



Department of Health and Human Services

# Semiannual

Report to Congress

April 1, 2008–September 30, 2008



## OIG Components

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

OAS

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

OEI

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

OI

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

OCIG

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

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Department of Health and Human Services  
Office of Inspector General

# Top Management Challenges

As part of the Department of Health and Human Service's (HHS) Agency Financial Report for Fiscal Year 2007, OIG has identified the most significant management and performance challenges facing the Department. These challenges are listed below:

| <b>Top Management Challenges</b>   |
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| <b>1. Oversight of Medicare Part D</b>                                   |
| <b>2. Medicare Integrity</b>   |
| <b>3. Medicaid and SCHIP Integrity</b>                                   |
| <b>4. Quality of Care</b>  |
| <b>5. Emergency Preparedness and Response</b>                            |
| <b>6. Oversight of Food, Drugs, and Medical Devices</b>                  |
| <b>7. Grants Management</b>  |
| <b>8. Integrity of Information Technology Systems and Infrastructure</b> |
| <b>9. Ethics Program Oversight and Enforcement</b>                       |

# 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 September 30, 2008.

Worth noting among the highlights for this period is a new standing section entitled “Industry Guidance.” As Health and Human Services health care programs have grown in size and complexity over the past decade, OIG has engaged in outreach to foster a culture of compliance within the health care industry. Among the most significant means of outreach are open letters and voluntary compliance program guidance (CPG). During this period, we issued an Open Letter to Health Care Providers setting forth certain key refinements to the original Self-Disclosure Protocol of 1998. In addition, we issued a new Supplemental CPG for nursing facilities. These new issuances, which can assist providers in their efforts to adhere to program requirements and to take corrective action, are important additions to the growing body of OIG compliance tools.

Additionally, OIG has continued to focus on an expanding docket of audits, investigations, and evaluations, yielding many notable accomplishments in advancing program savings, integrity and efficiency, and quality of care. It is through the efforts of our professional staff nationwide, in collaboration with program and law enforcement partners, that we once again report substantial audit and investigative receivables, as well as savings through implemented recommendations. Furthermore, our reviews of key Federal health care program payment processes have yielded findings and recommendations that are expected to contribute significantly to better financial accountability.

We have achieved significant results in our fight against health care fraud, waste, and abuse through the effective use of our statutory funding streams directed toward Medicare and Medicaid integrity activities. We have successfully employed innovative techniques, such as those used by the Medicare Fraud Strike Force in South Florida and Los Angeles, to identify and hold accountable those who have defrauded the program. As OIG begins to experience the beneficial impact of a new, dedicated \$25-million funding stream to address Medicaid oversight and integrity issues, we are becoming better positioned than ever before to help account for and protect the growing Federal Medicaid expenditures. On the other hand, we are increasingly challenged to provide comprehensive coverage of the Public Health and Human Service programs and other departmental issues, which also continue to grow in size, scope, and complexity.

As we enter the final months of this 30th anniversary year of the Inspector General Act of 1978, I would once again like to express my appreciation to Congress and to the Department 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 fiscal year (FY) 2008, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) reported savings and expected recoveries of more than \$20.4 billion: \$16.72 billion in implemented recommendations to put funds to better use, \$1.33 billion in audit receivables, and \$2.35 billion\* in investigative receivables.

Also for this FY, OIG reported exclusions of 3,129 individuals and entities for fraud or abuse involving Federal health care programs and/or their beneficiaries; 575 criminal actions against individuals or entities that engaged in crimes against departmental programs; and 342 civil actions, which included False Claims Act (FCA) and unjust enrichment lawsuits filed in Federal district court, Civil Monetary Penalties Law (CMPL) settlements, and administrative recoveries related to provider self-disclosure matters.

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

### **Cephalon To Pay \$425 Million Plus Interest for Marketing Three of its Drugs for Uses Not Approved by the Food and Drug Administration**

As part of a global criminal, civil, and administrative settlement, Cephalon, Inc., agreed to pay \$375 million plus interest to resolve its FCA liability for the off-label marketing (that is, marketing for uses not approved by the Food and Drug Administration) (FDA) of the drugs Actiq, Gabitril, and Provigil; plead guilty to a misdemeanor violation of the Federal Food, Drug, and Cosmetic Act; and pay a \$50 million criminal fine. Cephalon also agreed to enter a comprehensive 5-year corporate integrity agreement (CIA) that contains several unique provisions, including a requirement that Cephalon notify doctors about the settlement and establish a way for them to report questionable conduct by sales representatives. (Details on page 37.)

### **Marketing Materials for Medicare Prescription Drug Plan**

In our review of marketing materials developed by stand-alone Medicare prescription drug plans (PDP) in 2007, we found that the Centers for Medicare & Medicaid Services (CMS) provided limited oversight of the materials and that 85 percent of the materials failed to meet at least one element of the agency's guidelines. These deficiencies ranged from omitting required information about PDP benefits and rules to not using the required font size for footnotes. We found that, among other problems, CMS's model documents were not fully consistent with the agency's own guidelines, which in turn resulted in problems with PDP marketing materials. We recommended that CMS ensure that model documents are consistent with the guidelines, develop protocols for reviewing marketing materials, conduct more frequent retrospective reviews of file-and-use

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

materials, enforce the use of the materials tracking system, and enhance the tracking system to include an identifier for marketing materials written in non-English languages and alternative formats. In commenting on our report, CMS concurred with all of our recommendations, stating that it had implemented steps to improve its oversight of marketing materials and identified additional areas for improving the review process. CMS agreed with our recommendations. (OEI-01-06-00050) (Details on page 9.)

### **Medicare Part D Contracting Process**

In our congressionally requested review of contracting issues related to local, community pharmacies' participation in the Medicare Part D program, we found that 78 of the 100 local, community pharmacies in our sample relied on third-party contractors known as pharmacy services administrative organizations (PSAO) to contract with Medicare Part D PDP sponsors. The pharmacies were generally satisfied with the services that their PSAOs provided. Our review also found that almost all of the 100 sampled pharmacies and all of their PSAOs reported that they had experienced problems when contracting with PDP sponsors. These problems related to PDP sponsors' network development methods, standard terms and conditions, extended-day supply terms, negotiations, and network requirements and contracting deadlines. We recommended that Congress and CMS consider the results of our review in deliberations about Medicare Part D contracting. We provided specific recommendations related to the concerns voiced by the pharmacies and PSAOs. CMS concurred with five of our recommendations but did not concur with the remaining five recommendations, stating that they were contrary to the competitive market principles that are fundamental to the Part D program. We revised three of our recommendations to address CMS concerns. (A-06-07-00082) (Details on page 15.)

### **Hospital Agrees To Pay \$88.9 Million in One of the Largest Civil Fraud Recoveries Ever Against an Individual Hospital**

In one of the largest civil fraud recoveries ever against a single U.S. hospital, Staten Island University Hospital agreed to pay nearly \$89 million to resolve allegations that it defrauded Medicare, Medicaid, and TRICARE (the military's health insurance program). The settlement resolves two separate lawsuits filed in the U.S. District Court for the Eastern District of New York under the qui tam provisions of the FCA and two investigations conducted by the United States, including one initiated under OIG's Self-Disclosure Protocol. As part of the settlement, the hospital entered into a 5-year CIA. (Details on page 38.)

### **Medical Review of Claims in the Comprehensive Error Rate Testing Program**

In our review of CMS's Comprehensive Error Rate Testing (CERT) program, we estimated the error rate in the FY 2006 CERT durable medical equipment (DME) sample at 17.3 percent or 28.9 percent, depending on the extent of documentation reviewed. CMS established the CERT program to produce a Medicare fee-for-service paid claim error rate, which it reports annually to Congress pursuant to the Improper Payments Act of 2002. Our two-part review, performed by an independent medical review contractor, initially used the same procedures and limited medical records as CMS's CERT



contractor and produced an error rate of 17.3 percent. The second part of our review, which used additional medical records from physicians and other health care providers and information from beneficiaries and providers, produced the higher error rate of 28.9 percent. We recommended that CMS require the CERT contractor to review all available supplier documentation and all medical records necessary to determine compliance with applicable requirements on medical necessity and contact the beneficiaries named on high-risk claims to determine whether the DME items were received and were medically necessary. CMS generally concurred. (A-01-07-00508) (Details on page 4.)

### **Administrative Law Judge Affirms OIG's Sanctions Against Florida Durable Medical Equipment Owner**

Administrative Law Judge (ALJ) Steven T. Kessel issued a decision on June 24, finding that Cary Frounfelter and Kast Orthotics and Prosthetics, Inc. (Kast), a Florida-based DME company owned by Frounfelter, violated the CMPL by submitting false claims for Medicare Part B reimbursement. ALJ Kessel sustained the determination by OIG to impose a civil monetary penalty (CMP) of \$100,000; an assessment of \$42,220; and a 7-year exclusion, jointly and severally, against Frounfelter and Kast. (Details on page 35.)

### **Improper Medicare Payments for Facet Joint Injection Services**

In our medical review of Medicare payments in 2006 for facet joint injections, which are used to diagnose or treat back pain, we found that 63 percent of facet joint injections service claims allowed did not meet program requirements, resulting in approximately \$96 million in improper payments to physicians and \$33 million in associated facility claims. Among other billing errors, we found that 38 percent of the reviewed claims contained documentation errors, and just over 60 percent of the claims were overpaid because physicians incorrectly billed add-on codes for bilateral injections instead of using the required modifier code. Among other recommendations, we recommended that CMS strengthen program safeguards to prevent improper payment for facet joint services and clarify billing instructions for bilateral services. We also advised CMS that it should take appropriate action regarding the undocumented, medically unnecessary, or miscoded services identified in our review. CMS agreed with our recommendations. We advised CMS to strengthen program safeguards to prevent improper payment for these services and to clarify billing instructions for bilateral services. CMS agreed with our recommendations. (OEI-05-07-00200) (Details on page 14.)

### **Medicare Administrative Law Judge Hearings: Early Implementation, 2005–2006**

In our congressionally requested review of the Office of Medicare Hearings and Appeals' (OMHA) use of telephone, video teleconference, and in-person hearings to decide Medicare ALJ cases, we found that in its first 13 months of operation (July 1, 2005, to July 31, 2006), OMHA handled 78 percent of Medicare appeals by telephone and that most sample appellants were satisfied with their hearing format. We determined that OMHA's ability to manage its caseload was limited by incomplete and inaccurate data in

the appeals system. We also determined that OMHA did not meet the 90-day decision requirement for 15 percent of the cases with such a requirement and a decision date recorded in the appeals system. We recommended that OMHA consistently offer appellants the options of video teleconferencing, improve the timeliness of deciding cases with the 90-day decision requirement, address technical problems associated with hearings conducted by telephone and video teleconference, and improve the quality of data in the appeals system. OMHA agreed with our recommendations. (OEI-02-06-00110) (Details on page 20.)

### **Merck Agrees To Pay More Than \$650 Million To Resolve Claims of Fraudulent Price Reporting and Kickbacks**

Merck and Company, Inc. (Merck), agreed to pay more than \$650 million to resolve allegations that it failed to pay proper rebates to Medicaid and other Government health care programs and paid illegal remuneration to health care providers to induce them to prescribe the company's products. The allegations were brought in two separate lawsuits filed by whistleblowers under the qui tam provisions of the FCA. According to the allegations, Merck offered hospitals deep discounts on its products Pepcid, Vioxx, Zocor, and Mevacor, then overcharged Government programs by failing to properly include these discounts in the "best prices" reported to CMS under the Medicaid drug rebate program. (Details on page 37.)

### **Medicaid Disproportionate Share Hospital Eligibility**

In our review of Indiana's compliance with Medicaid disproportionate share hospital (DSH) payment requirements, we found that from July 2000 through June 2003, the State paid \$142.3 million (\$88.2 million Federal share) to three State-owned psychiatric hospitals that were not eligible to receive DSH payments. States are required to make DSH payments to hospitals that serve disproportionate numbers of low-income patients, but psychiatric hospitals qualify for such payments only if they meet special Medicare conditions of participation. The three hospitals did not meet these conditions. We recommended that the State refund \$88.2 million and ensure that Medicaid DSH payments are made only to eligible hospitals. The State disagreed. (A-05-06-00045) (Details on page 22.)

### **The Food and Drug Administration's Generic Drug Review Process**

In our review of generic drug applications reviewed by FDA in 2006, we determined that FDA had opportunities to better manage current reviews and to potentially increase the number of submissions reviewed and approved within 180 days. To market a generic drug, which is the same as the brand name drug with respect to key qualities, such as conditions of use and active ingredient(s), a pharmaceutical company must obtain FDA's approval of an Abbreviated New Drug Application (ANDA) and the agency is required by Federal law to approve or disapprove original ANDAs within 180 days of receipt. Of the original ANDAs that FDA reviewed in 2006, 96 percent did not meet review standards and were disapproved. FDA exceeded the 180-day statutory review requirement for nearly half of the ANDAs. We recommended that FDA identify common ANDA deficiencies and offer more guidance to industry to decrease the

percentage of disapproved original ANDAs, increase the percentage of original ANDAs that are reviewed by all divisions within 180 days, and implement new prioritization practices. FDA agreed with the first recommendation but did not indicate concurrence with the other two. (OEI-04-07-00280) (Details on page 49.)

### **Philadelphia County's Foster Care Claims**

In our review of Pennsylvania's claims for Title IV-E reimbursement on behalf of Philadelphia County children in foster care for whom the per diem rates were \$300 or less, we estimated that from October 1997 through September 2002, the State improperly claimed at least \$56.5 million of the total \$562.3 million (Federal share) claimed. We recommended, among other things, that the State refund \$56.5 million and work with the Administration for Children and Families to determine the allowability of \$100 million related to claims that included both allowable and unallowable services. The State disagreed with our recommendations. (A-03-07-00560) (Details on page 53.)

### **Industry Guidance**

OIG's efforts to promote the highest level of ethical and lawful conduct within the health care industry included activities in two particular areas of industry outreach. The first, an "Open Letter to Health Care Providers" issued on April 15, described refinements to OIG's Self-Disclosure Protocol, such as actions to streamline OIG's internal procedures regarding self-disclosures and an explanation that OIG will generally not require a self-disclosing entity to enter into a CIA or certification of compliance agreement when a resolution has been negotiated pursuant to the protocol. The second area of industry outreach was a draft Supplemental Compliance Program Guidance (CPG) for Nursing Facilities, issued for public comment on April 16. The final CPG, issued on September 30, described updates to the CPG for Nursing Facilities published in 2000, such as an expanded focus on quality-of-care issues, including staffing, care plan development, and patient neglect and abuse. (Details on page 31.)



# 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**

Inspector General (IG) Daniel Levinson 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, IG Levinson serves as chair of the PCIE Inspection and Evaluation Committee. He also sits on the Homeland Security Roundtable, a group composed of IGs with oversight responsibility for agency programs affecting national safety and security.

## **Office of Inspector General Attorneys Serving as Special Assistant United States Attorneys**

The Department of Justice (DOJ) and OIG launched a program in which OIG attorneys serve as Special Assistant United States Attorneys (SAUSA). Some are detailed full-time to DOJ's Criminal Division, Fraud Section, for 6-month assignments; others prosecute matters on a case-by-case basis. Both arrangements offer excellent litigation training for OIG attorneys and enhance collaboration between the departments in fighting fraud. Under this program, OIG attorneys have successfully litigated important criminal cases relating to DME or other Medicare and Medicaid fraud. Given its success, OIG and DOJ plan to expand the SAUSA program to augment prosecutorial resources in districts across the country.

## **Congressional Testimony**

OIG officials provided testimony to Congress on two occasions:

- On May 15, 2008, Lewis Morris, Chief Counsel to the Inspector General, testified before the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, at a hearing entitled "In the Hands of Strangers: Are Nursing Home Safeguards Working?" Chief Counsel Morris described our work to both promote the financial integrity of and improve the quality of care furnished by, nursing facilities.
- On July 9, 2008, Robert Vito, Philadelphia Regional Inspector General for Evaluation and Inspections, testified before the Permanent Subcommittee on Investigations, Senate Committee on Homeland Security and Governmental Affairs, at a hearing entitled "Medicare Payments for Claims With Identification Numbers of Dead Doctors." Mr. Vito discussed previous OIG reviews regarding vulnerabilities in the use of unique physician identification numbers on DME claims and OIG's plans for future work in this area.

The full texts of testimony provided at these hearings can be found at <http://oig.hhs.gov/testimony.html>.

## Speeches

Speeches by OIG officials included the following:

- On April 14 and 15, 2008, in New Orleans, LA, IG Levinson and Chief Counsel Morris provided the keynote address and a presentation on Federal enforcement roles, respectively, to the Health Care Compliance Association's 12th Annual Compliance Institute. Conference attendees included compliance officers, health care attorneys, compliance consultants, and representatives from Federal and State enforcement agencies.
- On May 2, 2008, in Washington, DC, IG Levinson participated in a Public Interest Dialogue Session on pandemic influenza. The IG made a presentation regarding OIG's ongoing pandemic influenza oversight initiative. This event was cosponsored by OIG, the American Health Lawyers Association, the Centers for Disease Control and Prevention, and George Washington University.
- On May 9, 2008, Principal Deputy Inspector General (PDIG) Larry Goldberg spoke at the Ethics and Compliance Officer Association Conference on Public Sector Approaches to Ethics and Compliance.
- On May 16, 2008, in Fairfax, VA, IG Levinson served as convocation speaker at the George Mason University College of Health and Human Services.
- On June 17, 2008, in Washington, DC, the IG delivered a keynote address at American University's Inaugural Health Law and Policy Institute.
- From June 27 through July 3, 2008, in San Francisco, at the American Health Lawyers Association's annual meeting, Chief Counsel Morris was the keynote speaker at the fraud and abuse interest group luncheon and also made presentations on the Government's role in promoting quality of care and techniques companies can use to effectively operate under CIAs.
- On August 25, 2008, Tim Brady, San Francisco Regional Inspector General for Evaluation and Inspections, gave a presentation entitled "OIG's Role in Combating Medicaid Fraud Through Audits, Evaluations, and Investigations" to the National Association for Medicaid Program Integrity National Conference in Williamsburg, VA.

## Events

OIG officials participated in the following events:

- From December 2007 through July 2008, OIG sponsored Medicaid Integrity Program (MIP) training conferences in Arizona, Colorado, Iowa, and Washington. These 2-day conferences provided technical assistance to those involved in addressing fraud and abuse in the Medicaid program. Since March 2007, we have held 13 MIP training conferences for more than 1,500 attendees from a variety of Federal, State, and local agencies.

## **Significant Awards From External Organizations**

■ In May 2008, during a ceremony held in Richmond, VA, Attorney General Robert McDonnell recognized the OIG Medicaid Fraud Unit Oversight Division (MFUOD) for outstanding work in its collaborative efforts with the Virginia Medicaid Fraud Control Unit to eliminate Medicaid fraud. Individual awards were presented to MFUOD Director Sharon Colby-Elborn and Senior Program Analysts Michael Goforth and Susan Powell.

## **External Organizations**

The IG and the PDIG are Invited Ethics Resource Center (ERC) Fellows from the Government sector. ERC is America's oldest nonprofit organization devoted to the advancement of high ethical standards and practices in public and private institutions.

## **E-mail List**

OIG currently maintains an e-mail list of more than 14,000 subscribers who regularly receive updates to OIG's Internet Web site. Notice is sent regarding new reports and changes to the OIG Exclusions database, as well as Federal Register notices and other OIG postings. During this reporting period, 73 e-mail notices of new postings on the OIG Web site were sent to subscribers. Information about the OIG e-mail list, including the link to subscribe to the list, is at <http://www.oig.hhs.gov/maillinglist.html>.





