



Department of Health and Human Services

Semiannual

Report to Congress

October 1, 2007–March 31, 2008



OIG

Office of Inspector General

OIG COMPONENTS

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

OAS

Office of Audit Services – The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

OEI

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 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 criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice (DOJ) and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

OCIG

Office of Counsel to the Inspector General – The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

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Report to Congress



October 1, 2007-March 31, 2008



Department of Health and Human Services
Office of Inspector General

TOP MANAGEMENT CHALLENGES

The programs of the Department of Health and Human Services (HHS) help fulfill the President's vision of a healthier, safer, and more hopeful America. These essential programs bring with them a number of management challenges that have been identified by the Inspector General, as listed below.

1. Oversight of Medicare Part D
2. Integrity of Medicare Payments
3. Appropriateness of Medicaid and State Children's Health Insurance Program Payments
4. Medicaid Administration
5. Quality of Care
6. Public Health Emergency Preparedness and Response
7. Oversight of Food, Drug, and Medical Device Safety
8. Grants Management
9. Integrity of Information Technology Systems and Infrastructure
10. Ethics Program Oversight and Enforcement

The Office of Inspector General's (OIG) assessment of the challenges is included in Section III of the HHS Fiscal Year 2007 Agency Financial Report. The assessment is available on OIG's Web site at:

oig.hhs.gov/publications/challenges/files/TM_Challenges07.pdf

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, 2008.

As detailed in these pages, OIG's work during this period encompasses a broad range of audits, evaluations, and compliance and enforcement activities designed to protect the integrity and promote the efficiency and effectiveness of the programs of the Department of Health and Human Services (HHS). Our efforts touch upon many of the 300 programs administered by HHS. In accordance with OIG's statutory funding allocations, we have directed the majority of our resources toward safeguarding the Medicare and Medicaid programs and the health and welfare of beneficiaries.

This report, consistent with our previous Semiannual Reports, reflects a robust oversight agenda and summarizes our achievements through successful case resolution and issuance of reports to the Department containing significant recommendations. OIG's recent activities also reflect the expansion of HHS programs, which continue to grow in scope, size, and complexity. We rely on our more than 1500 dedicated professionals to address both longstanding and emerging issues that collectively constitute the top management challenges of HHS. Such issues of longstanding OIG focus include Medicare payment integrity, appropriateness of Medicaid and State Children's Health Insurance Program (SCHIP) payments, Medicaid administration, quality of care, and grants management. Issues of more recent focus include oversight of Medicare Part D; public health emergency preparedness and response; oversight of food, drug, and medical device safety; integrity of information technology and systems; and ethics program oversight and enforcement.

In addressing these challenges, I would like to underscore the importance that we attach to ensuring the quality, timeliness, and utility of our work. Much of our success depends on building our institutional knowledge and expertise and working collaboratively with our multiple partners and stakeholders throughout Government and in the health care community.

This year marks the 30th anniversary of the Inspector General Act of 1978, and with that important milestone in mind, I want to express my sincere appreciation to Congress and the Department for their support not just over the past 6 months, but for their sustained commitment to supporting the important mission 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) 2008, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) reported expected recoveries of \$2.2 billion: \$1.1 billion in audit receivables and \$1.1 billion* in investigative receivables.

Also for this semiannual period, OIG reported exclusions of 1,291 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 142 civil actions, which include False Claims Act and unjust enrichment suits filed in Federal district court, Civil Monetary Penalties Law (CMPL) settlements, and administrative recoveries related to provider self-disclosure matters.

Medicare Part D Sponsors: Estimated Reconciliation Amounts for 2006

In our analysis of the Centers for Medicare and Medicaid Service's (CMS) Medicare Part D preliminary reconciliation data estimates (as of August 2007) and data from 16 sponsors with high enrollments, we estimated that Part D sponsors owed Medicare a net total of \$4.4 billion for the 2006 program year. Eighty percent of the sponsors owed CMS money and 20 percent were due money. We also found that CMS had no mechanism to collect funds or adjust prospective payments prior to the reconciliation that is conducted after the close of the plan year. As a result, sponsors had the use of billions of dollars for a significant length of time. In response to our recommendations, CMS agreed to use data collected from 2006 and subsequent plan years in reviewing future bids, acknowledged its authority to change certain payment methodologies, and agreed to examine related options. CMS did not agree to implement an interim process or to seek legislation delaying changes to risk corridors. (Details on pages 9-10.)

Medicare Part D Payments to Local, Community Pharmacies

In our review of the relationship between Medicare Part D payments to local, community pharmacies and the pharmacies' drug acquisition costs we found that in September 2006, pharmacies almost always (97 percent of the time) acquired drugs for less than the reimbursement amounts. We performed this review at the request of 33 Senators who raised concerns about the sufficiency of reimbursement to local, community pharmacies. We estimated that, excluding dispensing fees and including rebates that drug wholesalers paid to pharmacies, Medicare Part D payments to local, community pharmacies exceeded the pharmacies' drug acquisition costs by 18.1 percent. We recommended that Congress and CMS consider the results of the review in deliberations regarding Medicare Part D reimbursement, and CMS agreed. (Details on page 12.)

*This amount represents HHS investigative receivables only; receivables of other Federal agencies, States, and other entities are not included here.

Tracking Beneficiaries' True Out-of-Pocket Costs for the Part D Prescription Drug Benefit

In our review of Medicare Part D plans' tracking of True Out-of-Pocket (TrOOP) costs, we found that in 2006, 29 percent of Part D plans did not, as required, submit their enrollees' additional prescription drug coverage information to Coordination of Benefits Contractors (COBC). Accurate tracking of beneficiaries' TrOOP costs is critical to ensuring appropriate cost sharing under the Part D program. To track TrOOP costs accurately, Part D plans must have information on any prescription drug coverage that enrollees have in addition to Part D coverage. We also found that 34 percent of Part D plans had not submitted prescription drug event data to CMS, 63 percent of the plans cited problems with transferring TrOOP balances when enrollees changed plans, and CMS had conducted limited oversight of Part D plans' tracking of TrOOP costs. Our recommendations addressed collecting and submitting data to track costs, increasing the number of COBC agreements, and expanding data collections and oversight authorities. CMS indicated it had taken or would take responsive steps. (Details on pages 8-9.)

Artificial-Joint Makers Pay \$310 Million to Settle Kickback Case

Medical device makers Zimmer Holdings, Inc.; DePuy Orthopaedics, Inc. (a unit of Johnson & Johnson); Smith & Nephew, Inc.; and Biomet, Inc., agreed to pay a total of approximately \$310 million to resolve allegations of anti-kickback statute and FCA violations. The four companies allegedly used consulting deals with orthopedic surgeons to induce the purchase of their respective artificial hip and knee products. As part of the settlement, the companies entered into 5-year CIAs with OIG. (Details on pages 28-29.)

Payments for Outpatient Services in Skilled Nursing Facility Stays

We found that Medicare Part B made a total of \$106.9 million in potential overpayments to suppliers of outpatient services on behalf of beneficiaries in Part A-covered skilled nursing facilities (SNF) during calendar years (CY) 2001 and 2002. These potential overpayments occurred because CMS did not have system edits in place during most of this period. For CY 2003, when the edits were fully implemented, potential overpayments were reduced to \$22.7 million. CMS agreed with our recommendations about reviewing overpayments, testing and refining edits, and establishing recovery controls. (Details on pages 6-7.)

Bristol-Myers Squibb Co. Pays More Than \$499 Million to Resolve Allegations of Illegal Drug Marketing and Pricing

As part of a civil settlement, the Bristol-Myers Squibb Co. (BMS) and its wholly owned subsidiary, Apothecon, Inc., agreed to pay \$499 million plus interest to resolve allegations relating to a variety of Federal and State claims. The Government alleged that BMS fraudulently set and maintained inflated prices for a wide assortment of oncology and generic drug products, paid various forms of illegal kickbacks to physicians and pharmacies, promoted off-label uses of the antipsychotic drug Abilify, and knowingly misreported its best price for the antidepressant drug Serzone. BMS entered into a 5-year corporate integrity agreement (CIA) with OIG as part of the resolution of this FCA case. (Details on pages 26-27.)

Dermatologist Sentenced for Upcoding Surgical Procedures

A Michigan dermatologist was sentenced to 10 years and 6 months in prison and ordered to pay approximately \$1.3 million in restitution and a \$175,000 fine for upcoding surgical procedures, billing for medically unnecessary procedures, and improperly billing for follow-up office visits. The dermatologist falsely informed patients that they had cancer when, in fact, laboratory results indicated that their tissue specimens were benign. He then performed surgeries based on these false diagnoses. (Details on page 30.)

A California Laboratory's Compliance With Select Agent Regulations

A California laboratory (Laboratory) agreed to resolve its liability for an alleged violation of the Select Agent Regulations. OIG alleged that the Laboratory transferred vials of a select agent to two laboratories located in Florida and Virginia in a manner that violated the transfer requirements. During the transfers, the select agent was released from the shipped vials. An investigation of the packaging for the shipments revealed several violations of regulations governing the shipment of the select agent. OIG specifically alleged that the Laboratory violated the transfer requirements of the select agent regulations by failing to comply with the applicable shipping and packaging laws when transferring a select agent. In addition, OIG alleged that the Laboratory failed to comply with security and access requirements by allowing an individual not authorized to have access to select agents to package the shipments of the select agent and that the Laboratory's responsible official failed to ensure compliance with the shipping and packaging requirements of the select agent regulations. Under the terms of the settlement, the Laboratory agreed to pay OIG \$450,000 to resolve these allegations. As a separate matter, the Laboratory's compliance is subject to monitoring by the Centers for Disease Control and Prevention (CDC). (Details on page 41.)

Temporary Assistance for Needy Families Improper Payment Pilot Reviews

In our pilot reviews of Temporary Assistance for Needy Families (TANF) basic assistance payments during a 6-month period in 2005, we found that three States—Michigan, New York, and Pennsylvania—collectively claimed an estimated \$95 million in improper payments. The estimated error rates ranged from 11.5 percent to 40 percent of the Federal dollars expended. We found errors related to eligibility, calculations, and documentation. The Administration for Children and Families (ACF) and the Office of Management and Budget (OMB) requested that OIG conduct these pilot reviews to develop a methodology for calculating a national TANF error rate for FY 2008. Our recommendations focused on State compliance with requirements, enrollee eligibility, and recalculating improperly paid benefits. Michigan disagreed, New York did not address the recommendations, and Pennsylvania agreed. (Details on pages 42-43.)

National Institutes of Health: Conflicts of Interest in Extramural Research

In our review of financial conflicts of interest reported by grantee institutions to the National Institutes of Health (NIH), we found that the agency needed to improve its oversight of such conflicts. For FYs 2004–2006, NIH could not provide an accurate count of the financial conflicts of interest reports that it received from grantees; of 438 financial conflicts of interest reports received from grantee institutions in 2006, at least 89 percent did not state the nature of the conflicts or the way in which they would be managed; for oversight, NIH's institutes most often relied on grantees' assurances that

financial conflict-of-interest regulations were being followed. NIH agreed with our recommendations to increase oversight of grantee compliance with regulations, require Institutes to forward grantee conflict of interest reports, and ensure that all of the reports are included in its database. NIH did not agree with our recommendation to require grantees to provide details about financial conflicts of interest. (Details on page 38.)

Departmental Financial Statement Audit

Independent external auditors provided an unqualified opinion on the FY 2007 HHS consolidated/combined financial statements. This means that for the ninth consecutive year, the statements were reliable and fairly presented. However, the report on internal controls noted four material weaknesses: financial reporting systems and processes, budgetary accounting, financial management information systems, and Medicare claim-processing controls. (Details on page 50.)

External Activities

During this reporting period, OIG officials participated in a range of external activities to further the organization's mission. Following are examples of such activities.

President's Council on Integrity and Efficiency

The Inspector General (IG) participates in the President's Council on Integrity and Efficiency (PCIE), a forum through which Inspectors General coordinate interagency policy issues, set professional standards for OIG work, coordinate studies on topics of governmentwide concern, and provide training for OIG executives and their staffs. In addition, the IG serves as Chair of the PCIE Inspection and Evaluation Committee. The IG also sits on the PCIE's Homeland Security Roundtable, a group comprising IGs with oversight responsibility for agency programs impacting our Nation's safety and security.

Congressional Testimony

On February 27, 2008, Gregory Demske, Assistant Inspector General for Legal Affairs, testified before the Senate Special Committee on Aging regarding the financial relationships between physicians and the medical device industry. The testimony described the risks associated with industry-physician financial relationships; highlighted some of OIG's recent investigations involving kickbacks from medical device companies to physicians; and indicated ways in which these risks can be mitigated through enforcement actions, outreach to promote compliance, and increased transparency.

The full text of OIG's testimony provided at this hearing is available on OIG's Web site at <http://oig.hhs.gov/testimony.html#1>.

Speeches

On October 1, 2007, Stuart Wright, Deputy Inspector General for Evaluations and Inspections, made a presentation to the National Association of Medicaid Fraud and Control Units. The topic of discussion was OIG's role in oversight of MFCUs.

On December 4–5, 2007, Steven Lack, Assistant Special Agent in Charge from the San Francisco Region, presented, "A Picture Is Worth a Thousand Words and a Prosecution" to the National Health Care Anti-Fraud Institutes' Annual Training Conference. For an audience of over 200 health care fraud managers, investigators, attorneys, auditors, and other professionals, the presentation described case charting, an investigative tool used to plan and conduct health care fraud investigations for obtaining prosecutions and convictions.

On December 8, 2007, Ann Maxwell, Regional Inspector General for Evaluation and Inspections in Chicago, addressed the Health Care Compliance Association's (HCCA) Medicare Prescription Drug Part D Compliance Conference. She presented an overview of the evaluations, audits, investigations, and legal guidance that OIG has published related to Medicare Part D. She also discussed planned work outlined in OIG's 2008 "Work Plan."

On March 11, 2008, Timothy Brady, Regional Inspector General for Evaluation and Inspections in San Francisco, and Scott Hutchison of his staff made a presentation to the American Society for Public Administration during its annual meeting in Dallas, Texas. The topic of discussion was reducing Medicare and Medicaid fraud, waste, and abuse in the 21st century.

Events

OIG officials participated in the following events:

- October–November 2007, OIG sponsored Medicaid integrity training conferences in Pennsylvania, Florida, and California. These 3-day conferences addressed requirements of the fraud and abuse provisions contained in section 6034 of the Deficit Reduction Act (DRA) of 2005. The conferences were also tailored to address specific Medicaid integrity issues in the hosting States or regions and methods to better identify Medicaid program vulnerabilities. Since March 2007, we have held nine Medicaid integrity training conferences for over 1,100 attendees from a variety of Federal, State and local agencies, and independent/nonprofit health insurance associations.
- On December 6, 2007, OIG and HCCA cosponsored a Government-industry roundtable, *Driving for Quality in Long-Term Care: A Board of Directors Dashboard*. The roundtable discussions provided representatives from the long-term care industry with an opportunity to share experiences and inform OIG and HCCA of issues related to boards of directors' oversight of quality of care. On January 31, 2008, OIG and HCCA published a report summarizing the roundtable discussions. The report is available on the OIG Web site at <http://www.oig.hhs.gov/fraud/docs/complianceguidance/Roundtable013007.pdf>

Significant Awards From External Organizations

The following OIG individuals and teams received 2007 PCIE Awards on October 23, 2007:

- Susan C. Callahan, Senior Counsel, Individual Accomplishment Award
- Judith Holtz-Rock, Director, Public Affairs (retired), June Gibbs Brown Career Achievement Award
- Vicki L. Robinson, Chief, Industry Guidance Branch, Law and Legislation Award for Excellence
- Medicare Part D Team, Audit Award for Excellence
- 340B Drug Discount Program Team, Evaluation Award for Excellence
- Purdue Pharma L.P. Team, Investigation Award for Excellence

External Organizations

The IG and Principal Deputy Inspector General are Invited Ethics Resource Center Fellows from the Government sector. The Ethics Resource Center (ERC) is America's oldest nonprofit organization devoted to the advancement of high ethical standards and practices in public and private institutions. ERC serves as a resource for institutions committed to a strong ethics culture. ERC's expertise also informs the public dialogue on ethics and ethical behavior.

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Please note: Numerical information in this report is rounded.

