processes to identify these events and deny payment. We plan to continue additional work related to adverse events through 2009.

The results of the reports issued during this semiannual period are as follows:

■ **Overview of Key Issues** – We found that reducing the incidence of adverse events is a high priority for policymakers, patients, and providers and that new policies, such as Medicare’s nonpayment for care associated with events and public disclosure of events, strengthen hospitals’ incentives to develop safer practices. Based on interviews with stakeholders and a review of current literature, we identified several factors that are critical to understanding the landscape of adverse events in hospitals, including:

- Estimates of the incidence of adverse events in hospitals vary widely and measurement is difficult.
- Nonpayment policies for adverse events are gaining in prominence and are viewed as a powerful incentive to reduce incidence but raise potential drawbacks.
- Hospitals rely on staff and managers to report adverse events internally, but barriers can inhibit reporting.
- Hospitals report adverse events to various oversight entities, although stakeholders suspect substantial underreporting.
- Public disclosure of adverse events can benefit patients but also raises legal concerns for patients and providers.
- Information to help prevent adverse events is widely available, but some hospitals and clinicians may be slow to adopt or routinely apply recommended practices.
- There are strategies that may accelerate progress in reducing the incidence of adverse events in hospitals. (OEI-06-07-00470)

■ **State Reporting Systems** – We determined that as of January 2008, 26 States had adverse event reporting systems that collect data regarding adverse events that have taken place in hospitals and other health care settings. In 2000, the Institute of Medicine recommended the creation of a nationwide system to provide for the collection of standardized data by State governments when adverse events occur. As of the date of our review, there was no national adverse event reporting system nor any Federal standards regarding State systems. We found variations among the 26 State systems, making their data unsuitable for use in the aggregate to identify national incidence and trends. However, 23 of the 26 States used the reported data in similar ways to hold individual hospitals accountable for their patient care performance, and 18 of the 26 States used the data to promote learning and prevent adverse events. (OEI-06-07-00471)

■ **Incidence Among Medicare Beneficiaries in Two Selected Counties** – Using physician reviewers, we found that during a 1-week period in August 2008, 15 percent of hospitalized Medicare beneficiaries in 2 selected counties experienced an adverse event during their hospital stays. This includes 1 percent of sampled beneficiaries who experienced an event that was a “never event” on the NQF’s list. One of these “never events” resulted in higher Medicare reimbursement to the hospital. We identified another 15 percent of Medicare beneficiaries who experienced events that resulted in temporary harm. We excluded these temporary harm events from our overall rate of adverse events because they did not prolong the hospital stay, require life-saving intervention, or result in permanent harm. Although not nationally representative, these results substantiate concerns about the incidence of adverse events in hospitals and the importance of safety initiatives to reduce occurrences. (OEI-06-08-00220)

Medicare Payments in 2007 for Medical Equipment and Supply Claims With Invalid or Inactive Physician Identifiers

In our review of Medicare payments for medical equipment and supply claims, we found that Medicare allowed almost \$34 million in 2007 for medical equipment and supply claims with unique physician identification numbers (UPIN) that had never been issued or had been deactivated by CMS. We found that Medicare allowed over \$6 million in 2007 for claims with invalid UPINs that had never been issued by CMS. During the same year, Medicare also allowed almost \$28 million for claims with UPINs that CMS had deactivated, including \$5 million for claims with a date of service after the physician identified on the claims had died. Medicare also allowed over \$300,000 for claims with invalid referring physician national provider identifiers (NPI) in 2007.

We recommended that CMS determine why Medicare claims with identifiers associated with deceased referring physicians continue to be paid. We encouraged CMS to implement changes to the claims-processing systems to ensure the validity of NPIs for both referring physicians and suppliers listed on claims. In addition, we recommended that CMS emphasize to suppliers the importance of using accurate NPIs for both referring physicians and suppliers when submitting Medicare claims. We suggested that CMS determine the earliest date to end its provision that allows suppliers to submit claims without referring physician NPIs, while maintaining beneficiary access to services. CMS

concluded with our recommendations, stating that it has already taken several important steps toward alleviating the problems identified and incorporating the recommendations from this report. (OEI-04-08-00470)

Comparing Special Needs Plan Beneficiaries to Other Medicare Advantage Prescription Drug Plan Beneficiaries

In our review comparing beneficiaries of Medicare Advantage Special Needs Plans (SNP) with beneficiaries of other Medicare Advantage Prescription Drug Plans (MA-PD) in 2006, we found that, on average, SNP beneficiaries had higher prescription drug utilization and costs than other MA-PD beneficiaries. Congress created the SNP authority to allow MA managed care plans to develop targeted clinical programs to care more effectively for high-risk beneficiaries. Concerns about SNPs include whether SNP beneficiaries, who are more likely to have complicated medical regimens, have an increased risk of exposure to therapeutic duplications (when two drugs that treat the same medical condition, taken together, increase the risk of toxicity) or drug-drug interactions (when two drugs taken together lead to increased toxicity or changes in the efficacy of one or both drugs). Despite SNP beneficiaries' higher rates of drug utilization, we determined that SNP beneficiaries and other MA-PD beneficiaries were similarly exposed to potentially inappropriate drug pairs. The majority of potentially inappropriate drug pairs for both SNP and other MA-PD beneficiaries were potential drug-drug interactions, most of which were of moderate risk. Severe and serious drug-drug interactions accounted for 17 percent of all potential drug-drug interactions for SNP and other MA-PD beneficiaries.

Other specific findings included the following:

- SNP beneficiaries filled 11 percent more prescriptions than other MA-PD beneficiaries.
- The average annual prescription cost per SNP beneficiary was 49 percent higher compared to that of other MA-PD beneficiaries.

We recommended that CMS help SNPs and other MA-PDs to provide physicians and pharmacists with the information needed to prevent inappropriate drug pairs leading to adverse drug events, specifically by: continuing to encourage plans to fully implement e-prescribing programs that improve information physicians and pharmacists have about beneficiaries' medication histories; providing plans with information on inappropriate drug pairs most likely to lead to severe or serious adverse drug events in the Medicare population; and encouraging plans to provide tools to assist physicians and pharmacists so they can appropriately analyze and use the information they receive.

- CMS concurred with our recommendation to help SNPs and other MA-PDs to provide physicians and pharmacists with the information needed to prevent inappropriate drug pairs that could lead to adverse drug events. It noted that Part D sponsors are required to maintain systems to monitor drug utilization, including the use of potentially

inappropriate drug pairs. In addition, it cited a number of efforts it supports aimed at preventing inappropriate drug pairs that could lead to adverse drug events. (OEI-05-07-00490)

Emergency Health Services Furnished to Undocumented Aliens

- Medicare-participating hospitals are required to provide an appropriate medical screening examination to any person, regardless of ability to pay, who comes to the hospital emergency department to determine whether an emergency medical condition exists. In our review of a Florida hospital's claims for payment for emergency health services furnished to undocumented aliens covered by section 1011 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), we found that the hospital had received \$17,000 in unallowable payments for these services furnished from May 10 to September 30, 2005.
- Section 1011 of the MMA, "Federal Reimbursement of Emergency Health Services Furnished to Undocumented Aliens," provided \$250 million per year for FYs 2005–2008 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 requirements.
- The payments were unallowable because they were for claims for services that went beyond patient stabilization, lacked supporting documentation, were not offset by payments by third-party payers, or were for services for nonemergency conditions. Had the hospital followed its own policies or procedures, it might have precluded some of these errors. Furthermore, the hospital's written policies and procedures did not address section 1011 requirements regarding reimbursements from third-party payers.
- We recommended that the hospital refund \$17,000 received for services that did not meet section 1011 reimbursement requirements; that it review the remaining claims for our audit period and claims for subsequent periods and submit adjustments for any claims that did not meet section 1011 reimbursement requirements; that it follow its existing policies and procedures to ensure that future section 1011 program claims meet reimbursement requirements; and that it develop and implement procedures to ensure that reimbursements for services are made to the extent that a third-party payer did not otherwise reimburse care. The hospital agreed with our recommendations. (A-04-07-07030)

Hospital Reporting of Wage Data in Medicare Cost Reports

In our reviews of hospitals' compliance with Medicare requirements for reporting wage data in their Medicare cost reports, we found that three hospitals did not fully comply with the requirements. Under the acute-care hospital inpatient prospective payment system (PPS), 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. Our specific findings, by hospital, follow:

■ A hospital in Pennsylvania overstated its wage data by \$12.2 million and 412,397 hours for the FY 2006 Medicare cost report period. Correcting the hospital's errors increased the average hourly wage rate from \$35.25 to \$35.45. 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 agreed with or accepted most of our findings; however, it disagreed in part with our finding regarding \$4.2 million in pension benefit costs and the need to submit a revised FY 2006 cost report to correct the wage data overstatements. The hospital said that it would work to strengthen its review and reconciliation procedures. Our conclusion regarding overstated pension costs remains unchanged. After reviewing the hospital's comments and information provided by the intermediary, we deleted our recommendation to submit a revised cost report. (A-03-07-00024)

■ A hospital in California overstated its wage data by \$11.8 million and more than 250,000 hours in its FY 2005 Medicare cost report. Correcting the hospital's errors increased the average hourly wage rate from \$49.75 to \$50.17. We recommended that the hospital submit a revised FY 2005 Medicare cost report to the intermediary to correct the wage data overstatements and that it strengthen 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. In its comments, the hospital provided information on actions taken to implement our recommendations. (A-09-07-00083)

■ A hospital in Kansas overstated its wage data by \$634,000 and understated its wage data by more than 12,000 hours in its FY 2005 Medicare cost report. Correcting the hospital's errors decreased the average hourly wage rate from \$29.14 to \$29. We recommended that the hospital submit a revised FY 2005 Medicare cost report to the intermediary to correct the wage data overstatement and understatement and that it 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 concurred with three of our findings but did not concur with two other findings. Based on discussions with the hospital after the issuance of our draft report but before our receipt of the hospital's written comments, we revised our finding on overstated contract labor costs, on the recommended adjustment amount, and on the wage rate calculation. (A-07-07-02726)

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

During this semiannual period, we issued three reports related to our continuing work comparing average sales prices (ASP) with average manufacturer prices (AMP) and

widely available market prices (WAMP) for Medicare Part B prescription drugs. From April 2006 through January 2009, we issued 11 reports of such comparisons. Section 1847A(d)(2)(B) of the Social Security Act (the Act) mandates that OIG perform these comparisons. For instances in which the ASP for a drug exceeds the AMP or WAMP by a certain threshold (currently 5 percent), section 1847A(d)(3) of the Act provides that the Secretary may disregard the ASP pricing methodology for that drug and that the Secretary substitute the payment amount for the drug code with the lesser of the WAMP (if any) or 103 percent of the AMP (for the drug).

In December 2007, the Medicare, Medicaid, and SCHIP Extension Act of 2007 (the Extension Act), P.L. No. 110–173, amended section 1847A(b) of the Act and changed the way that CMS calculates volume-weighted ASPs, effective April 1, 2008. Analyzing CMS’s Healthcare Common Procedure Coding System (HCPCS) codes for drugs covered under Medicare Part B, we identified in both the previous comparisons and those issued during this semiannual period instances in which drug codes met the threshold for price adjustments. We determined that such adjustments, if implemented by the Secretary, would save Medicare millions of dollars in Part B drug costs. Although these reports did not include recommendations, CMS has commented previously that it would like to better understand fluctuating differences between ASPs and AMPs and that it intends to develop a process to adjust payment amounts based on the results of our pricing comparisons. To date, no changes have been made to reimbursement for drugs covered under Part B as a result of our price comparisons.

In the three comparisons issued during this reporting period, we specifically found the following:

■ **Comparison of First-Quarter 2008 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Third Quarter 2008** – Using a revised payment methodology implemented by CMS in April 2008, we identified a total of 41 HCPCS drug codes with an ASP that exceeded the AMP by at least 5 percent in the first quarter of 2008. If reimbursement amounts for these 41 codes had been based on 103 percent of the AMPs, Medicare expenditures would have been reduced by \$7.8 million during the third quarter of 2008 alone. Of the 41 drug codes that met the threshold for price adjustment, 16 had AMP data for every National Drug Code (NDC) that CMS used to establish reimbursement amounts. In addition, 8 of these 16 codes were previously eligible for price adjustment under the revised payment methodology, and 3 of the codes would have met the 5-percent threshold in each of the past five quarters had the revised ASP methodology been in effect since the beginning of 2007. The remaining 25 of 41 drug codes also met the 5-percent threshold in the first quarter of 2008 but did not have AMP data for every NDC that CMS used when calculating reimbursement. We could not compare ASPs and AMPs for 76 HCPCS drug codes because AMP data were not submitted for any of the NDCs that CMS used to calculate reimbursement. Manufacturers for over one-fifth of these NDCs had Medicaid drug rebate agreements and were therefore generally required to submit AMPs. We are working with CMS to evaluate and pursue appropriate actions against those manufacturers that fail to submit required data. (OEI-03-08-00530)

■ **Comparison of Second-Quarter 2008 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2008** – Using a revised payment methodology recently implemented by CMS, we identified a total of 31 HCPCS drug codes with an ASP that exceeded the AMP by at least 5 percent in the second quarter of 2008. If reimbursement amounts for these 31 drug codes had been based on 103 percent of the AMPs, Medicare expenditures would have been reduced by \$3.5 million during the fourth quarter of 2008.