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

# Centers for Medicare & Medicaid Services

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

- Medicare provides health insurance for people 65 years of age or older, people younger than 65 years old with certain disabilities, and people of any age with end stage renal disease. In fiscal year (FY) 2007, Medicare served an estimated 43.9 million enrollees at a cost of more than \$370.7 billion. Medicare has four parts: Part A (Hospital Insurance), which helps cover inpatient care in hospitals, including critical access hospitals, skilled nursing facilities (SNF), and hospice and certain home health care; Part B (Supplementary Medical Insurance), which helps pay for physician services, outpatient care, and other medical services that Part A does not cover, such as certain services offered by physical and occupational therapists; Part C (Medicare Advantage (MA)), which offers a range of prepaid managed health care choices; and Part D (the Medicare Prescription Drug Benefit), which provides an optional prescription drug benefit to individuals enrolled in Medicare, generally through private prescription drug plans (PDP).
- Medicaid, a joint Federal-State program, supports States' coverage of medical care and other support services for low-income individuals. In FY 2007, the enrollment for Medicaid was estimated at 49.1 million beneficiaries; total Federal and State outlays were \$333.2 billion, of which the Federal share was \$190.6 billion.
- The State Children's Health Insurance Program (SCHIP), a joint Federal-State program established in 1997 under Title XXI of the Social Security Act, provides health insurance for children who do not qualify for Medicaid but whose families are not able to afford private coverage. In FY 2007, SCHIP served 7.1 million beneficiaries at a Federal cost of \$6 billion.

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

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA), P.L. No. 104-191, established the Health Care Fraud and Abuse Control program (HCFAC) under the direction of the Attorney General and the Secretary of HHS to combat waste, fraud, and abuse in the Medicare and Medicaid programs. HCFAC funding constitutes a major portion of OIG's annual operating budget and must be used for work related to Medicare and Medicaid.

- The Deficit Reduction Act of 2005 (DRA), P.L. No. 109–171, provides OIG annual funding of \$25 million from FYs 2006–10 to undertake fraud and abuse control activities related to the Medicaid program.

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

# Reports Related to CMS's Programs

## Medicare-Related Reports

### Long Term Care Hospitals Short-Stay Outliers

Consistent with CMS's efforts to cut payments for short-stay outliers in long term care hospitals (LTCH), which treat patients with complex medical conditions requiring prolonged postacute hospital-level care and receive higher reimbursement than general acute-care hospitals, we found that short-stay outliers decreased from 40 percent of LTCH stays discharged in FY 2003 to 27 percent in FY 2006. Short-stay outliers are LTCH stays that end before they reach five-sixths of the average length of stay for the patient's long-term care diagnosis-related group (LTC-DRG). Despite the decline in short-stay outliers, some discharge patterns raised concern that patients are inappropriately placed in LTCHs or discharged based on financial incentives. Patients discharged at least 10 days before the short-stay outlier threshold or who were readmitted to general acute-care hospitals directly after LTCH stays may have more appropriately received treatment at a general acute-care hospital.

We also estimated an aggregate amount of improper payments for short-stay outliers based on our review of data from Quality Improvement Organization (QIO) medical record reviews of LTCH claims for FYs 2005 and 2006. As part of the Hospital Payment Monitoring Program, CMS selects a national random sample of 116 LTCH claims each month for review by QIOs, which are Medicare contractors in each State that conduct case reviews to oversee and enhance the quality of care provided to Medicare beneficiaries. We found that almost all of the payment errors that QIOs identified with LTCH claims in that period resulted from inaccurate LTC-DRGs and inappropriate LTCH admissions. Based on our analysis of QIO reviews of LTCH claims, we estimated that about \$85 million, or 6 percent, of CMS payments to LTCHs for short-stay outlier claims during the FY 2005 to FY 2006 period were erroneous. We did not make recommendations for additional modifications to the program. (OEI-01-07-00290)

### Nursing Home Enforcement: Processing Denials of Medicare Payment

In our review of denials of payment for new admissions (DPNA), a CMS enforcement action imposed on SNFs that have been found to be noncompliant with Federal program participations standards, we found that, in FY 2004, CMS and its fiscal intermediaries (FI) incorrectly processed 74 percent of such actions, with 40 percent of the DPNA cases resulting in a total of over \$5 million of overpayments to SNFs. CMS is responsible for imposing denial of payment remedies but relies on its FIs, which will eventually be replaced by Medicare administrative contractors (MAC), to identify and reject the relevant Medicare claims. We identified various processing errors, including CMS not providing the FIs with the instructions on a timely basis or at all, CMS providing information to the wrong FIs, and FIs misinterpreting CMS's instructions.

We recommended that CMS manage DPNA cases to ensure that all DPNA instructions are sent timely; to ensure that FIs and MACs retrospectively review cases that are processed late to correct any payment errors, address communication breakdowns by implementing a standard format to notify FIs or MACs that a DPNA remedy will be in effect, and require confirmation that instructions are received and understood; and to update guidance on coding readmissions and verifying readmission status for DPNA claims. CMS agreed with our recommendations and outlined specific actions that it planned to address each recommendation. (OEI-06-03-00390)

### **Medical Review of Claims in the Comprehensive Error Rate Testing Program**

In our review of CMS's Comprehensive Error Rate Testing (CERT) program, we estimated the error rate in the FY 2006 CERT durable medical equipment (DME) sample at 17.3 percent or 28.9 percent, depending on the extent of documentation reviewed. An error is the difference between the amount that Medicare paid to a provider and the amount that it should have paid. CMS established the CERT program to produce a Medicare fee-for-service paid claim error rate. Pursuant to the Improper Payments Information Act of 2002, CMS submits annually to Congress an estimate of the improper payments for Medicare fee-for-service claims.

Our two-level review, performed by an independent medical review contractor, initially used the same procedures and limited medical records as CMS's CERT contractor and produced an error rate of 17.3 percent. We found that the CERT contractor's review was adequate for 324 of the 363 sampled claims. However, our medical review contractor identified 39 additional errors that the CERT contractor had not identified. We attributed these review discrepancies to the CERT contractor's inadequate review of available documentation and to CMS's lack of written policies and procedures on the appropriate use of clinical inference. The second part of our review used additional medical records from physicians and other health care providers and, in some cases, information from beneficiaries, and produced the higher error rate of 28.9 percent. Our medical review contractor confirmed 20 of the 23 errors identified by the CERT contractor and identified an additional 39 errors. We attributed these review discrepancies to the CERT contractor's reliance on clinical inference rather than medical records available from health care providers, CMS's inconsistent policies regarding proof-of-delivery documentation, and the agency's lack of procedures for obtaining information on high-risk DME items from beneficiaries.

We recommended that CMS require the CERT contractor to review all available supplier documentation and all medical records necessary to determine compliance with applicable requirements on medical necessity, and to contact the beneficiaries named on high-risk claims to help determine whether the DME items were received and were medically necessary. We also recommended that CMS establish a written policy to address the appropriate use of clinical inference, instruct its Medicare contractors to provide additional training to physicians to improve their medical record documentation, and document oral guidance that conflicts with written policies. CMS generally concurred with our findings and recommendations. (A-01-07-00508)



## Transition Stays at Inpatient Psychiatric Facilities

In our review of billing for transition stays at inpatient psychiatric facilities (IPF) in calendar year 2005, we estimated that IPFs received about \$9 million in Medicare overpayments for incorrectly billed transition stays. Under Medicare's prospective payment system (PPS), IPFs must submit a single discharge bill for an entire inpatient stay. If a beneficiary's stay begins before and ends on or after the date on which the facility becomes subject to the PPS (called a transition stay), the FI should base its payments to the facility on prospective payment rates and rules. IPFs that split the stay and submit two separate claims must cancel the split bills and then rebill the FI after the cancellation has been accepted. In our sample of 100 transition stays, we identified 62 stays for which the IPFs had not canceled the split bills and resubmitted correct bills. These 62 stays resulted in overpayments of \$408,000.

We recommended that CMS instruct the FIs to adjust claims for the sampled stays that resulted in overpayments of \$408,000; review our information on the stays not included in our sample which had potential overpayments estimated at \$8.6 million (\$9 million less \$408,000); work with the IPFs to recover any overpayments; and analyze postpayment data for claims submitted after our review to ensure that IPFs billed the claims properly and FIs paid them correctly. CMS agreed with our recommendations. (A-01-07-00520)

## Fiscal Integrity of Quality Improvement Organizations in Maryland, Tennessee, and Texas

At the request of the Senate Finance Committee, we assessed the fiscal integrity of QIOs in several States. A QIO operates in each State under contract with CMS to promote the effective, efficient, and economical delivery of health care services and the quality of those services. We focused our audits in the following areas: board member and executive staff compensation and travel, legal fees, equipment and related administrative charges, business relationships and conflicts of interest, and contract modifications. Our findings were as follows:

**Maryland** – We found that most of the QIO's \$22.8 million in Federal reimbursement for November 2002 through October 2005 appeared reasonable. However, the QIO had improperly classified \$1.6 million as indirect costs, which may have resulted in inflated indirect costs charged to the CMS contract. We recommended that the QIO work with CMS to resolve the status of the \$1.6 million in indirect costs. In its comments on our draft report, the QIO took exception to the recommendation but stated that it had changed its accounting practices. We modified our recommendation in response. (A-03-06-01650)

**Tennessee** – Of the \$13.81 million of costs reviewed (out of a total of \$18.2 million), \$13.7 million appeared reasonable for Federal reimbursement. We determined that from August 2002 through July 2005, \$31,000 of costs incurred by the QIO was unallowable and that \$124,000 was potentially unallowable. We recommended that the QIO refund

\$6,700 for unallowable physician consultant fees, reduce the indirect cost pool by \$24,000 for the balance of unallowable costs incurred, and work with CMS to determine the portion of the \$124,000 incurred for conference-related costs that should be excluded from the indirect cost pool for purposes of determining final rates. The QIO partially agreed with our findings and recommendations; however, its response and additional documentation did not cause us to change our findings or recommendations. (A-04-06-00023)

**Texas** – For the period February 1, 2003, through January 31, 2006, we found that most of the \$6.5 million in costs that we reviewed appeared reasonable for reimbursement. However, \$404,000 was unallowable and \$49,200 was potentially unallowable. We recommended that the QIO refund \$17,500 for unallowable legal fees and consultant travel; reduce the indirect cost pool by \$386,000 for severance packages for executives, board member and executive travel, and conference costs; and work with CMS to determine the portion of the \$49,200 incurred for compensation during our audit period that should be excluded from the indirect cost pool for purposes of determining final rates. The QIO disagreed with most of our findings and provided additional supporting documentation to support its position; we revised our report accordingly. However, the QIO's supporting documentation did not cause us to revise the majority of our findings and recommendations. (A-06-06-00072)

### **Medicare Payment for Irinotecan**

In our review comparing the Medicare payment amount to manufacturer prices for irinotecan hydrochloride (irinotecan), an injectable drug covered by Part B for the treatment of colorectal cancer, we found that Medicare paid 145 percent more than the OIG-calculated average manufacturer sales price in March 2008. The Food and Drug Administration (FDA) approved the first generic version of irinotecan on February 20, 2008. In March 2008, lower-priced generic versions of irinotecan were available for purchase but were not yet factored into the calculation of Medicare reimbursement.

For this review of irinotecan pricing, we determined the following:

- Lower-priced generic versions of irinotecan accounted for 86 percent of the drug's sales in March 2008; based on the average price for the generic version and sales volume during the month, we calculated that any purchaser of generic irinotecan received a Medicare payment that was approximately \$85 more than the average manufacturer sales price.
- Medicare payment amounts would have been reduced by \$6.5 million in March 2008 alone if the generic prices been considered in the Medicare calculation; however, there is a two-quarter lag for establishing Medicare payments and CMS had not yet considered generic prices in calculating the Medicare payment for this drug.

We recommended that CMS explore options to expedite the process to ensure that the Medicare payment amounts for drugs with newly available generic versions accurately reflect market prices. CMS concurred with our recommendation. (OEI-03-08-00310)

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

During this semiannual period, we issued three reports related to our continuing work comparing average sales prices (ASP) with average manufacturer prices (AMP) and widely available market prices (WAMP) for Medicare Part B prescription drugs. From April 2006 through September 2008, we issued nine reports of such comparisons. Section 1847A(d)(2)(B) of the Social Security Act (the Act) mandates that OIG perform these comparisons. For instances in which the ASP for a drug exceeds the AMP or WAMP by a certain threshold (currently 5 percent), section 1847A(d)(3) of the Act provides that the Secretary may disregard the ASP pricing methodology for that drug and that the Secretary shall substitute the payment amount for the drug code with the lesser of the WAMP (if any) or 103 percent of the AMP (for the drug).

In December 2007, the Medicare, Medicaid, and SCHIP Extension Act of 2007 (the Extension Act), P.L. No. 110–173, amended section 1847A(b) of the Act and changed the way that CMS calculates volume-weighted ASPs, effective April 1, 2008.

Analyzing CMS’s Healthcare Common Procedure Coding System (HCPCS) codes for drugs covered under Medicare Part B, we identified in both the previous comparisons and those issued during this semiannual period instances in which drug codes met the threshold for price adjustments. We determined that such adjustments, if implemented by the Secretary, would save Medicare millions of dollars in Part B drug costs. Although these reports did not include recommendations, CMS has commented previously that it would like to better understand fluctuating differences between ASPs and AMPs and that it intends to develop a process to adjust payment amounts based on the results of our pricing comparisons. To date, no changes have been made to Part B reimbursement as a result of our price comparisons.

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

- **Comparison of Third-Quarter 2007 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for First-Quarter 2008** – For the third quarter of 2007, we identified 41 of 369 drug codes with ASPs that exceeded AMPs by at least 5 percent. Of the 41 codes, 31 also met the threshold for price adjustments in at least one of the prior OIG studies comparing ASPs to AMPs. We estimated that if reimbursement amounts for all 41 codes had been based on 103 percent of AMP, Medicare expenditures would be reduced by \$16 million during the first quarter of 2008 alone.

Had the revised payment methodology, mandated by the Extension Act and effective in April 2008, been in effect during our review period, ASPs for fewer drug codes—35 of 369—would have exceeded AMPs by at least 5 percent. However, of these 35 codes, 32 are included in the 41 identified as meeting the 5-percent threshold under the method for volume-weighting data that was effective during the review period. (OEI-03-08-00130)

■ **Comparison of Fourth-Quarter 2007 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Second-Quarter 2008** – For the fourth quarter of 2007 using the revised ASP payment amount methodology, we identified 12 of 285 drug codes with ASPs that exceeded AMPs by at least 5 percent. We estimated that if reimbursement amounts for all 12 codes had been based on 103 percent of AMP, Medicare expenditures would have been reduced by \$20 million during the second quarter of 2008 alone. Lowering reimbursement amounts for the 12 HCPCS codes to 103 percent of the AMPs would have reduced Medicare allowances by an estimated \$20 million in the second quarter of 2008. Two of the 12 HCPCS codes accounted for almost 90 percent of the \$20 million. If the reimbursement amounts for the two codes had been based on 103 percent of the AMP during the second quarter of 2008, Medicare expenditures would have been reduced by an estimated \$11 million and \$7 million, respectively. This was our first pricing comparison since CMS implemented a revised ASP payment methodology mandated by section 112(a) of the Extension Act. (OEI-03-08-00340)

■ **Comparison of Average Sales Prices to Widely Available Market Prices for Inhalation Drugs** – In our review of inhalation drugs, for which Medicare and its beneficiaries paid more than \$900 million in 2006 to treat and prevent symptoms related to lung diseases, we determined that Medicare could have reduced expenditures in the second quarter of 2007 by \$27 million had pricing for two drugs—albuterol and levalbuterol—been based on WAMPs rather than ASPs. We calculated that use of the WAMP, defined in law as the price that a prudent physician or supplier would pay for the drug, net of any routinely available price concessions, would have saved \$6 million for albuterol and \$21 million for levalbuterol.

Additional findings included the following:

■ For the second quarter of 2007, the ASP for both albuterol and levalbuterol exceeded the price threshold (i.e., 5 percent) that would permit the Secretary of HHS to disregard the ASP, which is the basis for reimbursement. The volume-weighted ASP for albuterol exceeded the WAMP by 85 percent, and the volume-weighted ASP for levalbuterol exceeded the WAMP by 19 percent.

■ As a result of CMS establishing a single drug code for the two drugs, effective July 1, 2007, the Medicare payment amount for albuterol in the third quarter of 2007 may have been 13 times greater than the WAMP in the previous quarter. In contrast, the Medicare payment amount for levalbuterol in the third quarter of 2007 was 57 percent below the WAMP in the previous quarter.

■ After we completed our analysis, but before issuing the draft report, CMS reestablished two codes for albuterol and levalbuterol. As of April 1, 2008, the new Medicare payment amount for albuterol was very close to the WAMP that we had calculated for the second quarter of 2007 and, for levalbuterol, the new payment was substantially lower than the WAMP calculated for that quarter.

In commenting on our draft report, which had no recommendations, CMS indicated that our review had certain limitations. Our report provides explanations to address these areas. (OEI-03-07-00190)

## **Marketing Materials for Medicare Prescription Drug Plans**

In our review of marketing materials developed by stand-alone Medicare PDPs in 2007, we found that CMS provided limited oversight of the materials and that 85 percent of the materials failed to meet at least one element of the agency's guidelines. These deficiencies ranged from omitting required information about PDP benefits and rules to not using the required font size for footnotes. Under Medicare Part D, private health insurance organizations contract with CMS to offer PDPs. To help Medicare beneficiaries make an informed decision about PDP enrollment, CMS has issued regulations and developed guidelines specifying the type of information that must be provided in PDP marketing materials and created model documents to ensure the accuracy of information and expedite the review process for certain materials. PDP marketing materials—including advertisements, enrollment forms, and benefit summaries—must be submitted to CMS before they are distributed. CMS has two review processes: a standard review process, in which the agency manually reviews the marketing materials; and a “file and use” process, in which PDP sponsors attest that their marketing materials comply with CMS guidelines.

Our specific findings included the following:

- CMS had not completed its retrospective review of the 2006 file and use marketing material until April 2008. Therefore, it was unable to determine whether any sponsors should have had their file and use privileges revoked until more than 2 years after Part D began.
- The agency had completed standard reviews of marketing materials on a timely basis but the reviews were not consistent across regions.
- Marketing materials' identification numbers, used for oversight purposes, failed to match numbers in CMS's system for 45 percent of the materials that we reviewed.
- CMS did not have a systematic way to track the materials that were written in non-English languages or alternative formats.
- CMS's model documents were not fully consistent with the agency's own guidelines, which in turn resulted in problems with PDP marketing materials. For example, because

the model language for summaries of benefits omitted certain required information on the low-income subsidy, nearly all summaries of benefits on marketing materials that we reviewed lacked this information.

■ In addition to having problems that stemmed from model documents, PDP marketing materials did not meet the guidelines in several areas. For example, 79 percent of the advertisements with pharmacy cobranding (that is, a business relationship between the sponsor of a Medicare plan and another entity, such as a pharmacy) failed to include a required statement that other pharmacies were also available; and 42 percent of pharmacy directories did not describe, as required, the process for beneficiaries to obtain prescriptions if mail order service is delayed.