Centers for Medicare & Medicaid Services

OIG allocates about 80 percent of its resources to work related to CMS, which administers the following programs:

- Medicare provides health insurance for people 65 years old or older, people younger than 65 years old with certain disabilities, and people of any age with end stage renal disease (ESRD). In FY 2007, Medicare served 43.9 million beneficiaries at a cost of \$375.2 billion. Medicare has four parts: Hospital Insurance (Part A), which helps cover inpatient care in hospitals, including critical access hospitals, SNFs, and hospice and certain home health care; Supplementary Medical Insurance (Part B), which helps pay for physician services and outpatient care; Medicare Advantage (MA), which offers a range of prepaid managed health care choices; and the Medicare Prescription Drug Benefit (Part D), which provides an optional prescription drug benefit to individuals enrolled in Medicare, generally through private prescription drug plans.
- Medicaid, a joint Federal-State program, supports States' coverage of medical care and other support services for low-income individuals. In FY 2007, Medicaid enrollment was estimated at 49 million people; total Federal and State outlays were \$350 billion, of which the Federal share was \$192 billion.
- SCHIP, a joint Federal-State program established in 1997 under Title XXI of the Social Security Act (the Act), provides health insurance for children who do not qualify for Medicaid but whose families are not able to afford private coverage. In FY 2007, SCHIP served 7.5 million beneficiaries at a Federal cost of \$6.1 billion.

OIG's focus on these health care programs reflects the spending of HHS: CMS expenditures have accounted for about 80 percent of the Department's budget over the last several years. This 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) 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 DRA (P.L. No. 109-171) provides OIG annual funding of \$25 million from FY 2006—FY 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, partnerships with States on Medicaid reviews, administrative sanctions, and criminal and civil enforcement activities.

Reports Related to CMS's Programs

Medicare-Related Reports

Hospital Wage Data

We found that two hospitals did not fully comply with Medicare requirements for reporting wage data in their Medicare cost reports. Under the acute care hospital inpatient prospective payment system, CMS adjusts the Medicare base rate paid to participating hospitals by the wage index applicable to the area in which the hospitals are located. CMS updates the wage indexes annually based on hospitals' reported wage data.

- **Massachusetts:** A hospital in Massachusetts overstated the wage data included in its FY 2006 Medicare cost report by \$13.4 million and 139,916 hours. Correcting the hospital's errors reduced the average hourly wage rate from \$41.45 to \$40. We recommended that the hospital submit a revised FY 2006 Medicare cost report to the fiscal intermediary and implement procedural improvements. The hospital did not agree with all of our findings but said that it would resubmit its cost report and strengthen its procedures. (A-01-07-00509)

- **New Jersey:** A hospital in New Jersey understated the wage data included in its FY 2005 Medicare cost report by \$572,108 and 110,107 hours. Correcting the hospital's errors reduced the average hourly wage rate from \$36.51 to \$35.76. We recommended that the hospital submit a revised FY 2005 Medicare cost report to the fiscal intermediary and implement procedural improvements. The hospital agreed. (A-02-07-01047)

Comparison of Average Sales Prices To Average Manufacturer Prices for Part B Prescription Drugs: Impact on Medicare Reimbursement

During this semiannual period, we issued two reports related to our continuing work comparing average sales prices (ASP) with average manufacturer prices (AMP) for Medicare Part B prescription drugs. From April 2006–July 2007, we issued three reports of such comparisons. Section 1847A(d)(2)(B) of the Act mandates that OIG perform these comparisons. For instances in which the ASP for a drug exceeds the AMP 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 shall substitute the payment amount for the drug code with the lesser of widely available market price for the drug (if any) or 103 percent of the AMP.

Analyzing CMS's Healthcare Common Procedure Coding System (HCPCS) codes for drugs covered under Medicare Part B, we have identified in all five comparisons 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 Medicare costs. Although these two reports did not include recommendations, CMS has commented on previous occasions 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 Part B reimbursement as a result our price comparisons.

In the fourth and fifth comparisons, issued during this reporting period, we specifically found the following:

■ **Comparison of First-Quarter 2007 Average Sales Prices to Average Manufacturer Prices for Part B Prescription Drugs: Impact on Medicare Reimbursement for Third Quarter 2007**—For the first quarter of 2007, we found that 34 of the 371 HCPCS codes included in our review were eligible for price adjustments and determined that such adjustments would have reduced Medicare third-quarter expenditures by \$9 million. Of these 34 codes, 20 had been identified in our previous comparisons as meeting the thresholds for price adjustment. (OEI-03-07-00530)

■ **Comparison of Second-Quarter 2007 Average Sales Prices and Average Manufacturer Prices for Part B Prescription Drugs: Impact on Medicare Reimbursement for Fourth Quarter 2007**—For the second quarter of 2007, we found that 22 of the 292 HCPCS codes in our review were eligible for price adjustments and determined that such adjustments would have reduced Medicare fourth-quarter expenditures by \$8 million. Of these 22 codes, 16 had been identified in our previous comparisons as meeting the thresholds for price adjustment. (OEI-03-08-00010)

Growth in Advanced Imaging Paid Under the Medicare Physician Fee Schedule

We reviewed the extent and nature of the growth in the use of advanced imaging that was paid under the Medicare Physician Fee Schedule (MPFS) from 1995–2005 and concluded that this area continues to warrant CMS’s attention to ensure that Medicare beneficiaries receive reasonable, appropriate, and high-quality imaging services in all ambulatory settings, including independent diagnostic testing facilities (IDTF). Advanced imaging enables doctors to diagnose and treat patients by providing detailed images of tissues deep inside the body. Under the Medicare program, advanced imaging (e.g., magnetic resonance, computed tomography, and positron emission tomography) has proliferated in ambulatory settings, where services are paid for under MPFS.

We found that:

- Advanced imaging paid under the MPFS grew more than fourfold, from 1.4 million to 6.2 million services; by 2005, advanced imaging billed under MPFS made up nearly one quarter of all advanced imaging covered by Medicare. Allowed charges and the utilization rate per beneficiary grew to \$3.5 billion and 163 services per 1,000 beneficiaries.
- Services provided by IDTFs accounted for nearly 30 percent of the total growth in advanced imaging under the MPFS.
- Growth varied widely among States, from 24 percent to over 1,000 percent.
- In every year from 1995–2005, a small number of procedure codes consistently accounted for over half of all advanced imaging billed under MPFS.

We recommended that CMS monitor the growth of advanced imaging in ambulatory settings. In addition, in a related report issued in 2006, we found numerous problems with IDTFs, including noncompliance with Medicare requirements and services that were not reasonable and necessary. Following our 2006 recommendation that CMS monitor IDTFs, the agency took certain actions, such as establishing IDTF performance standards, which partially addressed our earlier recommendation. The rapid growth of advanced imaging provided by IDTFs reinforces the importance of implementing our prior recommendation to consider conducting site visits to monitor IDTFs' compliance with Medicare requirements. CMS concurred with our recommendation to monitor growth of advanced imaging and described steps taken to improve oversight of IDTFs; however, the agency stated that it lacked funding to support unannounced site visits to IDTFs. (OEI-01-06-00260)

A Comparison of Medicare Program and Consumer Internet Prices for Power Wheelchairs

In a review of power wheelchairs, for which Medicare and its beneficiaries spent over \$900 million in 2006, we found that the Medicare fee schedule amounts were 45 percent higher than median Internet prices available to consumers in the first quarter of 2007. Medicare beneficiaries are eligible to receive power wheelchairs under Part B coverage of durable medical equipment (DME). Medicare will pay up to 80 percent of the cost of a power wheelchair, up to the fee schedule amount, and beneficiaries are responsible for paying the remaining amounts. Our 2004 review found that Medicare and its beneficiaries paid higher prices than consumers and suppliers. In 2006, CMS revised the fee schedule for power wheelchairs as part of its strategy to reform payments for these devices. For the period studied during this review, we determined that had suppliers been reimbursed for the same power wheelchairs at median Internet prices, Medicare and its beneficiaries would have spent 28 percent (\$39 million) less than actual payments; on average, each beneficiary could have saved \$233 in a power wheelchair copayment. We recommended that CMS consider performing additional reviews to determine whether current power wheelchair schedule amounts are appropriate. CMS concurred with our recommendation. (OEI-04-07-00160)

Los Angeles County Suppliers' Compliance With Medicare Standards: Results From Unannounced Visits

In our review of suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) in Los Angeles County in September and October 2007, we found that 194 of 905 suppliers (22 percent) did not meet one or both of the two Medicare enrollment standards that we selected for review. DMEPOS, which include items such as hospital beds, wheelchairs, respirators, walkers, and artificial limbs, are provided to Medicare beneficiaries by commercial suppliers, that are reimbursed by Medicare. At the time of our review, suppliers had to comply with 21 Medicare DMEPOS enrollment standards. During our unannounced site visits in Los Angeles County, where Medicare allowed \$245 million for these suppliers' claims in the 12-month period beginning July 1, 2006, we found that:

- Of 905 suppliers, 115 (13 percent) did not maintain physical facilities or were not open during posted business hours.

- Another 79 suppliers (9 percent) were open but did not post hours of operation or their business names, as required.
- An additional 124 suppliers (14 percent) met the requirements for the standards we reviewed, but we noted that they shared an atypical characteristic (i.e., more than half of Medicare beneficiaries did not receive other Medicare services, such as office visits by the physicians ordering the DMEPOS within the 6-month period preceding the claim).

These findings demonstrated continued vulnerabilities in the Medicare DMEPOS benefit, consistent with our findings in a similar review conducted in South Florida in 2006. In both reviews, we recommended that CMS strengthen the Medicare DMEPOS supplier enrollment process and ensure that suppliers meet Medicare supplier standards. The report provides a number of specific recommendations to achieve these objectives. (OEI-09-07-00550)

Medicare Payments for Home Blood-Glucose Test Strip and Lancet Supplies

We found that a Florida DME supplier did not claim reimbursement for home blood-glucose test strips and lancets provided in CYs 2002 and 2003 in accordance with Medicare requirements. Medical reviewers under contract with OIG found that none of the supplier's claims for 100 sampled beneficiaries met Medicare requirements and that each service line item on each claim had one or more errors. Errors included billing for medically unnecessary supplies and inadequate documentation. We estimated that at least \$8.2 million of the \$8.7 million paid to the supplier for test strips and lancets was unallowable for Medicare reimbursement.

We recommended that the supplier refund \$8.2 million to the Medicare program and work with CMS to determine the allowability of test strips and lancets billed after CY 2003. In its comments on our draft report, the supplier disagreed with our findings and recommendations but did not provide information that would cause us to revise them. (A-09-05-00063)

Payments for Outpatient Services on Behalf of Beneficiaries in Skilled Nursing Facility Stays

We found that for CYs 2001–2002, Medicare Part B made a total of \$106.9 million in potential overpayments to suppliers of outpatient hospital, laboratory, and radiology services on behalf of beneficiaries in SNF stays during which these services were already covered by Part A. The potential overpayments occurred because CMS did not have Common Working File (CWF) edits in place during most of this period. Without these edits, fiscal intermediaries could not properly identify or recover potential overpayments. For CY 2003, when the edits were fully implemented, potential overpayments were reduced to \$22.7 million. We estimated that the fiscal intermediaries and carriers had not recovered \$17.9 million of these CY 2003 potential overpayments. Unrecovered overpayments continued to occur because the edits did not identify all overpayments or because the edits identified the overpayments, but contractors experienced claim-processing system problems, misunderstood recovery instructions, or made errors during the recovery process.

We recommended that CMS direct the fiscal intermediaries and carriers to review the \$106.9 million in potential overpayments for CYs 2001–2002 and make appropriate recoveries, direct the fiscal intermediaries and carriers to initiate recovery of the estimated \$17.9 million in unrecovered overpayments for CY 2003, continue to test and refine the CWF edits to ensure that they properly identify claims subject to consolidated billing, and ensure that all fiscal intermediaries and carriers have established proper controls to recover overpayments that the CWF edits identify. CMS agreed with our recommendations. (A-01-06-00503)

Excessive Payments for Outpatient Services

We reviewed 45 high-dollar payments (i.e., \$50,000 or more) that a Medicare fiscal intermediary made to hospitals for outpatient services for CYs 2004 and 2005 and identified 44 overpayments. These overpayments totaled \$2.7 million that the hospitals had not refunded by the beginning of our audit in May 2007. CMS contracts with fiscal intermediaries to process and pay Medicare Part B claims submitted by hospital outpatient departments. We found that this fiscal intermediary incorrectly coded some claims and that the hospitals reported excessive units of service on other claims. We also found that neither the Fiscal Intermediary Standard System, used to process claims, nor CMS's CWF had sufficient edits in place during CYs 2004 and 2005 to detect and prevent excessive payments. The intermediary agreed with our recommendation to recover the overpayments. (A-05-07-00066)

Physician-Owned Specialty Hospitals' Ability To Manage Medical Emergencies

In our assessment of physician-owned specialty hospitals, we found deficiencies regarding the hospitals' ability to manage medical emergencies. The Senate Finance Committee requested that OIG evaluate patient care and safety in physician-owned specialty hospitals, which primarily perform cardiac, orthopedic, or surgical procedures and are partially or fully owned by physician investors. In two recent cases at such hospitals, patients experienced complications following elective surgery and no physicians were on duty to treat the patients, who later died when they were transferred to community hospitals.

We conducted a study of 109 physician-owned specialty hospitals between January and March 2007 with data from a sample of 8 days between July and December 2006 and found that:

- About half of all such hospitals had emergency departments, the majority of which had only one emergency bed.
- Not all of the hospitals had nurses on duty and physicians on call during the 8 sampled days.
- Less than one-third of the hospitals' administrators reported having physicians onsite at all times.
- Two-thirds of the hospitals instructed staff to call 9-1-1 as part of their emergency response procedures.

- Some of the hospitals' lacked basic information in their written policies about managing medical emergencies.

To improve the ability of physician-owned specialty hospitals to manage medical emergencies, we recommended that CMS develop a system to identify and regularly track these hospitals, ensure that hospitals meet the Medicare Conditions of Participation for staffing, ensure that hospitals have capabilities for the appraisal and initial treatment of emergencies and that they are not relying on 9-1-1, and require hospitals to have written policies to manage medical emergencies. CMS concurred with our recommendations. (OEI-02-06-00310)

Medicare Hospice Care: A Comparison of Beneficiaries in Nursing Facilities and Beneficiaries in Other Settings

We compared the characteristics of Medicare beneficiaries who receive hospice care in nursing facilities with beneficiaries who receive hospice care in other settings and found that beneficiaries in nursing facilities tended to be older and more likely to have ill-defined conditions. Studies by HHS and others have suggested that the use of hospice care is growing most rapidly in nursing facilities. The Medicare hospice benefit allows terminally ill beneficiaries to forgo curative treatment for their illness and instead receive palliative care, which is the relief of pain and other uncomfortable symptoms.

Our analysis of 2005 data found that:

- A total of 871,437 Medicare beneficiaries received hospice care, with 28 percent residing in nursing facilities.
- Medicare payments for hospice care for beneficiaries residing in nursing facilities amounted to \$2.55 billion.
- Hospice beneficiaries in nursing facilities were more than twice as likely as beneficiaries in other settings to have terminal diagnoses of ill-defined conditions, mental disorders, or Alzheimer's disease.
- On average, beneficiaries in nursing facilities spent more time in hospice care and were associated with higher Medicare reimbursements for hospice care than beneficiaries in other settings.

CMS commented that our report provided a helpful general description of the current utilization patterns. (OEI-02-06-00220)

Tracking Beneficiaries' True Out-of-Pocket Costs for the Part D Prescription Drug Benefit

In our review of Medicare Part D plans' tracking of TrOOP costs, we found that in 2006, 29 percent of Part D plans did not, as required, submit their enrollees' additional prescription drug coverage information to COBC. CMS contracts with COBCs to consolidate the activities that support the collection, management, and reporting of other insurance coverage for Medicare beneficiaries. Part D plans are responsible for tracking beneficiaries' TrOOP costs, which are the prescription drug expenditures that count

toward the annual out-of-pocket threshold that beneficiaries must reach before catastrophic drug coverage begins. To track TrOOP costs accurately, Part D plans must have information on any prescription drug coverage that enrollees have in addition to Part D coverage. We also found that:

- Thirty-four percent of Part D plans did not submit prescription drug event data in accordance with CMS requirements. Such data include prescription drug costs and payment data that enable CMS to make payments to the plans and otherwise administer the Part D benefit.
- Sixty-three percent of Part D plans cited problems with transferring TrOOP balances when enrollees changed plans.
- CMS had conducted limited oversight of Part D plans' tracking of TrOOP costs.

We recommended that CMS ensure that Part D plans collect, process, and submit all data required for the tracking of TrOOP costs; consider options for increasing the number of data-sharing agreements and seek to expand its authority to collect data under those agreements; and begin or complete planned oversight activities regarding tracking TrOOP costs. Although CMS did not indicate whether it concurred with our recommendations, the agency noted that it had taken or would take steps in response to each of our recommendations. (OEI-03-06-00360)

Medicare Part D Sponsors: Estimated Reconciliation Amounts for 2006

Based on our analysis of CMS's Medicare Part D preliminary reconciliation data estimates (as of August 2007) and data from 16 sponsors with high enrollments, we estimated that Part D sponsors owed Medicare a net total of \$4.4 billion for the 2006 program year. We also found that CMS had no mechanism to collect funds or adjust prospective payments prior to the reconciliation that is conducted after the close of the plan year. As a result, sponsors had the use of billions of dollars for a significant length of time.