Of the 31 HCPCS drug codes that met the threshold for price adjustment, 10 had AMP data for every drug product that CMS used to establish reimbursement amounts. Eight of the 10 HCPCS codes were previously eligible for price adjustment under the revised payment methodology, with 3 codes meeting the 5-percent threshold in each of the past six quarters, dating back to the first quarter of 2007. The remaining 21 of 31 HCPCS codes also met the 5-percent threshold in the second quarter of 2008 but did not have AMP data for every drug product that CMS used when calculating reimbursement. We could not compare ASPs and AMPs for 68 HCPCS codes because AMP data were not submitted for any of the drug products that CMS used to calculate reimbursement. Manufacturers for almost one-fifth of these drug products had a Medicaid drug rebate agreement and were therefore generally required to submit AMPs. OIG continues to work with CMS to evaluate and pursue appropriate actions against manufacturers that fail to submit required data. (OEI-03-09-00050)

■ **Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2007** – In our comparison of average sales prices and average manufacturer prices, we identified 71 Medicare Part B drug codes that would have been eligible for price adjustment in one or more quarters of 2007 if the revised payment methodology recently implemented by CMS had been in effect throughout 2007. Additional codes may have been eligible for price adjustments; however, we could not examine certain drug codes because pricing data were missing or unavailable.

Of the 71 drug codes that met the threshold for price adjustment during 2007, one-fourth would have met the 5-percent threshold during more than one quarter of 2007. Because some drug products did not have AMP data, we could not compare prices for 25 percent of drug codes in each of the first and third quarters and for over 40 percent of codes in each of the second and fourth quarters.

Consistent with statutory requirements, we recommended that CMS develop a process to adjust payment amounts based on the results of OIG's pricing comparisons, lower Medicare reimbursement amounts for drugs that meet the 5-percent threshold, and ensure that drug manufacturers submit the required AMP data in a timely manner. CMS concurred with our recommendation to develop a process for adjusting payment amounts but did not specifically concur with our recommendation to lower Medicare reimbursement for drugs that meet the 5-percent threshold. CMS stated that it would continue its efforts to ensure that manufacturers submit required AMP data in a timely manner. (OEI-03-08-00450)

Payments to Medicare Suppliers and Home Health Agencies Associated With “Currently Not Collectible” Overpayments

In our review of 10 suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) with total outstanding Medicare debt of \$7.3 million, we found that 6 suppliers were associated with 15 other DMEPOS suppliers and home health agencies (HHA) that collectively received \$58 million in Medicare payments during 2002–2007. The associations are of interest because Federal investigators suspect that principals of DMEPOS suppliers with outstanding Medicare debt may be benefitting from Medicare payment through businesses publicly fronted by associates or family members. Most of the DMEPOS suppliers associated with the six suppliers had themselves lost billing privileges by January 2005 and had collectively accumulated \$6.2 million of their own “currently not collectible” debt to Medicare; however, most associated HHAs received Medicare payments as recently as December 2007. This suggests that associations among DMEPOS suppliers and HHAs may be less frequently detected than those among DMEPOS suppliers alone. The sample DMEPOS suppliers we reviewed were most frequently connected with their associated DMEPOS suppliers and HHAs through shared owners or managers. Further, 11 of the 15 associated businesses’ enrollment applications did not include the name of at least one individual listed as an owner or a manager in public records. These results suggest that suppliers associated with Medicare debt could inappropriately receive Medicare payments by omitting owner/manager information on their enrollment applications and working through other DMEPOS suppliers and HHAs.

Given these associations, CMS may deem it appropriate to conduct a similar review of DMEPOS suppliers with outstanding Medicare debt to identify associations with other suppliers or HHAs receiving Medicare payment and take appropriate action if it confirms that ownership or management information was misreported on these associated businesses’ enrollment applications. We issued this early alert memorandum without recommendations and without comment from CMS; we intend to conduct follow-up work regarding these issues and vulnerabilities. (OEI-06-07-00080)

Compliance With Medicare’s Postacute Care Transfer Policy

In our nationwide review of hospital compliance with Medicare’s postacute care transfer policy, we estimated that for the 3-year period that ended September 30, 2005, hospitals improperly coded 15,051 claims, resulting in Medicare overpayments of \$24.8 million. Under the postacute care transfer policy, Medicare pays full prospective payments to hospitals that discharge inpatients to their homes. For specified diagnosis-related groups, Medicare generally pays a lesser amount to hospitals that transfer inpatients to certain postacute care settings, such as SNFs or home health care. Of the 150 claims in our sample, hospitals improperly coded 92 claims, totaling \$137,000, as discharges to home rather than transfers to postacute care.

Most of the overpayments occurred because CMS lacked adequate payment system controls before implementing a system edit on January 1, 2004, to detect transfers improperly coded as discharges to home. Although overpayments were significantly

reduced after implementation of the edit, the edit did not detect 12 overpayments in our sample.

We recommended that CMS (1) instruct the fiscal intermediaries to recover \$137,000 in overpayments identified in our sample, review the remaining claims in our sampling frame, and identify and recover additional overpayments estimated at \$24.7 million and (2) determine why the system edit did not detect 12 overpayments and amend the edit as appropriate. CMS concurred with our recommendations. (A-04-07-03035)

Results of Supplier Appeals Demonstrate Weakness in Appeals Process

For a March 2007 report, we made unannounced visits to 1,581 South Florida medical equipment suppliers, determining that 491 failed to meet Medicare supplier standards. These suppliers had their billing privileges revoked by CMS, and nearly half of them appealed the revocations and received hearings. As of October 2008, 91 percent of the suppliers that appealed and received hearings had their billing privileges reinstated. We found that without criteria regarding the types of evidence necessary to reinstate the billing privileges of suppliers, hearing officers reinstated the suppliers' billing privileges based on a variety of evidence. Following a review of reinstated suppliers, two-thirds of the reinstated billing numbers were revoked or inactivated, and some individuals connected to reinstated suppliers have been indicted.

We recommended that CMS strengthen the appeal process by developing criteria regarding the types of evidence required for hearing officers to reinstate suppliers' billing privileges. CMS agreed. (OEI-03-07-00540)

Medicare Administrative Law Judge Hearings: Update, 2007–2008

At the request of the Senate Finance Committee, we updated a previous review of the early implementation of administrative law judge (ALJ) hearings by the Office of Medicare Hearings and Appeals (OMHA). In 2005, when assuming responsibility from the Social Security Administration (SSA) for certain Medicare administrative appeals, OMHA became subject to a new statutory requirement that certain cases be decided within 90 days. In contrast to SSA's mostly in-person hearings, OMHA planned to use primarily telephone and video conferences to conduct ALJ hearings. Our previous review, which examined the first 13 months of OMHA's operation, found that an estimated three-quarters of the hearings were conducted by telephone, that most appellants were satisfied with their hearing format, that incomplete and inaccurate data limited OMHA's ability to manage its caseload, and that a number of cases were not decided in a timely manner.

In our updated review, which examined OMHA's first through third years of operation (2007–2008), we found the following:

- OMHA's caseload increased 37 percent and the proportion of cases subject to the 90-day decision requirement also increased.

- There was little change in the hearing formats used and in the types of primary appellants.
- OMHA improved the timeliness of its decisions during this time. For cases that had a 90-day decision requirement, OMHA decided 94 percent on time in its third year, compared to 85 percent in its first year of operation.
- For cases without the 90-day decision requirement, OMHA decided a slightly greater percentage of cases within 6 months; however, there was also a slight increase in the average number of days to decide these cases.
- OMHA improved the quality of the data in the appeals system.

This report had no recommendations. (OEI-02-06-00111)

Medicaid-Related Reports

Medicaid Outpatient Prescription Drug Expenditures

In our reviews of the Medicaid outpatient prescription drug expenditures in two States, we found that both States had claimed Federal Medicaid reimbursement for prescription drug 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 a 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:

- **Tennessee** – In our review of Tennessee's claims for reimbursement of Medicaid outpatient drug expenditures for FYs 2004–2005, we determined that of the \$4.5 billion (\$3 billion Federal share) claimed, \$8 million (Federal share) represented expenditures for drug products that were not eligible for Medicaid coverage because their termination dates had passed or because the drugs were determined to be less than effective. An additional \$13.2 million (Federal share) represented expenditures for drug products that were not listed on CMS's quarterly drug tapes; because the State did not verify that the drugs missing from the tapes were eligible for Medicaid coverage, some of the expenditures may not have been allowable for Medicaid reimbursement.

We recommended that the State refund \$8 million to the Federal Government for drug expenditures that were not eligible for Medicaid coverage; that it work with CMS to determine whether the \$13.2 million in payments for drugs not listed on the quarterly drug tapes was eligible for Medicaid coverage; and that it strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements. The

State agreed in part with our first recommendation but did not directly address our second or third recommendations. (A-04-07-00027)

■ **Pennsylvania** – Our review of Pennsylvania’s claims for reimbursement of Medicaid outpatient drug expenditures for FYs 2004 and 2005 found that the State had not fully complied with Federal requirements. Of the State’s \$1.96 billion (\$1.1 billion Federal share) in Medicaid outpatient claims, \$4.4 million (Federal share) represented expenditures for drug products that were not eligible for Medicaid coverage because, for example, the drugs were terminated or the drug expenditures were not supported by adequate documentation. An additional \$5.9 million (Federal share) represented expenditures for drug products that were not listed on the quarterly drug tapes. Because the State had not verified whether these drugs were eligible for Medicaid coverage, the drug expenditures may not have been allowable for Medicaid reimbursement.

We recommended that the State refund \$4.4 million to the Federal Government, that it work with CMS to resolve \$5.9 million in payments for drugs that were not listed on the quarterly drug tapes, and that it strengthen internal controls to ensure that claimed Medicaid drug expenditures comply with Federal requirements. The State generally agreed with our recommendations and provided additional documentation to support \$958,000 (Federal share) of its claim. We modified our finding accordingly. (A-03-07-00203)

Medicaid Overpayments in Indiana

In our review of Indiana’s Medicaid Rehabilitation Option Program for FYs 2000–2005, we found that the State did not report overpayments totaling \$23.4 million (\$14.5 million Federal share) and interest earned on the overpayments totaling \$130,000 (\$82,000 Federal share) in accordance with Federal requirements. States are required to refund the Federal share of Medicaid overpayments and to report to CMS any interest earned on overpayments each quarter.

We recommended that the State (1) report to CMS Medicaid overpayments totaling \$23.4 million and refund \$14.5 million, (2) report interest earned on Medicaid recoveries totaling \$130,000 and refund \$82,000, and (3) make procedural improvements. The State disagreed with our first and third recommendations and did not address our second recommendation. After reviewing the State’s comments, we maintain that our findings and recommendations are valid. (A-05-07-00072)

Ohio Medicaid Long-Term-Care Payments

In our review of Ohio’s Medicaid claims for payments to long-term-care providers, we determined that the State overpaid more than \$18 million (\$10.5 million Federal share) from FYs 1999–2005 for long-term-care services claimed by more than one provider for the same services to the same beneficiary on the same date. As of the start of our audit in July 2007, the State had reported and refunded \$8.4 million (\$4.9 million Federal share) of the unallowable payments through adjustments, decreasing its Medicaid claims for

prior quarters on its report to CMS for the quarter ended June 30, 2005. However, the State had not reported and refunded \$9.6 million (\$5.6 million Federal share).

We recommended that the State (1) refund to the Federal Government \$5.6 million for unallowable Medicaid reimbursements and (2) review payments totaling \$31.9 million (\$18.6 million Federal share) made to the providers that we did not review and refund to the Federal Government any unallowable Medicaid reimbursements. The State commented that it would need to complete an analysis before agreeing to a final refund amount. Regarding the second recommendation, the State said that it had initiated a review and would refund overpayments after completing the review. (A-05-07-00074)

Medicaid Payments for Personal Care Services

In our review of Medicaid payments for personal care services (PCS) made by five State Medicaid programs from October 1 through December 31, 2005, we found that four States paid 871 claims to providers that had billed for more than 24 hours of PCS in a day. PCS—such as dressing, bathing, cooking, and light housekeeping—help beneficiaries stay in their homes rather than receive constant care in more expensive institutional settings. A related OIG report issued in August 2008 focused on Medicaid payments for beneficiaries with overlapping institutional and PCS claims.

Additional findings of this review included the following:

- Medicaid programs in all five States paid 2,324 PCS claims, totaling \$3 million, which were associated with billings of between 16 and 24 hours of services per day.
- Three State Medicaid programs allowed providers to bill for PCS in date ranges that included days on which no services were provided, a practice that makes it difficult to identify the number of PCS hours billed on any given day in a date range.

Although the report had no recommendations, we suggested that CMS consider providing States with information regarding the vulnerability associated with claims for PCS billed more than 24 hours per day or claims for date ranges that include days on which no services were provided. (OEI-07-06-00621)

Colorado's Medicaid Mental Health Capitation and Managed Care Program

In our review of Colorado's supplemental Medicaid payments made from 2001–2004 for mental health services provided to foster care children in child placement agencies, we determined that these payments were not fully consistent with Federal and State requirements. Because of unanticipated stresses on Medicaid funding for these services, the State began making supplemental payments (i.e., payments in addition to the monthly capitation payments) to its contracted mental health assessment and service agencies (MHASA) in 2001. Of the \$23 million (\$11.7 million Federal share) in supplemental payments, \$3.3 million (Federal share) was unallowable because the State had not obtained, as required, CMS's approval of contracts covering the supplemental payments

for a portion of the audit period. In addition, the State did not provide documentation that the remaining \$8.4 million (Federal share) in supplemental payments had been removed from the capitation payments that the State made to MHASAs.

We recommended that the State refund \$3.3 million to the Federal Government and work with CMS to resolve \$8.4 million. The State disagreed with our findings and recommendations. After reviewing the State's comments, we modified our report and removed the finding on unallowable costs related to the failure to comply with State contract provisions. We also modified our report to set aside, rather than question, the \$8.4 million in potentially unallowable supplemental payments. (A-07-06-04067)

New Mexico's Medicaid Administrative Costs

In our review of New Mexico's claimed Medicaid administrative costs for the quarter ending September 30, 2004, we found that the State claimed \$1.5 million (\$1.1 million Federal share) of unallowable costs. The Federal share of Medicaid administrative costs is typically 50 percent, but enhanced rates of 75 or 90 percent may be claimed for some costs. For the period reviewed, the State claimed administrative costs totaling \$16.3 million (\$10.3 million Federal share).