We recommended that CMS ensure that model documents are consistent with the guidelines, develop protocols for reviewing marketing materials, conduct more frequent retrospective reviews of file-and-use materials, enforce the use of the materials tracking system, and enhance the tracking system to include an identifier for marketing materials written in non-English languages and alternative formats. In commenting on our report, CMS concurred with all of our recommendations, stating that it had implemented steps to improve its oversight of marketing materials and identified additional areas for improving the review process. (OEI-01-06-00050)

### **Review of Disaster-Related Medicare Claims for Durable Medical Equipment**

In our review of a Louisiana DME supplier's 2005 Medicare claims for beneficiaries affected by Hurricanes Katrina and Rita, we found that all of the individuals in our sample were eligible for replacement DME and were provided with allowable DME. As authorized by section 1135(b) of the Act and in response to Hurricanes Katrina and Rita, the Secretary of HHS waived certain requirements of the Act to ensure that sufficient health care items were available to meet the needs of affected individuals, including Medicare beneficiaries, in emergency areas. The waivers were intended to ensure that health care providers that furnished items and services in good faith but who were unable to comply with certain program requirements because of the hurricanes would be reimbursed and exempt from sanctions for noncompliance, except in cases of fraud and abuse. This report contained no recommendations. (A-06-07-00079)

### **Hospice Beneficiaries' Use of Respite Care**

In our review of Medicare Part A hospice claims filed in 2005, we found infrequent use of inpatient respite hospice care, which is one of four levels of hospice care available to Medicare beneficiaries. The Medicare hospice benefit allows a beneficiary with a terminal illness to forgo curative treatment for the illness and instead receive palliative care, which is the relief of pain and other uncomfortable symptoms. Inpatient respite care is short-term inpatient care provided to the beneficiary who is otherwise cared for at home, but whose caregiver is in need of relief. Our specific findings included the following:

- Only 2 percent of all hospice beneficiaries received respite care, with 81 percent of these cases meeting the Federal regulations specifying that such care not exceed 5 consecutive days.
- There were a number of inappropriate uses of respite care: 54 beneficiaries received respite care for more than 5 consecutive days; 685 beneficiaries had claims for more than 5 days, but those claims did not show whether the respite days were consecutive care; and 62 beneficiaries received respite care that was not appropriate because they were already residing in facilities. We provided CMS additional information about potentially inappropriate respite care claims.
- Hospice claims may not have all of the information needed by CMS to determine hospice agencies' compliance with the 5 consecutive day respite care requirement.

This report had no recommendations. (OEI-02-06-00222)

### **Duplicate Medicaid and Medicare Home Health Payments: Medical Supplies and Therapeutic Services**

In our review of Medicare and Medicaid home health payments in five States during 2005, we found in four of the States that Medicaid inappropriately paid home health providers a combined total of \$1 million for more than 84,000 claims for nonroutine medical supplies (e.g., catheters, dressings, syringes, and needles) and therapeutic services that were also paid by Medicare. This represented nearly 1 percent of the \$113 million that the four States spent on home health nonroutine medical supplies and therapeutic services in our review and 6 percent of the 1.5 million total claims.

Both Medicaid and Medicare pay home health providers for home health services specified in the plans of care for beneficiaries; however, both programs should not pay for the same supplies or services for the same beneficiaries. When both Medicaid and Medicare cover particular supplies and services, Medicaid is the payer of last resort and Medicare should pay first for services provided to individuals who meet both Medicaid and Medicare eligibility requirements. Additional findings from our review included the following:

- In two States, Medicaid paid \$6.6 million for routine medical supplies (e.g., cotton balls, gloves, and incontinence items) on the same dates that Medicare covered home health services. It was possible that these medical supplies were included in the Medicare payments and that Medicaid should not have paid for them; however, the Medicaid claims data did not include enough information to determine whether the supplies qualified for Medicare payment.
- Each of the five States reviewed had established payment system edits to compare claims for home health services to Medicare eligibility information; however, incomplete eligibility information and payment system edit overrides resulted in inappropriate payments.

- The five States did not have direct access to the Medicare PPS data that would provide information about whether and when a beneficiary is receiving Medicare paid services.

We recommended that CMS ensure that Medicaid does not pay providers for Medicare-paid nonroutine medical supplies and therapeutic services and clarify the agency's policy on Medicare PPS coverage of routine medical supplies. CMS stated that it "did not disagree" with our first recommendation and concurred with our second recommendation. (OEI-07-06-00640)

### **Role of Nursing Homes and Long Term Care Pharmacies in Assisting Dual-Eligible Residents With Selecting Part D Plans**

In our review of the role of nursing homes and long term care pharmacies (LTCP) in providing assistance to dual-eligible residents—beneficiaries eligible to receive both Medicare and Medicaid coverage—in selecting their Part D plans, we found that the facilities provided different levels of assistance and that certain practices, such as enrolling beneficiaries into a single plan or recommending only one plan, may not have been in accordance with CMS's guidance. CMS permits and encourages nursing homes to provide information and education to residents about available Part D plans but states that nursing homes and the pharmacies serving them are not to, under any circumstance, require, request, coach, or steer any resident to select or change a plan. Prior to Medicare Part D, Medicaid paid for most of the prescription drugs for dual-eligible nursing home residents. Under Part D, dual-eligible residents receive drug coverage through Medicare and they are eligible to have their premiums, deductibles, and copayments fully subsidized.

Interviews that we conducted with nursing home administrators (with responses projected to the population of administrators) and pharmacy directors (with responses limited to the sample) between September 2006 and March 2007 revealed the following:

- **Identifying multiple plans for dual-eligible residents** – Thirty-eight percent of the nursing home administrators and 26 of the 79 pharmacy directors reported that their nursing homes or LTCPs had identified multiple plans to meet the needs of their dual-eligible residents.
- **Recommending one plan to dual-eligible residents** – About 9 percent of nursing home administrators reported that they enrolled most dual-eligible residents in a single plan or recommended one plan to each resident; 6 of the 79 pharmacy directors reported that their pharmacies generally recommended one plan to each resident.
- **Providing general or no assistance to dual-eligible residents** – Thirty-seven percent of nursing home administrators and 17 of the 79 pharmacy directors reported that they provided only general information about the Part D benefit to dual-eligible residents; 17 percent of the administrators and 30 of the 79 pharmacy directors said that they provided no assistance to dual-eligible residents in selecting their Part D plans.



We made no recommendations. (OEI-02-06-00191)

## **External Quality Review in Medicaid Managed Care**

In our review of the 37 States that had arranged for external quality reviews of Medicaid managed care organizations (MCO) in 2005, we determined that most of the States found the results of such reviews useful, but more than half reported concerns about the external review process. Federal regulations require States to provide for an external, independent review of their MCOs, which, as of 2006, enrolled 65 percent of the 45.6 million Medicaid beneficiaries. States may contract with an independent entity called an external quality review organization (EQRO) to conduct the external quality review.

Our specific findings included the following:

- Of the 37 States surveyed, 33 required their MCOs to make changes based on EQRO reports.
- The three primary concerns about external quality review that were cited by 24 States related to staffing (turnover and training), EQRO report quality (timeliness and feasibility of recommendations), and redundancy with other monitoring efforts.
- Some EQRO reports did not include all of the information required by their contracts.

We recommended that CMS work with States to ensure that EQROs provide complete information and also provide States with additional technical assistance and written guidance. In commenting on the draft report, CMS agreed with these recommendations and cited actions that it had taken in both areas. (OEI-01-06-00510)

## **Availability of Medicare Part D Drugs to Dual-Eligible Nursing Home Residents**

In our review of the availability of Medicare Part D drugs to dual-eligible nursing home residents, 93 percent of nursing home administrators, medical directors, and LTCP directors told us that between September 2006 and March 2007, dual-eligible residents were receiving all necessary Part D drugs. Prior to Medicare Part D, Medicaid paid for most of the prescription drugs for dual-eligible nursing home residents. Under Part D, dual-eligible residents receive drug coverage through Medicare and are eligible to have their premiums, deductibles, and copayments fully subsidized.

Our review brought to light specific areas of concern raised by respondents, as follows:

- Of the nursing home administrators interviewed, 45 percent reported paying for at least one Part D drug for dual-eligible residents, some citing the responsibility to comply with conditions of participation (CoP) to ensure that residents receive needed drugs in a timely manner. Administrators and pharmacy directors indicated that the drugs most often paid for were those not covered by the residents' Part D plan formularies or those requiring prior authorization.

- Some respondents indicated that the Part D plan formularies may not meet all of the needs of some dual-eligible nursing home residents. For example, plans may offer therapeutically equivalent drugs that are not always appropriate for residents because of adverse side effects or dosage form. In addition, the plans do not always cover all drugs needed by residents, such as injectable anemia drugs, oral cancer drugs, or drugs administered through nebulizers.
- Of the pharmacy directors interviewed, 80 percent reported that dual-eligible nursing home residents were incorrectly identified by their Part D plans in the latter part of 2006 as requiring copayments, even though these beneficiaries are eligible to have their premiums, deductibles, and copayments fully subsidized for prescription drugs covered under Part D. Some respondents found that the prior authorization process could be burdensome in the nursing home setting, noting problems with long wait times to speak with plan staff or the plan staff's lack of knowledge of formulary and coverage issues.
- Of the pharmacy directors interviewed, 54 percent reported that their pharmacies received rebates from drug manufacturers, and only three reported that their pharmacies provide any information to nursing homes or to physicians about the rebates that they can receive.
- Rebates may create incentives for pharmacists to recommend certain drugs on financial considerations as opposed to clinical considerations that the physician may be unaware of.

We recommended that CMS work with Part D plans to ensure that the formularies meet the needs of dual-eligible nursing home residents; continue to work with plans to improve the prior authorization process; ensure that copayments for dual-eligible nursing home residents are fully subsidized, as appropriate; and consider methods to encourage LTCs to disclose to physicians information about rebates they receive from drug manufacturers. CMS concurred with our first two recommendations and the intent of our third recommendation but, citing a lack of authority in the area, it did not concur with our last recommendation. (OEI-02-06-00190)

### **Improper Medicare Payments for Facet Joint Injection Services**

In our medical review of Medicare payments in 2006 for facet joint injections, which are used to diagnose or treat back pain, we found that 63 percent of the facet joint injections service claims allowed did not meet program requirements, resulting in approximately \$96 million in improper payments to physicians and \$33 million for associated facility claims. Between 2003 and 2006, Medicare Part B claims for facet joint injections increased by 76 percent, with payments rising from \$141 million to \$307 million.

Our specific findings included the following:

- More than 60 percent of net overpayments identified were the result of incorrect billing of bilateral services, which are injections performed on both the right and left side of the joint level.
- Claims for facet joint injection services provided in a practitioner's office were more likely to have errors than claims for services provided in an ambulatory surgical center or a hospital outpatient department.
- Although most carriers had policies and safeguards for facet joint injection services claims, they identified limits to using these safeguards.

We recommended that CMS strengthen program safeguards to prevent improper payment for facet joint services and clarify billing instructions for bilateral services. We also advised CMS that it should take appropriate action regarding the undocumented, medically unnecessary, or miscoded services identified in our review. CMS agreed with our recommendations. (OEI-05-07-00200)

### **Medicare Part D Contracting Process**

In our review of certain contracting aspects related to local, community pharmacies' participation in the Medicare Part D program, we found that 78 of the 100 local, community pharmacies in our sample relied on third-party contractors known as pharmacy services administrative organizations (PSAO) to contract with Part D PDP sponsors and that the pharmacies were generally satisfied with the services that their PSAOs provided. We conducted this review at the request of 33 Senators who expressed concern about PDP sponsors' contracting strategies. Previous OIG reports addressed the Senators' concerns regarding network adequacy and reimbursement.

Our review also found that almost all of the 100 sampled pharmacies and all of their PSAOs reported that they had experienced problems when contracting with PDP sponsors. These problems related to PDP sponsors' network development methods, standard terms and conditions, extended-day supply terms, negotiations, and network requirements and contracting deadlines.

We recommended that Congress and CMS consider the results of our review, including the data provided, in any deliberations regarding Medicare Part D contracting. We provided specific recommendations related to the concerns voiced by the pharmacies and PSAOs. CMS concurred with five of our recommendations but did not concur with the remaining five recommendations, stating that they were contrary to the competitive market principles that are fundamental to the Part D program. After reviewing CMS's comments, we revised three recommendations. (A-06-07-00082)

### **Hospital Wage Data**

In our reviews of hospitals' compliance with Medicare requirements for reporting wage data in their Medicare cost reports, we found that three hospitals did not fully comply

with the Medicare requirements. Under the acute-care hospital inpatient PPS, 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' wage data reported 4 years earlier. Our specific findings, by hospital, follow:

- A hospital in Florida overstated its wage data by \$12.8 million and 165,006 hours in its FY 2006 Medicare cost report. Correcting the hospital's errors decreased the average hourly wage rate from \$31.61 to \$30.31. We recommended that the hospital submit a revised FY 2006 Medicare cost report to the fiscal intermediary (FI) and implement procedural improvements. The hospital agreed. (A-04-07-06034)

- A hospital in Michigan overstated its wage data by \$27 million and 316,281 hours in its FY 2005 Medicare cost report. Correcting the hospital's errors decreased the average hourly wage rate from \$32.26 to \$31.08. We recommended that the hospital submit a revised FY 2005 Medicare cost report to the FI and implement procedural improvements. The hospital agreed. (A-05-07-00063)

- A hospital in North Carolina overstated its wage data by \$9.3 million and 50,857 hours in its FY 2006 Medicare cost report. Correcting the hospital's errors decreased the average hourly wage rate from \$31.51 to \$30.96. We recommended that the hospital submit a revised FY 2006 Medicare cost report to the FI and implement procedural improvements. The hospital generally agreed with our findings but disagreed, in part, that it had included in its wage data unsupported costs for Part B services provided by nurse practitioners. Based on the hospital's additional documentation, we revised the finding related to nurse practitioners. (A-01-07-00511)

### **Place-of-Service Coding**

In our review of place-of-service coding for claims submitted by physicians to the Medicare Part B contractor in Connecticut and Florida during 2004 and 2005, we found that physicians improperly coded place of service 85 percent of the time, resulting in an estimated \$1.5 million in overpayments. Physicians are required to identify, among other things, the place of service—their own office or another facility—on the health insurance claim forms that they submit to Medicare Part B to ensure that Medicare does not duplicate payment to the physician and the facility. Medicare generally reimburses physicians a higher amount for services performed in their offices than it does for services performed in an outpatient hospital or an ambulatory surgical center (ASC).

Our specific findings included the following:

- Of 100 sampled services, 85 services coded as having been performed in physicians' offices were actually performed in outpatient hospitals or ASCs.

- Of the 85 incorrectly coded services, 31 did not result in overpayments because the physicians' billings (i.e., their actual charges) did not exceed the Medicare fee schedule

amount that would have applied if the physicians had used the correct facility place-of-service code. For each of the remaining 54 services, the physicians' actual charges exceeded the Medicare fee schedule amount associated with the facility place-of-service code, resulting in overpayments of \$2,900.

We recommended that the Medicare contractor recover \$2,900 in overpayments for the sampled services, review our information on the nonsampled services to identify services estimated at \$1.5 million that were potentially billed with incorrect place-of-service codes and recover any overpayments, reemphasize to physicians and their billing agents the importance of correctly coding the place of service, and work with the program safeguard contractor to identify physician services at high risk for place-of-service miscoding. The contractor agreed with our recommendations. (A-01-07-00518)

### **Illinois "Full-Dual" Beneficiary Contributions**

In our review of Illinois's monthly contributions to CMS for beneficiaries who were eligible for both full Medicaid benefits and Medicare benefits (full-duals), we found that, contrary to Federal requirements, the State did not contribute a projected \$2.1 million to CMS for the period from January through October 2006. Medicare subsidizes the Part D prescription drug benefit for full-duals, and States are required to make contributions to CMS to defray a portion of Medicare's cost.

In our sample of 300 full-dual beneficiary-months, we determined that the State had not made contributions for 22 beneficiary-months. Although the State's monthly Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) file included full-dual information for 18 of the 22 beneficiary-months, CMS did not include the information in the MMA return file that identifies the amount billed to the State. For the remaining 4 beneficiary-months, the State did not include full-dual information in its MMA file nor did CMS in its MMA return file. We recommended that the State work with CMS to develop a process for reconciling the MMA file to the MMA return file to ensure that required contributions are identified and made for all full-duals and identify and accurately report all full-duals to CMS in the MMA file. The State concurred with the recommendations. (A-05-07-00009)

### **Early Implementation Review of Qualified Independent Contractor Processing of Medicare Appeals Reconsiderations**

In our review of the extent to which qualified independent contractors (QIC) followed timeliness, correspondence, and data entry requirements for Medicare Part A and Part B claims reconsiderations received from May 2005 to July 2006, we found that the QICs did not always meet the requirements in these areas. Medicare beneficiaries, providers, and suppliers of health care services may appeal certain decisions related to their Medicare claims through a four-level administrative appeals process. This review focused on the second level, QIC reconsiderations; CMS contracted with two QICs that began processing Part A reconsiderations in May 2005 and with two QICs that began processing Part B reconsiderations in January 2006.

Our findings included the following:

■ **Timeliness requirements** – Part A QICs met the 60-day processing requirement, but Part B QICs did not meet this requirement for 58 percent of the reconsiderations.

■ **Correspondence requirements** – Twenty-six percent of the case files reviewed did not contain documentation that QICs had sent letters acknowledging reconsideration requests, and 12 percent were missing reconsideration letters. In files containing reconsideration letters, we determined that they included the appropriate content. Forty percent of case files did not contain documentation substantiating that QICs sent processing delay notifications for Part B cases that were decided late.

■ **Data entry requirements and the Medicare Appeals System** – QICs entered inaccurate information into the Medicare Appeals System for 54 percent of the reconsiderations.

QICs attributed these deficiencies to case transfer delays, unexpected case volume, and appeals system challenges. We recommended that CMS take further action to ensure that QICs meet timeliness, correspondence, and data entry requirements and described several options. CMS concurred with our recommendation and indicated in its comments to our report that it had already implemented several changes that resulted in the Part B QICs completing over 98 percent of reconsiderations on a timely basis during the first half of FY 2008. CMS also awarded a contract to conduct a performance evaluation to assess QICs' adherence to Federal requirements and awarded three new Part B QIC contracts. (OEI-06-06-00500)

### **Deficiency History and Recertification of Medicare Home Health Agencies**

In our review of the deficiency history of more than 5,000 Medicare-certified home health agencies (HHA) as of January 2007, we found that 15 percent of HHAs were cited for the same deficiency on three consecutive surveys and that CMS could improve its oversight of HHAs. HHAs, which provide a range of services to Medicare beneficiaries who are confined to their homes, must meet specific Medicare CoPs and health and safety standards. CMS contracts with State agencies to conduct initial HHA certification and recertification surveys of CoP compliance. States cite deficiencies when HHAs are found to be noncompliant with the Medicare CoPs and health and safety standards. We refer to HHAs found repeatedly deficient on subsequent surveys as cyclically deficient HHAs. In terms of enforcement, provisions in the Omnibus Budget Reconciliation Act (OBRA) of 1987 directed CMS to implement intermediate sanctions against HHAs that are not in compliance with Federal requirements. Although CMS proposed intermediate sanctions in 1991, the regulation has never been finalized. As a result, CMS's only remedy in response to HHA noncompliance is termination from the Medicare program.

Our specific findings included the following:

- Among the cyclically deficient HHAs in our sample, the most repeated deficiency citation related to patient plans of care.
- Most cyclically deficient HHAs were located in six States and tended to be concentrated in highly populated areas.
- Cyclically deficient HHAs received twice as many deficiency citations as did HHAs without repeat citations.
- CMS did not use all available deficiency history information in its oversight of HHAs. We found that deficiency history beyond the most recent survey could be an important indicator of performance on the next survey and could improve CMS's identification of at-risk HHAs.
- For HHAs with one or more condition-level deficiencies, CMS has no sanction other than initiating a termination.

We recommended that CMS use existing survey data to identify patterns of deficiency citations and at-risk HHAs and implement intermediate sanctions, as directed by OBRA. In responding to our draft report, CMS generally concurred with our recommendations but did not agree with all of our specific recommended actions within each recommendation. (OEI-09-06-00040)

### **Payments Made in Error for Personal Care Services During Institutional Stays**

In our review of payments in five States for claims for personal care services (PCS) provided from October 1 through December 31, 2005, we found that in the first quarter of FY 2006, these States paid nearly \$500,000 in error for PCS provided during periods of institutionalization. PCS—described by Medicaid as assistance related to such activities as eating, bathing, dressing, and toileting—provide the elderly, persons with disabilities, and individuals with chronic or temporary conditions with the assistance that they need to remain in their homes or communities. State Medicaid programs should not separately reimburse for PCS furnished during institutional stays. Our specific findings included the following:

- The five States paid a total of \$11.6 million for more than 29,000 PCS claims that overlapped with the dates of paid Medicaid or Medicare institutional stays; of these, almost 4,000 claims (13.5 percent) were paid in error, with State Medicaid programs paying \$243,000 for PCS provided during Medicaid-paid institutional stays and \$251,000 for PCS provided during Medicare-paid institutional stays.
- Because of vulnerabilities in the billing practices of three States in our review, up to \$11 million for PCS claims could have been paid in error.