CMS contracts with private Part D sponsors to provide prescription drug coverage for enrollees. CMS approves the sponsors' bids prior to the plan year and makes monthly prospective payments to the sponsors based on those bids. After the close of the plan year, CMS must reconcile the prospective payments with sponsors' actual costs and also determine whether risk-sharing payments are required. Risk-sharing requires the Federal Government to share in sponsors' unexpected profits and losses. For the 2006 plan year, we found that 80 percent of the sponsors owed CMS money and 20 percent were due money. Of the amount owed, almost two-thirds resulted from risk-sharing requirements—these sponsors' bids overestimated the costs of providing the benefit.

We recommended that CMS ensure that sponsors' bids accurately reflect the cost of providing the benefit to Medicare beneficiaries; consider implementing an interim reconciliation process to reduce the amounts owed to Medicare; better align monthly prospective payments with sponsors' actual costs; and consider seeking legislative

changes to delay the adjustments to the risk corridors as specified by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003.

CMS agreed with the recommendation that data collected from 2006 and subsequent plan years be used in the review of future bid submissions, acknowledged having the authority to change certain payment methodologies, and stated that it was examining possible options. CMS did not agree with our recommendations to implement an interim reconciliation process for 2007 or to seek legislation to delay changes to the risk corridors.

In response to the recommendation that CMS consider conducting an interim reconciliation process, CMS stated that it believes bidding accuracy will improve in coming years, thus eliminating this as an issue. Based on its interpretation of the statute, CMS also stated that there is no legal authority for an interim reconciliation of risk-sharing payments. In response to our recommendation that CMS consider seeking legislative changes to delay the adjustments to the risk corridors, CMS responded that it is only now able to analyze a full set of bidding and first-year utilization data and that it would be premature to make recommendations to Congress for statutory changes before having a more complete analytic picture of whether the Government would benefit or be harmed by a change in the risk corridors.

We continue to recommend that CMS consider implementing an interim reconciliation process and consider seeking legislative changes to delay the adjustments to the risk corridors. CMS could request that sponsors make interim reconciliation settlements on a voluntary basis, when appropriate. Alternatively, CMS could consider pursuing statutory or regulatory changes necessary to implement a mandatory interim reconciliation process. Also, because only limited data are currently available, there remains a significant risk that plans will owe large sums of money back to Medicare for 2008 and beyond. (OEI-02-07-00460)

Medicare Part D Prescription Drug Plan Sponsor Internet Web Sites: Content and Accessibility

In our review of Medicare Part D Prescription Drug Plan (PDP) sponsors' Internet Web sites, we found that of the 84 PDP sponsors offering drug plans within the 50 States and the District of Columbia in 2007:

- Thirty-three percent had Web sites that did not contain all federally required content. The most commonly omitted content pertained to enrollee disenrollment rights and responsibilities, the potential for PDP contract termination, and information related to the formulary.
- Eighty-five percent of the sponsors' Web sites did not meet at least one of the four Federal requirements for Web site accessibility, potentially affecting Medicare beneficiaries' access to content.

Pursuant to Federal regulations, CMS must review and approve marketing material for Part D prescription drug plans, including materials provided through Part D sponsors'

Web sites, where an increasing number of adults aged 65 and older seek information on PDPs. Our findings demonstrated the need for CMS to oversee the PDPs' Web sites to ensure that all Medicare beneficiaries, including persons with disabilities, have access to federally required content to make informed decisions about their prescription drug coverage. (OEI-06-06-00340)

Implementation of Safeguards During Fiscal Year 2006 To Prevent and Detect Fraud and Abuse in Medicare Prescription Drug Plans

In this early assessment, we found that CMS had made progress in implementing Medicare Part D fraud and abuse safeguards but that some safeguards had not been fully implemented by the end of FY 2006. Based on a document review and interviews with agency staff, we identified six activities that comprised CMS's strategy for safeguarding Medicare Part D. These strategies and their status are as follow:

- **Complaint process:** We determined that CMS relied largely on complaints to identify potential fraud and abuse; however, not all complaints were investigated in a timely manner
- **Data monitoring:** We found that neither CMS nor the Medicare Prescription Drug Integrity Contractor (MEDIC) had conducted any significant data analysis for fraud detection purposes. According to CMS, data monitoring was delayed by a lag in data submissions.
- **Financial audits:** We found that CMS had awarded a contract to develop the financial audit program before the end of FY 2006, with an expectation that the first audits would be initiated in January 2008.
- **Monitoring PDP sponsor compliance:** CMS's routine account management activities and operational safeguards were in place prior to the first beneficiary enrollment period. However, the agency's compliance audits, slated to be initiated in the summer of 2006, had not begun by the end of FY 2006 because CMS encountered problems with a data system used to track such audits.
- **Oversight of PDP efforts to reduce fraud and abuse:** CMS issued requirements for PDP sponsors' fraud, waste, and abuse compliance plans before the benefit began and updated guidance in April 2006.
- **Education and guidance:** We were concerned that CMS had not completed the "Prescription Drug Benefit Manual" and had not issued more fraud alerts.

We also found that CMS's efforts to safeguard Medicare Part D PDPs were complicated by limits to legal authority, jurisdiction, and the agency's inability to monitor enrollees who switch plans. We recommended that CMS develop a comprehensive Medicare Part D safeguard strategy, ensure that all fraud complaints receive proper attention, and address legal concerns that may impede program integrity efforts. CMS did not indicate whether it concurred with our recommendations but stated that many of its ongoing activities satisfied our recommendations. (OEI-06-06-00280)

Relationship Between Medicare Part D Payments to Local, Community Pharmacies and the Pharmacies' Drug Acquisition Costs

In our review of the relationship between Medicare Part D payments to local, community pharmacies and the pharmacies' drug acquisition costs, we found that in September 2006, pharmacies almost always (97 percent of the time) acquired drugs for less than the reimbursement amounts. We performed this review at the request of 33 Senators who raised concern about the sufficiency of reimbursement at local, community pharmacies. Under Medicare Part D, CMS contracts with PDPs and Medicare Advantage plans, which then act as the payers and insurers for prescription drug benefits. The PDPs, referred to as sponsors, pay pharmacies a rate for ingredient costs (i.e., drug acquisition costs), which is usually a published average wholesale price of the drug minus some percentage, as well as a dispensing fee.

We estimated that excluding dispensing fees and including rebates that drug wholesalers paid to pharmacies, Medicare payments to local, community pharmacies exceeded the pharmacies' drug acquisition costs by 18.1 percent. Excluding rebates, Part D payments exceeded drug acquisition costs by an estimated 17.3 percent. The Part D payment for each prescription in our analysis exceeded the drug acquisition cost by an estimated \$9.13, including rebates, and \$8.78, excluding rebates. We found that the percentage difference between Part D payments and drug acquisition costs was more than nine times higher for generic drugs than brand-name drugs. We also estimated that the average Medicare Part D dispensing fee paid to local, community pharmacies was \$2.27, which was about \$2 less than the average Medicaid dispensing fee.

We recommended that Congress and CMS consider the results of our review, including the data provided, in any deliberations regarding Medicare Part D reimbursement. CMS concurred with the recommendation. (A-06-07-00107)

Generic Drug Utilization in the Medicare Part D Program

Generic drugs, which are chemically identical to their brand-name counterparts and have the same therapeutic effects and risk-benefit profiles, are generally cheaper than brand-name drugs. Using generic drugs rather than brand-name drugs may lower the costs of Part D for the Federal Government and reduce beneficiaries' out-of-pocket costs for premiums, copayments, or coinsurance. In a congressionally requested review of generic drug utilization in the Medicare Part D program, we found that for the first two quarters of 2006, generic drugs were dispensed 88 percent of the time when generic substitutes were available. Overall, 56 percent of all drugs dispensed were generic drugs. Of the prescriptions issued during the review period, 37 percent were for drugs that had no generic substitutes.

Without making recommendations, we concluded that prescribing drugs having no generic equivalent primarily accounted for variation in generic drug utilization. We also concluded that, to achieve increases in generic drug utilization, Part D plans may realize gains by encouraging the prescribing of multisource drugs, which have generic equivalents. We suggested that such efforts be undertaken with caution to ensure that beneficiaries maintain access to appropriate treatment. In response to our draft report, CMS generally agreed with our findings. (OEI-05-07-00130)

1-800-MEDICARE: Caller Satisfaction and Experiences

In our review of callers' satisfaction and experience with Medicare's telephone customer service system, we found that 71 percent of callers who completed their calls during a 1-week period in FY 2007 were satisfied with the customer service they received. This represented a 13-percent decrease compared to the results from a prior OIG study of calls made in 2004. Medicare's telephone customer service system, which callers access by calling 1-800-MEDICARE, is the most commonly used communication channel in educating and assisting Medicare's 42 million beneficiaries.

Repeating a process used to collect the 2004 baseline data, we interviewed a random sample of callers during January 22–26, 2007. We found that 21 percent of callers hung up before receiving responses to their questions, compared to 12 percent of callers in 2004. Similar to the 2004 baseline data, 44 percent of callers in the 2007 evaluation reported difficulty in accessing information. Thirty-one percent of these callers reported that the Interactive Voice Response (IVR) system, which provides information to callers or routes callers to customer service representatives, was not easy to use.

We recommended that CMS reassess the level of resources directed toward improving the question-answering capabilities of the IVR system, ensure that callers receive all needed information, and continue to seek ways to reduce caller wait times. CMS did not indicate whether it concurred with our recommendations; however, it described several actions that it had taken or planned that relate to our findings and recommendations. CMS also provided information on efforts underway or planned for the future that were aimed at improving call-center operations. (OEI-07-06-00530)

Claim Payment Adjustments Identified by Quality Improvement Organizations

We found that fiscal intermediaries, which contract with CMS to process and pay inpatient provider claims, properly processed the majority of payment adjustments for claims referred to them by Quality Improvement Organizations (QIO) during the FY 2005 Hospital Payment Monitoring Program (HPMP). CMS contracts with QIOs to, among other things, review and make a final determination on erroneous claims identified through the HPMP process and notify fiscal intermediaries to make claim adjustments. Fiscal intermediaries properly processed 3,440 (96.4 percent) of the 3,568 claims that QIOs referred, with net overpayments totaling \$9.2 million. However, fiscal intermediaries did not properly adjust 128 claims, with net overpayments totaling \$416,000.

We recommended that CMS instruct fiscal intermediaries to recover the \$416,000 and follow up with QIOs and fiscal intermediaries when adjustments identified by the QIOs are not processed properly. CMS agreed with the first recommendation and specified an alternative procedure that met the objective of the second recommendation. (A-03-06-00005)

Fiscal Integrity of Quality Improvement Organizations

At the request of the Senate Finance Committee, we assessed the fiscal integrity of QIOs in nine States with respect to the following specified areas: board member and executive staff compensation and travel, legal fees, administrative and equipment charges, business

relationships and conflicts of interest, and contract modifications. We completed reviews of four QIOs during this reporting period. Our findings were as follow:

- **Iowa:** Most of the \$10.3 million in costs reviewed for the period February 2003–January 2006 appeared reasonable for Federal reimbursement. However, the QIO incurred \$209,000 of costs that were unallowable and \$531,000 of costs that may not have complied with Federal requirements. We recommended that the QIO make financial adjustments and work with CMS to resolve the potentially unallowable costs. In its comments on our draft report, the QIO disagreed with our findings and recommendations but did not provide information that caused us to revise our findings. (A-07-06-01035)
- **New York:** Of the \$11.3 million of costs reviewed for the period August 2002–July 2005, \$11.1 million appeared reasonable for Federal reimbursement. Of the remaining costs, the QIO incurred \$77,000 of costs that were unallowable and \$157,000 of costs that may not have complied with Federal requirements. We recommended that the QIO make financial adjustments and work with CMS to resolve the potentially unallowable costs. Although it did not specifically agree to refund any costs, the QIO stated that it had reclassified or recharacterized costs associated with our recommended financial adjustments. The QIO disagreed with our recommendation regarding potentially unreasonable conference-related costs. Based on our evaluation of the QIO’s comments, we revised our report regarding legal fees but did not find cause to alter any other conclusions and recommendations. (A-02-06-01023)
- **Ohio:** Of the \$7.7 million of costs reviewed for the period August 2002–July 2005, \$7.6 million appeared reasonable for Federal reimbursement. Of the remaining costs, the QIO incurred \$12,000 for costs that were unallowable and \$78,000 for costs that may not have complied with Federal requirements. We recommended that the QIO make financial adjustments, work with CMS to resolve the potentially unallowable costs, and maintain an accurate inventory of Government-owned equipment. In its comments on our draft report, the QIO did not address our findings or recommendations related to unallowable costs and disagreed with our findings related to potentially unallowable costs. However, the QIO did not provide information that caused us to revise our findings. (A-05-06-00043)
- **Washington:** Of the \$12.2 million of costs reviewed for the period November 2002–October 2005, \$12.1 million appeared reasonable for Federal reimbursement. The remaining \$74,000 represented unallowable indirect costs that the QIO allocated to subcontracts in excess of the allowable limit. In addition, the QIO overstated its modified total direct cost bases by \$404,000 and its indirect cost pool by \$72,000. We recommended that the QIO make financial adjustments. In its comments on our draft report, the QIO agreed with the finding related to unallowable indirect costs but disagreed with the amount of the recommended refund. Based on our evaluation of information provided by the QIO, we revised the recommended refund amount related to the indirect cost rates. (A-09-06-00039)

Medicare Contractor Pension Reimbursement

During the semiannual period, we issued three reports related to unallowable pension costs claimed by a Medicare contractor. Medicare reimburses a portion of the annual contributions that contractors make to their pension plans. In claiming costs, contractors must follow cost reimbursement principles contained in the Federal Acquisition Regulation, Cost Accounting Standards, and Medicare contracts. Our findings were as follow:

- **Excess Plan Costs:** For FYs 1996–2004, the contractor improperly based its Excess Plan costs on accrual accounting principles and, as a result, overclaimed \$1.8 million. The Excess Plan is a nonqualified pension plan designed to restore benefits lost under the regular qualified plan as a result of certain sections of the Internal Revenue Code. We recommended that the contractor revise its final administrative cost proposals to reduce claimed Excess Plan costs by \$1.8 million. The contractor did not directly address our recommendation but stated that it would amend the Excess Plan to meet Federal requirements and work with CMS to resolve issues regarding costs previously claimed. (A-07-07-00235)
- **Supplemental Executive Retirement Plan Costs:** For FYs 1999–2004, the contractor’s claim for Supplemental Executive Retirement Plan (SERP) costs included some costs that were unreasonable and therefore unallowable for Medicare reimbursement. A SERP is a nonqualified pension plan designed to provide supplemental benefits to a select group of highly compensated employees. However, the contractor’s executive salaries used to calculate SERP costs were \$15.6 million greater than the executive compensation limits established in Federal regulations. We were unable to determine the impact of these unallowable compensation costs on SERP costs because the contractor did not provide the necessary documentation. We recommended that the contractor work with CMS to determine the allowability of \$5.9 million in SERP costs. The contractor concurred. (A-07-07-00234)
- **Postretirement Benefit Costs:** The contractor overclaimed a subsidiary’s accrued postretirement benefit (PRB) costs on the final administrative cost proposals for FYs 2000–2004. We determined that the allowable accrued costs for this period were \$2.4 million. However, the contractor claimed accrued costs of \$4 million because it did not compute the costs in accordance with its Medicare contract and an agreement with CMS. We recommended that the contractor revise the subsidiary’s proposals for FYs 2000–2004 to reduce its claimed PRB costs by \$1.7 million and claim future PRB costs in accordance with the Medicare contract. The contractor did not concur with our

recommendations, stating that its understanding was that contributions in excess of the reimbursable limits created a prepayment credit that could be applied to future funding requirements. However, we continue to support our recommendations.
(A-07-07-00229)

Medicaid-Related Reports

Generic Drug Price Increases

Our review of the Medicaid drug rebate program found that the program could have received \$966 million in additional rebates for the top 200 generic drugs in 1991–2004 had a rebate provision that applies to brand-name drugs been extended to generic drugs. For covered outpatient drugs to be eligible for Federal Medicaid funding, manufacturers must enter into rebate agreements with CMS and pay quarterly rebates to the States. Manufacturers are required to pay an additional rebate when the AMP for a brand-name drug increases more than a specified inflation factor. There is no similar inflation-based rebate provision for generic drugs. The President’s budget request for FY 2001 sought extension of the rebate provision to generic drugs, but the proposal has not been adopted. In response to our recommendation to consider seeking legislative authority to extend the additional rebate provisions to generic drugs, CMS agreed to do so once it had sufficient time to assess the impact of recent changes to the Medicaid prescription drug program required by the DRA. (A-06-07-00042)

Unit of Measure Inconsistencies in the Medicaid Prescription Drug Program

In our review of the impact of unit of measure inconsistencies on Medicaid rebate claims, we identified \$11.8 million in inappropriately claimed Medicaid rebates during the first 6 months of 2006. The method for defining units determines the number of units in a package, or package size; the unit of measure and package size are used together to calculate the per unit reimbursement that Medicaid makes to retail pharmacies and per unit rebate amounts that prescription drug manufacturers pay to States.