The \$1.5 million of unallowable costs consisted of \$1.1 million (\$883,000 Federal share) for costs claimed because of errors in compiling the Federal claim and \$374,000 (\$187,000 Federal share) resulting from errors in the random moment timestudy base that was used to allocate eligibility fieldworker costs. The State also claimed \$509,000 at unallowable enhanced Federal funding rates (75 or 90 percent). Although these costs were eligible for Federal reimbursement at the standard 50-percent rate, they did not meet enhanced-rate guidelines; therefore, the State improperly received \$128,000 in enhanced funding. We could not determine what portion of \$772,000 (\$386,000 Federal share) in salary costs for medical assistance workers and temporary assistance for needy families (TANF) and what portion of \$8.5 million (\$6.4 million Federal share) in TANF transition costs were allowable because these costs benefited other programs.

We recommended that the State (1) refund \$1.2 million to CMS, (2) work with CMS to identify the allowable portion of the \$772,000 (\$386,000 Federal share) in costs for medical assistance workers and TANF program employees, (3) work with CMS to identify the allowable portion of the \$8.5 million (\$6.4 million Federal share) adjustment made to claim TANF transition costs at an enhanced Federal funding rate, and (4) make administrative changes related to our findings. The State agreed with most of our findings and recommendations. The State said that it would refund to CMS \$1.18 million of the \$1.2 million in unallowable costs and enhanced Federal funding rate costs but disagreed with findings totaling \$22,000 in the "Miscellaneous Overcharges" section of the report. After reviewing the State's comments and the documentation that it provided, we maintain that our findings and recommendations are valid. (A-06-07-00072)

Connecticut's Community-Based Medicaid Administrative Claim

In this CMS-requested review of Connecticut's claims for community-based Medicaid administrative costs for State FY 2004, we found that the State's \$9.3 million claim may not have fully complied with Federal requirements. The State claimed reimbursement from CMS for administrative case management activities provided by contracted organizations. Because the State made omissions and deviations from acceptable practices when calculating its claim and was unable to provide adequate documentation, we were unable to express an opinion on the claim's allowability.

We recommended that the State draft its future contracts to identify and properly value the amount of administrative case management activities and that it work with CMS to determine what portion of the \$9.3 million was allowable under Federal requirements. The State generally agreed with our recommendations. (A-01-06-00008)

Clinic and Practitioner Claims Billed as Family Planning Services Under the New York State Medicaid Program

In our review of New York's claims for Federal Medicaid reimbursement for family planning services from April 2003 through March 2007, we estimated that the State improperly received \$17.2 million for improperly claiming enhanced 90-percent Federal reimbursement. The Federal share of the Medicaid program was 52.95 percent or 50 percent for New York during our audit period. Under Federal law, a State may provide family planning services and supplies to individuals of childbearing age who are eligible under the State Medicaid plan and receive enhanced 90-percent Federal reimbursement for items and procedures that are clearly furnished or provided for family planning purposes.

Our specific findings included the following:

- Of our 119 sampled claims, 17 qualified as family planning services that were eligible for enhanced 90-percent Federal reimbursement.
- Of the 102 claims that did not qualify for the 90-percent Federal reimbursement rate, 33 were not eligible for any Federal Medicaid reimbursement, including 27 claims for abortion procedures and 63 were eligible for reimbursement at the applicable matching rate of 50 or 52.95 percent. The remaining six claims were unallowable for reasons including lack of adequate or required documentation.

The overpayment occurred because providers incorrectly claimed services as family planning, and the State's Medicaid Management Information System (MMIS) edit routines did not adequately identify claims unrelated to family planning. We recommended that the State refund \$17.2 million to the Federal Government, reemphasize to providers that only services directly related to family planning should be billed as family planning, ensure that MMIS edits use all appropriate claim information to identify claims that are ineligible for enhanced 90-percent Federal reimbursement, and

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 concurred with our recommendations. (A-02-07-01037)

Disproportionate Share Hospital Payments by Pennsylvania

For State FYs 2005–2006 and 2006–2007, we reviewed whether three hospitals associated with universities in Pennsylvania retained Medicaid DSH payments that are authorized by CMS to ensure that services are provided to the medical assistance population and help offset medical education costs incurred. States are required to make Medicaid DSH payments to hospitals that serve a disproportionately large number of low-income patients. As recommended by a contractor retained by the State to generate Federal funding, the State submitted State plan amendments (SPA) that authorized DSH payments limited to the three hospitals in our review. This report was part of an OIG initiative to determine the extent to which State Medicaid agencies have contracted with consultants through contingency fee arrangements and the effect of those arrangements on the submission of questionable or improper claims to the Federal Government.

We determined that two of the three hospitals did not retain their DSH payments but instead redirected payments totaling \$35.1 million (Federal share) to their university medical schools. Because the two hospitals did not require the medical schools to account for how they used the funds, we could not determine whether the schools used the DSH funds in compliance with the SPAs.

We recommended that the State work with CMS to resolve \$35.1 million (Federal share) in DSH payments redirected to university medical schools in State FYs 2005–2006 and 2006–2007 and DSH payments redirected to university medical schools after our review period, including any portion of the \$25.5 million estimated Federal share for State FY 2007–2008. The State agreed to work with CMS on any future SPA pertaining to academic medical centers but said that it was not aware of any Federal regulation or legislation that requires the hospitals to retain their DSH payments. We revised our second recommendation to acknowledge CMS’s approval of the SPA for State FY 2007–2008 subsequent to our review. We support our recommendations, as revised.

(A-03-07-00222)

Audits Related to Hurricane Katrina

Audits of Hospitals in the New Orleans Area

During this semiannual period, we issued two reports related to five hospitals in the New Orleans region that had requested additional assistance following Hurricane Katrina. Officials of five hospital groups (the testifying hospitals) appeared at an August 1, 2007, post-Katrina health care hearing held by the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce (Committee), and testified that their hospitals had experienced significant post-Katrina operating losses, due largely

to the increased costs of providing hospital care following the August 2005 hurricane. Using a summary of financial data compiled by the Louisiana Hospital Association comparing pre-Katrina (January through May 2005) with post-Katrina (January through May 2007) expenses and revenues, the officials requested Federal financial assistance for the recovery of the health care delivery system in the New Orleans area, including additional grant funds from HHS. In a September 27, 2007, letter, the Committee requested that OIG review the more significant operating loss items cited by the testifying hospitals in their testimony and also perform a profitability analysis of them.

Related audits issued during this semiannual reporting period are as follows:

■ **Profitability Analysis of New Orleans Hospitals** – Our analysis of the testifying hospitals’ profitability trends for FYs 2002–2006 showed that each hospital had a different profitability trend. The testifying hospitals’ cumulative results, broken down into four measures of profitability, varied by type of expenditure and fiscal year.

Patient-related care margin (revenues and expenses related to day-to-day patient care): For FYs 2002 and 2003, the testifying hospitals had cumulative positive patient-related care margins; for FYs 2004–2006, they had cumulative negative patient-related care margins.

Total margin (all revenues and expenses): For FYs 2002 and 2003, the testifying hospitals had cumulative positive total margins; for FYs 2004 and 2005, they had cumulative negative total margins. For FY 2006, the hospitals had a cumulative positive total margin, which included additional funding from Business Interruption insurance payments and additional Federal funding for hurricane damage.

Medicare program margin (payments received from Medicare): For FY 2002, the testifying hospitals had a cumulative positive Medicare program margin; for FYs 2003–2006, they had cumulative negative Medicare program margins.

Medicaid program margin (payments received from Medicaid): For FYs 2002–2006, the testifying hospitals had cumulative negative Medicaid program margins.

As this was an informational report, we made no recommendations. (A-07-07-02733)

■ **Profitability Analysis of New Orleans Hospitals Compared With Peer Hospitals** – We compared profitability trends and characteristics of the testifying hospitals with three sets of peer hospitals in the FY after Hurricane Katrina. We determined that the testifying hospitals’ profitability trends differed from those of the peer hospitals and reflected both the adverse financial impact of Hurricane Katrina and subsequent financial improvements after the testifying hospitals received Business Interruption insurance payments and additional Federal funding because of their hurricane damage. As this was an informational report, we made no recommendations. (A-07-07-02734)

Louisiana's Hurricane Katrina Health-Care-Related Provider Stabilization Grant

In our review of Louisiana's computation of Hurricane Katrina Health-Care-Related Provider Stabilization grant payments made following Hurricane Katrina to hospitals and other providers, we found that the State had followed the approved methodology for computing the grant payments but made data entry errors on grant payment spreadsheets that resulted in most of the hospitals' receiving incorrect grant amounts. In 2007, Louisiana received a total of \$97.9 million in grant funding, which was available to Katrina-affected States to make payments to hospitals and other providers facing wage rates that had not yet been reflected in Medicare prospective payment system methodologies. We determined that the data entry errors led to incorrect grant payments, ranging from a \$60,162 overpayment to a \$60,942 underpayment. We recommended that the State use the results of our review to adjust incorrect grant payments received by the hospitals. The State agreed with our recommendation. (A-06-08-00025)

Hurricane-Related Uncompensated Care Claims: Louisiana

Under section 1115 of the Social Security Act, 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. The pool, which was 100 percent federally funded, was generally limited to services that were covered under the State Medicaid plan and provided within a specified period.

In this review, we found that Louisiana did not comply with applicable Federal and State laws and regulations or with the approved provisions of the State's UCCP plan in claiming, as of December 31, 2006, an estimated \$19.8 million for services provided by one hospital to Hurricane Katrina and Rita evacuees. Of the \$8 million in costs claimed for services provided to 100 sampled patients, we determined that \$7.8 million claimed for 98 patients was unallowable. The reasons for services being unallowable included the following: care was not covered under the State Medicaid plan, services were not received on the dates claimed, costs were paid by other sources, or costs were reimbursed from the Hurricane Rita UCCP for patients who were not evacuees.

We recommended that the State refund to CMS the estimated \$19.8 million in unallowable costs claimed. The State did not address our recommendation but disagreed with our findings. Nothing in the State's comments caused us to revise our findings or recommendation. (A-06-07-00024)

Other CMS-Related Reports

Oversight of the Implementation of the Health Insurance Portability and Accountability Act of 1996

In our review of CMS's oversight of the implementation of the HIPAA, we found that the agency had taken limited actions between October 2003 and August 2007 to ensure that covered entities adequately implemented requirements of the Security Rule. The HIPAA Security Rule requires a covered entity, such as a health plan or health care provider that transmits any health information in electronic form, to ensure the integrity and confidentiality of the information, to protect against any reasonably anticipated threats or risks to the security or integrity of the information, and to protect against unauthorized uses or disclosures of the information. HHS has delegated to CMS the authority and responsibility to interpret, implement, and enforce HIPAA Security Rule provisions.

Our findings included the following:

- CMS had no effective mechanism to ensure that covered entities were complying with the HIPAA Security Rule or that electronic health information was being adequately protected. The agency had not conducted any HIPAA Security Rule compliance reviews of covered entities, relying instead on complaints to identify noncompliant entities that it might investigate.
- CMS had not established any policies or procedures for conducting compliance reviews at covered entities.
- CMS had an effective process for receiving, categorizing, tracking, and resolving complaints.

We recommended that CMS establish policies and procedures for conducting HIPAA Security Rule compliance reviews of covered entities. CMS agreed with our recommendation; however, it did not agree with our findings and indicated that the agency's complaint-driven enforcement process had furthered the goal of voluntary compliance. We continue to recommend that CMS add compliance reviews to its oversight process. (A-04-07-05064)

Financial Statement Audit

The CMS FY 2008 financial statements received an unqualified audit opinion, which means that the statements were fairly presented in accordance with generally accepted accounting principles. However, auditors identified a material weakness in CMS's information systems controls. The weakness related primarily to CMS oversight of information security, access to programs, and control over application configuration management for shared systems. (A-17-08-02008)

Resolution of Audit Recommendations

In our review of CMS's resolution of audit recommendations during FYs 2006 and 2007, we determined that the agency had resolved 3,462 of the 4,650 audit recommendations that were outstanding during this period. However, the agency did not resolve 2,813 of the 3,462 recommendations within the required 6-month period. Office of Management and Budget Circular A-50 requires prompt resolution and corrective actions on audit recommendations; resolution is to be made within a maximum of 6 months after the issuance of a final report.

We also found that as of September 30, 2007, CMS had not resolved 1,188 audit recommendations that were past due for resolution. The dollar amounts associated with these recommendations totaled \$1.165 billion.

By not resolving audit recommendations in a timely manner, CMS did not have reasonable assurance that it was exercising proper stewardship over Federal dollars. During the audit period, CMS revised its audit resolution procedures and made progress resolving outstanding audit recommendations in a more timely manner. We recommended that CMS resolve all audit recommendations within the required 6-month audit resolution period and resolve the 1,188 outstanding audit recommendations that were past due as of September 30, 2007. CMS concurred with our recommendations. (A-07-07-04112)

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 instances of waste, fraud, 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 October 1, 2008, through March 31, 2009, OIG received 33 advisory opinion requests and issued 12 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 doing business with Federal health care programs. The protocol guides providers and suppliers through the process of structuring a disclosure to OIG about matters that appear to 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 undertake a thorough internal investigation of 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 procedures regarding self-disclosures. 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 the 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, which 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 Stark 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 \$17.5 million in HHS receivables. The following are examples:

■ **Illinois** – To resolve a matter reported under OIG’s Provider Self-Disclosure Protocol, the City of Chicago (City) agreed to pay \$6.9 million to resolve its Civil Monetary Penalties Law (CMPL) liability for submitting false claims to Medicare. The City allegedly submitted claims to Medicare for ambulance services that were not medically necessary, billed at the wrong level of service, or submitted without the patient’s or other appropriate person’s signature, as required by CMS regulations.