- All five States reported having controls such as system edits and postpayment audits to prevent or recover payments for PCS provided during institutional stays, but these controls were not fully effective.

We recommended that CMS enforce existing Federal Medicaid payment policies that prohibit Medicaid reimbursement for PCS provided over a range of dates if the range includes dates on which the beneficiary was institutionalized and work with States to reduce erroneous Medicaid payments for such services. In commenting on our draft report, CMS agreed to work with the States to reduce erroneous payments. However, CMS stated that existing Federal reimbursement policies are sufficient to prohibit such payments for PCS claims billed with date ranges when States have effective controls in place. (OEI-07-06-00620)

### **Medicare Administrative Law Judge Hearings: Early Implementation, 2005--2006**

In our congressionally requested review of the Office of Medicare Hearings and Appeals' (OMHA) use of telephone, video teleconference, and in-person hearings, we found that in its first 13 months of operation (July 1, 2005, to July 31, 2006), OMHA handled 78 percent of Medicare appeals by telephone and that most sample appellants were satisfied with their hearing format. Medicare beneficiaries, providers, and suppliers of health care services may appeal certain Medicare claims decisions through a four-level administrative appeals process. The third level of appeal, the subject of this review, is a hearing before an Administrative Law Judge (ALJ). OMHA assumed responsibility for these hearings from the Social Security Administration (SSA) in July 2005; unlike SSA, which held in-person hearings, OMHA primarily uses telephone and video teleconference to conduct ALJ hearings. OMHA is required by statute to decide certain cases within 90 days.

We also found the following:

- OMHA conducted 12 percent of its hearings by video teleconference and 10 percent in person.
- OMHA's ability to manage its caseload was limited by incomplete and inaccurate data in the appeals system. For example, for more than 70 percent of the cases that were decided in the first 13 months of OMHA's operation, there was no indication about which parties were the primary appellants. Other data problems included inconsistently entered appellant information, inaccurate or missing key dates, and incomplete or incorrect information about the hearing type and format.
- OMHA did not meet the 90-day decision requirement for 15 percent of the cases with such a requirement and a decision date recorded in the appeals system.

We recommended that OMHA consistently offer appellants the option of video teleconferencing, improve the timeliness of deciding 90-day decision requirement cases,



address technical problems associated with hearings conducted by telephone and videoconference, and improve the quality of the data in the appeals system. OMHA concurred with all four of our recommendations, noting that it had previously identified the same findings and had taken measures to address them. (OEI-02-06-00110)

## Medicaid-Related Reports

### Medicaid Outpatient Prescription Drug Expenditures

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

Our specific findings were as follows:

■ **Illinois** – For FYs 2004 and 2005, Illinois claimed \$108,000 in unallowable expenditures for prescription drugs that were no longer eligible for reimbursement. The State claimed an additional \$3.5 million for drugs that were not listed on the quarterly drug tapes. Because the State did not verify whether these drugs were eligible for the coverage, latter expenditures may not be allowable.

We recommended that the State refund \$108,000, work with CMS to resolve \$3.5 million in payments for drugs that were not listed on the quarterly drug tapes, and strengthen its internal controls. The State agreed with the first two recommendations but said that it would not change its internal controls because they were sufficient to comply with Federal requirements. (A-05-07-00019)

■ **Missouri** – For FYs 2003 and 2004, Missouri claimed \$2.9 million in unallowable expenditures for prescription drugs that were no longer eligible for reimbursement or were inadequately documented. In addition, the State claimed \$1.9 million for drugs that were not listed on the quarterly drug tapes and therefore may not be allowable.

We recommended that the State refund \$2.9 million, work with CMS to resolve \$1.9 million in payments for drugs that were not listed on the quarterly drug tapes, and strengthen its internal controls. The State disagreed with all of our findings and said that its internal controls were adequate. The State did not provide information that would cause us to revise our findings. (A-07-06-04063)

## Indiana Medicaid Disproportionate Share Hospital Eligibility

In our review of Indiana's compliance with Medicaid disproportionate share hospital (DSH) payment requirements, we found that from July 2000 through June 2003, the State paid \$142.3 million (\$88.2 million Federal share) to three State-owned psychiatric hospitals that were not eligible to receive DSH payments. States are required to make additional Medicaid payments to hospitals that serve disproportionate numbers of low-income patients. For psychiatric hospitals to qualify for such DSH payments, they are required to meet special Medicare CoP related to staffing and medical records. Although the State believed that the three hospitals met the special requirements by virtue of being accredited by the Joint Commission on Accreditation of Healthcare Organizations, we found that the hospitals had not complied with the more stringent requirements for psychiatric hospitals.

We recommended that the State refund \$88.2 million and ensure that Medicaid DSH payments are made only to eligible hospitals. The State disagreed with our finding and recommendations but did not provide additional information to demonstrate compliance with the special requirements for psychiatric hospitals. (A-05-06-00045)

## States' Medicaid Claims for Hurricane Katrina Evacuees

During this semiannual period, we issued three audit reports on the allowability of States' claims for services provided to Hurricane Katrina evacuees from Alabama, Louisiana, and Mississippi. To ensure the continuity of health care services for victims following Hurricane Katrina, States could apply to CMS for demonstration projects authorized by section 1115 of the Social Security Act and, with an approved demonstration, be eligible under section 6201(a)(1)(A)(i) of the DRA to receive Federal payment of the non-Federal share of medical assistance costs for evacuees. The results of our audits, which covered costs claimed as of March 31, 2007, follow:

■ **Maryland** – The State claimed a total of \$1.3 million for medical assistance services provided to 929 evacuees; of this amount, \$412,000 was not allowable. Under section 1115, CMS approved Maryland's request for Medicaid demonstration authority to provide benefits to eligible hurricane evacuees for a maximum of 5 months, ending June 30, 2006, and limited eligibility to individuals from specified counties or parishes. The claims that we identified as unallowable were not supported by actual recorded expenditures, were for services provided to individuals whose eligibility had expired, or were for services provided to individuals who may not have met eligibility requirements. We recommended that the State refund \$412,000 and revise its waiver reports for Alabama, Louisiana, and Mississippi by our audit adjustment amounts. The State agreed with our recommendation. (A-03-07-00200)

■ **Pennsylvania** – The State claimed a total of \$1.4 million for medical assistance services provided to 747 evacuees; of this amount, \$552,000 was not allowable. Under its approved section 1115 demonstration project, Pennsylvania was allowed to provide benefits to eligible evacuees for a maximum of 5 months. Most of the claims that we

identified as unallowable included costs for services provided to individuals after their eligibility periods had expired or costs that were not supported by actual recorded expenditures. We recommended that the State refund \$552,000 in unallowable reimbursement and revise its waiver reports for Alabama, Louisiana, and Mississippi by our audit adjustment amounts. The State agreed with our recommendations. (A-03-07-00210)

■ **Virginia** – The State claimed nearly \$523,000 for medical assistance services provided to 641 evacuees and associated administrative costs; of this amount, we determined that \$73,000 was not allowable. Under the terms of the approved section 1115 demonstration project and section 6201 of the DRA, the State could claim reimbursement for reasonable administrative costs related to providing services to evacuees. The claims that we identified as unallowable were for administrative costs that did not pertain to the demonstration project, were for medical assistance costs that were erroneously reported, or were related to services provided to ineligible individuals. We recommended that the State refund \$73,000 in unallowable reimbursement and revise its waiver reports for Alabama, Louisiana, and Mississippi by our audit adjustment amounts. The State agreed with our recommendation. (A-03-07-00211)

### **Substance Abuse Treatment Facilities**

In our reviews of two States' claims for Federal Medicaid reimbursement for services provided in inpatient substance abuse treatment facilities, we found that both States had made improper claims. Federal Medicaid funding generally does not cover substance abuse treatment when it is provided to residents of institutions for mental diseases (IMD) who are between the ages of 22 and 64. The specific findings follow:

■ **New Jersey** – From January 2002 through December 2006, the State improperly claimed \$1.7 million in Federal Medicaid reimbursement for substance abuse services that were provided to beneficiaries between the ages of 22 to 64 residing in facilities that were IMDs or to beneficiaries residing in nonparticipating institutional Medicaid facilities or nonaccredited psychiatric facilities. This overpayment occurred because the State had not established controls to designate the claims in question as federally nonparticipating. The State informed us that, following the period of our review, it had modified its controls to designate these facilities as federally nonparticipating.

We recommended that the State refund \$1.7 million, ensure that its new controls are working properly, determine the amount of improper Federal Medicaid reimbursement claimed subsequent to our audit period, and refund the overpayments. The State concurred with our finding and recommendations. (A-02-07-01005)

■ **New York** – From April 2001 through March 2006, New York improperly claimed \$21.5 million in Federal Medicaid reimbursement for services provided to beneficiaries between the ages of 22 and 64 who resided in IMDs. The State had improperly designated certain detoxification claims as eligible for Federal Medicaid reimbursement; one provider had billed Medicaid for inpatient rehabilitation services using an outpatient

category-of-service code; and the State had continued to claim Federal Medicaid reimbursement after another provider increased its number of beds and, as a result, met the Medicaid definition of an IMD. After our audit period, the State refunded a portion of the overpayment.

We recommended that the State refund the \$6.6 million balance of the overpayment, ensure that its controls to designate certain detoxification claims as federally nonparticipating are working properly, designate two providers as federally nonparticipating for beneficiaries under age 65, determine the amount of improper Federal Medicaid reimbursement claimed subsequent to our audit period, and refund the overpayments. The State concurred with the recommendations. (A-02-06-01021)

### **Kansas's Medicaid Claims for the Child Welfare Services and Family Preservation Programs**

In our reviews of Kansas's Medicaid claims for child welfare services during State FYs 2001–2003, we found that the State's documentation did not provide assurance that its \$61.4 million (\$37 million Federal share) claim for the Child Welfare Services program or its \$3.4 million (\$2 million Federal share) claim for the Family Preservation Program were, respectively, equal to or less than the limit specified in the State's Medicaid plan. Without auditable documentation, we were unable to express an opinion on the reasonableness of the State's claims for these programs on its quarterly Medicaid reports to CMS.

CMS requested these reviews subsequent to its 2004 review of Kansas's Child Welfare Services program, which found that the State had submitted claims for Federal reimbursement that did not reflect actual payments to providers. CMS deferred reimbursement of expenditures that did not meet Federal and State requirements and requested these reviews.

For both programs, we recommended that the State work with CMS to determine the allowability of claims for the audit period and all subsequent periods and ensure that State plan requirements are followed in submitting future claims. In response to both reports, the State concurred with our first recommendation but did not directly address our second recommendation. (A-07-06-03079, A-07-06-03076)

### **CMS's Medicaid Information Technology Audit Resolution Process**

In our review of CMS's resolution of 197 information technology (IT) recommendations that we made regarding the Medicaid Management Information System in 16 reports between 2002 and 2005, we found that CMS:

- Resolved 17 recommendations within the required 6-month period following report issuance,
- Resolved 124 recommendations after the 6-month period had expired, and

- Had not resolved 56 recommendations as of June 30, 2007.

CMS is responsible for resolving Federal and non-Federal audit report recommendations related to its activities, grantees, and contractors within 6 months after formal issuance of reports.

We recommended that CMS establish procedures to ensure that all IT audit recommendations are resolved within 6 months of receiving an audit report. In commenting on our draft report, CMS concurred with our recommendation and described steps that it had taken to improve the audit resolution process. (A-04-06-05039)

### **Medicaid Payments for Services Provided to Beneficiaries With Concurrent Eligibility in Two States**

In our review of States' payments in August 2003 on behalf of individuals who should not have been Medicaid-eligible because of their eligibility in another State, we estimated that States paid approximately \$2 million in that month on behalf of individuals who were already eligible in another State. In each of these States, Medicaid eligibility depends in part on residency, and the general definition of residency provides that an individual can be a resident in only one State at a time. Thus, when an individual establishes residency in one State, he or she should lose resident status (and Medicaid eligibility) in other States.

We recommended that CMS share the results of our review with all States to emphasize the need to identify beneficiary eligibility changes and encourage States to identify opportunities to use existing eligibility data to minimize concurrent Medicaid eligibility periods. CMS concurred with the recommendations. (A-05-06-00057)

### **Medicaid Buy-In Payments in North Carolina**

In our review of North Carolina's claims of Medicare Part B premiums that it paid on behalf of Medicaid beneficiaries for the quarters ended June 2004 through March 2007, we determined that the State had not met Federal requirements in claiming the Federal share of Medicare Part B premiums that it paid on behalf of some Medicaid beneficiaries. Of the \$722 million that the State claimed, approximately \$24 million (\$16 million Federal share) was for beneficiaries in "buy-in" eligibility categories that were ineligible for the Federal share.

Under the buy-in program, States that have an agreement with CMS may enroll individuals who are eligible for benefits under both Medicare and Medicaid (dual eligibles) in Medicare Part B and pay the monthly premium on behalf of these recipients. Participating States are eligible to receive the Federal Medicaid share of the Part B premiums for certain groups of dual eligibles.

We recommended that the State refund the \$16 million, review claims submitted following our audit period, refund any unallowable Federal reimbursement, and develop

adequate internal controls. The State concurred with our finding and recommendations. (A-04-07-03011)

### **Rhode Island Medicaid Transportation Claims**

In our review of Rhode Island's claimed nonemergency transportation costs for the period March 2004 through May 2005, we found that the State had not claimed the costs in accordance with Federal and State requirements. States must ensure that Medicaid beneficiaries have transportation to and from medical providers and that the transportation is cost-effective. Rhode Island provided nonemergency transportation by distributing monthly bus passes. We determined that the State could have saved at least \$9.8 million (\$4.9 million Federal share) by purchasing 10-ride bus passes instead of monthly passes. We also found that the State had claimed \$386,000 (\$193,000 Federal share) in unallowable costs for beneficiaries of two non-Medicaid State programs.

We recommended that the State either refund \$4.9 million or provide documentation to show that monthly bus passes were the most cost-effective means of providing nonemergency transportation; refund \$193,000 in unallowable costs; recalculate claims for bus passes reimbursed after our audit period and refund the excess reimbursement; and establish policies and procedures to comply with Federal requirements and the State plan. The State agreed to refund the \$193,000 related to our second recommendation but disagreed with the other recommendations. After considering the State's comments, we maintain that our findings and recommendations are valid. (A-01-06-00007)

### **Separate State Children's Health Insurance Program Enrollees' Eligibility for Medicaid in 2006**

In this review, the third in a series of congressionally mandated reviews of SCHIP enrollment, we found that 4 percent of the children enrolled in separate SCHIPs (16 sample cases and about 105,000 children projected nationwide) were eligible for their States' Medicaid programs. Federal regulations require States to screen SCHIP applicants for Medicaid eligibility in part to prevent inappropriate enrollment of Medicaid-eligible children in SCHIP, whose expenditures have a higher Federal match than Medicaid expenditures. Details of this review included the following:

- The 4-percent enrollment error rate found in this review was somewhat higher than error rates found in our earlier reviews (i.e., 1.8 percent in 2000 and 1 percent in 2003).
- The 16 cases erroneously enrolled in SCHIP were due to miscalculations of the families' net income, clerical mistakes, and other unclassified errors.
- An additional 4.5 percent (18 sample cases) lacked sufficient documentation to determine Medicaid eligibility, raising the possibility that the actual number of children enrolled in separate SCHIPs who were eligible for Medicaid in 2006 could have been higher than our projection.

We recommended that CMS take further action to ensure that children are appropriately enrolled in their States' Medicaid programs. In responding to our draft report, CMS indicated that it supported the spirit of the recommendation and requested additional information on the cases that we had identified as enrollment errors. (OEI-06-07-00310)

### **Texas Medicaid Upper Payment Limit for Hospitals**

In our review of Texas' June 2005 upper payment limit (UPL) payments to State-owned and -operated hospitals for inpatient services, we were unable to determine whether the State had calculated UPL payments totaling \$112.3 million in accordance with Federal regulations and the State plan because the State did not retain the required supporting documentation. The Medicaid program provides payments to certain hospitals for inpatient services insofar as the aggregate payments do not exceed the UPL, which is a reasonable estimate of the amount that would be paid for Medicaid services under Medicare payment principles.

We recommended that the State work with CMS to recalculate the UPL, refund the Federal share of any overpayments identified, and implement procedures to retain supporting documentation for UPL payments. In commenting on our draft report, the State said that it had recalculated the UPL and planned to provide the revised calculation and documentation to CMS. The State also said that it had implemented the recommended procedures. (A-06-07-00025)

### **Fee-for-Service Payments for Services Covered by Capitated Medicaid Managed Care**

In our review of the extent to which Medicaid programs in five States paid noninstitutional fee-for-service claims for services provided to beneficiaries enrolled in capitated Medicaid managed care plans during the first quarter of FY 2005, we identified approximately \$1.8 million (State expenditures and Federal financial participation) in total Medicaid claims paid, or potentially paid, in error.

In capitated managed care arrangements—through which 65 percent of the Nation's Medicaid beneficiaries received all or some of their health or mental health services in 2006—State Medicaid programs pay managed care plans a fixed rate per Medicaid beneficiary in exchange for services included in the plan. Except in limited circumstances specified by the State, Medicaid programs should not pay claims for services that are included in capitated Medicaid managed care plans on a fee-for-service basis. Otherwise, Medicaid programs pay twice for the same service: once through the fee-for-service claim and once as a portion of the capitated payment.

Our specific findings included the following:

- Four of the States reimbursed fee-for-service claims totaling nearly \$864,000 (\$462,000 Federal share) in error. Manual overrides of Medicaid automated payment system edits and faulty system logic contributed to these errors.

- Two States potentially paid an additional \$974,000 in error, but Medicaid staff in these States were unable to confirm whether these fee-for-service claims were paid in error without conducting a detailed, resource-intensive claims-level review.

We recommended that CMS work with States to prevent erroneous fee-for-service payments by issuing guidance to States addressing Medicaid payment systems' vulnerabilities, identifying erroneous payments, and developing payment systems to prevent payment errors. We also recommended that CMS take appropriate action to collect overpayments associated with Medicaid claims paid in error. In responding to our draft report, CMS agreed with our recommendation and listed actions it planned to take to eliminate erroneous payments. The agency also indicated that it would work with the four States to voluntarily collect the overpayments associated with erroneous fee-for-service payments. (OEI-07-05-00320)

## **Other CMS-Related Reports**

### **Audits of Hospitals in the New Orleans Area**

During this semiannual period, we issued 10 reports related to five hospitals in the New Orleans region that had requested additional assistance following Hurricane Katrina. Officials of the five hospitals appeared at an August 1, 2007, post-Katrina health care hearing held by the Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, and testified that their hospitals had experienced significant post-Katrina operating losses, largely due to the increased costs of providing hospital care following the August 2005 hurricane. Using a summary of financial data compiled by the Louisiana Hospital Association comparing pre-Katrina (January through May 2005) with post-Katrina (January through May 2007) expenses and revenues, the officials requested Federal financial assistance for the recovery of the health care delivery system in the New Orleans area, including additional grant funds from HHS. In a September 27, 2007, letter, the committee requested that OIG review the more significant operating loss items cited by these hospitals as a basis for their testimony.

Our initial audits focused on the hospitals' expense and revenue data that were presented in the congressional testimony. We audited various expense categories—including salary and contract labor, utilities, insurance, depreciation and amortization, and bad debt—to determine whether the hospitals' data were accurate and supported by their financial records. We also analyzed the hospitals' revenue data, which reflected amounts received from Medicare, Medicaid, commercial sources, and other sources.

At the five hospitals, we initiated additional audits of the wage costs included in FY 2005 Medicare cost reports. Hospitals must accurately report wage data so that CMS can determine the equitable distribution of payments and ensure that there is an appropriate level of funding to cover hospital costs. CMS uses the hospital wage index to adjust prospectively set Medicare payment rates for regional variation in labor costs. Because wage indexes for a given year are based on wage data collected from hospitals 4 years



earlier, an overstatement in a hospital's FY 2005 cost report could result in Medicare overpayments in FY 2009 to hospitals within the same geographic area.