We specifically found that:

- Most inconsistencies involved the unit type “each.”
- On average, States converted 45 percent of their utilization data for drugs with unit of measure inconsistencies.
- States could not use package size data from CMS to efficiently detect or correct for unit of measure inconsistencies.

Inappropriately claimed Medicaid rebates can lead to incorrect rebate payments or disputes with manufacturers. In addition, unit of measure inconsistencies have implications for future Medicaid reimbursement based on AMPs.

We recommended that CMS provide more specific guidance to manufacturers regarding the unit type “each” and improve its guidance to States regarding detecting and

converting unit of measure inconsistencies. CMS disagreed, stating that unit of measure inconsistencies did not account for significant improper Medicaid rebate payments. However, we consider that the effects of unit of measure inconsistencies may increase as AMP data are increasingly used for Medicaid reimbursement. (OEI-05-07-00050)

Hurricane Katrina Uncompensated Care Costs Claimed by Two Mississippi Medical Facilities

During this semiannual period, we issued reports on two Mississippi medical facilities' claims, as of December 2006, for medically necessary uncompensated care furnished to Hurricane Katrina evacuees and other affected individuals without other coverage in eligible States. In response to Hurricane Katrina, section 6201 of the DRA authorized Federal funding for such costs. The findings of these reports were as follow:

- **Medical Center:** We found that the State appropriately claimed most of the \$17.9 million in uncompensated care reimbursement for services provided by a medical center. However, 4 of the 200 claims that we sampled, totaling \$22,400, were improper because the individuals who received the services had health care coverage under other programs. We recommended that the State refund to CMS the unallowable reimbursement and consider reviewing the medical center's claims that were not included in the sample to ensure that no other health care coverage was available and make refunds if appropriate. The State did not fully agree with the recommendations but said that it would make the proper adjustments in cooperation with CMS. The State also provided detailed explanations for three of the seven claims we originally questioned. Based on this additional information, we allowed the three claims and amended our findings and recommendations accordingly. (A-04-07-06004)
- **Hospital:** We found that the State appropriately claimed \$7.9 million in uncompensated care reimbursement for services provided by a hospital. This report had no recommendations. (A-04-07-06017)

Medical Assistance to Hurricane Katrina Evacuees

We issued two reports on unallowable reimbursement claimed through section 1115 demonstration projects for Hurricane Katrina evacuees. Under section 1115 of the Act, CMS approved certain States' requests for Medicaid demonstration authority to provide the benefits included in their Medicaid State plans to eligible evacuees. Reimbursement consisted of the Federal Medicaid share and the non-Federal share authorized for Federal payment by section 6201 of the DRA. The findings of these reports were as follow:

- **Delaware:** Delaware generally claimed reimbursement in accordance with its approved demonstration project. However, we found no evidence that three applicants met displacement requirements. As a result, the State claimed a net total of \$9,300 (of a total of \$173,000) in unallowable reimbursement. We recommended that the State refund the \$9,300 and revise its claims by our audit adjustment amounts. In its comments on our draft report, the State generally disagreed with our findings and recommendations but did not provide information that caused us to revise our findings. (A-03-07-00201)

■ **District of Columbia:** The District of Columbia improperly claimed reimbursement for services provided to 18 applicants after their eligibility periods had expired and to 3 applicants who did not meet eligibility requirements. As a result, the District claimed a net total of \$44,900 (of a total of \$246,000) in unallowable reimbursement. We recommended that the District refund the \$44,900 and revise its claims by our audit adjustment amounts. The District generally agreed. (A-03-07-00202)

Medicaid Targeted Case Management Services Provided by Several States

During this semiannual period, we issued five reports on States' claims for Medicaid targeted case management (TCM) services. Such services help specific Medicaid populations gain access to medical, social, educational, and other services. CMS has specified that TCM services not include direct medical, educational, or social services to which Medicaid eligibles have been referred. All of the reports identified inappropriate claimed costs, as follow:

■ **Georgia:** For FYs 2003 and 2004, we estimated that the State claimed \$4.7 million (\$2.8 million Federal share) in unallowable claims for TCM costs for individuals deemed at risk of incarceration. Claims were unallowable because they were not supported as TCM in case records, were for TCM services provided to ineligible incarcerated juveniles, or had no supporting documentation. We recommended that the State refund the estimated overpayment, examine later claims and refund any overpayment identified, and establish monitoring procedures to provide assurance that claims comply with Federal and State requirements. The State said that it would refund the overpayment once a final determination had been made and that it would implement the other recommendations. (A-04-06-00022)

■ **Iowa:** For FYs 2003 and 2004, we estimated that the State improperly claimed \$2.5 million (\$1.5 million Federal share) in unallowable TCM costs. The State provides TCM services to Medicaid-eligible pregnant women; recipients with a diagnosis of mental retardation, developmental disability, or chronic mental illness; eligibles under the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program; and children from age 3 to 21 who meet the eligibility categories under Part B and Part C of the Individuals with Disabilities Education Act. We questioned the costs because they lacked sufficient documentation or were for services that did not meet the definition of TCM services. We also found that the State claimed direct medical services as TCM costs; because these costs may be allowable under other provisions of the Medicaid program, we set aside \$303,000 (\$196,000 Federal share) for CMS adjudication. We recommended that the State refund \$1.5 million to the Federal Government for unallowable TCM claims, work with CMS to determine the allowability of the \$196,000 in direct medical services claimed as TCM services, and strengthen related internal controls. The State partly agreed with the first two recommendations and fully agreed with the third. (A-07-06-03078)

■ **Kansas:** For State FYs 2001 and 2003, the State did not ensure that its \$62 million (\$37.2 million Federal share) in TCM claims for recipients of child welfare services was equal to or less than the limit specified in the State's Medicaid plan. Because the State could not produce the rate and cost data necessary to apply the limit,

we were unable to express an opinion on the reasonableness of the claim. We recommended that the State work with CMS to determine the allowability of the \$62 million claimed for the audit period, as well as claims for all subsequent periods, and strengthen internal controls to ensure that State plan requirements are followed in submitting future TCM claims. The State generally agreed. (A-07-06-03074)

■ **Maine:** For FYs 2002 and 2003, the State overstated by a total of \$44.2 million (\$29.8 million Federal share) the cost of Medicaid TCM services provided to recipients of family services because the State did not have procedures for ensuring that Medicaid TCM costs were reasonable, allowable, and allocable, in accordance with Federal requirements. We were unable to express an opinion on the remaining \$12.4 million (\$8.3 million Federal share) claimed for TCM-type activities that we were not able to separate from services provided by State family services programs. We recommended that the State refund to the Federal Government \$29.8 million in unallowable costs, work with CMS to determine the allowability of the \$8.3 million for which we were unable to express an opinion, identify and refund any unallowable TCM costs reimbursed after the audit period, and establish procedures to ensure that claims for Medicaid TCM reimbursement include only allowable and adequately documented TCM costs. The State disagreed with our findings and recommendations but did not provide information that would cause us to revise our findings. (A-01-05-00004)

■ **Minnesota:** For FYs 2003 and 2004, we estimated that the State claimed \$7.3 million (\$3.8 million Federal share) for various services for which the claims did not meet Federal and State documentation requirements. We recommended that the State refund the \$3.8 million overpayment and ensure that TCM services are properly documented. The State did not address our recommendations but requested information about the claims that lacked documentation. Based on a review of these claims, the State indicated that it may modify existing procedures or develop new ones to correct the problem. (A-05-05-00059)

Tennessee Home- and Community-Based Mental Retardation Services

Based on our review of Tennessee's claims for home- and community-based services (HCBS) provided to Medicaid beneficiaries with mental retardation and developmental disabilities during State FY 2003, we estimated that the State claimed approximately \$11 million (\$7 million Federal share) for HCBS that were not supported by provider records. We recommended that the State refund the excess Federal reimbursement, establish certain HCBS controls and procedures, and review claims after the audit period and refund any overpayments. The State did not address our recommended refund but agreed that additional oversight and controls were needed. (A-04-03-03026)

Medicaid School-Based Services in Utah

We found that Utah's claims for Medicaid reimbursement of school-based services provided in FYs 2001–2005 generally did not comply with Federal requirements or the State's Medicaid plan. It was not possible to determine what portion of the \$36.8 million Federal share claimed was allowable as final payments. The State had not, as required by its plan, performed a cost settlement reconciling interim payments to actual costs to determine final payments. The State concurred with our recommendations to work with

CMS to determine the portion of the \$36.8 million that was allowable and to perform cost settlements to ensure that final payments for school-based services are based on actual costs. (A-07-06-04069)

Improper Payments for Medicaid Pediatric Dental Services

State MFCUs have periodically identified improper Medicaid payments for dental services. We reviewed this area in five States and found that 31 percent of Medicaid pediatric dental services provided under the EPSDT program during 2003 did not meet Federal and State requirements, resulting in improper Medicaid payments of approximately \$155 million (\$96 million Federal share). Documentation errors accounted for \$138 million (89 percent) of the total improper payments identified. Under this program, children and youth enrolled in Medicaid are eligible to receive routine and preventive health care services, including dental services. Federal regulations require State Medicaid programs to ensure that claims for EPSDT services are accurate, are supported by documentation, and are provided as medically necessary. We recommended that CMS increase its efforts to ensure that States enforce existing policies relating to the proper documentation of pediatric dental services and provide assistance to States to promote provider awareness and ensure compliance with documentation requirements. CMS stated that it “does not disagree” with our recommendations and added that our recommendations dovetailed into the agency’s Medicaid Integrity Group’s charge to provide effective support and assistance to States. (OEI-04-04-00210)

New Jersey Medicaid Contingency Fee Contract Payments

We found that New Jersey made improper claims of \$16 million (\$8 million Federal share) to the Medicaid program for contingency fees paid to two consultants. The State had hired the consultants to generate increased Federal reimbursement by identifying and submitting to the Federal Government unclaimed State expenses. According to the terms of the contracts, the consultants were paid fees contingent on additional Federal funds recovered. OMB Circular A-87, “Cost Principles for State, Local, and Indian Tribal Governments,” prohibits Federal reimbursement for consultant services that are contingent on recovery of costs from the Federal Government. We recommended that the State refund \$8 million to the Federal Government. The State disagreed with our interpretation of the OMB circular, but we maintained that OMB Circular A-87 prohibits Federal reimbursement for consultant services when the costs of those services are contingent on recovery of costs from the Federal Government. (A-02-06-01006)

California’s Medicaid Management Information System Expenditures

In a review of costs claimed by California for operating its Medicaid Management Information System (MMIS) from July 1, 2003, to June 30, 2005, we found that most costs were allowable. However, \$2.3 million was improperly claimed, mostly because the costs were not equitably allocated to all benefiting programs, were not related to the Medicaid program, or were claimed twice. An MMIS is a system of software and hardware used to process Medicaid claims and manage information about beneficiaries and services. States may receive Federal reimbursement from CMS for the operation of an MMIS at an enhanced rate of 75 percent. We recommended that the State refund the improperly claimed costs, strengthen its internal controls, and review the appropriateness

of costs claimed after the audit period. The State generally agreed with our recommendations. (A-09-06-00032)

State Children's Health Insurance Program-Related Report

Assessing States' Progress in Meeting SCHIP Goals

We found that, nationally, the percentage of uninsured low-income children had a statistically significant decrease from 20 percent in 2002 to 18.5 percent in 2005. However, no State experienced a statistically significant change. The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, P.L. No. 106-113, requires that, every 3 years, OIG assess States' progress in reducing the number of uninsured low-income children, including their progress in meeting the strategic objectives and performance goals included in State plans.

We also found that CMS had made improvements to the Annual Report template, which the agency developed for States to document their progress in reducing the number of uninsured and meeting goals. However, States' progress remains difficult to assess because of Census Bureau data limitations. Additionally, States' use of nondirectional performance goals and measures missing from the Annual Report limited the report's usefulness in assessing States' progress in meeting performance goals.

We recommended that CMS continue efforts to address concerns regarding Census Bureau data, provide guidance to States on developing directional performance goals with a target, and ensure that States report on all goals and measures. CMS agreed with our description of the limitations of the census data and noted that it did not have accountability for or control over the Census Bureau data or funding. (OEI-05-07-00330)

Financial-Related Report

CMS Financial Statement Audit

The CMS FY 2007 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 Medicare claim-processing controls. The weakness related primarily to direct update access to Medicare claim data, controls over edit settings in application systems, controls over the use of supplemental software used to process claims, and lack of CMS oversight. (A-17-07-02007)

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 the HIPAA, OIG, in consultation with DOJ, issues advisory opinions to outside parties regarding the interpretation and applicability of certain statutes relating to Federal health care programs. This authority allows OIG to provide case-specific formal guidance 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, 2007–March 31, 2008, OIG received 20 advisory opinion requests and issued 16 advisory opinions. OIG advisory opinions are available on the Internet at <http://oig.hhs.gov/fraud/advisoryopinions.html>.

Provider Self-Disclosure Protocol

OIG is committed to assisting health care providers and suppliers in detecting and preventing fraudulent and abuse 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.

The self-disclosure guidelines are available on OIG’s Web site at <http://www.oig.hhs.gov> in the “Fraud Prevention & Detection” section under “Self-Disclosure Information.”

In addition, OIG issued an “Open Letter to Providers” in 2006 to promote the use of the self-disclosure protocol to resolve CMP liability under the physician self-referral and anti-kickback statutes for financial arrangements between hospitals and physicians.

During this reporting period, self-disclosure cases resulted in \$8.8 million in HHS receivables. For example:

- **Pennsylvania:** Inglis House, a specialty nursing care facility for adults with physical disabilities, agreed to pay \$5,547,940 to resolve its liability under the CMPL and Pennsylvania State law. Inglis utilized OIG’s Provider Self-Disclosure Protocol to report that it submitted eight types of false claims to Medicare and Medicaid. Violations included overly frequent comprehensive resident assessments, which improperly inflated Inglis’ Medicaid case mix index; billing Medicaid for services covered by Medicare Part A; billing Medicare Part B and Medicaid for services that should have been included in the Medicare Part A payment; and wrongful billing to

Medicare and Medicaid for Certified Registered Nurse Practitioner services. In addition to the monetary settlement, Inglis entered into a 5-year CIA with OIG.

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 participating in Federal health care programs and imposing CMPs for submitting false or fraudulent claims to a Federal health care program or violating the anti-kickback statute, physician self-referral statute, or the "patient dumping" provision of the Act.

During this reporting period, OIG administered 1,330 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 1,291 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:

- **California:** John Derrick Van Doren, an anesthesiologist, was excluded indefinitely based on the Medical Board of the State of California's revocation of his license to practice medicine. Van Doren's license was revoked based on his unlawful use of controlled substances, gross negligence, repeated negligent acts, incompetence, and unprofessional conduct. It was discovered that over a 4-year period, Van Doren frequently used marijuana and cocaine; left the operating room to get food while a patient was under general anesthesia; and made sexual, offensive, and/or inappropriate remarks to staff.
- **Florida:** Yvonne May Richards, the business manager for a community mental health center, was excluded for a minimum period of 30 years based on her conviction related to a Medicare fraud scheme. Richards billed Medicare from about February 1996 to January 2003 for psychiatric services that were not rendered, were not needed, and/or were performed by unlicensed personnel. Richards also conspired to pay kickbacks and launder money. Richards was sentenced to 121 months of incarceration and ordered to pay more than \$9.8 million in restitution.
- **New York:** Neil E. Norwood, a pharmacist, was excluded for a minimum period of 25 years based on his conviction for his scheme to defraud Medicaid and a private insurer. As part of the scheme, Norwood provided patients with less medication than prescribed but billed Medicaid and the private insurer as if the full prescription had

been dispensed. Norwood was sentenced from 2 to 6 years of incarceration and ordered to pay \$3 million.

■ **Utah:** J. Jesus Partida, a certified nurse aide, was excluded for a minimum period of 20 years based on his conviction related to patient abuse or neglect. For over 1 year, Partida sexually abused elderly patients suffering from dementia or Alzheimer's disease at the care center where he was employed. Partida was sentenced to an indeterminate term of from 5 years to life in prison.

■ **Michigan:** Gordon Michael Ziegler, a licensed practical nurse and registered nurse, was excluded for a minimum period of 13 years based on his conviction related to patient abuse or neglect. Ziegler engaged in criminal sexual conduct with multiple patients. He was sentenced from 8 to 15 years of incarceration, and his licenses to practice as a practical nurse and as a registered nurse were revoked by the Michigan Bureau of Health Professions.