■ **Pennsylvania** – Milton S. Hershey Medical Center (Hershey) agreed to pay the Government approximately \$3,174,224 to settle its False Claims Act (FCA) liability for improperly classifying certain costs for organ transplants. Specifically, as disclosed under OIG’s Provider Self-Disclosure Protocol, Hershey inappropriately included costs unrelated to organ acquisition on its 2000–2005 Cost Reports received by Medicare. The fraud allegedly resulted because Hershey shifted from post-transplant to pre-transplant activities. Hershey, already operating under a CIA for the submission of false claims for infusion therapy services, agreed to CIA amendments relating to policies and procedures for the proper allocation of transplant costs.

■ **Michigan** – Courtyard Manor of Farmington Hills, Inc. (Courtyard Manor), an adult foster care facility, agreed to pay \$1.7 million to resolve its CMPL liability for receiving Federal health care program funds while being subject to a 10-year exclusion from participation in all Federal health care programs. The company also agreed to an additional 2-year period of exclusion. The original exclusion, imposed in August 2002, was the result of a May 2001 no contest plea to a charge of involuntary manslaughter after the death of a Courtyard Manor resident. As disclosed under OIG’s Provider Self-Disclosure Protocol, Courtyard Manor discovered in May 2007 that it had contracted with several agencies that were funded, in part, by the Michigan Medicaid Program.

■ **Wisconsin** – To resolve a matter reported under OIG’s Provider Self-Disclosure Protocol, ShopKo Stores Operating Co., LLC, and its predecessor, ShopKo Stores, Inc. (ShopKo), agreed to pay \$669,824 to resolve its CMPL liability in connection with its employment of an excluded pharmacist, John M. Tuckett, RPh. In November 1987, Tuckett was excluded from participation in Federal health care programs for a period of 5 years. At the conclusion of the exclusion period, Tuckett failed to seek reinstatement to participate in Federal health care programs. In November 2006, as part of the implementation of its new exclusion compliance policy, ShopKo began performing annual exclusion searches for all of its pharmacy employees. The initial search pursuant to this new policy revealed Tuckett’s exclusion.

■ **California** – Alliance Nursing and Rehabilitation Center (Alliance) agreed to pay \$500,000 to settle its liability under the OIG’s CMPL authority for allegedly submitting false claims to Medicare. Pursuant to OIG’s Provider Self-Disclosure Protocol, Alliance disclosed that, from January 2001 through July 2005, it presented or caused to be

presented claims for wound care supplies using incorrect billing codes, which resulted in receipt of reimbursements in excess of amounts to which it was entitled.

■ **Hawaii** – To resolve a matter reported under the OIG’s Provider Self-Disclosure Protocol, Queen’s Medical Center (QMC) agreed to pay \$150,500 to resolve its CMPL liability related to the inappropriate disclosure of confidential information from the National Practitioner Data Bank (NPDB). The NPDB is an information clearinghouse used to collect and release information related to the professional competence and conduct of health care practitioners, providers, and suppliers. QMC allegedly sent confidential NPDB reports on over 250 of its medical staff members to its insurance carrier, which, in turn, sent the reports to the carrier’s insurance broker and underwriter.

Office of Inspector General Administrative Sanctions

OIG has the authority to impose administrative sanctions for instances of fraud or abuse or other activities that pose a risk to Federal health care programs and their beneficiaries (see Appendix C 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 1,450 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 of these sanctions follow.

Program Exclusions

During this reporting period, OIG excluded 1,415 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 include the following:

■ **Florida** – Angel Castillo, Jr., who owned or controlled several durable medical equipment (DME) companies, was excluded for a minimum period of 50 years based on his conviction for a health care fraud and money-laundering scheme. From August 2005 to October 2006, Castillo’s DME companies submitted false claims to Medicare for DME items and services that were not provided to beneficiaries. Castillo then laundered the proceeds obtained through the scheme. Castillo was sentenced to 235 months of incarceration and was ordered to pay \$7,236,992 in restitution.

■ **Michigan** – Robert Stokes, an osteopath, was excluded for a minimum period of 50 years based on his conviction for health care fraud. From August 2001 to December 2004, Stokes submitted claims to Medicare, TRICARE (the military’s health insurance

program), and private insurance companies for upcoded surgical procedures and medically unnecessary procedures. Stokes, who lied to patients about their medical conditions, was sentenced to 126 months of incarceration, was ordered to pay \$1,315,682 in restitution, and had his osteopath license revoked by the Michigan Board of Osteopathic Medicine.

■ **Kansas** – Momodou Alieu Jallow, a nurse aide, was excluded for a minimum of 25 years based on his conviction for rape and attempted rape of patients in a nursing home where he was employed. Jallow was sentenced to 226 months of incarceration.

■ **Colorado** – Raymond Francis Armelino, a physical therapist, was excluded for a minimum of 20 years based on his conviction for sexual assault on a child by one in a position of trust and for unlawful sexual contact. During therapy sessions, Armelino sexually assaulted patients, including a teenage girl. Armelino received a sentence of between 8 years and life in prison.

■ **Rhode Island** – John Montecalvo, a nursing home executive, was excluded for a minimum period of 17 years based on two convictions—one for equity skimming and the other for embezzlement, conspiracy, and patient neglect. From January 1998 to May 2004, Montecalvo used monies that had been issued by the United States Department of Housing and Urban Development for the operation of nursing homes for purposes other than what was reasonable and necessary. He was sentenced to 24 months of incarceration and was ordered to pay \$780,539 in restitution. In a related State case, Montecalvo was sentenced to 10 years in prison with 9 years suspended, to be served concurrently with the Federal sentence, for his involvement in a Medicaid fraud scheme and for failing to provide treatment and care to patients at a nursing home.

■ **Connecticut** – ALJ Carolyn Cozad Hughes issued a decision on January 9, 2009, affirming OIG’s determination to exclude former Purdue Frederick executives Michael Friedman, Paul Goldenheim, M.D., and Howard Udell from participation in Federal health care programs for a period of 15 years. The exclusions were based on the executives’ convictions for their failure—as responsible corporate officers of Purdue Frederick—to “prevent or correct” the fraudulent misbranding and distribution of OxyContin. In July 2007, when Purdue Frederick pleaded guilty to felony misbranding of OxyContin, the three executives pleaded guilty to related misdemeanor misbranding in their role as responsible corporate officers. In sustaining the 15-year period of exclusion, ALJ Hughes found that the executives’ fraud-related conduct “endangered the health and safety of program beneficiaries and others” and caused “astronomical” losses to Government programs. ALJ Hughes also considered the long-running nature of the misbranding activities in determining that a 15-year period of exclusion was warranted. Michael Friedman is the former Chief Operating Officer and Chief Executive Officer, Paul Goldenheim the former Chief Scientific Officer, and Howard Udell the former General Counsel at Purdue Frederick.

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 \$11.8 million in CMPs and assessments. The following are among the CMP actions resolved during this reporting period:

■ **Tennessee** – Methodist Health Care-Memphis Hospitals (Methodist) agreed to pay \$136,627 to resolve its CMPL liability for allegedly employing an excluded nurse. On January 19, 2005, Lee Ann McCain was excluded from participation in the Federal health care programs; on June 12, 2006, Methodist hired her as a full-time registered nurse despite a pre-employment sanction check that revealed McCain’s exclusion. As part of the settlement, Methodist certified that it has policies and procedures in place to prevent the hiring or contracting with any ineligible person or entity.

■ **Mississippi** – Valerie Tolley, doing business as Health Care Medical (HCM), agreed to pay \$100,000 and enter into a 3-year CCA to resolve its CMPL liability arising from HCM’s payment and attempted payment of kickbacks in exchange for direct and indirect patient referrals. HCM, a DME supplier, allegedly arranged for Sherrie Alexander, a nurse employed at Sta-Home Home Health Agency (Sta-Home), to obtain patient census rosters. HCM allegedly used the rosters to solicit DME sales and paid Alexander for every completed sale. This arrangement ended in June 2003, when Sta-Home fired Alexander after learning of the arrangement. HCM also allegedly offered sales personnel kickbacks if they obtained patient information that HCM could use in making targeted DME sales.

Patient Dumping

Some of the CMP cases that OIG resolved between October 1, 2008, and March 31, 2009, were pursued under the Emergency Medical Treatment and Labor Act, a statute designed to ensure patient access to appropriate emergency medical services. The following is an example of a settlement under this statute:

■ **California** – On January 30, 2009, ALJ Steven T. Kessel sustained OIG’s determination to impose a \$50,000 CMP against St. Joseph’s Medical Center (St. Joseph’s) for failure to provide a medical screening examination or stabilizing treatment to an individual who presented to the emergency department (ED) with an acute emergency medical condition. The patient complained of general weakness or a possible stroke and presented with a swollen tongue, slurred speech, and abnormal vital signs. The patient’s condition deteriorated after waiting several hours in the ED, and despite his family’s repeated requests for help, the patient did not receive a medical screening examination. Approximately 3½ hours after arriving at St. Joseph’s, the patient went into cardiopulmonary arrest and subsequently died. ALJ Kessel found St. Joseph’s failures “shocking” and characterized St. Joseph’s treatment of the patient as

“constituting a complete collapse of the system of care it purported to offer emergency patients.” ALJ Kessel found that St. Joseph’s conduct warranted the maximum penalty.

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 C.

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 and to be permitted to continue participating in Medicare, Medicaid, and other Federal health care programs. Such agreements are monitored by OIG and require the providers to enhance existing compliance programs or establish new ones. The compliance programs are designed, in part, to prevent a recurrence of the underlying fraudulent conduct.

During this semiannual period, the Government’s enforcement efforts resulted in 222 criminal actions and 239 civil actions against individuals or entities that engaged in health-care-related offenses. These efforts resulted in \$1.6 billion in HHS and \$540.8 million in non-HHS investigative receivables, including civil and administrative settlements or civil judgments related to Medicare; Medicaid; and other Federal, State, and private health care programs. 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 (SAUSA). 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 Medicare and Medicaid fraud. In one detail, beginning in May 2007, OIG partnered with the United States Attorney’s Office for the Southern District of Mississippi to focus on physical therapy and physical medicine fraud enforcement. The detail focused on physical therapy clinics believed to be submitting false and fraudulent claims to the Medicare and Medicaid

programs. The scheme involved the use of unlicensed individuals, often with little or no training, to render unsupervised in-home physical therapy services to beneficiaries. The services were billed under a physician's provider number as if the physician personally rendered the services or directly supervised a licensed physical therapist rendering the services.

■ **Mississippi** – Neil Lenwood Lanning, owner of Progressive Physical Medicine, Inc. (PPM), was sentenced to 3 years in prison and ordered to pay \$1,026,555 in restitution following his guilty plea to making a false statement in a health care matter. Beginning in approximately April 2003 and continuing through May 2005, Lanning submitted claims to the Medicare program falsely claiming that in-home physical therapy/physical medicine services had been rendered by PPM's medical director or by a licensed clinic employee under the physician's direct supervision. In fact, the services were provided by unlicensed and unsupervised employees.

■ **Mississippi** – Morris Pernell Richardson, Zackery Paul Bennett, and Venus Jeanette Callahan (collectively the "Defendants"), owners of Southeastern Rehab Professionals, Inc., each pleaded guilty to misprision of a felony. Callahan was sentenced to 6 months in prison, while Richardson and Bennett were each sentenced to 5 years' probation. The Defendants were also held jointly and severally liable for \$102,639 in court-ordered restitution. The Defendants concealed from authorities the fact that, from May 2004–April 2005, their company fraudulently submitted claims to the Medicare program for physical therapy/physical medicine services that were not rendered by qualified or licensed individuals.

Medicare Fraud Strike Force

The Medicare Fraud Strike Force (Strike Force) uses real-time analysis of Medicare billing data to assist in the identification, investigation, and prosecution of individuals and companies that have committed DME and infusion therapy fraud. The Strike Force continues to yield convictions throughout South Florida and is also proving to be a valuable fraud detection tool in Los Angeles.

During this reporting period, Strike Force efforts in South Florida resulted in 48 convictions and \$135.9 million in investigative receivables and efforts in Los Angeles resulted in the filing of charges against 14 individuals or entities. Examples of Strike Force efforts during this reporting period include the following:

■ **Florida** – Miami physician Ana Alvarez-Jacinto was sentenced to 30 years in prison and ordered to pay \$8,289,286 in joint and several restitution in connection with her role in an HIV infusion fraud scheme. The Strike Force found that in a 5-month period between June and November 2003, Alvarez-Jacinto ordered hundreds of medically unnecessary HIV infusion treatments at the Saint Jude Rehab Center, Inc. (Saint Jude), clinic. HIV-positive Medicare patients at Saint Jude were allegedly paid cash kickbacks of approximately \$150 per visit in exchange for allowing Alvarez-Jacinto and her co-conspirators to prescribe the unnecessary treatments. After her 2-week trial, the judge

found her trial testimony to be perjurious and enhanced her sentence for obstruction of justice.

■ **Florida** – Jorge Infante, owner of DME providers F.A. Medical Supply & Equipment Inc. (F.A. Medical) and Unique Medical Equipment and Supply Inc. (Unique Medical), was sentenced to 39 months' imprisonment and ordered to pay \$2,004,230 in restitution following his guilty plea to health care fraud. From February through October 2007, Infante caused the submission of false and fraudulent claims to Medicare on behalf of F.A. Medical and Unique Medical for wound care and suction pump supplies that were neither prescribed by physicians nor received by beneficiaries.

■ **Florida** – Reinel Pulido was sentenced to 36 months' incarceration and ordered to pay \$1,565,410 in restitution for health care fraud. The Strike Force found that Soroa Medical Services, Inc., an infusion clinic owned and operated by Pulido, billed Medicare for infusion-related therapies that had not been ordered by a physician and were never provided to beneficiaries.