Findings from the expense and revenue audits and the wage data audits are as follows:

### **Hospital A**

■ **Expenses and revenues** – We determined that Hospital A's expenses presented in the testimony were generally accurate and supported by its financial records. However, the hospital's revenue for the first 5 months of 2007, as described in the testimony, did not include \$4 million that it received in Medicare Wage Stabilization grants during this period. This was an informational report, and we had no recommendations.

(A-06-08-00009)

■ **Wage data** – We found that Hospital A had overstated fringe benefit costs by \$4.5 million (\$4.9 million with overhead factored in) in its FY 2005 Medicare cost report. Our correction of the error resulted in a 4-percent decrease in the average hourly wage rate from \$28.99 to \$27.85. To prevent Medicare overpayments to the hospitals using the wage index in the statistical area, we recommended that Hospital A submit a revised FY 2005 cost report to CMS and make procedural improvements. The hospital agreed.

(A-01-08-00515)

### **Hospital B**

■ **Expenses and revenues** – We determined that Hospital B's expenses presented in the testimony were generally accurate and supported by its financial records. However, its revenue for the first 5 months of 2007, as described in the testimony, did not include \$1.1 million that it received in a Medicare Wage Stabilization grant during this period. This was an informational report, and we had no recommendations. (A-01-07-00521)

■ **Wage data** – We found that Hospital B reported unsupported and unallowable costs totaling \$3.2 million and 40,523 hours in its FY 2005 Medicare cost report. Our correction of the error decreased the average hourly wage rate approximately 3 percent from \$28.83 to \$28.11. To prevent Medicare overpayments to the hospitals using the wage index in the statistical area, we recommended that the hospital submit a revised FY 2005 Medicare cost report and implement procedural improvements. The hospital agreed with our findings. (A-01-08-00516)

### **Hospital C**

■ **Expenses and revenues** – We determined that Hospital C's expenses presented in the testimony were generally accurate and supported by its financial records. However, its revenue for the first 5 months of 2007, as described in the testimony, did not include \$3.9 million that it received in Medicare Wage Stabilization grants and funds from other sources during this period. This was an informational report, and we had no recommendations. (A-06-08-00012)

■ **Wage data** – We found that Hospital C overstated its salaries by more than \$605,000 and understated its hours by 4,168 in its FY 2005 Medicare cost report. Our correction of the hospital’s errors reduced the average hourly wage rate approximately 1.3 percent from \$25.19 to \$24.86. To prevent Medicare overpayments to the hospitals using the wage index in the statistical area, we recommended that the hospital submit a revised FY 2005 Medicare cost report and implement procedural improvements. The hospital agreed with our findings. (A-01-08-00513)

## **Hospital D**

■ **Expenses and revenues** – We determined that Hospital D’s expenses presented in the testimony were generally accurate and supported by its financial records. However, the hospital’s revenue for the first 5 months of 2007, as described in the testimony, did not include \$6 million that it received in Medicare Wage Stabilization grants and other funds during this period. This was an informational report, and we had no recommendations. (A-06-08-00011)

■ **Wage data** – We found that Hospital D reported unsupported and unallowable costs totaling \$298,000 in its FY 2005 Medicare cost report. Our correction of the error reduced the average hourly wage rate less than 1 percent from \$35.69 to \$35.59. To prevent Medicare overpayments to the hospitals using the wage index in the statistical area, we recommended that the hospital submit a revised FY 2005 Medicare cost report and implement procedural improvements. In commenting on our draft report, the Hospital provided information on actions that it had taken to implement our recommendations. (A-01-08-00518)

## **Hospital E**

■ **Expenses and revenues** – We determined that Hospital E’s expenses presented in congressional testimony were generally accurate and supported by its financial records. However, as described in the testimony, the hospital’s revenue for the first 5 months of 2007 did not include \$20 million that it had received during this period. The Louisiana Hospital Association had removed this amount when compiling the testimony data and referenced the amount in an explanatory note. This was an informational report, and we made no recommendations. (A-01-08-00507)

■ **Wage data** – We found that, after factoring in overhead, Hospital E reported unsupported costs totaling \$6.6 million and 57,539 hours in its FY 2005 Medicare cost report. Our correction of the error decreased the average hourly wage rate approximately 3.5 percent from \$29.49 to \$28.47. To prevent Medicare overpayments to the hospitals using the wage index in the statistical area, we recommended that the hospital submit a revised FY 2005 Medicare cost report and implement procedural improvements. The hospital agreed with our finding. (A-01-08-00519)

## Grant Closeout Procedures

In our review of 197 CMS grants that had not been closed out by the cutoff date of March 31, 2006, we determined that these grants, with unexpended balances of \$1.3 billion, were not closed out in a timely manner. CMS is responsible for initiating the closeout of its various grants by instructing HHS's Program Support Center (PSC), Division of Payment Management (DPM), to close out grants in the Payment Management System. As a general rule, grants must be closed within 180 days after the end of the grant period (the cutoff date). A previous internal controls review by an outside auditor found that CMS had not actively reviewed grants eligible for closeout and lacked a process for ensuring that grant financial activity recorded on the general ledger agreed with activity recorded in the payment system.

Our specific findings included the following:

- For 33 grants with unexpended balances totaling nearly \$1.2 billion, CMS's program offices did not initiate closeout because they were awaiting the results of legislative proposals or because they lacked an adequate monitoring system to ensure that grants were closed by the cutoff date.
- For 164 grants with unexpended balances totaling nearly \$104.2 million, CMS's program offices initiated closeout; however, DPM did not complete closeout primarily because of differences (sometimes of \$1 or less) among the grant award, expenditure, and drawdown amounts in the payment system.

We recommended that CMS establish an adequate monitoring system to ensure that its program offices close grants by the cutoff date, deobligate any unexpended balances on grants open past the cutoff date, and work with DPM to establish a dollar threshold for differences in payment system balances and procedures for closing grants with differences below the threshold. CMS generally concurred with our recommendations. (A-02-06-02001)

## 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 the Department of Justice (DOJ), issues advisory opinions to outside parties regarding the interpretation and applicability of certain statutes relating to Federal health care programs. This authority allows OIG to provide case-specific formal guidance regarding the application of the anti-kickback statute and safe harbor provisions and other OIG health care fraud

and abuse sanctions. For the period April 1 through September 30, 2008, OIG received 25 advisory opinion requests and issued 10 advisory opinions. OIG advisory opinions are available at <http://oig.hhs.gov/fraud/advisoryopinions.asp>.

### **Provider Self-Disclosure Protocol**

OIG is committed to assisting health care providers and suppliers in detecting and preventing fraudulent and abusive practices. Since 1998, we have made available comprehensive guidelines describing the process for providers to voluntarily submit to OIG self-disclosures of fraud, waste, or abuse. The guidelines, entitled “Provider Self-Disclosure Protocol,” give providers an opportunity to minimize the potential costs and disruption that a full-scale OIG audit or investigation may entail if fraud is uncovered. In doing so, the self-disclosure also enables the provider to negotiate a fair monetary settlement and potentially avoid being excluded from doing business with Federal health care programs. The protocol guides providers and suppliers through the process of structuring a disclosure to OIG about matters that appear to constitute potential violations of Federal laws (as opposed to honest mistakes that may have resulted in overpayments). After making an initial disclosure, the provider or supplier is expected to undertake a thorough internal investigation of the nature and cause of the matters uncovered and make a reliable assessment of their economic impact (e.g.; an estimate of the losses to Federal health care programs). OIG evaluates the reported results of each internal investigation to determine the appropriate course of action.

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

On April 15, 2008, OIG published another Open Letter to Health Care Providers. The letter sets forth certain refinements to the October 1998 Self-Disclosure Protocol. To improve the self-disclosure process, OIG, among other steps, streamlined its internal procedures regarding self-disclosures. In addition, OIG explained that it will generally not require a self-disclosing entity to enter into a corporate integrity agreement (CIA) or certification of compliance agreement (CCA) when a resolution has been negotiated pursuant to the protocol.

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

During this reporting period, self-disclosure cases resulted in \$47.6 million in HHS receivables. The following are examples:

■ **California** – M.A.C.T. Health Board, Inc. (MACT), an association of Native American tribal organizations and provider of direct care services to Native Americans through its five primary care clinics and three dental clinics, agreed to pay \$447,287 to resolve its liability to the United States and California for submitting claims to Medicare and

Medi-Cal for clinic visits that did not occur. MACT reported these violations under the OIG Self-Disclosure Protocol following an internal investigation into improper billing practices by a physician assistant between January 1998 and March 2005. Services billed by MACT as clinic visits did not, in fact, qualify as clinic visits because patients were not seen by physicians, physician assistants, or nurse practitioners. For most such claims, the only services provided were medication refills, telephonic consultations, or blood or urine samples taken for laboratory analysis.

■ **Pennsylvania** – Sharon Regional Health System agreed to pay the Government \$362,838 and enter into a 3-year CCA with OIG following its disclosure under the OIG Self-Disclosure Protocol that it improperly billed Medicare for various services. The reported violations included billing for services provided by certified registered nurse practitioners and physician assistants at physicians’ rates even though the services were not provided “incident to” physicians’ services. Sharon allegedly double billed for admission visits by billing for the time after the physician was called by an admitting midlevel provider or social worker and for the time after the physician saw the patient the next morning. Sharon also allegedly submitted claims for hospital discharges at a rate that was not justified by the actual medical records.

## 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 E for an explanation of OIG’s sanction authorities). These sanctions include the exclusion of individuals and entities from Federal health care programs and the imposition of CMPs for submitting false or fraudulent claims to a Federal health care program or violating the anti-kickback statute, physician self-referral statute, or the “patient dumping” provision of the Social Security Act.

During this reporting period, OIG administered 1,866 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 1,838 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:

■ **Virginia** – Kenneth D. Beverly, the owner of a rehabilitation facility, was excluded for a minimum of 25 years based on his scheme to bill Medicaid for psychosocial rehabilitation services for Medicaid beneficiaries who were not eligible to receive such services. In addition to the health care fraud scheme, Beverly was convicted of various

other charges, including charges related to income tax evasion. Beverly was ordered to pay \$2,604,500 in restitution and was sentenced to 151 months of incarceration.

■ **New Jersey** – Juan C. Fischberg, a medical doctor, was excluded for a minimum of 25 years based on his health care fraud-related conviction. From about January 1998 to August 2003, Fischberg submitted false claims to various private insurance companies indicating that his patients, who had been injured in automobile accidents, needed electrodiagnostic testing for him to diagnose and treat them. In some cases, the testing was not necessary or even performed. Fischberg was ordered to pay \$2,126,200 in restitution and was sentenced to 3 years of incarceration. In addition, Fischberg surrendered his licenses to practice medicine in the States of New Jersey and New York.

■ **Oregon** – John Lawrence Shadley, a caregiver at a long term care facility for disabled individuals, was excluded for a minimum of 25 years based on his conviction related to patient abuse or neglect. From about January 2004 to July 2006, Shadley unlawfully and intentionally attempted to engage in sexual intercourse with a person incapable of consent by reason of mental defect; knowingly engaged in deviant sexual intercourse with a person incapable of consent by reason of mental defect; and subjected a person who was mentally defective to sexual contact. Shadley was sentenced to 303 months of incarceration.

■ **Iowa** – Ronald Dean Agee, a nurse aide at a health care facility, was excluded for a minimum of 13 years based on his conviction of sexual abuse. Agee admitted that he had had inappropriate contact with a female patient during the course of providing her care. The patient was physically incapacitated and could not give consent. Agee was sentenced to incarceration for a period not to exceed 10 years.

■ **California** – Qing Wang, an acupuncturist, was excluded indefinitely based on the surrender of her license to the State Acupuncture Board for unprofessional conduct and acts involving dishonesty or corruption. Wang used her acupuncture license as part of a scheme to own and operate a massage parlor where employees solicited for prostitution. The investigation was prompted by advertisements in adult publications. On at least seven separate occasions, sex for money was offered.

### **Civil Monetary Penalties Law**

The Civil Monetary Penalties Law (CMPL) authorizes OIG to impose administrative penalties and assessments against a person who, among other things, submits or causes to be submitted claims to a Federal health care program that the person knows or should know are false or fraudulent. During this reporting period, OIG concluded cases involving more than \$5.5 million in CMPs and assessments. The following are among the CMP actions resolved during this reporting period:

■ **Arkansas** – Sparks Health System, Sparks Medical Foundation, and Sparks Regional Medical Center (collectively, Sparks) agreed to pay \$1,142,973 for allegedly violating the CMPL. The agreement resolved allegations, self-disclosed by Sparks, that from

January 1, 2001, through November 30, 2003, it billed Medicare for medically unnecessary hospital services and upcoded physician services generated by an internal medicine physician.

■ **South Carolina** – Spartanburg Regional Healthcare System (Spartanburg) agreed to pay \$780,000 to settle its liability under OIG’s CMPL authorities for physician referral and anti-kickback violations. Spartanburg disclosed that, between August 1, 2005, and September 30, 2007, it provided IT resources to nonemployee physician groups without written contracts in place. Specifically, Spartanburg reported that it failed to document IT agreements with 10 different physician practices/groups and also failed to bill and collect for those IT resources.

■ **Massachusetts** – Caritas Christi, the parent entity of a health care system comprising hospitals, physicians groups, laboratories, and home care agencies in southern New England, agreed to pay \$250,060 to resolve its liability under the CMPL. In May 2007, Caritas Christi disclosed to OIG that it employed or contracted with five individuals who were excluded from participating in Federal health care programs. Caritas Christi discovered this problem during an annual review of the Federal sanctions lists in late 2006. After disclosing this matter, Caritas Christi cooperated with OIG in determining the damages related to the employment of four of these individuals and a one-time contract with the fifth person. In addition, as part of the settlement agreement, Caritas Christi provided a certification of its policy and procedures to prevent hiring or contracting with ineligible providers.

■ **Florida** – Based upon evidence submitted during an administrative hearing held in Tampa, FL, ALJ Steven T. Kessel issued a decision on June 24, finding that Cary Frounfelter and Kast Orthotics and Prosthetics, Inc., violated the CMPL by submitting false claims for Medicare Part B reimbursement. The ALJ sustained the determination by OIG to impose a CMP of \$100,000, an assessment of \$42,220, and a 7-year exclusion against Frounfelter and Kast.

Frounfelter is the founder and owner of Kast, a DME supplier in Clearwater, Florida, that provided custom-made orthotic devices to inpatients at HealthSouth Rehabilitation Hospital in Largo, FL. Frounfelter and Kast falsely claimed that they provided the devices after Medicare beneficiaries had been discharged from HealthSouth, or within a 48-hour window prior to discharge, and illegally billed the devices to Medicare Part B. The ALJ found that Frounfelter and Kast struck a “corrupt bargain” with HealthSouth, whereby Frounfelter and Kast “systematically, fraudulently, and falsely claim[ed] reimbursement under Part B of the Medicare Program for orthotic devices which they knew or should have known were not eligible for compensation under Part B.”

## **Patient Dumping**

Some of the CMP cases that OIG resolved between April 1 and September 30, 2008, 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 under this statute:

■ **North Carolina** – Cape Fear Valley Medical Center paid \$42,500 to resolve allegations that it failed to provide an appropriate medical or psychiatric examination for a 13-year-old girl who presented to its emergency department. The girl had reportedly taken a knife to school and threatened to harm herself and others. Without conducting either a medical or psychiatric exam, Cape Fear discharged the girl after a 5-minute meeting with an emergency department physician and provided no discharge instructions. Less than 50 minutes later, the patient returned to Cape Fear after jumping from a car moving at approximately 40 miles per hour, sustaining a skull fracture, subdural hematoma, possible splenic laceration, and skin abrasions.

■ **California** – Mark Twain St. Joseph’s Hospital paid \$25,000 to resolve allegations that it failed to provide an appropriate medical screening to a pregnant woman who presented to its emergency department complaining of severe pain and bleeding. After the woman arrived at the hospital, the emergency department physician failed to place her on a fetal baby monitor or conduct a pelvic exam. Following discharge from Mark Twain, the woman delivered her baby in a private vehicle while traveling to another hospital for treatment. However, the baby died before an ambulance arrived. The \$25,000 settlement amount is the statutory maximum given the size of the hospital.

## **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 False Claims Act (FCA). A description of these enforcement authorities can be found in Appendix E.

The successful resolution of false claims often involves the combined investigative efforts and resources of OIG, the Federal Bureau of Investigation (FBI), Medicaid Fraud Control Units (MFCU), and other law enforcement agencies. OIG is responsible for assisting DOJ in bringing and settling cases under the FCA. Many providers elect to settle their cases prior to litigation. As part of their settlements, providers often agree to enter into integrity agreements with OIG to avoid exclusions 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 FY 2008, the Government’s enforcement efforts resulted in 455 criminal actions and 337 civil actions against individuals or entities that engaged in health-care-related offenses. These efforts resulted in \$2.35 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 the notable enforcement



actions are described below. Summaries are organized by the sector of the health care industry involved or by the nature of the offense.

## **Pharmaceutical Manufacturers and Distributors**

■ **Pennsylvania** – Cephalon, Inc., entered a global criminal, civil, and administrative settlement under which the company agreed to pay a total of \$425 million plus interest; plead guilty to a misdemeanor violation of the Federal Food, Drug and Cosmetic Act; and enter into a comprehensive 5-year CIA with OIG. The civil settlement resolves allegations filed in four separate FCA qui tam cases, three of which were filed by former Cephalon sales representatives. The qui tam relators collectively alleged that between approximately January 2001 and December 2006, Cephalon promoted the drugs Actiq, Gabitril, and Provigil for “off-label” uses (that is, uses other than those approved by FDA). Cephalon’s off-label promotional practices involved a variety of techniques, including training its sales force to disregard restrictions of the FDA-approved label and promote the drugs for off-label uses. For example, Cephalon allegedly marketed Actiq for general pain treatment to internists and general practitioners, despite the fact that Actiq is an opioid approved only to treat cancer patients when their usual pain medication fails to control “breakthrough” episodes of extreme pain. In addition to the \$375 million civil settlement, Cephalon entered into a criminal plea agreement with the United States under which it will pay \$50 million.

The CIA between OIG and Cephalon contains several unique provisions. Cephalon must notify doctors about the settlement and establish a way for them to report questionable conduct by sales representatives. The CIA also requires Cephalon to post on its Web site information about payments made to physicians and requires increased accountability by Cephalon’s Board of Directors and management through an annual resolution by the Board and annual compliance-related certifications by managers. The CIA contains flexible audit provisions to allow Cephalon to substitute internal audits for certain independent review organization reviews.

■ **Pennsylvania and Louisiana** – Merck and Company (Merck), Inc., agreed to pay \$399 million plus interest to resolve its FCA liability in connection with certain discounting, pricing, and marketing practices associated with some of its drug products. Specifically, the United States alleged that Merck had established certain tiered discount programs, in effect between 1998 and March 2006, under which it offered hospitals deep discounts on Vioxx (no longer marketed), Zocor, and Mevacor. Under these so-called nominal price programs, hospitals that met certain market share requirements could purchase the Merck products at discounts of up to 92 percent off the AMP. The United States alleged that Merck failed to properly include the discounts in the “best prices” that are required to be reported to CMS under the Medicaid drug rebate program and, as a result, underpaid rebates owed to the States. The United States further contended that through this conduct, Merck overcharged covered entities that purchased Merck products under the 340B Drug Pricing Program, which limits the costs of certain outpatient prescription drugs to Federal entities and Federally Qualified Health Centers, such as community health centers and AIDS drug assistance programs that serve vulnerable

populations. Finally, the United States alleged that between January 1997 and December 2001, Merck sales representatives used approximately 15 different programs to induce physicians to use its drug products. These programs primarily consisted of excess physician payments that were disguised as fees paid to them for “training,” “consultation,” or “market research.” The Government alleged that these fees were, in fact, illegal kickbacks intended to induce the purchase of Merck drug products.