■ **National:** Eight doctors were excluded for the minimum period of 5 years based on their convictions for conspiracy to distribute controlled substances over the Internet. The doctors dispensed, or caused to be dispensed, various controlled substances by means of electronic prescriptions that were issued outside the usual course of medical practice and without a legitimate medical purpose. The doctors convicted as a result of this investigation were Michael Millette, an emergency medicine physician in Illinois; Edward Schwab, an osteopath in Louisiana; Absyom Nayamekye and Apryl McNeil, both family practitioners in New York; Thomas Hanny, a cardiologist in Connecticut; Rene Guerra, a doctor of internal medicine in Florida; Mario Diaz, an anesthesiologist in Florida; and Juan Gonzalez, a general practice medical doctor in Florida. The doctors were sentenced to various prison or home detention terms, ranging from 8 to 41 months. In addition, based on Millette's exclusion, his business, Michael J. Millette, M.D., LLC, was excluded for a minimum period of 5 years.

Civil Monetary Penalties Law

The CMPL authorizes OIG to impose administrative penalties and assessments and exclusion against a person who, among other things, submits claims to a Federal health care program that the person knows or should know are false or fraudulent. During this reporting period, OIG resolved cases involving over \$6.9 million in CMPs and assessments. The following are among the CMP actions resolved during this reporting period:

■ **Florida:** To resolve its CMPL liability, America's Health Choice Medical Plans, Inc. (AHC), agreed to pay \$100,000. The agreement settled allegations that as a participating provider in Medicare Advantage (formerly known as a Medicare+Choice organization), AHC misrepresented information furnished to HHS on at least 10 occasions. Specifically, on at least three occasions, AHC submitted expansion applications that allegedly misrepresented the academic credentials of an AHC employee. In addition, AHC submitted at least seven effectuation notices to the Center for Health Care Dispute Resolution (CHCDR) in which dates of submission were allegedly falsified to appear in compliance with CHCDR's request for claims data.

Patient Dumping

Of the CMPs OIG collected between October 1, 2007, and March 31, 2008, some were pursued under the Emergency Medical Treatment and Labor Act, a statute designed to ensure patient access to appropriate emergency medical services. The following are examples of two settlements in Texas and one settlement in Florida involving alleged violations of that statute:

- **Texas:** Brackenridge Hospital paid \$25,000 to resolve allegations that it failed to provide an appropriate medical screening examination and stabilizing treatment to a 49-year-old man who presented to its emergency department. He complained of a severe headache for the past 4 days and was diagnosed as having a subarachnoid hemorrhage. When the emergency department's physician called the on-call neurosurgeon to come in to examine and treat this patient, she refused. The patient was then transferred to another hospital over 60 miles away to be treated by a neurosurgeon.
- **Texas:** Tomball Regional Hospital paid \$32,500 to resolve allegations of patient dumping. A 13-year-old boy was brought to the hospital's emergency department by his parents for examination and treatment. The boy had recently taken drugs and was acting out, and among other things, the parents were concerned about a possible drug overdose. While at the emergency department, the boy was extremely combative, uncooperative, and threatening (including threatening to kill his father). The hospital's on-call psychiatrist was not called to evaluate and treat this patient. Instead, the boy was discharged after he tested positive for marijuana and benzodiazepines and told to see his primary care doctor on Monday, over 2 days later. This patient was immediately taken to another hospital where he was diagnosed with bipolar disorder and admitted for treatment and placed on assault, suicide, and elopement precautions.
- **Florida:** Orlando Regional Healthcare Systems (Orlando) paid \$85,000 to resolve three allegations of patient dumping. Two instances involved allegations that services were denied because of the patients' insurance status. A 27-year-old woman presented to the emergency department in active labor and was inappropriately transferred allegedly because of her insurance status. Another violation occurred when Orlando refused to accept an appropriate transfer of a patient suffering from an acute episode of psychosis with delusions, allegedly because the patient did not have insurance. The third allegation involved a 50-year-old woman being sent home before tests revealed that she was suffering from acute renal failure. There was no evidence that the hospital made any attempt to contact the patient, who had been discharged approximately 3 hours earlier.

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 actions—which may be brought under the *qui tam* provisions of the FCA by private persons (known as relators)—often involves the combined investigative efforts and resources of OIG, the Federal Bureau of Investigation (FBI), MFCUs, and other law enforcement agencies. OIG has the responsibility of 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 CIAs 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 223 criminal actions and 141 civil actions against individuals or entities that engaged in health-care-related crimes. These efforts resulted in \$1.1 billion in HHS investigative receivables, including civil and administrative settlements or civil judgments related to Medicare, Medicaid, and other Federal health care programs. Some of these 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.

Pharmaceutical Manufacturers and Distributors

■ **Illinois:** CVS Caremark Corporation (CVS) agreed to pay \$36.7 million and enter into a 5-year CIA with OIG to resolve its FCA liability based on allegations that it fraudulently overcharged Medicaid programs in 23 States by improperly switching drugs it dispensed. Specifically, the Government and relator alleged that CVS dispensed ranitidine (generic Zantac) capsules rather than tablets in order to increase its reimbursement from Medicaid. As a result of dispensing and billing Medicaid for capsules, CVS was reimbursed, on average, four times what it would have been reimbursed had it dispensed tablets. The CIA requires CVS’s Board of Directors Audit Committee to oversee and evaluate CVS’s Compliance program and requires annual reviews by an Independent Review Organization to determine whether similar conduct is occurring on an ongoing basis to avoid FUL and MAC prices. No patient harm was alleged.

■ **Massachusetts:** The Bristol-Myers Squibb Co. (BMS) and its wholly owned subsidiary, Apothecan, Inc., agreed to pay \$499 million plus interest as part of the resolution of an FCA case associated with a variety of drug marketing and pricing practices. The settlement and a 5-year CIA between BMS and OIG resolved, in whole or in part, allegations made in seven *qui tam* actions.

The investigation revealed that BMS and Apothecan devised and implemented fraudulent marketing and pricing schemes aimed at inducing providers to purchase and prescribe their drugs. First, BMS and Apothecan allegedly reported fraudulent and inflated prices for a wide assortment of oncology and generic drug products with the knowledge that Federal health care programs established reimbursement rates based on those prices. This type of pricing scheme benefits providers by creating a “spread”

between the reimbursement rates for Federal health care providers and the actual prices for the drugs charged to its customers. Second, BMS allegedly paid illegal remuneration to physicians and other health care professionals in the form of consulting fees and expenses associated with certain consulting programs. Third, the Government alleged that Apothecon knowingly and willfully paid illegal remuneration to retail pharmacy and wholesaler customers to induce them to purchase its products. Fourth, allegations were made that BMS used fraudulent marketing tactics to promote the sale of the drug Abilify, an atypical antipsychotic drug, for pediatric uses and to treat dementia-related psychosis—both off-label uses. Finally, BMS allegedly violated the requirements of the Federal Medicaid drug rebate statute by failing to accurately report the “best price” at which it sold its antidepressant drug Serzone. In this scheme, the Medicaid programs received fewer rebates for the drug than they would have received had BMS reported the discounted price given to Kaiser Permanente, a large commercial purchaser.

■ **Michigan:** Four institutional pharmacies owned by Omnicare, Inc., agreed to pay \$3,498,570 and enter into an amendment to a preexisting CIA to settle allegations of improper Medicaid billing. The TCPI Acquisition Corp.; Specialized Pharmacy Services, Inc.; Specialized Pharmacy Services North, Inc.; and excellRx, Inc., (collectively, “Specialized”) allegedly double-billed Medicaid for drugs provided to hospice patients. Specifically, in Michigan, Medicaid pays hospice providers a flat fee that includes all medications that are related to a hospice patient’s terminal diagnosis. Therefore, the pharmacy is required to bill the hospice provider directly for all drugs related to the patient’s terminal diagnosis. Drugs not related to the terminal diagnosis are not included in this flat fee, and the pharmacy must bill Medicaid directly for these other drugs. The *qui tam* relator in the case alleged that Specialized knowingly billed Medicaid for all drugs that it dispensed to hospice patients, including those unrelated to the patients’ terminal diagnoses. Therefore, Specialized allegedly caused Medicaid to pay twice for the same drugs—one payment to the hospice provider and another payment to the pharmacy.

Durable Medical Equipment Suppliers

■ **Florida:** The Medicare Fraud Strike Task Force (Strike Force) was launched in March 2007 as part of the South Florida Initiative (Initiative), a joint investigative and prosecutive effort against health care fraud in South Florida. The Strike Force builds upon the Initiative’s first two phases, Operation Equity Excise I (OEE I), also known as Operation Whack-a-Mole, and Operation Equity Excise II (OEE II). Through OEE I, infusion clinics and DME companies suspected of fraud were identified, investigated, and pursued for civil violations. Through OEE II, providers identified through the investigative efforts in OEE I were investigated and pursued for criminal violations. As the third phase of the Initiative, the Strike Force is a multi-organizational, multidisciplinary project that uses real-time analysis of Medicare billing data, as well as findings from OEE I and II investigations, in its ongoing efforts to identify, investigate, and prosecute individuals and companies that have committed DME fraud.

During this reporting period, Strike Force efforts resulted in 46 convictions and \$35.2 million in investigative receivables. Also reported in this period, OEE II yielded 9 convictions and \$7.8 million in investigative receivables, and OEE I added \$13.7 million in civil remedies.

Examples of successful Strike Force efforts for OIG include the following:

- DME company owner Nelson Valdes was sentenced to 151 months in prison and ordered to pay \$3,467,083 in restitution. Valdes was convicted by a Federal jury for his scheme involving fraudulent prescriptions for non-commercially-available aerosol medications so that they could be illegally “compounded.” In this scheme, a pharmacist, as opposed to a pharmaceutical manufacturer, made the nonapproved medications. The unapproved medications were then billed to the Medicare program. Pharmacy owners involved in the scheme returned half of the Medicare reimbursement to the DME company owner for each fraudulent prescription. Patients and physicians involved in the fraud scheme were also paid cash kickbacks.
- Alfredo Gourrie, owner of a fraudulent DME company, was sentenced to 51 months in prison and ordered to pay \$853,062 in restitution. Gourrie billed the Medicare program for diabetic supplies, pressure-reducing air mattresses, and other health care supplies purportedly provided to beneficiaries.
- DME company owner William Garcia was sentenced to 41 months in prison and ordered to pay \$503,740 in restitution. Garcia billed the Medicare program for unnecessary wound care supplies, pressure-reducing mattresses, and oxygen concentrators.

The following example was a result of OIG’s efforts under OEE II:

- DME company owner Alejandro De La Victoria was sentenced to 30 months’ incarceration and ordered to pay \$1,465,000 in restitution for health care fraud. From April 2006 through October 2006, Victoria fraudulently billed Medicare for DME that was never ordered by physicians or provided to beneficiaries.

■ **New Jersey:** Four of the Nation’s largest makers of artificial hip and knee orthotics entered into settlement agreements with the Government to resolve their liabilities under the anti-kickback statute and the FCA. Zimmer Holdings, Inc.; DePuy Orthopaedics, Inc. (a unit of Johnson & Johnson); Smith & Nephew, Inc.; and Biomet, Inc., agreed to pay a total of more than \$310 million to settle Federal allegations that they used consulting agreements with orthopedic surgeons to induce the purchase of their devices. The investigation found that these companies entered into consulting agreements with hundreds of surgeons throughout the 2002–2006 timeframe. In some instances, physicians allegedly performed little or no work for these financial inducements. As part of the settlement, the four companies executed Deferred Prosecution Agreements (DPAs) with the United States Attorney’s Office (USAO) for the District of New Jersey and entered into 5-year CIAs with OIG. Under these

agreements, the companies are required to implement new corporate compliance procedures and they have also agreed to 18 months of Federal monitoring. Criminal complaints that were filed against the companies charging them with conspiring to violate the anti-kickback statute will be dismissed at the conclusion of the 18-month DPAs if the companies comply with their terms. A fifth company, Stryker Orthopaedics (a unit of Stryker Corp.), did not enter into a civil settlement because it voluntarily cooperated with the Government. Stryker executed a Non-Prosecution Agreement with the Government, under which it is required to implement the reforms imposed under the other companies' DPAs.

Hospitals

■ **Georgia:** Saint Joseph's Hospital of Atlanta, Inc., and St. Joseph's Health System, Inc. (collectively, "SJHS"), agreed to pay \$26 million, including interest, to resolve FCA allegations that from 2000–2005, the hospital improperly billed Medicare for inpatient admissions and other services. The allegations concerned primarily the submission of claims that should have been billed as "outpatient visits" but were instead billed at the higher rate as "inpatient admissions." Specifically, the Government's investigation revealed that, among other things, SJHS routinely admitted patients unnecessarily and discharged them the same day or the following day; admitted patients for 3-day lengths-of-stay without meeting the criteria for a covered admission so that the patients would qualify under Medicare payment rules for subsequent coverage for SNF services; and submitted claims for inpatient admissions relating to placement of carotid artery stents, which were not covered under Medicare benefits. To address the inpatient admission problems, SJHS is instituting an experimental admission protocol, currently being tested by CMS and several QIOs, which shifts responsibility for admission status decisions from physicians to care managers. SJHS also entered into a 5-year CIA that requires an independent review organization to review patients' medical records and SJHS's initial decisions for admission. In addition, under a separate agreement with the USAO, SJHS is expected to pay the Government between \$3 million and \$4 million to cover Medicare overpayments for 1-day inpatient stays in 2006.

■ **Texas:** Tomball Regional Hospital (Tomball) and Dr. Emanuel Paul Descant II agreed to pay \$816,081 to resolve their liability for allegedly submitting false or fraudulent Medicare and Medicaid claims for hyperbaric oxygen (HBO) therapy. Tomball also entered into a 5-year CIA with OIG. The investigation was predicated on information received from a whistleblower complaint filed by a former hospital employee. Allegations asserted that the subjects submitted claims for HBO therapy when the patients' conditions did not warrant payment by Medicare and Medicaid, the documentation failed to support the diagnosis code billed, and/or the services were not rendered.

Home Health

■ **Iowa:** Floyd Seibert, owner of a Medicare-certified home health business, and his lawyer, James Golden, were ordered to pay \$5,719,340 in restitution for Medicare fraud

and pension plan fraud. Seibert was also sentenced to 46 months' imprisonment. The investigation found that Seibert accomplished the Medicare fraud in a variety of ways. He concealed his relationship with his various business entities, located across five States, even to the point of using one or more fictitious identities for his business dealings. Seibert knowingly and willfully "sold" goods and services from one of his companies to another of his companies at inflated costs and improperly passed the inflated costs on to Medicare. Seibert also fraudulently passed on to Medicare costs from his businesses which were not related to Medicare. Golden assisted Seibert in his efforts to defraud the Government, pleaded guilty to misprision of a felony, and was sentenced to 3 years' probation.

Practitioners

■ **Texas:** Dr. Raul Marquez, an orthopedic surgeon, agreed to pay \$3,128,466 and enter into a CIA to resolve allegations of Medicare and Medicaid fraud brought against him and hospitals with which he was affiliated and in which he had an ownership interest. The Government's investigation, initiated with information presented in a *qui tam* suit, found that Marquez and the Orthopedic Surgery Center and Sports Medicine billed Medicare and Medicaid programs for services not rendered as represented. Also, the Government alleged that Marquez and Cornerstone Regional Hospital obtained inflated payments from the Medicare program by billing post-surgical patients as though they had been discharged to home, when, in fact, they had been discharged to Cornerstone Rehabilitation Hospital for continuing treatment.

■ **Michigan:** Dr. Robert Stokes, a licensed and board-certified dermatologist, was sentenced to 10 years and 6 months in prison and ordered to pay \$1,315,682 in restitution and a \$175,000 fine following his jury trial conviction for health care fraud. The evidence at trial showed that Dr. Stokes falsely informed patients that they had cancer and performed unnecessary procedures when, in fact, laboratory results indicated that their tissue specimens were benign. In addition, he used fraudulent billing schemes, including upcoding surgical procedures to receive higher reimbursement rates and billing for follow-up office visits for which he was not entitled to reimbursement. Dr. Stokes justified the unnecessary office visits by claiming that beneficiaries had developed postoperative infections, such as impetigo, a disease rarely seen in adults. During trial preparation, it was discovered that Dr. Stokes reused single-use needles and sutures without proper sterilization and failed to properly sterilize surgical equipment used in procedures. OIG assisted the local health department in informing patients of their possible risk of contracting a blood-borne pathogen, such as hepatitis B or C or HIV, because of his unsanitary medical practices.