■ **Florida** – Jose Perez Morales was sentenced to 30 months' imprisonment and ordered to pay \$786,749 in restitution for health care fraud. Perez Morales controlled and operated Med Life Supplies Inc. (Med Life), a DME provider, from May 18 through November 28, 2007. During that time, Med Life billed Medicare for enteral nutrition and infusion supplies that were neither prescribed by physicians nor received by beneficiaries.

Pharmaceutical Manufacturers and Distributors

■ **Pennsylvania** – Eli Lilly and Company (Lilly) entered an approximately \$1.4 billion global criminal, civil, and administrative settlement to resolve allegations that it illegally marketed its antipsychotic drug Zyprexa. Under the civil settlement agreement, Lilly agreed to pay the Federal Government \$438,171,544 and participating States up to \$361,828,456 to resolve FCA allegations that by marketing Zyprexa for certain unapproved uses, it caused false claims for payment to be submitted to Federal health care programs, such as Medicaid, from September 1999 to the end of 2005. The civil allegations were originally brought in four separate qui tam lawsuits. Lilly will also pay a criminal fine of \$515 million and forfeit assets of \$100 million. In its plea agreement, Lilly admitted that from September 1999 to March 31, 2001, it promoted Zyprexa for unapproved uses in elderly populations as treatment for dementia, including Alzheimer's dementia. Lilly entered a 5-year CIA with several unique provisions, including (1) a requirement that Lilly notify doctors about the settlement and provide a means by which the physicians may report questionable conduct by sales representatives; (2) a requirement that Lilly post on its Web site information about payments made to physicians; and (3) flexible audit provisions, which allow for additional audits to be conducted throughout the term of the CIA at OIG's discretion and with limited advance notice. The CIA also provides for increased accountability by Lilly's board of directors and management in the form of an annual resolution by a board committee and annual certifications from managers about compliance.

■ **Florida** – Bayer HealthCare LLC (Bayer) agreed to pay \$97.5 million plus interest to settle allegations that it paid kickbacks to several DME mail order suppliers and diabetic supply distributors, to induce them to convert Medicare beneficiaries to Bayer diabetic supplies from diabetic supplies manufactured by Bayer’s competitors or to provide Bayer diabetic supplies to Medicare beneficiaries. The United States alleged that this conduct caused the suppliers and distributors to submit false claims to Medicare from January 1998–December 2007 for certain diabetic supplies manufactured by Bayer.

Bayer also executed a 5-year CIA in connection with the settlement. The CIA, which also applies to Bayer affiliates, requires the company to establish a database to manage certain arrangements with sources of Federal health care program business. It also includes (1) flexible audit provisions, which allow for additional audits to be conducted throughout the term of the CIA at OIG’s discretion and with limited advance notice; (2) requirements for increased accountability by Bayer’s board of directors in the form of an annual resolution by the board (with input from and a compliance program review to be conducted by a three-party independent Compliance Expert Panel engaged by Bayer); and (3) annual certifications from managers regarding compliance.

■ **Texas** – Abbott Laboratories Inc. (Abbott), an Illinois-based pharmaceutical company, agreed to pay the State of Texas and the Federal Government a total of \$28 million in a Medicaid fraud settlement to resolve its civil liabilities related to the false pricing of certain intravenous drugs and blood products. Under Texas law, drug manufacturers participating in Medicaid are required to report their wholesale and other prices to the Medicaid program. These prices are the basis on which the Texas Medicaid program calculates reimbursement to Medicaid providers. The Government alleged that Abbott falsified price reports and inflated its prices for products that it submitted to the Texas Medicaid program. As a result of the alleged illegal pricing, Texas Medicaid allegedly overreimbursed providers for Abbott’s drugs.

■ **Minnesota** – Walgreen Co. (Walgreens) agreed to pay the United States \$9.9 million to resolve allegations that it overcharged the Medicaid program in Minnesota, Michigan, Florida, and Massachusetts for prescription drugs by charging Medicaid for the difference between the Medicaid negotiated amounts and the third-party primary insurer negotiated amounts for the drugs. The Government alleged that Walgreens charged Medicaid a larger amount when it should have charged Medicaid only for the co-pay after the primary payer’s payment. In addition to agreeing to the monetary settlement, Walgreens agreed to enter into an amendment to its June 2008 CIA. Under the amendment, Walgreens must train its pharmacists regarding the importance of billing Medicaid appropriate amounts and hire an independent review organization to annually audit its Medicaid claims in each of the four States.

Durable Medical Equipment Suppliers

■ **Florida** – Abner and Mabel Diaz, owners of the medical billing company All Med Billing Corp. (All Med), were each sentenced to 168 months in prison for health care

fraud and conspiracy to commit health care fraud. In addition, Suleidy Cano, an All Med employee, was sentenced to 132 months in prison for aggravated identity theft and conspiracy to commit health care fraud. The Diazes were ordered to pay \$125,762,489 in joint and several restitution and forfeit various pieces of real estate. All Med submitted claims to Medicare on behalf of suppliers who purportedly provided DME to Medicare beneficiaries. These claims were for equipment that had not been ordered by physicians or delivered to the beneficiaries as claimed. All Med facilitated the fraudulent billings by assisting in the concealment of the true owners of the DME companies, forging prescriptions, forging certificates of medical necessity, improperly acquiring the identities of Medicare beneficiaries, and directing the DME companies to use certain billing codes.

Hospice

■ **Alabama** – SouthernCare, Inc. (SCI); SouthernCare Holdings, Inc.; SouthernCare Carry, LLC; and Michael Parly agreed to pay the United States \$24.7 million and enter into a 5-year CIA to resolve their FCA liability for allegedly submitting false claims to Medicare. Operating in locations in 15 States, SCI allegedly submitted claims for treating patients who did not meet Medicare’s hospice eligibility criteria. This settlement resolved allegations in two qui tam lawsuits filed by former SCI employees.

Clinics

■ **California** – Goar “Gina” Alibalian, the owner and operator of a medical clinic, was ordered to pay \$4,676,647 in restitution and was sentenced to 72 months of incarceration following her guilty plea to health care fraud. The clinic paid a kickback to every patient or marketer bringing a patient into the clinic, billed for patients who never came to the clinic, and created patient files with falsified notes to support the fraudulent claims.

■ **Connecticut** – Carlson Therapy Network, P.C. (Carlson), a network of 20 physical therapy clinics in Connecticut and Rhode Island, agreed to pay \$1,886,834 and enter into a 5-year CIA to resolve its FCA liability. The Government alleged that from October 2002 through December 2005, Carlson submitted false or fraudulent claims for individual, one-on-one physical therapy services when, in fact, group physical therapy services were provided.

■ **Georgia** – Fernando, Michael, and Ricardo Visbal, owners of Savannah Medical Services Inc. (SMS), were ordered to serve prison terms of 47, 20, and 6 months, respectively, and pay a total of \$423,596 in restitution for their involvement in an infusion fraud scheme. SMS billed Medicare for infusion therapy and gamma globulin that were not provided to patients. The investigation also revealed that SMS paid patients to receive treatment at the facility.

Contractors

■ **Massachusetts** – Medical transcription service provider MedQuist Inc. agreed to pay the United States \$6.6 million to resolve FCA allegations that it overbilled Federal Government clients. The Government alleged that from approximately 1998 through 2004, the New Jersey-based company knowingly overbilled the Department of Veterans Affairs, the Department of Defense, and the Public Health Service for medical transcription services by inflating the number of lines billed to the Government instead of applying the contractually prescribed method. The settlement resolves in whole or in part allegations made in two qui tam actions.

Practitioners

■ **California** – Dr. Paul Lessler agreed to pay \$2.18 million to resolve FCA allegations that between 2002 and 2006, he inappropriately allowed his UPIN to be used to bill Medicare for respiratory therapy. The United States alleged that the claims were billed incident to Dr. Lessler’s services when he did not provide direct supervision and as if they were performed at his office instead of the noncovered board and care facilities. The United States also alleged that Dr. Lessler paid kickbacks to “marketing coordinators,” who recruited patients at the board and care facilities. As part of the settlement, Dr. Lessler also agreed to be excluded for 15 years.

■ **Nevada** – Physicians Wen Liang, Craig M. Jorgenson, Robert Schreck, Tony Q.F. Chin, Mohammed Najmi, and Edmund Pasimio agreed to pay \$212,515, \$133,110, \$94,574, \$70,640, \$60,451, and \$54,440, respectively, for allegedly violating the FCA and other statutes. The agreement resolved allegations that the physicians received kickbacks in exchange for patient referrals made to a nurse practitioner.

■ **Maryland** – Virginia Vought Acree, a State-licensed clinical specialist in child and adolescent psychiatric and mental health nursing, was sentenced to 36 months of imprisonment and ordered to pay restitution in the amount of \$390,000 following her guilty plea to health care fraud. Acree falsely billed Medicare, Medicaid, and private health care plans for services that she did not provide on hundreds of occasions from January 2003 to November 2007. Acree often billed for face-to-face psychotherapy services on dates when she was on vacation in other States or countries or attending out-of-town conferences.

■ **Illinois** – Podiatrist Ernest A. Nwani was sentenced to 12 months and 1 day of imprisonment and ordered to pay \$109,127 in restitution following his guilty plea to health care fraud. From 2002 to 2006, Dr. Nwani billed Medicare for surgical procedures that he had not actually performed, including the permanent removal of partial or complete toenails, bunion corrections, and the removal of bones from patients’ feet.

Nursing Homes

■ **District of Columbia** – Grant Park Care Center (GPCC), a 296-bed skilled nursing facility, agreed to pay to pay the United States and the District of Columbia \$2 million to settle FCA allegations. GPCC is owned and managed by Centennial HealthCare Corporation, Grant Park Nursing Home Limited Partnership, Grant Park Management LLC, Centennial Service Corporation-Grant Park, Centennial Acquisition Corporation, Centennial Healthcare Management Corporation, Centennial Employee Management Corporation, Hilltopper Acquisition Corporation, Hilltopper Holding Corporation, Shoreline HealthCare Management LLC, and Coastal Administrative Services LLC (collectively, Centennial). Centennial is one of the largest nursing home owners in the United States.

The United States alleged that from January 1998 through December 2007, Centennial submitted claims to the Medicare and Medicaid programs for services that failed to meet the needs of the residents at GPCC in one or more of the following areas: resident nutrition and hydration; needs assessments and evaluations; care planning and nursing interventions; medication management; fall prevention and management; and pressure ulcer care, including the prevention and treatment of wounds. In addition, the United States alleged that Centennial understaffed GPCC during the covered period with knowledge that resident care would be compromised.

As part of the settlement, Grant Park Nursing Home Limited Partnership and Grant Park Management, LLC, agreed to enter into a 5-year CIA with OIG that required them to establish a detailed compliance program and retain an independent monitor to assess their quality assurance and quality improvement systems.

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 (P.L. No. 95–142) with the objective of strengthening the Government’s capability to detect, prosecute, and punish fraud against Medicaid programs. 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 other outreach work. During FY 2008, OIG provided oversight for and administration of approximately \$185 million in Federal grants that were distributed to the 50 MFCUs.

Joint Investigations

■ **Texas** – Ithem Wilson was sentenced to 5 years and 10 months of imprisonment and was ordered to pay \$3,217,579 in joint and several restitution following his guilty plea to health care fraud and wire fraud. Wilson’s codefendant, Theresa Peter, had previously been sentenced in July 2008 to 1 year and 1 day of incarceration and held responsible for paying \$1,582,277, a portion of the restitution figure, for conspiracy. According to allegations in a 35-count indictment, Wilson and Peter owned or operated—in whole or in part—Access Medical Supply, a DME company that billed Medicare for motorized wheelchairs but routinely provided less expensive motorized scooters. The investigation involved OIG, the FBI, and the Texas MFCU.

■ **Indiana** – Gabriele Reginald Harden was sentenced to 41 months of imprisonment and ordered to pay restitution in the amount of \$1,683,412, following a guilty plea to health care fraud and money laundering. Harden owned and operated a mobile dental unit, Dental Express, which operated out of a recreational vehicle and focused primarily on low-income, Medicaid-eligible children. The mobile unit arranged for visits, typically to inner city schools, day care facilities, and subsidized housing projects. He routinely billed Medicaid for fillings when sealants were actually applied to primary teeth, a procedure not covered by Medicaid. He also improperly billed for x-rays that were not taken at the direction of a dentist, were not diagnostic, or were developed long after the patient was seen on the mobile unit. Harden had ceased billing for sealants as fillings because of mounting pressures from staff and an investigation in Ohio, but he restarted the scheme after the staff had either quit or been fired. The investigation involved OIG, the FBI, the Internal Revenue Service, and the Indiana MFCU.

Public Health and Human Service 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 service 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, the Chief Financial Officers Act of 1990, and information systems reviews required by the Federal Information Security Management Act.

This chapter describes the Office of Inspector General's (OIG) 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 provides or funds health care services for 1.6 million Native Americans 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 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 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.

This chapter summarizes OIG's reports related to public health and human service programs and departmentwide issues. It also provides statistics related to and examples of OIG actions and investigations related to public health and human service 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.

Reports Related to Public Health Programs

Public Health Laboratory Testing To Detect and Report Biological Agents

In our review of laboratory pandemic influenza preparedness, we found that as of June 2007, all States reported meeting at least three of nine CDC public health laboratory testing and reporting requirements included in our review, but no State reported meeting all nine. CDC “Preparedness Goal 3: Detect and Report” is the only goal that focuses on public health laboratory testing and reporting of biological threats. Our review focused only on 9 of the 11 requirements of Goal 3. State public health laboratories coordinate with private clinical laboratories, known as sentinel laboratories, which perform preliminary testing and then ship specimens to the State, and they test patient specimens to identify the agents that cause illness. In 2006, through its Public Health Emergency Preparedness Cooperative Agreement (Cooperative Agreement), CDC allocated approximately \$766 million to 62 awardees to meet specific goals by 2010. We reviewed the extent to which 9 of the 11 requirements were met.