Merck agreed to pay \$399 million to settle this matter at the same time that it settled a separate FCA lawsuit filed in the Eastern District of Louisiana for \$250 million plus interest. The Louisiana matter involved similar discounted pricing programs offered to hospitals for another Merck drug, Pepcid. Merck allegedly offered incentives to hospitals to obtain the benefit of spillover business when patients continued to purchase Pepcid following their hospital stays. Through both settlements, Merck agreed to pay a total of \$649 million plus interest. Merck further agreed to enter into a 5-year CIA with OIG that includes corrective measures to address its conduct in both cases.

■ **Illinois** – Walgreens Co. (Walgreens) agreed to pay the United States, 42 States, and Puerto Rico \$35,214,026 to settle Medicaid prescription drug fraud claims. The qui tam complaint alleged that Walgreens substituted different forms of generic prescription drugs for others (such as tablets for capsules) solely to increase its reimbursement rate rather than for any legitimate medical reason. The drugs at issue were ranitidine (generic Zantac), fluoxetine (generic Prozac), and selegiline (generic Eldepryl). The Government alleged that Walgreens’ systematic substitution of more expensive forms of these drugs for less expensive, prescribed forms was motivated by its intent to avoid CMS’s Federal Upper Limit (FUL) on prices for the drugs and States’ maximum allowable costs (MAC) for the drugs. In addition to the monetary settlement, Walgreens entered into a 5-year CIA that requires an independent review organization to review its Medicaid reimbursement for generic drugs for which Government reimbursement is limited by FUL and MAC lists.

## **Hospitals**

■ **New York** – Staten Island University Hospital (SIUH) agreed to pay \$88,916,448 in a global settlement resolving allegations that it defrauded Medicare, Medicaid, and TRICARE (the military’s health insurance program). The global settlement resolves two separate lawsuits filed in the U.S. District Court for the Eastern District of New York and two Government investigations. As part of the global settlement, SIUH also entered into a 5-year CIA with OIG.

In the first lawsuit, a former director of SIUH’s Chemical Dependency Services alleged that SIUH fraudulently billed Medicaid and Medicare for inpatient alcohol and substance abuse detoxification treatment. The Government’s investigation established that, during the period July 1, 1994, through June 30, 2000, SIUH submitted claims for payment for treatment provided to patients in beds for which SIUH had received no certificate of operation from the New York State Office of Alcoholism and Substance Abuse Services

(OASAS) and concealed the existence of those beds from OASAS. SIUH has agreed to pay \$11,824,056 to the United States and \$14,883,883 to the State of New York.

In the second lawsuit, a widow of an SIUH cancer patient asserted that SIUH fraudulently billed Medicare for stereotactic body radiosurgery treatment (in which radiation beams are used to treat cancerous tumors noninvasively) that was provided on an outpatient basis to cancer patients. The investigation established that, from 1996 through 2004, SIUH knowingly used incorrect billing codes for this cancer treatment performed at the hospital, and thus obtained reimbursement for treatment that was not covered by Medicare or TRICARE. SIUH will pay the United States \$25,022,766 to settle this lawsuit.

Conduct uncovered by SIUH's self-disclosure was resolved prior to the filing of the lawsuits. Pursuant to OIG's Self-Disclosure Protocol, SIUH disclosed that its medical resident count in the 1996 to 2003 cost reports had been inflated. SIUH has agreed to pay the United States \$35,706,754 to settle this issue. The Medicare program uses the resident count in determining the share it pays of the cost of graduate medical education at teaching hospitals, such as SIUH.

The global settlement also addresses SIUH's billings to Medicare and Medicaid for treatment of psychiatric patients in unlicensed beds during the period July 2003 through September 2005. The hospital has agreed to pay the United States \$1,478,989 to settle this claim.

■ **Georgia** – Memorial Health, Inc., Memorial Health University Medical Center, Inc., Provident Eye Physicians, Inc., and Georgia Eye Institute, Inc. (GEI) (collectively, Memorial), agreed to pay \$5.08 million to resolve allegations of Medicare fraud. Memorial is a nonprofit corporation located in Savannah, Georgia. This settlement, stemming from a 2006 qui tam lawsuit regarding Memorial and its physicians, resolved allegations that, from January 1, 2003, through December 31, 2006, Memorial violated the Physician Self-Referral law through excessive payments made to its employee ophthalmologists. Memorial characterized such payments using terms such as “teaching stipends” or “indigent care” when the payments were, in fact, not entirely for such purposes.

In 2006, a former employee of GEI and Memorial filed a qui tam lawsuit alleging that Memorial engaged in activities with its physicians that violated the Anti-Kickback Statute and the Physician Self-Referral law. The ensuing investigation, however, found violations of the Physician Self-Referral law only. Specifically, the investigation determined that, from January 1, 2003, through December 31, 2006, Memorial violated the Physician Self-Referral law through excessive payments made to its employed ophthalmologists. Memorial characterized such payments using terms such as “teaching stipends” or “indigent care” when the payments were, in fact, not entirely for such purposes.

■ **Pennsylvania** – As the 20th hospital to settle under the 3-year-long “Operation Vampire” project, aimed at uncovering hospitals’ erroneous Medicare claims associated with blood transfusions, the University of Pennsylvania Health System (UPHS) agreed to pay the Government \$3,528,907. The Government alleged that, from January 2001 through December 2005, UPHS failed to follow Medicare requirements by submitting erroneous, separate, and distinct Medicaid payment claims for blood transfusions on bills that had more than one unit per day. Further, from January 2001 through December 2004, UPHS allegedly submitted fraudulent claims associated with office visits for new patients, as well as fraudulent claims for infusion therapy. Including this case, Operation Vampire recoveries total approximately \$12.5 million.

■ **Maine** – Henrietta Goodall Hospital agreed to pay \$1.15 million to resolve its FCA liability. The Government alleged that the hospital overbilled Medicare by improperly coding for the drugs Herceptin, Tenecteplase, and Paclitaxel.

## **Practitioners**

■ **Florida** – Dr. Fred Steinberg and his wholly owned imaging centers and related entities located in Palm Beach County, FL, agreed to pay \$7 million plus interest to resolve several allegations of health care fraud. Dr. Steinberg and his companies allegedly entered into financial relationships or arrangements with certain referring physicians which failed to meet the requirements of the Physician Self-Referral Law and/or violated the anti-kickback statute; submitted, or caused the submission of, claims of patients of the referring physicians to Medicare; billed Medicare for several diagnostic studies that were not performed, not ordered, or not medically necessary; and improperly billed Medicare for studies that should not have been billed separately while using improper codes for these studies. Dr. Steinberg, individually and on behalf of his imaging centers and related entities, entered into a 5-year CIA with OIG that includes an Arrangements Review.

■ **Illinois** – Dr. Ajit Trikha was sentenced to 30 months of imprisonment and was ordered to pay restitution in the amount of \$1,755,754 following his guilty plea to health care fraud. TRX Health Systems PC (TRX), Dr. Trikha’s business practice, was also ordered to pay a \$400 special assessment for mail fraud. Dr. Trikha, a psychiatrist, and TRX billed Medicare and Medicaid for individual psychotherapy, group psychotherapy, and pharmacologic management services that he did not render. In some cases, Dr. Trikha was, in fact, traveling outside of the United States on the claimed dates of service.

■ **Missouri** – St. Louis Eye Clinic (SLEC), an ophthalmology practice with 11 locations in the St. Louis area, and Dr. Krishnarao Rednam, an SLEC employee, agreed to pay \$251,551 and \$304,225, respectively, to settle allegations that Dr. Rednam submitted false claims to Federal health care programs. An investigation revealed that Dr. Rednam engaged in two types of fraud when providing eye injections for macular degeneration. First, Dr. Rednam injected patients with Macugen while billing Medicare for Avastin, a more expensive drug. Second, he split single-use vials of Lucentis into multiple doses. Furthermore, during the Government’s execution of a subpoena seeking the medical

records of patients receiving eye injections, Dr. Rednam destroyed medical records material to the Government's investigation. He pleaded guilty to obstruction of criminal investigations of health care offenses. Dr. Rednam agreed to be excluded from Federal health care programs for 5 years.

## **Durable Medical Equipment Suppliers**

■ **Texas** – Dr. Charles Skripka, Jr., one of five defendants convicted in a far-reaching Medicare fraud scheme, was sentenced to 78 months in prison and held responsible for \$6,562,186 in restitution. Dr. Skripka and three other defendants were convicted after a 6-week trial, and a fifth defendant pleaded guilty. The trial showed that Dr. Skripka and Dr. Jayshree Patel were paid by DME company owners to authorize motorized wheelchairs for beneficiaries who had no medical necessity for them, routinely approving wheelchairs for as many as 30 to 80 patients a day without performing a physical examination or ordering any medical tests. The trial also revealed that David Brown, a patient recruiter, promised beneficiaries free scooters, paid them \$50, and transported them to either Dr. Skripka or Dr. Patel. Brown testified that he paid Dr. Skripka and Dr. Patel up to \$1,000 for fraudulent certificates of medical necessity and prescriptions for motorized wheelchairs and then sold the fraudulent paperwork to DME company owners Pius Ekiko and Harold Iyalla. The DME company owners, who also paid the physicians for the fraudulent paperwork, in turn billed Medicare for motorized wheelchairs but delivered significantly less expensive scooters to the beneficiaries. In total, the five defendants were sentenced to more than 380 months' imprisonment and ordered to pay more than \$18 million in restitution.

■ **Florida and California** – The Medicare Fraud Strike Force (Strike Force) was launched in March 2007 as part of the South Florida Initiative, a joint investigative and prosecutive effort against health care fraud in South Florida. The Strike Force builds upon earlier phases of the multiagency and multidisciplinary initiative to combat Medicare fraud and abuse among DME suppliers and infusion providers. In its initial phase, infusion clinics and DME companies suspected of fraud were identified, investigated, and pursued for civil violations. Providers identified through these efforts were also investigated and pursued for criminal violations. The Strike Force is using real-time analysis of Medicare billing data, as well as findings from investigations, in its ongoing efforts to identify, investigate, and prosecute individuals and companies that have committed DME fraud. Based on the success of these efforts, a second phase of Strike Force operations began in Los Angeles in March 2008.

During this reporting period, the South Florida Initiative, including Strike Force efforts in South Florida, have resulted in 50 convictions and \$68.9 million in investigative receivables. Strike Force prosecutive efforts in Los Angeles are ongoing.

Examples of successful OIG efforts as part of the South Florida Initiative and the Strike Force during this semiannual period include the following:

■ Several DME company owners were sentenced for conspiring to defraud the Medicare program by submitting false claims for medically unnecessary DME items and supplies, including aerosol medications and oxygen concentrators. The case was predicated upon information obtained during an investigation of Dr. Zabby Westerburger, who had been convicted in 2006 of conspiracy to violate the anti-kickback and False Claims Act by agreeing to sign bogus prescriptions in return for kickbacks paid by the DME companies. The companies also paid kickbacks to several Medicare beneficiaries in order to use their Medicare numbers to submit the fraudulent claims. The 13 convicted DME company owners involved in the scheme were ordered to pay a total of more than \$6.4 million in restitution and \$132,000 in fines and assessments. The 13 subjects were also sentenced to various terms of imprisonment, probation, and/or home detention, the longest prison sentence for the case being 6 years and 6 months.

■ Mitzi Del Toro, owner and operator of DME company Alegria Medical Equipment, Inc. (Alegria), was sentenced to 1 year and 6 months in prison and ordered to pay \$437,118 in restitution for her involvement in a DME fraud scheme. Through Alegria, Del Toro used fraudulently obtained names and Medicare identification numbers of three physicians and Medicare identification numbers of beneficiaries for the purpose of submitting or causing the submission of false claims to Medicare for DME and related items or services purportedly provided to the beneficiaries. Alegria did not deliver, supply, or provide any legitimate health care items or services to Medicare beneficiaries. In executing her scheme, Del Toro purchased three fake invoices and three fraudulent prescriptions from coconspirators Maria E. German and Esteban M. Carabeo, who were sentenced to 18 and 6 months in prison, respectively, for their roles in the scheme.

■ The real owner and nominee owners of Miranda Medical Supplies (MMS) were sentenced for conspiracy to commit health care fraud. MMS billed Medicare for wound care, enteral nutrition products, and custom mattresses that were neither prescribed nor delivered. Angel Castillo, the real owner of MMS, was sentenced to 120 months' incarceration and ordered to pay \$764,714 restitution. Junior Dominguez, a nominee owner of MMS, was sentenced to 9 months' incarceration and 6 months' home detention and ordered to pay \$549,391 restitution. Jorge Miranda, also an MMS nominee owner, was sentenced to 5 months' incarceration and 5 months' home detention and ordered to pay \$100,437 restitution. After release from incarceration, Dominguez and Miranda are to be surrendered to the custody of Immigration and Customs Enforcement for removal proceedings. In a related FBI investigation, Castillo was eventually identified as the real owner of several other fraudulent DME companies and was sentenced to 235 months' incarceration and ordered to pay more than \$7 million in restitution.

## Clinics

■ **Mississippi** – Frank Wiley and Michael Yant owned and operated Canton Rehabilitation Services, Inc., which billed Medicare and Medicaid for fraudulently

rendered physical therapy services. The scheme involved the submission of claims purporting that the physical therapy services were rendered by a physician or a licensed physical therapist under the direct supervision of a physician, as required by Medicare. The services were in fact rendered by unlicensed, untrained, and unsupervised individuals. Wiley and Yant also owned and operated Mississippi Central Rehabilitation, Inc., which was operated in the same manner. Wiley and Yant were sentenced to 37 and 48 months in prison, respectively, and ordered to pay restitution in the amount of \$4,568,560.

### **Health Care Consultants**

■ **New Jersey** – Besler & Company, Inc., a health care consulting firm; its principal, Philip Besler; and related entities (collectively, Besler) agreed to pay \$2,875,000 to resolve allegations arising from two qui tam lawsuits, which alleged that Besler caused hospitals to falsely bill Medicare for excessive inpatient and outpatient outlier payments. Based on the ensuing investigation, the United States alleged that Besler advised hospitals to artificially inflate their cost-to-charge ratios, triggering outlier payments to which they were not entitled. OIG reserved its mandatory and permissive exclusion authorities against Besler.

### **Transportation Providers**

■ **Puerto Rico** – The Government secured a default judgment for \$6,267,313 against Flash Ambulance, Inc. (Flash), and Luis N. Romero-Mejias following allegations that the defendants violated the FCA by presenting, or causing to be presented, false or fraudulent claims to Medicare for nonemergency ambulance services. The case was predicated on an OIG audit of ambulance transport services in Puerto Rico that had identified potential false claims by Flash and Romero-Mejias.

■ **District of Columbia** – Leonard Young, owner of nonemergency transportation company Young Star Tours (YST), was sentenced to 1 year and 1 day in prison and 6 months' home detention and ordered to pay \$173,491 and forfeit \$37,950 previously seized from his bank accounts. YST billed DC Medicaid for 6,660 transportation services that he never provided.

### **Individuals**

■ **California** – Related to his involvement in a kickback scheme, Terry Hill was sentenced to 1 year and 1 week in prison and ordered to pay \$1,358,436 in restitution following his guilty plea to health care fraud. Acting as a capper (or recruiter), Hill was paid to recruit Medicare beneficiaries who were transported to a fraudulent medical clinic. Hill would pay the beneficiaries following the provision of medically unnecessary services, such as diagnostic testing. Natasha Walker, another capper in the scheme, was sentenced to 3 months' home detention and ordered to pay \$5,571 in restitution for her guilty plea to health care fraud. Additionally, Hill's mother, Gertha Green, was

sentenced to 6 months' home detention and ordered to pay \$2,829 in restitution for lying to Federal agents during the investigation.

■ **Ohio** – Joe Winston Langley, who pleaded guilty to aggravated identity theft, was sentenced to 2 years' imprisonment and ordered to pay \$155,485 in restitution, of which \$93,915 is owed to the Medicaid program. Langley stole the identity of a Texas resident approximately 20 years ago and, beginning in 1998, falsely represented his identity to the State of Ohio to receive Medicaid and public assistance benefits. When the identity theft victim became eligible for Medicare in 2004, Langley began using the stolen identity to incur charges that were paid by the Medicare program.

## Medicaid Fraud Control Units

MFCUs are key partners in the fight against fraud, waste, and abuse in State Medicaid programs. State MFCUs operate in 49 States and the District of Columbia pursuant to the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977 (P.L. No. 95-142) with the objective of strengthening the Government's capability to detect, prosecute, and punish fraud against Medicaid programs. MFCUs investigate and prosecute, or refer for prosecution, providers charged with defrauding the Medicaid program or abusing, neglecting, or financially exploiting beneficiaries in Medicaid-sponsored facilities.

Since 1979, OIG has been responsible for administering the Medicaid fraud control grant program and providing oversight and guidance to State MFCUs. This involves administering Federal financial grants to MFCUs, assessing the performance of MFCUs, and partnering with MFCUs in conducting joint investigations and other outreach work. During FY 2008, OIG provided oversight for and administration of approximately \$185 million in Federal grants that were distributed to the 50 MFCUs.

### Joint Investigations

■ **Indiana** – Varnador K. Sutton, the sole owner and operator of Regenerations, Inc. (Regenerations), purportedly a mental health counseling agency employing high- and mid-level psychologists and counselors, was sentenced to 120 months in prison and ordered to pay \$3,288,347 in restitution for health care fraud. An investigation revealed that Sutton and Regenerations billed for 84,000 psychotherapy services that were never rendered and used 2,500 separate Medicaid recipients' identities and benefits to defraud the Medicaid program. The investigation involved OIG, the FBI, and the Indiana MFCU.

In another case in Indiana, Jennifer Williams was sentenced to 30 months' imprisonment and ordered to pay \$79,000 in restitution following her guilty plea to charges of health care fraud and being a felon in possession of a firearm. Williams, the owner of A New Way Transportation, knowingly submitted approximately 5,000 claims to Medicaid as nonambulatory transports when, in fact, the majority of the beneficiaries transported were ambulatory. During the investigation, large amounts of marijuana and prescription narcotics were found. Additionally, a semiautomatic handgun was recovered. This



investigation involved OIG; the Bureau of Alcohol, Tobacco, Firearms, and Explosives; and the Indiana MFCU.

■ **Illinois** – Heartland Dental Care, Inc., a provider of management services to dental practitioners located throughout the United States, and Richard E. Workman (collectively, Heartland) agreed to pay the United States and the State of Illinois a total of \$1.65 million to resolve allegations that Heartland violated the Federal FCA and the Illinois FCA. Specifically, Heartland allegedly allowed dentists to call in prescriptions for Medicaid beneficiaries under other dentists’ Drug Enforcement Administration registration numbers, in violation of the Controlled Substances Act; billed Medicaid for nonsurgical tooth extractions as surgical tooth extractions; and billed Medicaid for crown buildups, which are noncovered services, as four-surface restorations or amalgams, which are covered services. In addition to the monetary settlement, Heartland entered into a 5-year CIA with OIG. The investigation involved OIG and the Illinois MFCU.

■ **Oregon** – Susan Ilene Pearson was sentenced to 39 months’ imprisonment and ordered to pay \$108,225 in restitution and fines after being convicted of making false claims and theft. A 3-day jury trial revealed that Pearson, an in-home caregiver paid with Medicaid funds, and her codefendant, Carolyn Elliott, a Medicaid recipient, engaged in a 7-year fraud scheme whereby Elliott would pretend to be disabled and Pearson would claim to be providing caregiver services to Elliott. Each month for 7 years, Elliott and Pearson would bill the State Medicaid program for phantom services provided by Pearson and then split the Medicaid payments. Elliott died 1 month before trial; charges against her were dismissed. The investigation involved OIG, the Social Security Administration, and the Oregon MFCU.