■ **Pennsylvania:** Mamood Karimboccus, a physical therapist who operated Bustleton Aqua Therapy & Rehabilitation Center, Inc., was sentenced to 6 months' incarceration and ordered to pay \$1,201,982 in restitution for billing Medicare for work that was not performed. Karimboccus billed 271 days for which he would have had to have worked in excess of 15 hours per day, billed 186 days for which he would have had to have worked in excess of 20 hours per day, and billed 145 days for which he would have had to have worked in excess of 24 hours per day.

■ **Maryland:** Podiatrist LaVergne Andre-Hayes agreed to pay the Government \$534,884 plus interest and entered into a 5-year integrity agreement with OIG to resolve allegations of false Medicare and Medicaid billing. Dr. Andre-Hayes allegedly billed Medicare and Maryland Medicaid for separate evaluation and management services even though she performed no significant, separately identifiable evaluation and management service at the same time that she performed a procedure. Dr. Andre-Hayes also allegedly submitted claims to Medicare and Maryland Medicaid for services not rendered and for noncovered services. The Maryland State Board of Podiatric Medical Examiners had also previously investigated Dr. Andre-Hayes and on February 8, 2007, suspended Dr. Andre-Hayes's medical license in Maryland for 2 years (with 1 year stayed).

Laboratories

■ **Connecticut:** Dianon Systems, Inc. (Dianon), agreed to pay \$1.5 million to resolve FCA allegations that the company mischarged Medicare and the Department of Defense's (DOD) TRICARE program for certain tests that it performed. Dianon is a reference laboratory that specializes in conducting tests to detect and stage various types of cancer. A pathologist formerly employed by Dianon filed the original suit against the company. The *qui tam* complaint alleged that Dianon billed Medicare and TRICARE for medically unnecessary tests in that it performed 26 flow cytometry tests on every sample sent to the company for diagnosis regardless of whether all 26 were medically necessary for a particular patient. The complaint further alleged that Dianon knew that some of the antibody testing that it performed was unnecessary.

Nursing Homes

■ **Michigan:** Martin Luther Memorial Homes, Inc. (MLMH), agreed to pay \$550,000 to resolve its liability under the FCA. The Government alleged that MLMH violated the FCA by creating another entity, Lutheran Ancillary Services (LAS), to provide physical, occupational, and speech therapy services, as well as pharmacy supplies, to the residents of MLMH's nursing homes and failing to disclose this relationship to Medicare. LAS allegedly billed MLMH for those services, and MLMH submitted 1997 and 1998 cost reports to Medicare failing to disclose and adjust claims for the cost of the services provided by LAS.

The Government expressly reserved its exclusion authorities against defendants Lester Stauske and Roger McCaskey, the former owners and operators of MLMH's skilled nursing facilities. McCaskey currently operates MLMH as a private-pay-only facility; it will enter a 5-year CIA if it becomes involved in any Federal health care business.

Medicaid Fraud Control Units

MFCUs are key partners in the fight against fraud, waste, and abuse in State Medicaid programs. State MFCUs were created 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 Medicaid beneficiaries.

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. In this semiannual period, OIG provided oversight for and administration of approximately \$92 million in Federal grants that were distributed to the 50 MFCUs.

Joint Investigations

Examples of cases conducted jointly by OIG and MFCUs during the semiannual period include the following:

- **Georgia:** Chiropractors Rafael Razuri and Eric Baty were sentenced to 5 years of imprisonment and 42 months of imprisonment, respectively, and ordered to pay \$1.8 million in restitution on their convictions for conspiracy to commit health care fraud. While owners and operators of Southside Medical & Rehabilitation Center, Razuri and Baty conspired to bill over \$5 million in fraudulent physical therapy claims to Medicare and Georgia Medicaid. The investigation involved OIG, FBI, and the Georgia MFCU.
- **Texas:** Psychologist Joe Lerma was sentenced to 4 years in Federal prison and ordered to pay \$530,000 in restitution for fraudulently billing Medicare and Medicaid. A jury found Lerma guilty of billing Medicare and Medicaid for psychological interviews and testing as if he performed the services when, in fact, the services were performed by unlicensed technicians and associates. The investigation involved OIG and the Texas MFCU.
- **Wisconsin:** Nicole Stewart was sentenced to 5 years in prison and ordered to pay \$320,603 in restitution for defrauding the Wisconsin Medicaid program. Stewart owned and operated Compassionate Mothers, a company she founded to provide prenatal and child care coordination services. An investigation revealed that she billed the Medicaid program for services never rendered and for services not covered. In addition, Stewart attempted to cover up the fraudulent billings by paying employees to fabricate records to support the claims submitted. Four codefendants had been previously sentenced for their roles in fabricating documents. The investigation involved OIG and the Wisconsin MFCU.

OIG Reviews of MFCUs

During the semiannual period, we conducted onsite reviews of seven selected MFCUs period to determine their compliance with the following: (1) 42 CFR Part 1007, entitled, “State Medicaid Fraud Control Units,” containing OIG’s regulations for MFCUs; (2) 45 CFR Part 92, entitled, “Uniform Administrative Requirements for Grants and

Cooperative Agreements to State and Local Governments,” establishing uniform administrative rules for Federal grants; and (3) the 12 MFCU performance standards developed jointly by OIG and the National Association of Medicaid Fraud Control Units. As part of the onsite review process, we made recommendations and suggestions to improve the operation of the seven MFCUs reviewed.

Public Health and Human Services Programs and Departmentwide Issues

OIG allocates about 20 percent of its resources to reviews of 300 public health and human service programs and to departmentwide issues that affect more than one program. OIG has discretion in allocating most of these resources. 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 (CFOA) of 1990, and information systems reviews required by the Federal Information Security Management Act.

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

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

- The Centers for Disease Control and Prevention 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.
- The Health Resources and Services Administration (HRSA) maintains a safety net of health services for people who are low income or uninsured or who live in rural areas or urban neighborhoods where health care is scarce.
- The Indian Health Service (IHS) provides or funds health care services for 1.6 million American Indians and Alaska Natives.
- The National Institutes of Health supports medical and scientific research examining the causes of and treatments for diseases such as cancer and HIV/AIDS.
- The Substance Abuse and Mental Health Services Administration (SAMHSA) funds services to assist people with or at risk for mental and substance abuse disorders.

Human Services Programs—Several HHS agencies support human services to assist vulnerable individuals of all ages, including the following:

- The Administration for Children and Families operates over 60 programs that promote the economic and social well-being of children, families, and communities, including TANF; the Head Start program for preschool children; and programs relating to foster care and adoption services. Within ACF, the Office of Child Support Enforcement (OCSE) Child Support Enforcement (CSE) Program, through a Federal-State-local partnership, promotes family self-sufficiency and child well-being and ensures that assistance is available to children through locating parents, establishing paternity and support obligations, and enforcing those obligations.
- The Administration on Aging, through a nationwide network, supports programs that provide services such as meals, transportation, and caregiver support to older Americans at home and in the community.

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 services to operating and staff divisions within the Department.

In addition to summarizing OIG's reports related to public health and human service programs and departmentwide issues, this chapter 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

Laboratory Preparedness for Pandemic Influenza

In our review of laboratory preparedness for pandemic influenza, we found that there are opportunities to improve public health laboratory coordination with clinical laboratories to decrease the time needed to detect and report a pandemic influenza outbreak. We surveyed public health laboratory pandemic influenza preparedness in all 50 States and the District of Columbia and found that most States had implemented several of the eight critical tasks for public health laboratory testing that are required by CDC's "Pandemic Influenza Guidance Supplement to the 2006 Public Health Emergency Preparedness Cooperative Agreement, Phase II" (Guidance). For example, all States reported that their public health laboratories performed the requirement for year-round influenza testing.

In addition to surveying the 210 public health laboratories in operation at the time of our survey, we asked States to report on the role of privately owned clinical laboratories, which play a key role in the States' activities related to disease prevention, control, and surveillance. Such coordination is essential because clinical laboratories are likely to be among the first to detect an influenza outbreak.

For the critical tasks involving both public health and clinical laboratories, States reported performing the required activities for public health laboratories to a greater extent than for clinical laboratories. For example, over 80 percent of States reported developing operational plans to augment public health laboratory capacity during an influenza pandemic, but 55 percent reported such preparation for their clinical laboratories. This report did not have recommendations. (OEI-04-07-00670)

Superfund Financial Activities at the National Institute of Environmental Health Sciences

Our review found that the Superfund financial transactions recorded by the National Institute of Environmental Health Sciences (NIEHS) for FY 2006 were allowable, allocable, and reasonable in accordance with applicable laws and regulations. NIEHS, a component of NIH, receives funding to carry out certain functions of the Hazardous Substance Response Fund, commonly known as Superfund. In general, NIEHS took appropriate action to ensure that its Superfund grantees submitted required audit reports. This report contained no recommendations. (A-04-07-01050)

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

In our review of 28 procurements made by NIH for DOD during FYs 2002–2006, we found that NIH had complied with appropriation statutes and financial regulations for 13 procurements but may not have complied for the remaining 15. NIH acquires certain IT equipment and services for Defense through task orders awarded using a governmentwide contract. Pursuant to section 817 of the DOD Authorization Act for FY 2007 (P.L. 109-364), OIGs of both HHS and Defense are to jointly review the policies and procedures for these Defense purchases and assess compliance with applicable acquisition requirements.

Of the 28 procurements, totaling \$183 million in Defense appropriated funds, 4 procurements, totaling \$11.8 million, were charged to the wrong appropriation category. We also found that NIH did not always maintain adequate documentation with respect to acquisition planning, competition, award decisions, and contractor monitoring.

We recommended that NIH work with Defense to resolve the obligation of \$11.8 million in operations and maintenance funds instead of research, development, testing, and evaluation funds for 4 task orders; work with Defense to resolve the use of \$25.4 million for equipment and services that were not provided during the period of performance for 13 task orders; comply with Federal appropriation statutes and financial management regulations on obligating and expending funds; and improve controls for documenting the task order award and oversight processes. NIH concurred with our recommendations. (A-03-07-03000)

National Institutes of Health's Oversight of Conflicts of Interest in Extramural Research

In our review of financial conflicts of interest reported by grantee institutions to NIH, we found that the agency needed to improve its oversight of such conflicts. Federal regulations establish standards to ensure that the design, conduct, or reporting of research funded under Public Health Service grants not be biased by any conflicting financial interest of an investigator. The regulations require each institution receiving NIH funds to have a written policy for identifying financial conflicts of interest and ensuring that such conflicts are managed, reduced, or eliminated. Of NIH's 27 institutes and centers (Institutes), 24 have grant-making authority and are responsible for managing and overseeing their grants. NIH's Office of Extramural Research (OER) provides grantees with information about relevant policies and regulations and develops and maintains information systems related to extramural research grants administration.

Our examination of all available financial conflict of interest reports and related documentation for FYs 2004–2006 revealed that NIH could not provide an accurate count of the financial conflict of interest reports that it received from grantees; the regulations do not explicitly require the nature of the conflicts or other details to be reported; and the institutes' primary method of oversight was to rely on grantees' assurances that financial conflict of interest regulations were being followed.

We recommended that NIH increase oversight of grantee institutions to ensure their compliance with Federal financial conflict of interest regulations; require Institutes to forward to OER all financial conflict of interest reports received from grantee institutions and ensure that OER's conflict of interest database contains information on all conflict of interest reports provided by grantee institutions; and require grantee institutions to provide details regarding the nature of financial conflict of interest and the way in which they are managed, reduced, or eliminated. NIH agreed with our first two recommendations but did not concur with our recommendation to require grantee institutions to provide details about financial conflicts of interest and the way in which they are managed, reduced, or eliminated. (OEI-03-06-00460)

State, Local, Private, and Commercial Laboratories' Compliance With Select Agent Regulations

This report summarizes eight reviews of State, local, private, and commercial laboratories' compliance with Federal select agent regulations. Select agents are materials that not only have the potential to pose a severe threat to public health and safety, but also to animal and plant health and animal and plant products. CDC oversees select agents and registers entities that possess, use, or transfer these agents that pose a severe threat to public health and safety. The report pointed out that the eight entities had weaknesses in at least one of the following areas: accountability for select agents, restricted access to select agents, security plans, training, and incident response plans. Individual reports that we issued to the laboratories included recommendations to strengthen security controls. In responding to our draft report, CDC stated that it had resolved our recommendations at five of the eight entities and that the remaining three entities had withdrawn their certificates of registration and no longer possessed select agents. CDC attached audit clearance documents resolving the recommendations in our report to all eight entities. Therefore, this final report contains no recommendation. (A-04-06-01033)

Actions Related to Public Health Programs

OIG excludes individuals who fail to pay 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 such as misuse or theft of grant funds, conflict of interest, and kickbacks.

Following are statistics related to and descriptions of 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 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 Act permits, and in some instances mandates, exclusion from Medicare, Medicaid, and all 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, 17 individuals and related entities were excluded as a result of PSC's referral of their cases to OIG.

Individuals who have been excluded as a result of default may enter into settlement agreements whereby the exclusion is 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, a total of 2,128 individuals have taken advantage of the opportunity to enter into settlement agreements or completely repay their debts. That figure includes the 29 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 \$153.2 million. Of that amount, \$2.2 million is attributable to this reporting period.

In the following examples, each individual entered into a settlement agreement to repay the amount indicated:

- Illinois dentist Byron Thompson—\$317,000
- California osteopathic physician Kenneth Williams—\$176,000
- New York chiropractor Christina Roesler-Sirlin—\$128,000
- Georgia chiropractor Stephanie O’Brien—\$88,000

Public Health-Related Investigations

■ **Select Agents and Toxins:** A California laboratory (Laboratory) agreed to resolve its liability for an alleged violation of the Select Agent Regulations. OIG alleged that the Laboratory transferred vials of a select agent to two laboratories located in Florida and Virginia in a manner that violated the transfer requirements. During the transfers, the select agent was released from the shipped vials. An investigation of the packaging for the shipments revealed several violations of regulations governing the shipment of the select agent. OIG specifically alleged that the Laboratory violated the transfer requirements of the select agent regulations by failing to comply with the applicable shipping and packaging laws when transferring a select agent. In addition, OIG alleged that the Laboratory failed to comply with security and access requirements by allowing an individual not authorized to have access to select agents to package the shipments of the select agent and that the Laboratory’s responsible official failed to ensure compliance with the shipping and packaging requirements of the select agent regulations. Under the terms of the settlement, the Laboratory agreed to pay OIG \$450,000 to resolve these allegations. As a separate matter, the Laboratory’s compliance is subject to monitoring by CDC.

Reports Related to Human Service Programs

Division of Unaccompanied Children's Services: Efforts To Serve Children

In our case file reviews of unaccompanied children apprehended by the Department of Homeland Security (DHS), we found that most children were placed in and released from facilities funded by ACF's Division of Unaccompanied Children's Services (DUCS) in accordance with Federal standards. However, we determined from our file reviews and facility visits that improvements were needed with respect to case file documentation, DUCS's program oversight, and the delineation of responsibilities for DHS and HHS.

Federal standards for the placement, care, and release to sponsors of unaccompanied alien children in Federal custody are set forth in the Flores Agreement, so named for a class action law suit challenging detention policies and procedures for children in Federal custody. Pursuant to the Homeland Security Act of 2002, the Director of the Office Refugee Resettlement (ORR), which oversees DUCS, is responsible for the care and custody of unaccompanied alien children and DHS is responsible for immigration benefits and enforcement.

We recommended that ACF enforce documentation requirements to ensure that children's needs are assessed and care provided, enhance and define field staff role in ongoing oversight, and establish a memorandum of understanding between HHS and DHS. ACF did not indicate in its comments whether it concurred with our recommendations; however, it agreed that increased monitoring of facility documentation and practices was needed. ACF also stated that ORR's statutory mandate to ensure the well-being of an unaccompanied alien child ends at the time the child is released from ORR's care (OEI-07-06-00290)

Improper Temporary Assistance for Needy Families Basic Assistance Payments in Three States

We found that three States did not fully comply with Federal requirements pertaining to the basic assistance portion of TANF for the period July 1 through December 31, 2005. TANF is a block grant program that provides funding to States to help families move from welfare to self-sufficiency; TANF's basic assistance includes benefits designed to meet a family's ongoing basic needs. Our pilot reviews, conducted at the request of ACF and OMB, tested a methodology that OIG is using to calculate a national TANF error rate in FY 2008. 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. The results of our reviews are as follow:

- **Michigan:** We estimated that the overall TANF improper payment rate was 40 percent of the Federal dollars expended and 34 percent of the number of payments made for basic assistance. These improper payments totaled an estimated \$36.3 million (Federal share). The payments were improper because they were for families who were ineligible for TANF basic assistance, were calculated or disbursed improperly, or did not have required documentation.