Among our findings related to the nine requirements in our review:

- At least 87 percent of States reported meeting all elements in four requirements. These requirements related to the availability of biosafety testing facilities, the capacity to test and report on specific viruses, the performance of required laboratory tests, and the training of public health laboratory personnel on shipping-related tasks.
- Less than 65 percent of States reported meeting all elements in the other five requirements. These requirements related to planning, training, compliance monitoring, testing of laboratories’ abilities, and identification of sentinel laboratories.

We recommended that CDC continue to assist States in meeting the Cooperative Agreement requirements that are intended to decrease the time needed to detect and report biological public health threats. We specifically recommended that the agency focus on improving performance in two requirement areas that less than 10 percent of the States reported meeting. CDC concurred with our overall recommendation that it continue to assist States in meeting the Cooperative Agreement requirements intended to decrease the time needed to detect and report biological public health threats. (OEI-04-07-00750)

Bioterrorism and Public Health Response Funding

Pursuant to the Public Health Service Act, CDC provides funds to State and major local health departments to improve preparedness and response capabilities for bioterrorism and other public health emergencies. From 1999 to 2005, CDC provided this funding through the Public Health Preparedness and Response for Bioterrorism Program. Beginning in 2005, CDC has provided funding through the Public Health Emergency Preparedness Program. We refer to these two programs collectively as “the Program.”

We reviewed costs claimed for Program reimbursement in two States. The results were as follows:

■ **Florida** – We found that of the \$75 million that the State claimed for reimbursement for the period August 31, 2004, through August 30, 2006, \$71,000 was unallowable because the costs were improperly charged to the Program or inadequately documented. In addition, approximately \$3.6 million may be unallowable because the costs may not be authorized by Florida statutes limiting the number of authorized positions. These deficiencies occurred because the State did not have adequate policies and procedures to ensure that all costs claimed for reimbursement complied with applicable laws, regulations, and program guidance.

We recommended that the State refund \$71,000; determine whether it bypassed the position limitations imposed by State law and, if so, refund the approximately \$3.6 million in unallowable costs; and improve policies and procedures to ensure that all costs claimed for reimbursement comply with applicable laws, regulations, and program guidance. The State generally agreed with our findings and said that it was pursuing resolution of the \$3.6 million with the State agency that oversees the administration of State contract procurement and statutes. We modified our second recommendation in response to the State's comments. (A-04-07-01046)

■ **New Hampshire** – We found that \$9.2 million of the \$9.6 million in employee compensation costs charged to the Program for State FYs 2004–2007 were unallowable because the costs were not supported by the required employee certifications. In addition, the State claimed \$99,000 in compensation costs for an employee who had been transferred out of the Program.

We recommended that the State either refund \$9.2 million in compensation costs claimed for employees who may have worked on multiple programs or provide documentation to CDC to support these charges; refund \$99,000 in compensation costs for an employee who had been transferred out of the Program; and follow Federal requirements for charging compensation costs to the Program. The State disagreed with our findings and recommendations, saying that it had followed Federal requirements for charging compensation costs to the Program and that efforts that benefited other public health programs were allowable under the Program. We maintain the validity of our recommendations. (A-01-07-01502)

Safeguards Over Controlled Substances at the National Institutes of Health Clinical Center Pharmacy

Our review of NIH's handling of Schedule II controlled substances found that between May 2006 and June 2007, NIH complied with requirements to account for these substances but did not always appropriately secure or have adequate internal controls over the substances. Schedule II substances (e.g., OxyContin) have the highest potential for abuse among controlled substances with an accepted medical use. NIH's Clinical

Center Pharmacy (Pharmacy) dispenses Schedule II and other substances to inpatients and outpatients participating in intramural research protocols.

We concluded that the Pharmacy's Schedule II substances were vulnerable to loss, diversion, or mismanagement because:

- Schedule II substances were stored in an unlocked storage cabinet and in an unlocked lockbox located in a refrigerator with no lock.
- The Pharmacy did not always segregate the duties and responsibilities for ordering and receiving shipments of Schedule II substances among pharmacists.

We discussed our findings with the chief pharmacist, who concurred and immediately implemented corrective actions. We recommended that NIH ensure that the Pharmacy continues to enforce its policies and procedures to control Schedule II substances. NIH concurred with our recommendation. (A-03-07-00353)

National Institutes of Health's Handling of Allegations Concerning Conflicts of Interest and Ethics Violations

Our review of allegations related to conflicts of interest and ethics violations received by the National Institutes of Health (NIH) between January 1, 2006, and June 30, 2007, found that the most common such allegations involved employees' failure to complete required ethics training or ethics forms. NIH employees are responsible for reporting allegations of noncriminal misconduct to the appropriate supervisor, to a higher level management official within the organization, or to NIH's Office of Management Assessment. Other components handling conflict-of-interest and ethics allegations include the NIH Ethics Office; individual ethics offices within each of the Institutes and Centers (Institutes) at NIH; and the Office of the General Counsel, Ethics Division, at NIH.

We also found that the majority of Institutes did not have written procedures for the handling of allegations related to conflict-of-interest statutes and ethics regulations or uniform procedures for conferring about such allegations with other NIH offices. We noted that the various responsible offices at NIH coordinated the handling of allegations, but there is no written policy for such coordination.

We recommended that NIH develop a formal, written policy for the various ethics offices regarding the handling of allegations of conflicts of interest and ethics violations and that it ensures that documentation is maintained on the resolution of allegations. NIH concurred with our recommendations. In addition, in its comments on the report, NIH stated that it issued a new chapter in the "NIH Policy Manual" on August 15, 2008, which it considers to have addressed OIG's recommendation regarding the NIH ethics offices' handling of noncompliant behavior. (OEI-03-07-00220)

Allowability of Costs Claimed Under the Bioterrorism Hospital Preparedness Program

Under section 319 of the Public Health Service Act, the Bioterrorism Hospital Preparedness Program (the program) provides funds to State, territorial, and municipal governments or health departments to upgrade the preparedness of hospitals and collaborating entities to respond to bioterrorism and other public health emergencies. We examined the allowability of costs claimed under two States' programs. During our audit period, HRSA administered the program.

■ **Alabama** – Our review of \$12.1 million in selected costs claimed for reimbursement under Alabama's program between September 2004 and August 2006 found that \$5.7 million was unallowable. The costs were unallowable because the State had advanced funds to a subrecipient that did not obligate and disburse the funds within the specified program period. In addition, the subrecipient earned interest totaling \$216,000 on program funds that it did not remit to the Federal Government as required.

We recommended that the State refund \$5.7 million in unallowable costs, remit interest earned on program funds during our audit period and remit any additional interest earned after the completion of our fieldwork, and institute procedures to ensure that subrecipients obligate and expend funds within the periods specified in the grant awards. The State partly agreed with our finding and recommendations, but its comments did not cause us to change our conclusions. (A-04-07-01049)

■ **Florida** – Of the \$53.4 million that the State claimed for reimbursement for the period September 1, 2004, through August 31, 2006, \$51,000 was unallowable. In addition, \$1.3 million may have been unallowable because the costs may not have been authorized by Florida statutes. These deficiencies occurred because the State agency did not have adequate policies and procedures to ensure that all costs claimed for reimbursement complied with applicable laws, regulations, and program guidance.

We recommended that the State (1) refund \$51,000 for costs that were improperly charged to the program; (2) determine whether the State's initiation of staffing contracts bypassed the Florida Legislature's position limitations and, if so, refund the \$1.3 million in unallowable costs and stop initiating staffing contracts; and (3) improve policies and procedures to ensure that all costs claimed for reimbursement comply with applicable laws, regulations, and program guidance. The State agreed with our findings regarding the \$51,000 in unallowable costs and said that it was pursuing the \$1.3 million in potentially unallowable costs with the State's Department of Management Services. We modified our second recommendation in response to the State's comments. (A-04-07-01048)

Puerto Rico's Compliance With the Ryan White CARE Act Payer-of-Last-Resort Requirement

In our review of Puerto Rico's compliance with the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act payer-of-last-resort requirement, we estimated that for grant years 2002–2004, Puerto Rico inappropriately claimed \$24.3 million of CARE Act funding to pay for HIV/AIDS drugs that should have been covered by other sources. The CARE Act, which is administered by HRSA, funds health care and support services for more than 500,000 individuals each year who have HIV/AIDS and who either have no health insurance or are underinsured. Title II of the CARE Act provides grants to States and territories to fund the purchase of medications to treat HIV/AIDS. Grantees are required to use CARE Act funding as the payer-of-last-resort for HIV/AIDS drugs or services that are eligible for coverage by other Federal, State, or private health insurance.

We recommended that Puerto Rico refund \$24.3 million and develop procedures to bill HIV/AIDS drugs to the Federal, State, or private health insurance plans with primary payment responsibility. Puerto Rico did not directly address our recommendations but said that it was not willing to accept our findings because of unresolved issues concerning patients' eligibility status. Puerto Rico also disputed some of our error determinations. Based on additional documentation provided, we revised four of our original error determinations and the refund amount. (A-02-06-02000)

Management of Information Technology Contracts at the Food and Drug Administration's Center for Drug Evaluation and Research

In our congressionally requested review of the management of information technology (IT) contracts at FDA's Center for Drug Evaluation and Research (CDER), we found that CDER had demonstrated limited IT planning and inconsistently used quality assurance (QA) and monitoring plans. For the FYs 2004–2007 period, we reviewed CDER's process and monitoring for 28 CDER contract actions related to IT purchases valued at \$250,000 or more. Pursuant to the Federal Acquisition Regulation, agencies must establish procedures to select qualified contractors while protecting the Government from unnecessary financial risk. Agencies must perform acquisition planning, clearly define what they are buying in the requirements section of a statement of work, and select an appropriate contract type and method. Agencies must also monitor contractors to ensure quality results.

We found that CDER relied primarily on acquisition methods that emphasized speed and flexibility over planning and on time-and-materials contract actions that increased the risk for the Government. Also, because it did not clearly define its requirements or performance measures, CDER did not establish consistent QA plans. We recommended that FDA minimize its contract risk by defining IT requirements more clearly, converting ongoing time-and-materials contract actions to fixed-price contract actions when appropriate, using performance incentive plans when appropriate, and using documented QA plans.

FDA neither agreed nor disagreed with our first recommendation to define its IT requirements more clearly but specified actions that it was taking that support the recommendation. The agency agreed with our other recommendations. (OEI-01-07-00450)

The Food and Drug Administration's Oversight of Clinical Investigators' Financial Information

In our review of disclosure of financial interests to FDA, we found that the agency did not have complete information about the financial interests of clinical investigators associated with the 118 marketing applications approved by the agency in FY 2007. In 1999, FDA issued regulations requiring sponsors to disclose in their marketing applications the financial interests of the primary clinical investigators who contributed data to "covered clinical studies." Such studies are relied upon to demonstrate product efficacy and safety. Our findings included the following:

- Of the 29,691 clinical investigators listed in the 118 marketing applications approved in 2007, 1 percent (206) disclosed a financial interest.
- FDA could not systematically check whether marketing applications had financial information for all clinical investigators because the agency did not maintain a complete list of clinical investigators.
- Of the 118 FDA-approved marketing applications, 42 percent did not have complete financial information, including required financial forms.
- FDA did not document a review of any financial information for 31 percent of the marketing applications.
- Neither FDA nor the sponsors had taken action for 20 percent of the approved marketing applications for which the sponsor disclosed financial interests but had not taken action to minimize potential bias.

We recommended that FDA ensure that sponsors submit complete financial information for all clinical investigators. To ensure that FDA reviewers consistently review financial information and take action in response to disclosed financial interests, we recommended that FDA use a review template and provide guidance and training to reviewers. Lastly, we recommended that FDA require that sponsors submit financial information as part of the pretrial application process. FDA generally agreed with our recommendations but did not agree with our final recommendation to require sponsors to submit financial information for clinical investigators during the pretrial application process. We continue to support our recommendation because having financial information before the start of a clinical trial could help FDA to identify and manage potential conflicts and ensure that human subjects are protected and data are reliable. (OEI-05-07-00730)

Legal Actions and Investigations Related to Public Health Programs

OIG excludes from participating 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 service 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 participating 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 an income. Although the Department's PSC takes steps to ensure repayment, some loan recipients ignore their indebtedness.

After PSC has exhausted efforts to secure repayment of a debt, it declares an individual in default. Thereafter, the Social Security Act permits, 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. During the period covered by this report, 87 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, 2,188 individuals have chosen to enter into settlement agreements or completely repay their debts. That figure includes the 35 individuals who have entered into such settlement agreements or completely repaid their debts during this reporting period. The amount of money being repaid through settlement agreements or through complete repayment is \$159.9 million. Of that amount, \$3.7 million is attributable to this reporting period.

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

- **Florida** – Podiatrist Patricia Rosas-Guyon: \$132,946
- **California** – Medical Doctor Hanh-Nguyen Do: \$116,441
- **Massachusetts** – Optometrist Robert Kupsc: \$77,670
- **Puerto Rico** – Optometrist Aixa Rivera-Lopez: \$73,117

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:

- **Connecticut** – Yale University (Yale) agreed to pay \$7.6 million to resolve its liability under the FCA for improper management of Federal grants, most of which were awarded by NIH, between January 1, 2000, and December 31, 2006. The Government alleged that Yale was using Federal grants to pay for various expenses that were unrelated to the research approved for these particular grants. Yale also allegedly had irregularities in its reporting of the time and effort spent related to Federal grants. Specifically, the Government alleged that principal investigators who had 3-month summer research grants were performing portions of their research outside the 3-month timeframe, while improperly reporting and certifying that the work was done within the 3 months required by the grant. As a result of its unauthorized cost transfers and improper time and effort reporting, Yale allegedly submitted improper claims under Federal grants and collected reimbursement that was in excess of the amounts that it was entitled to claim and receive under these grants.