# Public Health and Human Service Programs and Departmentwide Issues

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

This chapter describes the Office of Inspector General's (OIG) work related to the following areas:

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

- The Centers for Disease Control and Prevention (CDC) operates a system of health surveillance to monitor and prevent disease outbreaks, including those that would result from acts of bioterrorism; implements disease-prevention strategies; and maintains national health statistics.
- The Food and Drug Administration (FDA) is responsible for ensuring the safety of the Nation's food, drugs, medical devices, biologics, cosmetics, and animal food and drugs and for ensuring the efficacy of the Nation's drug, medical device, biologics, and animal drugs.
- The Health Resources and Services Administration (HRSA) maintains a safety net of health services for people who have low incomes, are uninsured, or live in rural areas or urban neighborhoods where health care is scarce.
- The Indian Health Service provides or funds health care services for 1.6 million Native Americans and Alaska Natives.
- The National Institutes of Health (NIH) supports medical and scientific research examining the causes of and treatments for diseases such as cancer and HIV/AIDS.

- The Substance Abuse and Mental Health Services Administration funds services to assist people with or at risk for mental and substance abuse disorders.

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

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

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

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

# Reports Related to Public Health Programs

## The Food and Drug Administration's Generic Drug Review Process

In our review of generic drug applications reviewed by FDA in 2006, we determined that FDA had opportunities to better manage current reviews and to potentially increase the number of submissions reviewed and approved within 180 days. To market a generic drug, which is the same as the brand name drug with respect to key qualities such as conditions of use and active ingredient(s), a pharmaceutical company must obtain FDA's approval of an Abbreviated New Drug Application (ANDA). FDA is required by Federal law to approve or disapprove an original ANDA within 180 days of receipt. The agency had a 74-percent increase in funding for the generic drug program between FYs 2001 and 2006 and experienced a 158-percent increase in original applications during this period.

Three divisions within FDA's Office of Generic Drugs (OGD) review ANDAs: Chemistry, Bioequivalence, and Labeling. A fourth division, Microbiology, reviews a subset of ANDAs. Almost all original ANDAs contain deficiencies identified by the Division of Chemistry and are disapproved. Based on our examination of review times for 989 original ANDAs under review during 2006, a survey of OGD division reviewers assigned to a sample of 105 ANDAs with review times greater than 180 days, and structured interviews with OGD officials, our findings included the following:

- Of the original ANDAs that FDA reviewed in 2006, 96 percent did not meet review standards and were disapproved.
- FDA exceeded the 180-day statutory review requirement for nearly half of the ANDAs under review in 2006 because the reviews by the Division of Chemistry exceeded this timeframe.
- Microbiology, Bioequivalence, and Labeling reviews of the original ANDAs usually exceeded the 180-day review period.
- Seventy percent of sampled division reviews that exceeded 180 days did not begin before the 180-day review period ended.
- OGD's divisions did not consistently classify or prioritize amendments, nor did they consistently assign high priority to approvable ANDAs.

We recommended that FDA identify common ANDA deficiencies and offer more guidance to industry to decrease the percentage of disapproved original ANDAs, increase the percentage of original ANDAs that are reviewed by all divisions within 180 days, and implement new prioritization practices.

In its comments on our draft report, FDA indicated that it was implementing process improvements that were in line with our recommendations. It agreed with our first

recommendation but did not indicate concurrence with the other two. FDA stated that it was continuing to alter the review process to reduce queue times and ensure that original ANDAs are reviewed within 180 days. Consistent with our recommendation regarding offering more industry guidance, FDA stated that it had provided various forms of guidance aimed at making applications easier to review. Other process improvement efforts FDA cited included developing a hiring program to increase staff and decrease review times and prioritizing some ANDAs based on potential market entry dates. (OEI-04-07-00280)

### **National Cancer Institute's Monitoring of Research Project Grants**

In our review of grants funded by the National Cancer Institute (NCI) for at least 1 year during FY 2004 through FY 2006, we found that all grant files had the required progress reports and evidence of agency review; however, 41 percent of the progress reports were not received within the required timeframes. NCI, which is a part of NIH, funded more than 4,500 grants totaling \$3 billion during the period of our review to support research into the causes, diagnosis, prevention, or treatment of cancer. NCI is responsible for monitoring its grants, and grantees are required to submit progress and financial reports.

We also found the following:

- Grantee financial reports were not monitored at the same level as the progress reports.
- Five of the nine grant closeouts in our sample were not completed within timeframes specified in departmental guidelines.
- Grant files did not always have the required documentation for third-party review of grant files.

We recommended that NIH initiate earlier and more frequent followup with grantees to obtain required documents, improve grant monitoring by annually verifying grantees' self-reported fund balances with external sources, develop an approach for financial reviews that is not based solely on exceptions, and consistently document grantee correspondence and organize grant files to assist NCI staff and third-party reviewers in following grantees' actions from inception of the grant to closeout. In its written comments to the report, NIH generally agreed with our recommendations and described actions it planned to take to improve its monitoring of research grants. (OEI-07-07-00120)

### **Superfund Financial Activities at the National Institute of Environmental Health Sciences**

In our review of Superfund financial transactions at the National Institute of Environmental Health Sciences (NIEHS) for FY 2007, we found that the transactions were allowable, allocable, and reasonable in accordance with applicable laws and regulations. NIEHS receives Superfund funding to train people who handle hazardous waste and manage hazardous waste facilities and to conduct research on the effects of

hazardous substances on human health. We conducted this audit pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, which requires the inspector general of a Federal organization with Superfund responsibilities to audit all uses of the Superfund. Our report contained no recommendations. (A-04-08-01057)

## **Actions and Investigations Related to Public Health Programs**

OIG excludes from participating in Federal health care programs individuals who fail to repay HHS-secured educational loans, and investigates specific allegations of fraud, waste, and abuse affecting public health and human service programs. These investigations are often complex and can include allegations of misuse or theft of grant funds, conflict of interest, and kickbacks.

The following paragraphs provide descriptions and statistics related to these efforts.

### **Health Education Assistance Loan Defaults**

OIG excludes from participating in Federal health care programs individuals who have defaulted on loans obtained through the Health Education Assistance Loan (HEAL) program. Through the HEAL program, HRSA guarantees commercial loans to students seeking education in health-related fields of study. The students are allowed to defer repayment of the loans until after they have graduated and begun to earn an income. Although the Department's PSC takes steps to ensure repayment, some loan recipients ignore their indebtedness.

After PSC has exhausted efforts to secure repayment of a debt, it declares an individual in default. Thereafter, the Social Security Act permits, and in some instances mandates, exclusion from Medicare, Medicaid, and all 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, nine individuals and related entities were excluded as a result of PSC referral of their cases to OIG.

Individuals who have been excluded as a result of default may enter into settlement agreements whereby the 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 cannot appeal the exclusions. Some health professionals, upon being notified of their exclusion, immediately repay their HEAL debts.

After being excluded for nonpayment of their HEAL debts, 2,153 individuals have taken advantage of the opportunity to enter into settlement agreements or completely repay their debts. That figure includes the 25 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 \$156.1 million. Of that amount, \$2.8 million is attributable to this reporting period.

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

- **Texas** – Podiatrist Walter H. Williams: \$432,651
- **Ohio** – Dentist Mychael E. Davis: \$136,770
- **Michigan** – Medical doctor Carlton E. Little: \$105,910
- **California** – Psychologist Susan L. Boulware: \$102,225

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

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

■ **Select Agents and Toxin** – A Texas university agreed to pay \$1 million to resolve its liability for numerous violations of the select agent regulations. OIG’s allegations included the following: failure of the university’s responsible official (RO) to apply for an amendment to the university’s certificate of registration; failure of the RO to receive the necessary approval before university researchers conducted aerosolization experiments with select agents; failure of the RO to be familiar and ensure compliance with the requirements of the select agent regulations; failure of the RO to ensure that deficiencies identified during annual inspections were corrected; failure to obtain CDC approval to conduct restricted experiments with a select agent; allowing researchers, on multiple occasions, to have access to select agents without prior CDC approval and without having the appropriate education, training, and/or experience to handle or use select agents; failure to investigate whether elevated titers of three laboratory workers were caused by occupational exposure to a select agent; failure to ensure that appropriate biosafety and security plans were implemented; failure to ensure that laboratory personnel were trained in biosafety and security; failure to maintain a current list of individuals with access to select agents and toxins; failure to keep records of access to at least seven laboratory rooms where select agent work was conducted; failure to implement an accurate record-keeping system for its select agent inventory; and failure to report occupational exposures to select agents.



# Reports Related to Human Service Programs

## Philadelphia County's Title IV-E Claims

In our review of Pennsylvania's claims for Title IV-E reimbursement on behalf of Philadelphia County children for whom the per diem rates were \$300 or less, we estimated that from October 1997 through September 2002, the State improperly claimed at least \$56.5 million of the total \$562.3 million (Federal share) claimed. Title IV-E of the Social Security Act, as amended, authorizes States to claim Federal funding for foster care maintenance costs through ACF. The funding covers room and board payments to licensed foster care providers, administrative costs, and training.

Our findings included the following:

- Of the 30 improper claims in our sample, 27 included costs for services provided to children whose situations did not meet eligibility requirements or provided by unlicensed foster care facilities.
- For 16 other sampled claims, we were unable to determine the allowability of the costs claimed because the contractors' per diem rates did not distinguish between services that were eligible and ineligible for Title IV-E reimbursement.

We recommended that the State refund \$56.5 million and work with ACF to determine the allowability of \$100 million related to claims that included both allowable and unallowable services; 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 ineligible children and services and unlicensed facilities; 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 our findings and recommendations and provided additional documentation on some of the claims. Based on this documentation, we revised the report. (A-03-07-00560)

## Improper Payments for Temporary Assistance for Needy Families Payments

In our reviews of three States' TANF basic assistance payments, we sampled payments for the period April 1, 2006, through March 31, 2007, to estimate the payment error rates associated with noncompliance with Federal and State eligibility, payment, and documentation requirements. TANF is a block grant program that provides funding to States to help families move from welfare to self-sufficiency; TANF's basic assistance includes benefits designed to meet a family's ongoing basic needs. These reviews, part of an eight-State series, were requested by ACF and the Office of Management and Budget (OMB) to determine the FY 2008 national TANF error rate. Pursuant to the Improper Payments Information Act of 2002 (P.L. No. 107-300), Federal agencies must

estimate and report to Congress on the annual amount of improper payments in their high-risk programs.

■ **California** – We estimated that the overall TANF improper payment rate was 5.7 percent of the Federal dollars expended and 11.3 percent of the number of basic assistance payments made for the 1-year audit period. These improper payments totaled an estimated \$91.6 million (Federal share). The payments were improper because they were made to families who were ineligible for TANF basic assistance, were calculated improperly, or did not have required documentation.

We recommended that the State use the results of this review to help ensure compliance with Federal and State TANF requirements, follow State law and guidance by ensuring that recipients are experiencing hardship when extending TANF basic assistance payments beyond the 60-month Federal lifetime limit, 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 identified recipients who received improperly calculated payments. The State disagreed with the second recommendation but agreed with the others. (A-09-07-00087)

■ **Michigan** – We estimated that the overall TANF improper payment rate was 24.3 percent of the Federal dollars expended and 22.7 percent of the number of basic assistance payments made for the 1-year audit period. These improper payments totaled an estimated \$24 million (Federal share). The payments were improper because they were made to families who were ineligible for TANF basic assistance, were calculated 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 identified recipients who received improperly calculated payments. In its comments on our draft report, the State provided information on steps that it had taken or planned to take to implement the recommendations. (A-05-07-00067)

■ **Ohio** – We estimated that the overall TANF improper payment rate in Ohio was 21.1 percent of the Federal dollars expended and 20 percent of the number of basic assistance payments made for the 1-year audit period. These improper payments totaled an estimated \$44.1 million (Federal share). The payments were improper because they were made to families who were ineligible for TANF basic assistance, were duplicated or improperly calculated, or lacked required documentation.

We recommended that the State use the results of this review to help ensure compliance with Federal and State TANF requirements, determine the current eligibility of all recipients identified in this review as improperly enrolled in the TANF program and

ensure that further assistance is denied for those who remain ineligible, and recalculate assistance budgets for all identified recipients who received improperly calculated payments. In its comments on our draft report, the State provided information on steps that it had taken or planned to take to implement the recommendations. (A-04-07-03520)

### **Title IV-E Adoption Assistance Costs in Rhode Island**

In our review of Rhode Island's claims for high-dollar adoption assistance payments (claims in excess of \$3,700) for State fiscal years (SFY) 2003–2005, we determined that the State overclaimed \$2.7 million for cases that did not meet applicable requirements. Under Title IV-E of the Social Security Act, the Federal Government, through ACF's foster care and adoption assistance programs, shares in the States' costs of adoption assistance payments for children who meet Supplemental Security Income (SSI) requirements or other specific requirements.

During Rhode Island's SFYs 2003–2005, the State claimed approximately \$19.6 million (Federal share) in Title IV-E adoption assistance payments on its Federal quarterly expenditure reports; in SFY 2003, 996 of these payments were for more than \$3,700 each. We determined that of these high-dollar adoption assistance payments, the State had not met Federal reimbursement requirements for SFY 2003 payments totaling \$954,000 and continued to claim payments for many of these cases, totaling \$1.8 million in SFYs 2004–2005.

We recommended that the State make a financial adjustment of \$470,000 for children who did not meet Aid to Families with Dependent Children income eligibility requirements, work with ACF to resolve \$2.2 million in overpayments for children who did not meet requirements for voluntary placement agreements or judicial determinations, and review adoption assistance payments claimed after our audit period to ensure compliance with Federal requirements. The State concurred with our findings and recommendations. (A-01-07-02503)

### **Child Safety and Financial Management at a Head Start Grantee**

In our review of a Head Start grantee's compliance with Federal and State requirements regarding the safety of children in its care and the management of and accounting for Federal funds, we found that from September 1, 2006, through October 23, 2007, the grantee had not fully complied with requirements in these areas. The grantee provided educational and daycare services to more than 1,200 children in Rhode Island. Based on our preliminary findings of this ACF-requested audit, the grantee's funding was suspended in October 2007—a decision that the Departmental Appeals Board upheld in January 2008. Our specific findings were as follows:

- **Safety** – The grantee failed to follow fire inspection requirements at four of its eight childcare centers and did not always comply with Federal and State requirements for preemployment background checks. These weaknesses jeopardized the safety of children in the grantee's care.

■ **Financial management systems** – The grantee’s financial management systems did not meet Federal requirements for separately tracking the costs incurred for activities related to various programs. As a result, we were unable to verify that the grantee had met Head Start funding requirements. In addition, the grantee did not have written policies and procedures, as required, to ensure compliance with fiscal controls related to segregation of duties, inventory of assets, and prior ACF approval of obligations not included in a construction project.

Because ACF had suspended the grantee’s funding indefinitely, we did not make any recommendations to the grantee but instead provided this report to assist ACF in its oversight role. (A-01-07-02505)

### **Undistributable Child Support Collections**

In our review of three States’ reporting of program income from undistributable child support collections and interest earned on collections, we found that the States had not fully complied with Federal requirements. Within ACF, the Office of Child Support Enforcement (OCSE) Oversees the Child Support Enforcement program. OCSE requires States to offset program costs by recognizing and reporting income from undistributable child support collections and interest earned on 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. The results of these reviews were as follows:

■ **California** – From October 1998 through March 2006, California did not recognize or report program income totaling \$2.2 million (\$1.5 million Federal share) for Orange County’s undistributable child support collections and interest earned on child support collections. We determined that the State had not sufficiently monitored the county’s unclaimed collections and that the county had focused its resources on processing current child support collections.

We recommended that the State monitor the county’s progress in resolving the status of unclaimed child support collections and report as program income those collections recognized as abandoned; undistributable collections that the county had already recognized as abandoned; and interest earned on child support collections. In commenting on our draft report, the State concurred with the findings and described steps that it was taking to address the recommendations. (A-09-06-00040)

■ **Mississippi** – From October 1998 through June 2006, the State did not report program income totaling \$927,000 (\$612,000 Federal share) from undistributable child support collections; it also did not recognize or report program income totaling \$95,000 (\$63,000 Federal share) from interest earned on child support collections. During that period, the State should have reported the undistributable collections because the funds met the State’s definition of abandoned property. However, the State believed that the funds were exempt from its abandoned property laws. After submitting comments on our draft

report, the State provided information to us indicating that it had distributed \$526,000 of the \$927,000 in undistributable collections that we had identified.

We recommended that the State report as program income the balance of undistributable child support collections totaling \$927,000 (\$612,000 Federal share), or \$401,000 (\$265,000 Federal share); recognize and report program income totaling \$95,000 (\$63,000 Federal share) for interest earned on child support collections; ensure compliance with State laws regarding abandoned property; and implement procedural improvements. The State did not specifically address our recommendations. (A-04-07-03515)

■ **Texas** – From October 1998 through March 2006, the State did not report program income of up to \$2.2 million (\$1.4 million Federal share) from undistributable child support collections and interest earned on collections by the State and nine county child support offices. These deficiencies occurred because the State did not have adequate procedures to ensure that it reported program income for all undistributable child support collections and interest earned on collections by the State and the counties.

We recommended that the State work with OCSE and the county child support offices to determine the Title IV-D portion of the \$2.2 million (\$1.4 million Federal share) in undistributable collections and interest earned and report the amount as program income, and that the State review the county child support offices that we did not review to ensure that undistributable child support collections and interest earned on collections were reported as program income. The State generally disagreed with our findings and recommendations but did not provide any additional information to substantiate revisions to our findings and recommendations. (A-06-06-00088)

### **Iowa Child Care and Development Funds**

In our review of Iowa's claims for Child Care and Development Fund (CCDF) targeted funds for FYs 1998–2003, we found that the State had not complied with Federal requirements when claiming almost \$3.2 million. The CCDF, which is administered by ACF, assists low-income families in obtaining childcare so that family members can work or receive training or education. The program provides targeted discretionary funding for certain activities to improve the availability, quality, and affordability of childcare and to support the administration of these activities.

We found that the State had not:

- refunded to the Federal Government unliquidated targeted funds,
- returned funds to the Federal Government when it terminated a contract and transferred funds to a successor contractor after the obligation period for the funds had expired,
- limited cash advances to the contractor to the minimum amounts needed, or

- remitted \$155,000 of interest earned by the contractor on advanced CCDF targeted funds, as required.

We recommended that the State refund \$3.2 million of unexpended CCDF targeted funds; remit \$155,000 of interest earned on the funds; ensure that CCDF targeted funds are disbursed in accordance with Federal requirements in the future; and review CCDF targeted funds claimed after the audit period and refund any unallowable amounts. The State agreed with all but our first recommendation; it did not provide any additional information to substantiate our changing the recommended refund. (A-07-07-00231)

## Child Support Enforcement

The detection, investigation, and prosecution of noncustodial parents who fail to pay court-ordered child support are priorities for OIG. OIG works closely with the Office of Child Support Enforcement (OCSE); the Department of Justice (DOJ); U.S. Attorneys' Offices; the U.S. Marshals Service; and other Federal, State, and local partners to expedite the collection of child support.

### Task Forces

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

### Child Support Investigations

OIG investigations of child support cases, nationwide, resulted in 41 convictions and court-ordered restitution and settlements of \$2.3 million during this semiannual period. Examples of OIG's enforcement results for failure to pay child support include the following:

- **Nevada** – Charles Thurman was sentenced to 5 years of probation and ordered to pay \$66,639 in restitution for failure to pay child support. As a condition of probation, Thurman must serve 10 months of home confinement with electronic monitoring. Throughout a 15-year period, Thurman made only two voluntary payments, yet he owned and operated a law enforcement/emergency vehicle equipment installation business earning more than \$4,000 monthly and owned a residential property with more than \$100,000 in equity. A lien has been placed on Thurman's residential property.

■ **Indiana** – Pursuant to his guilty plea, Michael Stacy was sentenced to 8 years’ incarceration, with 4 years suspended and 4 years of probation, and was ordered to pay \$58,495 in total restitution for failure to pay child support in two separate cases. Stacy owed child support arrearages in the amounts of \$33,617 and \$24,878.