We recommended that the State develop criteria specifying the circumstances that warrant a hardship exception for extending TANF basic assistance payments beyond the 60-month Federal lifetime limit, ensure compliance with Federal and State TANF requirements, determine the current eligibility of all recipients identified as improperly enrolled in the TANF program and deny further assistance to those who remain ineligible, and recalculate assistance budgets for all recipients identified as having received improperly calculated payments. In its comments on our draft report, the State disagreed with our findings and recommendations but did not provide information that caused us to revise our findings. (A-05-06-00068)

■ **New York:** We estimated that the overall TANF improper payment rate was 28.5 percent of the Federal dollars expended and 46 percent of the number of payments made for basic assistance. These improper payments totaled an estimated \$46.7 million (Federal share). The payments were improper because they were for families who were ineligible for TANF basic assistance, were calculated improperly, or did not have required documentation. In addition, the State reported to ACF \$576 million in Federal and State basic assistance expenditures, but its payment system, which we verified, showed payments of \$327.8 million—a \$248.2 million difference.

We recommended that the State ensure compliance with Federal and State TANF requirements, consider conducting quality control reviews of TANF basic assistance eligibility and payment processes, determine the current eligibility of all recipients identified as improperly enrolled in the TANF program and deny further assistance to those who remain ineligible, recalculate assistance budgets for all recipients identified as having received improperly calculated payments, and ensure that TANF basic assistance expenditures are accurately reported to ACF. The State did not specifically address the recommendations. (A-02-06-02015)

■ **Pennsylvania:** We estimated that the overall TANF improper payment rate was 11.5 percent of the Federal dollars expended and 16 percent of the number of payments made for basic assistance. These improper payments represented an estimated \$12.2 million (Federal share). The payments were improper because they were for families who were ineligible for TANF basic assistance, were calculated improperly, or did not have required documentation.

We recommended that the State ensure compliance with Federal and State TANF requirements, determine the current eligibility of all recipients identified as improperly enrolled in the TANF program and deny further assistance to those who remain ineligible, and recalculate assistance budgets for all recipients identified in this review as having received improperly calculated payments. The State concurred with our recommendations. (A-03-06-00566)

Title IV-E Foster Care Costs Claimed by Two States

We found that two States—Pennsylvania and Virginia—did not fully comply with Federal requirements pertaining to Federal foster care claims. Title IV-E of the Act, as amended, authorizes States to claim Federal funding for maintenance costs through ACF.

The funding covers room and board payments to licensed foster care providers, administrative costs, and training. The results of our reviews follow.

Two reviews in Pennsylvania identified a number of improper claims for the 1997–2002 period:

■ **Claims for Castille Contracted Detention Facilities:** We estimated that of the total \$28.4 million (Federal share) that Pennsylvania claimed, an estimated \$11.6 million was unallowable. The Castille program is a court-ordered program for the placement of children convicted of delinquent acts in facilities under contract with the State. States may claim maintenance costs on behalf of adjudicated children if the children’s care is provided by an approved facility other than one operated primarily for the detention of delinquent children. Over half of the claims that we sampled were improper because they were for services that were not provided or were provided to children whose situations did not meet the program’s eligibility requirements. Because the Castille per diem rates did not distinguish between services that were eligible or ineligible for Title IV-E reimbursement, we were unable to determine the allowability of the remaining \$16.8 million claimed; however, the documentation indicated that some of this amount was for noneligible services, such as education and rehabilitation. We recommended that the State refund \$11.6 million, work with ACF to determine the allowability of the remaining \$16.8 million claimed, identify and resolve any unallowable claims made after the audit period and refund the appropriate amount, and discontinue claiming Title IV-E reimbursement for ineligible services and children. The State disagreed with our findings and recommendations and provided additional documentation on 45 of the 72 claims questioned in our draft report. Based on this documentation, we determined that 20 of these claims were allowable and revised the report. (A-03-05-00550)

■ **Philadelphia County’s Claims for Per Diem Rates Exceeding \$300:** We estimated that the State improperly claimed at least \$11.7 million of the total \$33.3 million of administrative costs (Federal share). Claims were unallowable because the services were provided by unlicensed foster care facilities or provided to children whose situations did not meet eligibility requirements. We were unable to determine the allowability of the remaining amount claimed because the contractors’ per diem rates did not distinguish between services that were eligible or ineligible for Title IV-E reimbursement. We recommended that the State refund \$11.7 million and work with ACF to determine the allowability of the remaining \$21.6 million claimed; work with ACF to identify and resolve any unallowable claims made after the audit period and refund the appropriate amount; discontinue claiming Title IV-E reimbursement for unlicensed facilities and ineligible children and services; and direct Philadelphia County to develop rate-setting procedures that separately identify maintenance and other costs, including related administrative costs, so that claims are readily allocable to the appropriate Federal, State, and local funding sources. The State disagreed with all of the recommendations but did not provide additional documentation or explain its disagreement. (A-03-06-00564)

Two reviews in Virginia identified a number of improper claims for the period April 2002 through March 2005:

■ **Fairfax County:** We estimated that Virginia improperly claimed administrative costs totaling \$5.6 million (Federal share) on behalf of Fairfax County. The costs were unallowable because the State's cost allocation plan did not describe, as required by Federal regulations, the methodology used to identify, measure, and allocate these costs; the State also did not equitably allocate costs between Title IV-E and non-Title IV-E programs, as directed by Federal policy. We recommended that the State refund \$2.4 million (\$5.6 million less \$3.2 million previously disallowed by ACF) in unallowable Title IV-E administrative costs. The State concurred with our recommendation but requested that repayment not be required in light of a June 2006 settlement agreement between the State and ACF. We noted, however, that the \$2.4 million was not included in that settlement agreement. (A-03-04-00585)

■ **Arlington County:** We estimated that Virginia had improperly claimed administrative costs totaling \$1.7 million (Federal share) on behalf of Arlington County. The costs were unallowable because the State's cost allocation plan did not describe, as required by Federal regulations, the methodology used to identify, measure, and allocate these costs; the State also did not equitably allocate costs between Title IV-E and non-Title IV-E programs, as directed by Federal policy. We recommended that the State refund \$1.3 million (\$1.7 million less \$417,000 previously disallowed by ACF) in unallowable Title IV-E administrative costs. The State concurred with our recommendation but requested that repayment not be required in light of a June 2006 settlement agreement between the State and ACF. We noted, however, that the \$1.3 million was not included in that settlement agreement. (A-03-06-00562)

Undistributable Child Support Collections

We found that four States did not fully comply with Federal requirements pertaining to undistributable child support 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. States are required to offset CSE program costs, for which they receive Federal matching funds, by recognizing and reporting undistributable collections and interest earned on collections as program income. The results of these reviews are as follow:

■ **Florida:** During 1982–2005, Florida accumulated about \$31 million in child support collections. However, in October 1998–December 2005, the State reported only \$1.4 million as program income as a result of an OCSE audit. We found that the large accumulation of collections was possible because the State had exempted outstanding checks from its abandoned property laws, had not established a rule for determining when child support collections are considered undistributable, and had no policy to deal with child support checks that are characterized as distributed but remain uncashed indefinitely. We also found that the State improperly reversed \$697,000 (\$460,000 Federal share) of program income related to outstanding checks. We recommended that the State report \$697,000 as program income and develop a rule, as

directed by Florida statutes, defining when a collection is deemed undistributable. The State partially agreed with our recommendation. (A-04-06-03508)

■ **Georgia:** During 1998–2001, Georgia appropriately recognized and reported program income for undistributable child support collections; however, in 2002–2005, the State did not report program income totaling \$360,300 (\$237,800 Federal share) for undistributable collections that it had recognized as abandoned. We recommended that the State report the \$360,300 in undistributable collections as program income and provide guidance and training to its accounting personnel on accurately reporting undistributable collections. The State agreed with our recommendation. (A-04-06-03506)

■ **Kentucky:** During 1998–2005, Kentucky did not recognize any undistributable child support collections nor did it report program income totaling \$2.7 million (\$1.8 million Federal share) for undistributable child support collections and interest on collections. We recommended that the State recognize and report program income totaling \$2.7 million and ensure that undistributable collections and interest are reported as program income in the future. The State agreed with our recommendation. (A-04-06-03507)

■ **Maryland:** During 1998–2005, Maryland did not report \$3.3 million (\$2.2 million Federal share) in program income from undistributable child support collections. The State properly reported program income for interest earned on collections. We recommended that the State report the \$3.3 million as program income, modify its system to recognize and report undistributable child support collections as program income, and provide training to ensure that State officials follow policies and procedures for identifying and reporting abandoned collections as program income. The State agreed with our recommendation. (A-03-06-00565)

State Use of Debt Compromise To Reduce Child Support Arrearages

We found that, in 2005, 43 States had in place some form of debt management to reduce the amount of unpaid child support, referred to as arrearages. As arrearage debt has continued to rise, States have implemented a number of strategies, including debt compromise, to reduce such debt. Debt compromise involves the State settling a portion or all of the child support debt owed to the State by a noncustodial parent. At the Federal level, OCSE provides funding to State child support programs, establishes policies and guidance, and oversees and monitors States' compliance with Federal requirements. Our findings follow.

- Of the 43 States using debt management, 20 had fully implemented or pilot debt compromise programs and 23 were settling arrearage debt on a case-by-case basis.
- Officials in 17 of the 20 States with debt management programs expressed positive views of debt compromise practices, and officials in the remaining 3 States expressed concern that settling debt is contrary to the enforcement process.

- The average arrearage amount, \$22,029, was reduced through debt compromise agreements by an average of \$9,383 per case.
- Noncustodial parents in 45 percent of the cases made lump-sum payments averaging \$5,515 at the time of the debt compromise agreements.
- Forty-one percent of the cases closed following debt compromise, either after lump-sum payments or with all debt settled.
- Four of the five States we reviewed in-depth did not routinely follow up when noncustodial parents paid irregularly.

We recommended that OCSE issue guidance encouraging States to routinely monitor cases that remain open following debt compromise agreements to ensure that noncustodial parents meet the provisions of their agreements. Because of the high level of interest in the use of debt compromise, we suggested that OCSE also consider issuing guidance regarding the administration of debt compromise programs to assist States that are considering new programs or revising current practices. ACF concurred with our recommendation and suggestion. (OEI-06-06-00070)

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 OCSE; DOJ; USAO; the U.S. Marshals Service; and other Federal, State, and local partners to expedite the collection of child support. Since 1995, OIG has opened 3,503 investigations of child support cases nationwide, resulting in 1,380 convictions and court-ordered restitution and settlements of \$73.9 million.

Task Forces

In 1998, OIG and OCSE initiated “Project Save Our Children,” a child support initiative made up 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, wherein 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.

To date, the task force units have received more than 13,760 cases from the States. As a result of the work of the task forces, 1,106 Federal arrests have been made and 1,080 individuals have been sentenced. The total ordered amount of restitution related to Federal investigations is \$68.4 million.

Investigations to date at the State level have led to 633 arrests and 602 convictions or civil adjudications, resulting in \$53.1 million in restitution ordered.

Overall, more than \$48.2 million of court-ordered restitution has actually been collected and distributed to families.

Child Support Investigations

Nationwide, OIG investigations of child support cases resulted in 57 convictions and court-ordered restitution and settlements of \$2.5 million during this semiannual period. Examples of OIG's enforcement results for failure to pay child support include the following.

- **New York:** David Martin was sentenced to 5 years' probation and ordered to pay \$296,935 in restitution for failure to pay child support. As conditions of probation, Martin must make restitution at a rate of 25 percent of his monthly net income; disclose his monthly finances to the U.S. Probation Department; and participate in outpatient and inpatient drug treatment, if necessary, with random drug testing. Special conditions of his probation include no contact with his ex-wife and their children and no medications unless prescribed by a medical doctor.

- **Nevada:** Pursuant to his guilty plea for failure to pay child support, Michael Reymann was sentenced to 5 years' probation and 6 months' home detention. He was also ordered to pay \$82,731 in restitution. After his indictment, Reymann remained a fugitive for more than 18 months before a fugitive investigation by OIG, along with the U.S. Marshals Service, led Reymann to turn himself in. Thereafter, Reymann made several regular payments. The investigation revealed that Reymann earned a six-figure salary during his nonpayment period.

- **Pennsylvania:** Scott Frederick Kapp, who pleaded guilty to charges of failure to register as a sex offender and failure to pay court-ordered child support, was ordered to pay \$50,672 in restitution for back child support, as well as funds owed because of the placement of his children in foster care. For periods of time, Kapp paid toward his court-ordered child support but ultimately quit his job and left Pennsylvania. After moving to Florida and finding a job, he failed to pay child support or register as a sex offender. Kapp was also sentenced to time served of over 11 months. He had previously served time for charges stemming from rape and aggravated assault.

Misuse of ACF Grant Funds

OIG also investigates cases involving the misuse of ACF grant funds as in the following example:

- **Maine:** Barbara Pearson, former president, Chief Executive Officer, and owner of the Cold Stream Oil Co., was sentenced to 21 months in prison and ordered to pay \$14,594 in restitution for theft of public funds. Pearson pleaded guilty to making false statements in her company's bankruptcy case and to her theft of more than \$1,000 from the HHS's Low Income Home Energy Assistance Program (LIHEAP). LIHEAP funds that had been received by Cold Stream Oil, as a LIHEAP vendor, were allegedly

converted by Pearson for personal use and for non-LIHEAP-related business use. Specifically, the investigation revealed that Pearson had been gambling online with LIHEAP money that had been sent to Cold Stream Oil, for the purchase of fuel for use by low-income individuals and households.

Reports Related to Departmentwide Issues

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 2007 HHS consolidated/combined financial statements. This means that for the ninth consecutive year, the statements were reliable and fairly presented. However, the report on internal controls noted four material weaknesses:

- Financial Reporting Systems and Processes—HHS continued to have internal control weaknesses in its financial management systems and reporting processes. Substantial manual procedures, numerous adjusting entries, and untimely and incomplete reconciliations and accrual processes hindered HHS’ ability to produce timely and reliable financial statements.
- Budgetary Accounting—HHS lacked sufficient controls over its accounting and business processes to ensure that budgetary transactions were properly recorded, monitored, and reported.
- Financial Management Information Systems—General control issues in both the design and the operation of key controls were noted. For example, weaknesses were reported in policies for the control and use of passwords.
- Medicare Claim-Processing Controls—Although improvements were made, HHS continued to have weaknesses in Medicare claim-processing controls. (A-17-07-00001)

Departmental Service Organizations

To support the audit of the Department’s FY 2007 financial statements, we contracted for examinations of several service organizations that provide common administrative, data processing, and accounting services to the operating divisions. In accordance with Statement on Auditing Standards No. 70, independent certified public accounting firms examined the organizations’ controls and tested their operating effectiveness. Auditors found that controls were suitably designed and operating with sufficient effectiveness, with the exception of certain conditions at the following service organizations: NIH’s Center for Information Technology and PSC’s Division of Payment Management and Enterprise Support Service. (A-17-07-00009, A-17-07-00010, A-17-07-00012)

Non-Federal Audits

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

period, OIG's National External Audit Review Center reviewed 1,417 reports that covered \$437.5 billion in audited costs. Federal dollars covered by these audits totaled \$86.3 billion, about \$35.1 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 quality control review 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	1,182
With major changes	196
With significant inadequacies	39
Total	<u>1,417</u>

The 1,417 reports included 5,108 recommendations for improving management operations. In addition, these audit reports provided information for 105 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	224	\$ 1,653,866,000	\$ 222,015,000
Issued during the reporting period	65	\$ 660,608,000	\$ 167,096,000
Total Section 1	289	\$ 2,314,474,000	\$ 389,111,000
Section 2			
For which a management decision was made during the reporting period ^{2,3}			
Disallowed costs	170	\$ 1,050,374,000	\$ 324,647,000
Costs not disallowed	4	\$ 22,072,000	\$ 113,000
Total Section 2	174	\$ 1,072,446,000	\$ 324,760,000
Section 3			
For which no management decision had been made by the end of the reporting period			
Total Section 1 Minus Total Section 2	115	\$ 1,242,028,000	\$ 64,351,000
Section 4			
For which no management decision was made within 6 months of issuance ⁴	72	\$ 756,960,000	\$ 75,696,000

*Supporting notes and list of reports are 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	24	\$ 586,317,000
Issued during the reporting period	9	\$ 987,833,000
Total Section 1	33	\$ 1,574,150,000
Section 2		
For which a management decision was made during the reporting period		
Value of recommendations agreed to by management	4	\$ 55,664,000
Based on proposed management action		
Based on proposed legislative action		
Value of recommendations not agreed to by management	4	\$ 74,432,000
Total Section 2	8	\$ 130,096,000
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	25	\$ 1,444,054,000

*Supporting notes and list of reports are in Appendix A.

Legislative and Regulatory Review and Development

Regulatory Review Functions

Section 4(a) of the Inspector General Act of 1978 requires that based on a review of regulations and legislation, the IG make recommendations in this report concerning the impact on the economy and efficiency of the administration of HHS's programs and on the prevention of fraud and abuse.

During this reporting period, OIG was involved in the review and clearance of the implementing regulations and other policy guidance from the various provisions of the MMA and DRA.