- **Virginia** – Francis H. George, a licensed medical doctor, was sentenced to 21 months in prison and ordered to pay \$173,918 in restitution following his guilty plea to wire fraud and tax perjury. George had received a \$393,426 grant from HRSA to be used specifically to renovate the building that housed his medical practice. To obtain the grant fund money, George used a computer program to initiate payments through wire transfers from the Federal Reserve Bank in Richmond to his business account. He received a total of \$327,000 in grant funds, most of which he used improperly for expenses, including mortgage payments; his child’s college tuition, room, and board; credit card payments; and personal legal fees. George also committed tax perjury in 2005 for calendar year 2004 by submitting a false tax return.

Reports Related to Human Service Programs

Improper Temporary Assistance for Needy Families Payments

In our reviews of four States’ TANF basic assistance payments, we sampled payments for the period April 1, 2006, through March 31, 2007, to estimate the payment error rates associated with noncompliance with Federal and State eligibility, payment, and documentation requirements. TANF is a block grant program that provides funding to

States to help families move from public assistance to self-sufficiency; TANF's basic assistance includes benefits designed to meet a family's ongoing basic needs. These reviews, part of an eight-State series, were requested by ACF and the Office of Management and Budget (OMB) to determine the FY 2008 national TANF error rate. Pursuant to the Improper Payments Information Act of 2002 (P.L. No. 107-300), Federal agencies must estimate and report to Congress on the annual amount of improper payments in their high-risk programs.

■ **Idaho** – Based on our sample results, we estimated that the overall TANF improper payment rate was 16.45 percent of the Federal dollars expended and 18 percent of the number of basic assistance payments made for the 1-year audit period. These improper payments totaled an estimated \$1 million (Federal share). The payments were improper because they were for families who were ineligible for TANF basic assistance or because the required documentation was lacking.

We recommended that the State use the results of this review to help ensure compliance with Federal and State TANF requirements and consider conducting quality control reviews of TANF basic assistance eligibility and payment processes. The State agreed with our recommendations. (A-06-07-00104)

■ **Minnesota** – We estimated that the overall TANF improper payment rate was 5.5 percent of the Federal dollars expended and 9.3 percent of the number of basic assistance payments made for the 1-year audit period. These improper payments totaled an estimated \$4.8 million (Federal share). The payments were improper because the recipient families were ineligible for TANF basic assistance or because the State improperly calculated the payments.

We recommended that the State use the results of this review to help ensure compliance with Federal and State TANF requirements; that it determine the current eligibility of all recipients identified in this review as improperly enrolled in the TANF program and ensure that further assistance is denied for those who remain ineligible; and that it recalculate assistance payments for all recipients who received improperly calculated payments. The State agreed with our recommendations and provided information on steps that it had taken. (A-07-07-01045)

■ **Pennsylvania** – We estimated that the overall TANF improper payment rate was 11.7 percent of the Federal dollars expended and 16 percent of the number of basic assistance payments made for the 1-year audit period. The improper payments totaled an estimated \$23.7 million (Federal share). The payments were improper because they were for recipient families who were ineligible for TANF basic assistance, were calculated improperly, or lacked required documentation.

We recommended that the State use the results of this review to help ensure compliance with Federal and State TANF requirements; that it determine the eligibility of all recipients identified in this review as improperly enrolled in the TANF program and ensure that further assistance is denied for those who remain ineligible; and that it

recalculate assistance budgets for all recipients identified in this review as having received improperly calculated payments. The State concurred with our recommendations. (A-03-07-00552)

■ **Vermont** – We estimated that the overall TANF improper payment rate was 5.85 percent of the Federal dollars expended and 10 percent of the number of basic assistance payments made for the 1-year audit period. These improper payments totaled an estimated \$956,000 (Federal share). The payments were improper because they were for recipient families who were ineligible for TANF basic assistance, were calculated improperly, or lacked required documentation.

We recommended that the State use the results of this review to help ensure compliance with Federal and State TANF requirements; that it determine the current eligibility of all recipients identified in this review as improperly enrolled in the TANF program and ensure that further assistance is denied for those who remain ineligible; and that it recalculate assistance budgets for all recipients identified in this review as having received improperly calculated payments. In its comments on our draft report, the State provided information on steps that it planned to take to implement the recommendations. (A-01-07-02504)

New Mexico's Title IV-E Administrative and Training Costs

Title IV-E of the Social Security Act, as amended, authorizes Federal funds for States to provide, under an approved State plan, foster care and adoption assistance for children. States may be reimbursed for certain Title IV-E administrative and training costs. In our review of New Mexico's Title IV-E administrative and training costs claimed for the 2 years that ended September 30, 2002, we determined that \$1.7 million (\$1.1 million Federal share) of the \$35.1 million that we reviewed was unallowable. The State did not claim training costs in accordance with its approved cost allocation plan, claimed administrative and training costs that were not reimbursable under Title IV-E, and used inaccurate data to allocate training costs.

Federal regulations require that administrative and training costs be allocated to the Title IV-E program, which is administered at the Federal level by ACF, in accordance with a cost allocation plan approved by HHS's Division of Cost Allocation (DCA). We could not determine what portion of the remaining \$33.4 million (\$17.6 million Federal share) in Title IV-E costs was allowable because the State agency did not use the timestudy methodology included in its approved cost allocation plan to allocate costs; could not produce sufficient documentation to support claimed costs; or did not sufficiently describe training course content in the State plan for us to determine whether the content was closely related to allowable Title IV-E activities.

We recommended that the State (1) refund the \$1.1 million Federal share of unallowable costs; (2) work with DCA and ACF to determine the allowable portion of the \$17.6 million Federal share of potentially unallowable costs and refund any unallowable costs; (3) work with DCA and ACF to revise its cost allocation plan to describe Title IV-

E training and a method for allocating the costs of part-time and full-time training programs in accordance with Federal requirements; and (4) implement procedures to ensure that it follows the allocation methods in the approved cost allocation plan, documents and verifies the allocation methods used, claims only reimbursable costs, and maintains records and data used to allocate costs in accordance with Federal regulations. The State did not specifically address our recommendations. It agreed with our findings on costs that were not claimed in accordance with the approved cost allocation plan and on training costs that were not reimbursable at the enhanced rate. The State disagreed with, or did not express an opinion on, the remaining findings but did not provide any additional information that would lead us to change our findings or recommendations. (A-06-06-00105)

Undistributable Child Support Collections in Tennessee

In our review of Tennessee's reporting of program income from undistributable child support collections and interest earned on collections, we found that from October 1998 through December 2007, the State did not recognize and report as program income \$8.7 million (\$5.8 million Federal share) in undistributable child support collections that met the State's definition of abandoned property. In addition, the State reported incorrect amounts for undistributed collections. Undistributable collections result when States receive child support payments but cannot identify or locate the custodial parents or return the funds to the noncustodial parents. Within ACF, the Office of Child Support Enforcement (OCSE) oversees the Child Support Enforcement program. OCSE requires States to offset program costs by recognizing and reporting income from undistributable child support collections.

We recommended that the State report as program income undistributable child support collections totaling \$8.7 million (\$5.8 million Federal share), that it ensure future compliance with State laws regarding abandoned property, and that it correct reporting errors on the next quarterly Federal filing. The State said that it would implement our recommendations. (A-04-08-03521)

Child Support Enforcement

The detection, investigation, and prosecution of noncustodial parents who fail to pay court-ordered child support are priorities for OIG. OIG works closely with the 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.

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 54 convictions and court-ordered restitution and settlements of \$3.1 million during this semiannual period. Examples of OIG's enforcement results for failure to pay child support include the following:

■ **Virginia** – Jonathan Novak was sentenced to 24 months of incarceration and was ordered to pay \$229,958 in restitution for failure to pay child support. Novak was found guilty after a 2-day jury trial in which he gave fraudulent testimony. Typically working as a self-employed forensic accountant earning more than \$200,000 a year, Novak, who has six children with three different women, collectively owed more than \$300,000 in child support. The investigation revealed that from August 2004 through July 2005, Novak earned over \$146,000, yet willfully chose not to pay a \$658 per month obligation pursuant to a California support order.

Also in Virginia, Thomas Noden was sentenced to 5 years of probation and ordered to pay \$138,776 in restitution for failure to pay child support. In 1992, Noden had been directed to pay \$900 per month in support of his three children; however, the only payments made resulted from involuntary wage garnishments, which proved difficult to collect, as Noden changed employers once a garnishment was established.

■ **North Dakota** – Kurt Dean Johnson was sentenced to 3 years of probation and ordered to pay \$66,116 in restitution for failure to pay child support. At the time of his indictment, Johnson, a father of three by two women, was more than \$127,000 in arrears. Subsequent to his arrest and prior to his sentencing, he had paid \$70,000 toward his outstanding child support.

Reports Related to Departmentwide Issues

Grant Closeout Procedures at the Administration for Children and Families and the Centers for Disease Control and Prevention

During this semiannual period, we issued two reports—one to ACF and the other to CDC—as part of a series of reviews focused on grant closeout procedures within HHS. HHS agencies are responsible for initiating the closeout of their various grants and for instructing the PSC, Division of Payment Management (DPM), to close grants in the Payment Management System. As a general rule, grants must be closed within 180 days after the end of the grant period (the cutoff date).

■ **ACF** – In our review of ACF grants identified by DPM as eligible for closeout as of September 30, 2006, we found that 9,877 grants with unexpended balances totaling more than \$472 million remained open in the payment system for several reasons. 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, ACF and PSC’s Division of Financial Operations lacked follow-up procedures to determine whether DPM had actually closed grants for which closeout had been initiated.

We recommended that ACF use the information in our report to ensure that grants are closed in a timely manner and to eliminate the backlog of grants eligible for closeout. In its comments, ACF described actions that it had taken or planned to take to implement our recommendation. ACF did not say that it concurred. (A-02-07-02000)

■ **CDC** – In our review of CDC grants identified by DPM as eligible for closeout as of March 31, 2007, we found that 2,740 grants with unexpended balances totaling more than \$245 million remained open in the payment system for several reasons. The grants remained open after the cutoff dates because CDC had allowed a backlog of grants awaiting closeout to develop; differences existed among the grant award, expenditure, and drawdown amounts; or the closeout code was not the final transaction in the payment system.

We recommended that CDC use the information in our report to ensure that grants are closed in a timely manner and to eliminate the backlog of grants eligible for closeout. In its comments, CDC concurred with our recommendation and described actions that it had taken or planned to take. (A-02-07-02014)

University Administrative Costs

In a review of administrative and clerical costs at a university in North Carolina, we estimated that the university claimed \$1.7 million in unallowable charges as direct costs to grants, contracts, and other agreements with HHS components during FYs 2003 and 2004. These unallowable charges occurred because the university had not established adequate controls to ensure consistent compliance with Federal requirements. The university’s policies essentially allowed direct charges to any project needing any administrative or clerical support.

We recommended that the university refund \$1.7 million to the Federal Government and revise its policies as needed to comply with Federal requirements and to ensure consistent treatment of administrative and clerical costs. The university partially agreed with our first recommendation and disagreed with our second recommendation. Based on a review of additional documentation that the university provided, we revised the recommended refund amount. (A-04-05-01014)

Departmental Financial Statement Audit

The Chief Financial Officers Act of 1990, as amended, requires OIG or an independent external auditor, as determined by OIG, to audit the HHS financial statements in accordance with applicable standards. Independent external auditors provided an unqualified opinion on the FY 2008 HHS financial statements. This means that for the 10th consecutive year, the statements were reliable and fairly presented. However, the report on internal controls noted two material weaknesses:

■ **Financial Reporting Systems, Analyses, and Oversight** – HHS continued to have internal control weaknesses in its financial management systems and financial analyses and oversight. The lack of an integrated financial management system, substantial manual procedures, and untimely or inadequate reconciliations and account analyses hindered HHS’s ability to produce financial statements.

■ **Financial Management Information Systems** – Weaknesses in both the design and the operation of key general controls were noted in the areas of security management and access controls. General controls are necessary to safeguard data, protect business application programs, and ensure continued computer operations in case of unexpected interruptions. In addition, weaknesses were noted in business process controls and data management system controls for specific financial applications.
(A-17-08-00001)

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 entity’s management of Federal funds. In this semiannual period, OIG’s National External Audit Review Center reviewed 1,193 reports that covered \$723 billion in audited costs. Federal dollars covered by these audits totaled \$190 billion, about \$99.5 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 box below.

Reports issued:	
Without changes or with minor changes	1,041
With major changes	131
With significant inadequacies	21
Total	<u>1,193</u>

The 1,193 reports included 4,179 recommendations for improving management operations. In addition, these audit reports provided information for 72 special memoranda that identified concerns for increased monitoring by management.

Resolving Recommendations

The following tables are provided in accordance with section 5 of the Inspector General Act and indicate the dollar value of actions taken on OIG's recommendations.

Table 1: Reports With Questioned Costs

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	204	\$1,279,916,000	\$34,687,000
Issued during the reporting period	102	\$245,222,000	\$61,990,000
Total Section 1	306	\$1,525,138,000	\$96,677,000
Section 2			
For which a management decision was made during the reporting period ^{2 3}			
Disallowed costs	174	\$274,860,000	\$2,917,000
Costs not disallowed	6	\$3,268,000	0
Total Section 2	180	\$278,128,000	\$2,917,000
Section 3			
For which no management decision had been made by the end of the reporting period			
Total Section 1 minus Total Section 2	126	\$1,247,010,000	\$93,760,000
Section 4			
For which no management decision was made within 6 months of issuance ⁴	70	\$1,074,139,000	\$107,414,000

Footnotes can be found in Appendix A.

Table 2: Funds Recommended To Be Put to Better Use

Reports	Number of Reports	Dollar Value
Section 1		
For which no management decision had been made by the beginning of the reporting period ¹	32	\$2,665,951,000
Issued during the reporting period	5	\$904,102,000
Total Section 1	37	\$3,570,053,000
Section 2		
For which a management decision was made during the reporting period		
Value of recommendations agreed to by management	17	\$1,610,347,000
Based on proposed management action		
Based on proposed legislative action		
Value of recommendations not agreed to by management	2	\$999,000
Total Section 2	19	\$1,611,346,000
Section 3		
For which no management decision had been made by the end of the reporting period ²		
Total Section 1 minus Total Section 2	18	\$1,958,707,000

Footnotes can be found in Appendix A.

Regulatory Development

OIG is responsible for the development and publication of a variety of sanction regulations addressing CMPs and program exclusion authorities administered by the Inspector General, as well as regulations promulgating safe harbors related to the anti-kickback statute.

OIG periodically publishes Federal Register (FR) notices that, among other things, offer guidance to alert program beneficiaries, health care providers, and other entities about potential problems or areas of special interest. During this semiannual period, we published the following FR notices:

- New OIG Privacy Act System of Records: Consolidated Data Repository (73 Fed. Reg. 66648 (Nov. 10, 2008)).
- Solicitation of New Safe Harbors and Special Fraud Alerts (73 Fed. Reg. 76575 (Dec. 17, 2008)).

Appendixes

Appendix A: Notes to Tables 1 and 2

Table 1

¹ The opening balance was adjusted upward by \$22.4 million.

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

Central Identification Number (CIN): A-01-02-00509, UNITED HEALTH CARE INSURANCE COMPANY. The Centers for Medicaid & Medicare Services (CMS) stated that it executed a global closing agreement with the company that reduced its original disallowance by \$6,344,219.

CIN: A-04-05-81883, STATE OF FLORIDA. CMS subsequently determined that previously disallowed costs had been recouped in the resolution of another audit. As a result, CMS reversed its original disallowance of \$2,773,667.

CIN: A-01-92-00523, BLUE CROSS AND BLUE SHIELD OF MASSACHUSETTS. CMS stated that it had been unable to determine whether claims for clinical laboratory services were recovered and was prohibited from reopening the claims at this point. CMS reversed its original disallowance of \$2,250,000.

CIN: A-01-02-00508, UNITED HEALTH CARE INSURANCE COMPANY. CMS stated that it executed a global closing agreement with the company that reduced its original disallowance by \$1,549,677.

CIN: A-10-05-82644, STATE of ALASKA. Based on a review of actual claims, CMS reduced the estimated disallowance by \$1,155,982.

Not detailed are net reductions to previously disallowed management decisions totaling \$2,685,702.

³ Included are management decisions to disallow \$13.1 million that was identified in non-Federal audit reports.

⁴ Because of administrative delays, many of which are beyond management control, resolution of the following 70 audits were 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 - MFR 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 - MFR C, MAR 2008, \$101,000,000

CIN: A-04-03-02027	REVIEW OF MEDICIAD UPPER PAYMENT LIMIT CALCULATIONS IN ALABAMA, DEC 2005, \$74,529,029
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	PA FOSTER CARE MAINTENANCE PAYMENTS PHILADELPHIA UNDER \$300, MAY 2008, \$56,513,439
CIN: A-05-01-00058	OHIO MEDICAID HOSPITAL-SPECIFIC DSH PAYMENT LIMITS, JUN 2004, \$47,000,000
CIN: A-09-02-00054	AUDIT OF STATE OF CALIFORNIA DSH 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 - CT, MAY 2003, \$32,780,146
CIN: A-06-07-00040	REVIEW OF AMP CALCULATION - MFR B, MAR 2008, \$27,700,000
CIN: A-02-06-02000	RYAN WHITE - PAYER OF LAST RESORT, SEP 2008, \$24,340,789
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	PA FOSTER CARE MAINTENANCE PAYMENT PHILADELPHIA OVER \$300/DAY, DEC 2007, \$11,693,989
CIN: A-03-05-00550	AUDIT OF PA FOSTER CARE MAINTENANCE PAYMENTS - CASTILLE SAMPLE, SEP 2007, \$11,611,822
CIN: A-01-07-01502	REVIEW OF NEW HAMPSHIRE'S PUBLIC HEALTH PREPAREDNESS FUNDS, SEP 2008, \$9,266,749
CIN: A-06-02-00034	COST REPORTS & MEDICARE FEE-FOR-SERVICE PYMTS - SCOTT & WHITE, MAY 2003, \$8,229,574
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-09-01-00085	AUDIT OF UCSDMC DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR SFY 1998, SEP 2002, \$3,776,054
CIN: A-04-07-01046	FL/CDC - ALLOWABILITY OF COSTS CLAIMED FOR REIMBURSEMENT UNDER BIOTERRORISM AND EMERGENCY PREPAREDNESS PROGRAM GRANTS, SEP 2008, \$3,633,671

CIN: A-07-07-00231	REVIEW OF INFANT AND TODDLER EARMARK ALLOTMENTS CLAIMED BY THE IOWA DEPARTMENT OF HUMAN SERVICES, AUG 2008, \$3,311,258
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-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	AL/CDC - ALLOWABILITY OF COSTS CLAIMED FOR REIMBURSEMENT UNDER BIOTERRORISM AND EMERGENCY PREPAREDNESS GRANT PROGRAMS, SEP 2008, \$570,400
CIN: A-05-02-72811	COMMUNITY ACTION OF GREATER INDIANAPOLIS INC., AUG 2002, \$547,899
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-02-07-02004	FOLLOW-UP REVIEW OF AFDC OVERPAYMENTS - UPSTATE NY, OCT 2007, \$347,375
CIN: A-05-01-00096	PAYMENTS TO INTER VALLEY FOR INSTITUTIONAL BENEFICIARIES, MAY 2002, \$319,355
CIN: A-07-06-03085	NEBRASKA UNDISTRIBUTABLE CHILD SUPPORT PAYMENTS, MAR 2007, \$308,841
CIN: A-07-05-01013	PAYMENTS FOR M+C ORGANIZATION FOR INSTITUTIONAL BENEFICIARIES, OCT 2005, \$293,885
CIN: A-05-05-00033	MI - 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-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 FYS 2000 - 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-04-04-01002	USE OF CDC BIOTERRORISM GRANT FUNDS, JUL 2005, \$98,929
CIN: A-05-02-00067	REVIEW OF MEDICARE FEE-FOR-SERVICE PAYMENTS & 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 NE PA FOR INSTITUTIONAL BENEFICIARIES, MAY 2002, \$62,432
CIN: A-03-02-00373	REVIEW OF US HELPING US, DEC 2003, \$45,558
CIN: A-04-06-00023	REVIEW OF QUALITY IMPROVEMENT ORGANIZATIONS - TENNESSEE, JUL 2008, \$30,654
CIN: A-01-02-01504	REVIEW OF CDC'S HIV PROGRAMS AT FENWAY COMMUNITY HEALTH CENTER, JUN 2003, \$30,095
CIN: A-08-03-73541	SOUTH DAKOTA FOUNDATION FOR MEDICAL CARE, JAN 2003, \$28,573
CIN: A-07-02-00150	PAYMENTS TO COVENTRY—PITTSBURG FOR INSTITUTIONAL BENEFICIARIES, JUN 2003, \$26,000
CIN: A-05-01-00078	PAYMENTS TO HEALTH NET-TUCSON, AZ.- FOR INSTITUTIONAL BENEFICIARIES, APR 2002, \$21,233
CIN: A-08-04-76779	COLORADO FOUNDATION FOR MEDICAL CARE, DEC 2003, \$18,925
CIN: A-05-01-00100	PAYMENTS TO FALLON HEALTH FOR 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-01-07-00603	REVIEW OF RETIREE DRUG SUBSIDY PLAN SPONSOR BLUE CROSS BLUE SHIELD OF MASSACHUSETTS, INC., FOR PLAN YEAR ENDED DECEMBER 31, 2006, JAN 2008, \$12,798
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 REPORTS : 70
TOTAL AMOUNT : \$1,074,139,088

Table 2

¹ The opening balance was adjusted downward by \$91.1 million.

² Management decision has not been made within 6 months on 13 reports. Discussions with management are ongoing, and it is expected that the following audits will be resolved by the next semiannual reporting period:

CIN: A-06-07-00042	INDEXING THE REBATE FOR GENERIC DRUGS, OCT 2007, \$966,000,000
CIN: A-04-01-02006	MEDICAID DISPROPORTIONATE SHARE PAYMENTS IN ALABAMA, JUN 2004, \$45,763,327
CIN: A-09-07-00083	MEDICARE INTEGRITY - REVIEW OF KAISER FOUNDATION HOSPITAL WAGE DATA USED FOR FY 2009 WAGE INDEXES, SEP 2008, \$11,762,404
CIN: A-04-06-03508	UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS - FLORIDA, JAN 2008, \$7,881,447
CIN: A-05-02-00077	MICHIGAN MEDICAID/SCHIP REVIEW, NOV 2003, \$5,908,350
CIN: A-03-02-00203	VIRGINIA - SCHIP/TITLE IV - D, JUL 2004, \$5,402,491
CIN: A-05-05-00033	MI - 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-05-02-00075	INDIANA MEDICAID/SCHIP REVIEW, NOV 2003, \$1,885,708
CIN: A-05-06-00038	IN - UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS, MAR 2007, \$871,677
CIN: A-01-08-00513	REVIEW OF TOURO INFIRMARY'S REPORTED FISCAL YEAR 2005 WAGE DATA, JUL 2008, \$605,419
CIN: A-05-01-00070	PAYMENTS FOR BENEFICIARIES WITH INSTITUTIONAL STATUS - MISSOURI GROUP HEALTH PLAN, JAN 2002, \$98,689
CIN: A-05-06-00023	MN - UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS, SEP 2006, \$28,240

TOTAL REPORTS: 13
TOTAL AMOUNT: \$1,054,604,885

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

The reporting requirements of the Inspector General Act of 1978, as amended, are listed in the following table along with the location of the required information. Page numbers in the table indicate pages in this report. The word “None” appears where there are no data to report under a particular requirement.

A complete listing of audit and evaluation reports is furnished to Congress under separate cover. Hard copies are available upon request.

Section of the Act	Requirement	Location
Section 4 (a)(2)	Review of legislation and regulations	p. 62
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. 35
(a)(5)	Summary of instances in which information was refused	None
(a)(6)	List of audit reports	Under separate cover
(a)(7)	Summary of significant reports	Throughout this report
(a)(8)	Statistical Table 1 – Reports With Questioned Costs	p. 60
(a)(9)	Statistical Table 2 – Funds Recommended To Be Put To Better Use	p. 61
(a)(10)	Summary of previous audit reports without management decisions	Appendix A
(a)(11)	Description and explanation of revised management decisions	Appendix A
(a)(12)	Management decisions with which the Inspector General is in disagreement	None

Appendix C: Summary of Sanction Authorities

The Inspector General Act of 1978 (P.L. No. 95–452), as amended, sets forth specific requirements for semiannual reports to be made to the Secretary for transmittal to Congress. A selection of other authorities appears below.

Program Exclusions

Section 1128 of the Social Security Act (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

Section 1867 of the Social Security Act (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

Under the Civil Monetary Penalties Law (CMPL), section 1128A of the Social Security Act (42 U.S.C. § 1320a–7a), a person is subject to 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. § 1320a–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, or ordering, or arranging for or recommending the purchasing, leasing, or ordering of any good, facility, service, or item payable under the Federal health care programs (section 1128B(b) of the Social Security Act, 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 (section 1128A(a)(7) of the Social Security Act, 42 U.S.C. § 1320a–7a); and/or program exclusion under OIG’s permissive exclusion authority (section 1128(b)(7) of the Social Security Act, 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.

Appendix D: Acronyms and Abbreviations

The following is a list of acronyms and abbreviations used in this publication.

ACF	Administration for Children and Families
ALJ	Administrative Law Judge
AMP	average manufacturer price
ASP	average sales price
CARE	Comprehensive AIDS Resources Emergency Act
CCA	certification of compliance agreement
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CIA	corporate integrity agreement
CMP	civil monetary penalty
CMPL	Civil Monetary Penalties Law
CMS	Centers for Medicare & Medicaid Services
CY	calendar year
DCA	Division of Cost Allocation
DME	durable medical equipment
DMEPOS	durable medical equipment, prosthetics, orthotics, and supplies
DOJ	Department of Justice
DPM	Division of Payment Management
DRA	Deficit Reduction Act of 2005
DSH	disproportionate share hospital
FBI	Federal Bureau of Investigation
FCA	False Claims Act
FDA	Food and Drug Administration
FY	fiscal year
HCFAC	Health Care Fraud and Abuse Control Program
HCPCS	Healthcare Common Procedure Coding System
HEAL	Health Education Assistance Loan
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HRSA	Health Resources and Services Administration
IG	Inspector General
IT	information technology
MA	Medicare Advantage
MA-PD	Medicare Advantage Prescription Drug
MEDIC	Medicare drug integrity contractors
MFCU	Medicaid Fraud Control Unit
MHASA	mental health assessment and service agencies
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MMIS	Medicaid Management Information System
MPFS	Medicare Physician Fee Schedule

MR	magnetic resonance
NDC	National Drug Code
NIH	National Institutes of Health
NPI	national provider identifier
NQF	National Quality Forum
OCSE	Office of Child Support Enforcement
OIG	Office of Inspector General
OMHA	Office of Medicare Hearings and Appeals
PCS	personal care service
PDP	prescription drug plan
PHS	Public Health Service
P.L.	Public Law
PPS	prospective payment system
PSC	Program Support Center
QA	quality assurance
SCHIP	State Children's Health Insurance Program
SNF	skilled nursing facility
SNP	special needs plan
SPA	State plan amendment
SSA	Social Security Administration
TANF	Temporary Assistance for Needy Families
UCCP	uncompensated care pool
U.S.C.	United States Code
WAMP	widely available market price

Department of Health and Human Services

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