Regulatory Development

OIG is responsible for the development and publication of a variety of sanction regulations addressing CMP and program exclusion authorities administered by the IG, as well as regulations promulgating safe harbors related to the anti-kickback statute. During this semiannual reporting period, we continued to develop new proposed rulemaking addressing the reorganization of, and revisions to, 42 Code of Federal Regulations (CFR) part 1003, which sets forth OIG's regulatory authorities for imposing CMPs and assessments. We published an interim final rulemaking to implement electronic payment of fees owed for OIG advisory opinions.

In addition, OIG periodically publishes Federal Register 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 period, OIG prepared and published in the Federal Register a notice soliciting recommendations for updating the OIG's Compliance Program Guidance for Nursing Facilities (January 24, 2008; 73 Federal Register 4248). This notice was published in connection with ongoing work to develop new compliance guidance for nursing facilities.

Employee Fraud and Misconduct

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

- **Maryland:** Charrisse Fairfax-Brown, a former NIH employee, was sentenced to 45 days in prison, followed by 3 years of supervised release and ordered to pay over \$24,221 in restitution for theft of Government property related to her unauthorized use of a Government credit card. From November 2004–September 2006, Fairfax-Brown was authorized to use an NIH commercial credit card to purchase approved supplies and services. During this period, she made more than \$24,000 in unauthorized charges, including purchases of travel services, a laptop computer, shoes, clothes, DIRECTV service, jewelry, furniture, and household items.

Appendixes

Appendix A: Notes to Tables 1 and 2

Notes to Table 1

¹The opening balance was adjusted upward \$382.5 million.

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

- Central Identification Number (CIN): A-03-01-00224 MEDICAID SCHOOL-BASED SERVICES/MARYLAND—The Departmental Appeals Board overruled part of the original \$19.9 million disallowance. \$4,950,270
- CIN: A-06-07-86409 NEW MEXICO HUMAN SERVICE DEPT.—Based on a review of supporting documentation provided by the State agency, CMS determined that previously disallowed costs were allowable. \$78,379,881
- CIN: A-09-95-00072 CA DEPT OF HEALTH SVS, REVIEW OF MEDICAID LABS—Based on reconsideration of the reimbursement requirements with respect to clinical laboratory services, CMS withdrew its disallowance. \$4,013,490
- CIN: A-10-03-00011 REGENCE HMO BIPA MODIFICATION TO CY 2001 ACRP—CMS subsequently determined that it did not have legal authority to recover the disallowance. \$7,320,614

Not detailed are revisions to previously disallowed management decisions totaling \$1.2 million.

³Included are management decisions to disallow \$365.7 million that was identified in nonfederal audit reports.

⁴Because of administrative delays, many of which are beyond management control, resolution of the following 72 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-02-03-01029 REVIEW OF RETROACTIVE SCHOOL HEALTH CLAIMS – NEW YORK CITY DEPT. OF EDUCATION, OCT 2006, \$259,433,325
- CIN: A-05-01-00099 U OF I HOSPITAL-DSH PAYMENT LIMITS, OCT 2004, \$140,281,912
- CIN: A-04-03-02027 REVIEW OF MEDICAID UPPER PAYMENT LIMIT CALCULATIONS IN ALABAMA, DEC 2005, \$73,432,381
- CIN: A-02-04-01021 REVIEW OF RETROACTIVE SCHOOL HEALTH CLAIMS – REST OF STATE (ROS), OCT 2006, \$60,188,395
- 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-01-04-00513 REVIEW OF MEDICARE PART B PAYMENTS FOR AMBULANCE SERVICES RENDERED TO BENEFICIARIES DURING AN INPATIENT STAY, MAR 2006, \$21,705,010
- CIN: A-06-99-00070 HIGHLAND COMMUNITY BANK PROCESSING OF MEDICARE DEP, MAY 2000, \$18,839,909
- CIN: A-09-01-00098 AUDIT OF KERN MEDICAL CENTER DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR FY 1998, SEP 2002, \$14,165,950
- CIN: A-03-05-00550 AUDIT OF PA FOSTER CARE MAINTENANCE PAYMENTS - CASTILLE SAMPLE, SEP 2007, \$11,611,822
- CIN: A-06-02-00034 REV OF COST REPORTS & MEDICARE FEE-FOR-SERVICE PYMTS @ SCOTT & WHITE, MAY 2003, \$8,229,574
- CIN: A-04-04-02003 MEDICARE OUTLIER PAYMENTS TO COMMUNITY MENTAL HEALTH CENTERS, APR 2006, \$4,762,036

CIN: A-05-01-00102 MT. SINAI HOSPITAL-DSH PAYMENT LIMITS, OCT 2004, \$4,516,112
 CIN: A-02-00-01047 DEMO BSWNY - FINANCIAL, MAR 2002, \$4,505,051
 CIN: A-09-01-00085 AUDIT OF UCSDMC DISPROPORTIONATE SHARE HOSPITAL
 PAYMENTS FOR SFYE 1998, SEP 2002, \$3,776,054
 CIN: A-07-06-00210 REVIEW OF PRB COSTS CLAIMED BY BLUE CROSS BLUE SHIELD OF
 RHODE ISLAND, OCT 2006, \$3,558,976
 CIN: A-06-04-00076 MEDICAL REVIEW OF SYNERGY'S PHP 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-04-01-05004 REVIEW MEDICARE CLAIMS FOR DEPORTED BENEFICIARIES,
 MAR 2002, \$836,711
 CIN: A-06-05-00062 MEDICARE PRESCRIPTION DRUG DISCOUNT CARD PROGRAM,
 JUL 2006, \$652,135
 CIN: A-06-06-00112 MEDICARE PRESCRIPTION DRUG CARD PROGRAM: COMPUTER
 SCIENCES CORPORATION, DEC 2006, \$606,824
 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-07-05-03069 MISSOURI UNDISTRIBUTABLE CHILD SUPPORT PAYMENTS,
 JUL 2006, \$457,128
 CIN: A-04-04-02010 REVIEW OF COMPREHENSIVE OUTPATIENT REHABILITATION
 THERAPY SERVICES PROVIDED BY ABSOLUTE THERAPY INC.,
 NOV 2006, \$414,712
 CIN: A-02-07-02003 REVIEW OF ACCOUNTING SYSTEM AT SANTA ISABEL HEAD START,
 JUL 2007, \$396,078
 CIN: A-05-01-00096 PAYMENTS TO INTER VALLEY FOR INSTITUTIONAL BENEFICIARIES,
 MAY 2002, \$319,355
 CIN: A-06-06-00022 MEDICARE PRESCRIPTION DRUG CARD PROGRAM, SEP 2006,
 \$311,526
 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-09-04-00068 REVIEW OF CA'S STATE AUTOMATED CHILD WELFARE
 INFORMATION SYSTEM (SACWIS) AT SANTA CLARA COUNTY,
 APR 2006, \$286,464
 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-02-01-01019 DEMO BSWNY - CASH MANAGEMENT, OCT 2002, \$208,271
 CIN: A-01-04-01501 NORTHEASTERN UNIVERSITY DHHS GRANT COSTS GRANT #s 9274,
 4000 AND 4111, JAN 2005, \$194,890
 CIN: A-06-05-00066 MEDICARE PRESCRIPTION DRUG CARD PROGRAM, SEP 2006,
 \$168,782
 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 FISCAL YEARS 2000, THROUGH 2003, SEP 2005, \$111,862

CIN: A-05-97-00017 FHP, INC. - HMO INSTITUTIONAL STATUS PROJECT, JUN 1998, \$109,114

CIN: A-05-01-00079 PAYMENTS TO BLUE CARE MID-MI FOR INSTITUTIONAL BENEFICIARIES, JUN 2002, \$100,692

CIN: A-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 FISCAL YEARS 2000, THROUGH 2003, AUG 2005, \$91,710

CIN: A-05-01-00090 PAYMENTS TO AETNA OF 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 FISCAL YEARS 2000 THROUGH 2003, SEP 2005, \$78,799

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

CIN: A-05-07-00049 REBATES PAID TO HOSPITALS – UNIVERSITY OF IOWA, MAY 2007, \$70,056

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-05-07-00045 REBATES PAID TO HOSPITALS – OPTION CARE, AUG 2007, \$43,451

CIN: A-01-03-01500 REVIEW OF CDC HIV PROGRAMS AT GREATER BRIDGEPORT ADOLESCENT PREGNANCY PROGRAM, JUL 2003, \$41,088

CIN: A-05-07-00051 REBATES PAID TO HOSPITALS – KAISER FOUNDATION HOSPITAL, JUN 2007, \$35,438

CIN: A-03-06-00352 AUDIT ASSISTANCE TO OI ON THE BLACK EDUCATIONAL AIDS PROJECT, JUN 2007, \$31,078

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-01-02-01504 REVIEW OF CDC'S HIV PROGRAMS AT FENWAY COMMUNITY HEALTH CENTER, JUN 2003, \$18,028

CIN: A-07-04-01011 PAYMENTS FOR UNITED HEALTHCARE FOR INSTITUTIONAL BENEFICIARIES, MAR 2005, \$13,128

CIN: A-05-07-00047 REBATES PAID TO HOSPITALS – METHODIST HOSPITAL GERMANTOWN, APR 2007, \$12,621

CIN: A-05-01-00070 PAYMENTS TO GHP MCO/ST LOUIS FOR INSTITUTIONAL BENEFICIARIES, JAN 2002, \$11,089

CIN: A-06-06-00014	MEDICARE PRESCRIPTION DRUG CARD PROGRAM: ACCLAIM, SEP 2006, \$8,800
CIN: A-03-03-00393	AUDIT OF CDC HIV/AIDS GRANT TO SEXUAL MINORITY YOUTH ASSISTANCE LEAGUE, OCT 2003, \$1,155

Total CINs: 72

Total Amount: \$756,960,148

Notes to Table 2

¹The opening balance was adjusted downward by \$ 2.4 million.

²Management decision has not been made within 6 months on 17 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-09-04-00038	WEDGE: LA COUNTY 1115 WAVIER, OCT 2006, \$285,200,000
CIN: A-05-05-00053	REVIEW OF LAYERED GPOs -- ROLL-UP, JUN 2006, \$59,000,000
CIN: A-04-01-02006	MEDICAID DISPROPORTIONATE SHARE PAYMENTS IN ALABAMA, JUN 2004, \$45,763,327
CIN: A-01-02-00503	FURTHER EXPANSION OF THE DRG PAYMENT WINDOW, AUG 2003, \$37,000,000
CIN: A-05-02-00078	ROLLUP OF MEDICARE PAYMENTS FOR BENEFICIARIES WITH INSTITUTIONAL STATUS, FEB 2004, \$12,764,202
CIN: A-05-04-00073	ROLL-UP ON ADDITIONAL GPOs, MAY 2005, \$6,600,000
CIN: A-05-02-00077	MICHIGAN MEDICAID/SCHIP REVIEW, NOV 2003, \$5,908,350
CIN: A-03-02-00203	VIRGINIA - SCHIP/TITLE IV - D SURVEY, 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	REV OF MGR CARE ADDTL BENEFITS FOR CY 00 OF NYLCAR, 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-05-06-00020	MEDICAID PAYMENTS FOR SERVICES TO BENEFICIARIES WITH CONCURRENT ELIGIBILITY IN MI AND OH – MICHIGAN REPORT, AUG 2006, \$467,317
CIN: A-01-06-02509	REVIEW OF TRAINING COSTS FOR TITLE IV-E FOSTER CARE AND ADOPTION ASSISTANCE PROGRAM IN RHODE ISLAND FOR STATE FISCAL YEARS 2003 THROUGH 2005, JUL 2007, \$238,411
CIN: A-05-01-00070	PAYMENTS TO GHP MCO/ST LOUIS FOR INSTITUTIONAL BENEFICIARIES, JAN 2002, \$98,689
CIN: A-05-06-00023	MN – UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS, SEP 2006, \$28,240
CIN: A-05-04-00051	ALLOWABILITY OF CDC BIOTERRORISM COSTS – OHIO DEPARTMENT OF HEALTH, FEB 2005, \$4,154

Total: 17

Amount: \$469,629,699

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 locations of the required information. Where there are no data to report under a particular requirement, the word “None” appears.

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

Section of the Act	Requirement	Location
Section 4(a)(2)	Review of legislation and regulations	p. 54
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. 26
(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. 52
(a)(9)	Statistical Table 2 – Funds Recommended To Be Put to Better Use	p. 53
(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 IG 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 (the 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. OIG has the discretion to exclude individuals and entities on several other grounds, including misdemeanors for 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 (including a hearing before an HHS administrative law judge and appeals to the HHS Departmental Appeals Board and Federal district and appellate courts) regarding whether the basis for the exclusion exists and the length of the exclusion is reasonable.

Patient Dumping

Section 1867 of the 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 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 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 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 also authorizes 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 Act, 42 U.S.C. § 1320a-7b).

Individuals and entities that engage in unlawful referral or kickback schemes may be subject to criminal penalties under the general criminal anti-kickback statute; civil monetary penalties under OIG’s CMPL authority (section 1128A(a)(7) of the Act, 42 U.S.C. § 1320a-7a), and/or program exclusion under OIG’s permissive exclusion authority (section 1128(b)(7) of the Act, 42 U.S.C. § 1320a-7(b)(7)).

■ **False Claims Amendments Act of 1986**—Under the Federal civil False Claims Act (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 that 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.

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 suit 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
AHC	America's Health Choice Medical Plans, Inc.
AMP	average manufacturer price
ASP	average sales price
BMS	Bristol-Myers Squibb Co.
CDC	Centers for Disease Control and Prevention
CFOA	Chief Financial Officers Act of 1990
CFR	Code of Federal Regulations
CHCDR	Center for Health Care Dispute Resolution
CIA	corporate integrity agreement
CMP	civil monetary penalty
CMPL	Civil Monetary Penalties Law
CMS	Centers for Medicare & Medicaid Services
COBC	Coordination of Benefits Contractors
CSE	child support enforcement
CWF	Common Working File
CY	calendar year
DHS	Department of Homeland Security
Dianon	Dianon Systems, Inc.
DME	durable medical equipment
DMEPOS	durable medical equipment, prosthetics, orthotics, and supplies
DOJ	Department of Justice
DPA	Deferred Prosecution Agreement
DRA	Deficit Reduction Act of 2005
DUCS	Division of Unaccompanied Children's Services
EPSDT	Early and Periodic Screening, Diagnostic, and Treatment
ERC	Ethics Resource Center
ESRD	end stage renal disease
FBI	Federal Bureau of Investigation
FCA	False Claims Act
FDA	Food and Drug Administration
FR	Federal Register
FY	fiscal year
Guidance	Pandemic Influenza Guidance supplement to the 2006 Public Health Emergency Preparedness Cooperative Agreement, Phase II
HBO	hyperbaric oxygen
HCBS	home- and community-based services
HCCA	Health Care Compliance Association
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
HPMP	Hospital Payment Monitoring Program
HRSA	Health Resources and Services Administration
IDTFs	independent diagnostic testing facilities
IG	Inspector General
IHS	Indian Health Service
IT	information technology
IVR	Interactive Voice Response
LAS	Lutheran Ancillary Services
LIHEAP	Low Income Energy Assistance Program
MA	Medicare Advantage
MEDIC	Medicare Prescription Drug Integrity Contractor
MFCU	Medicaid Fraud Control Unit
MLMH	Martin Luther Memorial Homes, Inc.
MMA	The Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MMIS	Medicaid Management Information System
MPFS	Medicare Physician Fee Schedule
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
OAS	Office of Audit Services
OCIG	Office of Counsel to the Inspector General
OCSE	Office of Child Support Enforcement
OEE I	Operation Equity Excise I
OEE II	Operation Equity Excise II
OEI	Office of Evaluation and Inspections
OER	Office of Extramural Research
OI	Office of Investigations
OIG	Office of Inspector General
OMB	Office of Management and Budget
OMP	Office of Management and Policy
Orlando	Orlando Regional Healthcare Systems
ORR	Office of Refugee Settlement
PCIE	President's Council on Integrity and Efficiency
PDP	prescription drug plan
PRB	postretirement benefits
PSC	Program Support Center
P.L.	Public Law
QIO	Quality Improvement Organization
SAMHSA	Substance Abuse and Mental Health Services Administration
SCHIP	State Children's Health Insurance Program
SERP	Supplemental Executive Retirement Plan
SJHS	Saint Joseph's Hospital of Atlanta, Inc., and St. Joseph's Health System, Inc.
SNF	skilled nursing facility
SSA	the Act
Strike Force	Medicare Fraud Strike Task Force
TANF	Temporary Assistance for Needy Families

TCM	targeted case management
the Act	Social Security Act
Tomball	Tomball Regional Hospital
TrOOP	True Out-of-Pocket
USAO	United States Attorney's Office
U.S.C.	United States Code

Department of Health and Human Services

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