■ **Michigan** – Mark Rocha was sentenced to 5 years of probation and ordered to pay \$57,275 in restitution for failure to pay child support. Rocha was arrested in February 2008 at his New Bedford, Massachusetts, employer; made his initial appearance in Rhode Island; and was ordered to appear in Michigan for a hearing. In March 2008, Rocha appeared in court, pleaded guilty, and was sentenced.

## **Misuse of Administration for Children and Families Grant Funds**

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

■ **Iowa** – The State of Iowa Attorney General Office, on behalf of Iowa Workforce Development (a State agency), agreed to pay \$1.3 million to resolve a civil matter pertaining to fraudulent use of HHS and Department of Labor (DOL) funds provided to the State agency. The settlement amount consisted of \$341,643 in fraudulent TANF expenditures, \$925,510 in fraudulent DOL expenditures, and \$32,847 in settlement costs imposed on the State that will be paid to the general Federal Treasury fund. This civil investigation stemmed from a criminal investigation that had determined that top executives at a job training grantee, with the assistance of governing board officials and a State employee, fraudulently used TANF and DOL funds to pay excessive bonuses to top grantee executives, salaries to employees while the employees spent official worktime at casinos, and personal expenses for the top executives.

■ **Ohio** – Vincent E. Beacon was sentenced to 27 months of imprisonment and ordered to pay \$557,650 in restitution for the misuse of grant funds awarded to the Beacon Agency by ACF to provide foster care services. The Beacon Agency, a nonprofit agency owned by Beacon, was founded in 1989 and had an annual operating budget of \$6 million. Beacon admitted to fraudulently diverting money from the Beacon Agency into a for-profit business that he controlled, called Business Solutions of America. Between 1998 and 2004, the Beacon Agency paid Business Solutions of America for rent and equipment that Beacon claimed were necessary to provide foster care services. In reality, most of these costs were fraudulent, and the money was eventually routed to personal investment accounts owned by Beacon. In addition, he concealed his ownership in the business and provided false documents to the State auditor, as well as to his own independent auditor, whom he hired to conduct yearly compliance audits as required by the State of Ohio.

## Reports Related to Departmentwide Issues

### Use of Discounted Airfares by the Office of the Secretary

In our review of airfares used by Office of the Secretary (OS) travelers during FY 2006, we found that discounted airfares were used for only 16 percent of the trips for which both standard and discounted fares were potentially available, as compared with a 50-percent use of discounted fares governmentwide. Travelers were required to use contracted airfares—a discounted fare (referred to as the “standard” fare) and a highly discounted fare (referred to as the “discounted” fare)—established through the General Services Administration (GSA); it was not until the end of the audit period, in September 2006, that GSA revised its Federal Travel Regulation to require travelers to use the discounted fare, rather than the standard fare, when available. We calculated that OS, which spent approximately \$4 million for employee airfare during FY 2006, could have saved \$530,000 if OS travelers had used all available discounted fares.

We recommended that OS educate its travelers and administrative staff on how to identify and select discounted fares and work with GSA to clarify the display of flights and fares in its automated system. OS concurred with our recommendations. (A-03-07-00500)

### 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 that expend \$500,000 or more in Federal awards must conduct annual organizationwide “single audits.” These audits are conducted by non-Federal auditors, such as public accounting firms and State auditors. OIG reviews the quality of these audits and assesses the adequacy of the entity’s management of Federal funds. In FY 2008, OIG’s National External Audit Review Center reviewed 1,232 reports that covered \$441 billion in audited costs. Federal dollars covered by these audits totaled \$115 billion, about \$53.5 billion of which was HHS money.

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

OIG maintains a quality control review process to assess the quality of the non-Federal reports it receives 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 on the following page.



|  |              |
|--|--------------|
| <b>Reports issued:</b>                       |              |
| <b>Without changes or with minor changes</b> | 1,050        |
| <b>With major changes</b>                    | 157          |
| <b>With significant inadequacies</b>         | 25           |
| <b>Total</b>                                 | <u>1,232</u> |

The 1,232 reports included 4,731 recommendations for improving management operations. In addition, these audit reports provided information for 93 special memorandums 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\***

| <b>Reports</b>   | <b>Number of Reports</b> | <b>Dollar Value Questioned</b> | <b>Dollar Value Unsupported</b> |
|--|--------------------------|--------------------------------|---------------------------------|
| <b>Section 1</b>   |                          |                                |                                 |
| For which no management decision had been made by the beginning of the reporting period <sup>1</sup> | 170                      | \$1,264,946,000                | \$51,107,000                    |
| Issued during the reporting period   | 93                       | \$268,267,000                  | \$12,085,000                    |
| <b>Total Section 1</b>   | 263                      | \$1,533,213,000                | \$63,192,000                    |
| <b>Section 2</b>   |                          |                                |                                 |
| For which a management decision was made during the reporting period <sup>2 3</sup>                  |                          |                                |                                 |
| Disallowed costs   | 111                      | \$274,982,000                  | \$28,505,000                    |
| Costs not disallowed   | 2                        | \$753,000                      | \$0                             |
| <b>Total Section 2</b>   | 113                      | \$275,735,000                  | \$28,505,000                    |
| <b>Section 3</b>   |                          |                                |                                 |
| For which no management decision had been made by the end of the reporting period                    |                          |                                |                                 |
| <b>Total Section 1 minus Total Section 2</b>   | 150                      | \$1,257,478,000                | \$34,687,000                    |
| <b>Section 4</b>   |                          |                                |                                 |
| For which no management decision was made within 6 months of issuance <sup>4</sup>                   | 77                       | \$999,529,000                  | \$99,953,000                    |

\*Supporting notes and list of reports are in Appendix B.

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

| <b>Reports</b>   | <b>Number of Reports</b> | <b>Dollar Value</b> |
|--|--------------------------|---------------------|
| <b>Section 1</b>   |                          |                     |
| For which no management decision had been made by the beginning of the reporting period <sup>1</sup> | 24                       | \$1,378,519,000     |
| Issued during the reporting period   | 24                       | \$1,438,961,000     |
| <b>Total Section 1</b>   | 48                       | \$2,817,480,000     |
| <b>Section 2</b>   |                          |                     |
| For which a management decision was made during the reporting period                                 |                          |                     |
| Value of recommendations agreed to by management   |                          |                     |
| Based on proposed management action  | 12                       | \$60,301,000        |
| Based on proposed legislative action   | 0                        | \$0                 |
| Value of recommendations not agreed to by management   | 1                        | \$65,000            |
| <b>Total Section 2</b>   | 13                       | \$60,366,000        |
| <b>Section 3</b>   |                          |                     |
| For which no management decision had been made by the end of the reporting period <sup>2</sup>       |                          |                     |
| <b>Total Section 1 minus Total Section 2</b>   | 35                       | \$2,757,114,000     |

\*Supporting notes and list of reports are in Appendix B.

## Regulatory Development

OIG is responsible for the development and publication of a variety of sanction regulations addressing civil monetary penalties (CMP) and program exclusion authorities administered by the Inspector General, 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 CFR Part 1003, which sets forth OIG's regulatory authorities for imposing CMPs and assessments. We published a final rulemaking to implement electronic payment of fees owed for OIG advisory opinions.

In addition, OIG periodically publishes Federal Register (FR) notices that, among other things, offer guidance to alert program beneficiaries, health care providers, and other entities about potential problems or areas of special interest. We published in the FR a draft OIG Supplemental Compliance Program Guidance for Nursing Facilities (74 Fed. Reg. 20680 (Apr. 16, 2008)).

We also published the following FR notices:

- Privacy Act of 1974, New OIG Privacy Act System of Records: Administrative Files (66 Fed. Reg. 18532 (Apr. 4, 2008)).
- Privacy Act of 1974, New OIG Privacy Act System of Records: Litigation Files (73 Fed. Reg. 20311 (Apr. 15, 2008)).
- Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by OIG (138 Fed. Reg. 40982 (Jul. 17, 2008)).

## Employee Fraud and Misconduct

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

- **District of Columbia** – Raymond Jackson, a former commander in the Public Health Service, was sentenced to 24 months' incarceration and ordered to pay \$150,882 in restitution for theft or embezzlement in connection with health care. While working as the chief pharmacist at St. Elizabeth's Hospital, Jackson stole prescription drugs from the hospital, then sold the drugs through a pharmaceutical company he owned with his wife, Brenda. Brenda, who was prosecuted by the State of Maryland, stole more than \$150,000 worth of drugs from her former employer, Kaiser Permanente.

# Appendixes



## Appendix A: Savings Achieved Through Implementation of Recommendations in Audits and Evaluations for Fiscal Year 2008

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

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

Total savings projected to accrue in fiscal year (FY) 2008 from legislative and administrative actions related to OIG recommendations amounted to \$16,722.7 million (\$16.7 billion).

| OIG Recommendation  | Implementing Action  | Savings (millions) |
|---|--|--------------------|
| <b>Centers for Medicare &amp; Medicaid Services (CMS)</b>   |  |                    |
| <b>State-Enhanced Payments Under Medicaid Upper Payment Limit Requirements:</b><br>CMS should move as quickly as possible to issue regulatory changes to the upper payment limit (UPL) rules governing enhanced payments to local government providers. (A-03-00-00216) | On January 12, 2001, CMS issued revisions to the UPL regulations that, among other things, created new payment limits for local government-owned providers. This final rule significantly affects a State's ability to reap windfall revenues by reducing the available funding pool from which to make enhanced payments to local government-owned providers. | \$6,900            |

| <b>OIG Recommendation</b>   | <b>Implementing Action</b>  | <b>Savings (millions)</b> |
|---|---|---------------------------|
| <p><b>Medicaid Enhanced Payments to Local Providers:</b><br/>           CMS should reconsider capping the aggregate UPL at 100 percent for all facilities, rather than the 150-percent allowance for non-State-owned Government hospitals. (A-03-00-00216)</p>  | <p>CMS issued a final rule that modified the Medicaid UPL provisions to remove the 150-percent UPL for services furnished by non-State-owned or -operated hospitals. The rule became effective in spring 2002.</p>  | <p>\$2,900</p>            |
| <p><b>Medicare Outlier Payments:</b><br/>           To prevent future inappropriate outlier payments, CMS should focus its attention on the following: (1) determining how to limit, if not eliminate, the policy that allows for the use of the statewide rate in place of a hospital-specific rate; (2) dramatically reducing the time lag between the payment of outliers and the actual closing of a specific hospital's cost report, particularly with regard to the hospitals identified by the fiscal intermediary as having significantly increased their charges; and (3) eliminating the hospitals' ability to construct and manipulate charges to determine whether an outlier payment is warranted in a specific medical case without regard to the actual costs involved in that case. (A-07-02-04007)</p> | <p>CMS issued new regulations in summer 2003. The new regulations restricted the use of the statewide rate, reduced the time lag between the payment of outliers and the closing of a hospital's cost report, and established a reconciliation process for outlier calculations that prevented hospitals from benefiting from manipulating their charges. As a result of these regulations, it is estimated that the Medicare program will save at least \$9 billion from 2004 to 2008.</p>   | <p>\$1,800</p>            |
| <p><b>Payment Reform for Part B Drugs and Biologicals:</b><br/>           CMS should reexamine drug reimbursement methodologies based on average wholesale price (AWP) with the goal of reducing payments in both Medicare and Medicaid. (Multiple reports and congressional testimony, including OEI-03-96-00420; OEI-03-97-00290; OEI-03-00-00310; OEI-03-97-00293; A-06-00-00023; A-06-01-00053; A-06-02-00041)</p>  | <p>Sections 303 through 305 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) revised the current payment methodology for Part B-covered drugs and biologicals that were not paid on a cost or prospective payment basis. Under the MMA, most drugs were to be paid at 85 percent of the April 1, 2003, AWP effective January 1, 2004, through December 31, 2004, unless they meet certain exceptions. CBO specifically attributed the FY 2004 savings to sections 304 and 305. Since January 1, 2005, most drug prices have been based on the average sales price or competitive acquisition instead of AWP.</p> | <p>\$1,300</p>            |
| <p><b>Medicare Secondary Payer:</b><br/>           CMS should ensure sufficient resources and contractor training for retroactively examining paid claims to identify other payer sources and initiating recovery action on all related overpayments. (Multiple reports and testimonies, including A-02-98-01036; A-04-92-02057; A-09-89-00162; A-10-86-62005)</p>  | <p>Section 301 of the MMA clarifies the Secretary's authority to make certain reimbursable conditional payments and to take recovery actions against all responsible entities, including collection of damages, under Medicare Secondary Payer (MSP) provisions. This section builds on other program improvements related to OIG's work that were implemented by the Balanced Budget Act (BBA), Omnibus Budget Reconciliation Act (OBRA) 1993, OBRA 1990, and OBRA 1989.</p>   | <p>\$900</p>              |



| <b>OIG Recommendation</b>  | <b>Implementing Action</b>  | <b>Savings (millions)</b> |
|--|---|---------------------------|
| <p><b>Clinical Diagnostic Laboratory Tests:</b><br/>           CMS should seek legislation to allow across-the-board adjustments in Medicare laboratory fee schedules, bringing them in line with the prices that laboratories charge physicians in a competitive marketplace, and periodically evaluate the national fee schedule levels. (A-09-89-00031; A-09-93-00056)</p>                  | <p>Section 628 of the MMA froze annual updates for FY 2004 through FY 2008. This action builds on prior legislative actions in the BBA, OBRA 1993, OBRA 1990, and legislation in 1984 that were also responsive to OIG's recommendations to curb excessive clinical laboratory test reimbursements by Medicare.</p>   | \$800                     |
| <p><b>Payments for Durable Medical Equipment:</b><br/>           CMS should take steps to reduce payments for a variety of durable medical equipment (DME) and related supplies. (Multiple reports, including OEI-03-01-00680; OEI-03-02-00700; OEI-07-96-00221; OEI-03-96-00230; OEI-03-94-0021; OEI-06-92-00861; OEI-06-92-00866)</p>  | <p>Section 302 of the MMA froze payments for certain DME items, including prosthetics and orthotics, effective January 1, 2004.</p>   | \$700                     |
| <p><b>Medicare Home Health Payments:</b><br/>           The Home Health Agency (HHA) update factor should be reduced to account for the high error rate found in OIG's review. The annual update was defined as the home health market basket percentage increase. (A-04-99-01194)</p>   | <p>Section 701 of the MMA changed the updates of home health rates from fiscal year to calendar year beginning in 2004, with the update for the last three quarters of 2004 equal to the market basket increase minus 0.8 percent.</p>  | \$600                     |
| <p><b>Payment for Services Furnished in Ambulatory Surgical Centers:</b><br/>           CMS should set rates that are consistent across sites and reflect only the costs necessary for the efficient delivery of health services and establish parity among ambulatory surgical centers (ASC) and outpatient departments. (OEI-05-00-00340; OEI-09-88-01003; A-14-98-00400; A-14-89-00221)</p> | <p>Section 626 of the MMA limited the ASC update starting April 1, 2004, then froze updates for a period beginning the last quarter of FY 2005, effectively reducing the payment advantage to ASCs for those procedure codes that are more highly paid in the surgical center compared to outpatient departments. Section 626 also mandated that CMS implement a new payment system that takes into account disparities in the costs of procedures performed in ASCs and the costs of procedures performed in hospital outpatient departments, which CMS implemented by regulation effective January 1, 2008.</p> | \$300                     |
| <p><b>Capped Rental Durable Medical Equipment:</b><br/>           CMS should eliminate the semiannual maintenance payment allowed for capped rental DME, pay only for repairs when needed, eliminate the 15-month rental option, and convert rentals to purchases after the 13<sup>th</sup> month. (OEI-03-00-00410)</p>   | <p>Section 5101 of the Deficit Reduction Act of 2005 (DRA) revised the payment rules for capped rental DME to require that ownership of the item transfer to the beneficiary after the 13<sup>th</sup> month and that Medicare pay for maintenance services on a cost-reimbursement basis.</p>  | \$200                     |
| <p><b>Medicaid Third Party Liability:</b><br/>           CMS should determine whether legislation is needed to explicitly include pharmacy benefit management companies in the Medicaid definition of a third party, require third parties to match their eligibility files</p>  | <p>Section 6035 of the DRA made several changes to strengthen Medicaid's third-party liability provisions, including clarification regarding pharmacy benefit managers. The section also includes</p>   | \$120                     |

| <b>OIG Recommendation</b>  | <b>Implementing Action</b>   | <b>Savings (millions)</b> |
|--|--|---------------------------|
| with Medicaid's eligibility files, and allow Medicaid up to 3 years to recover payments from liable third parties. (OEI-03-00-00030)   | requiring States to ensure that health insurers, as a condition of doing business in the State, provide requested coverage data, accept the State's right of recovery, and agree, conditionally, not to deny a claim solely on the basis of date of submission of the claim when the claim is submitted by the State within a 3-year period beginning on the date on which the item or service was furnished.              |                           |
| <b>Part B Drugs Average Sales Price:</b><br>CMS should adopt an alternate calculation of volume-weighted average sales price that is consistent with the results set forth in section 1847A(b)(3) of the Social Security Act. (OEI-03-05-00310)  | Section 112 of the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Extension Act of 2007 establishes a revised calculation method for calculating volume weighted average sales price for Medicare Part B drugs that comports with OIG's recommendation.   | \$100                     |
| <b>Medicaid Drug Rebates—Sales to Repackagers Excluded From Best Price Determinations:</b><br>Medicaid rebates were lost because sales to health maintenance organizations (HMO) were improperly excluded from drug manufacturers' best price determinations in FYs 1998 and 1999.<br><br>CMS should require drug manufacturers that excluded sales to HMOs from their best price calculations to repay the rebates and evaluate the policy guidance relating to exclusion of sales to other (non-HMO) repackagers from best price determinations. (A-06-00-00056) | CMS issued Medicaid Drug Rebate Program Release #47 in July 2000, reiterating that section 1927(c) of the Social Security Act requires that manufacturers include in the best price the lowest price available to, among other entities, any wholesaler, retailer, provider, and health maintenance organization. The release specifically stated that this includes sales to organized health care settings such as HMOs. | \$81                      |
| <b>Rebates for Physician-Administered Drugs:</b><br>CMS should encourage States to take actions to collect rebates on physician-administered drugs, especially single-source drugs. States should either use National Drug Codes (NDC) instead of procedure codes or link procedure codes to NDC for single source drugs. (OEI-03-02-00660)  | Section 6002 of the DRA requires States to provide for the collection and submission of utilization data needed to secure rebates for physician-administered drugs and provide that the utilization data for single source and specified multiple source physician-administered drugs be submitted using NDC numbers (unless the Secretary specifies an alternative coding system).  | \$15                      |
| <b>Administration for Children and Families</b>  |  |                           |
| <b>Availability of Health Insurance for Title IV-D Children:</b><br>Connecticut should either implement policies and procedures to require noncustodial parents to pay all or part of the Medicaid costs for their dependent children or establish a Statewide health insurance plan that provides reasonably priced, comprehensive coverage for children, with costs paid by noncustodial parents. (A-01-97-02506)  | The BBA established SCHIP to enhance Medicaid coverage provided to children and to allow States to create insurance options for families that exceed Medicaid resource and income limits. Under Connecticut law, applicants include noncustodial parents ordered to provide health insurance.  | \$5.7                     |

| <b>OIG Recommendation</b>  | <b>Implementing Action</b>   | <b>Savings (millions)</b> |
|--|--|---------------------------|
| <p><b>Triennial Reviews of Child Support Orders and Medical Support by Parents.</b><br/> OIG reviewed the effects of 1996 legislation that no longer required States to conduct periodic reviews and adjustments of child support orders (unless requested by a State agency or parent) and found that many States had, in effect, discontinued the reviews. We recommended actions to ensure that more periodic reviews would be initiated. In the context of this review, we also recommended taking action to increase medical support by parents.<br/> (OEI-05-98-00100)</p> | <p>Section 7307 of the DRA requires, for court orders that are issued or amended after enactment, that all States to look to the ability of either or both parents to provide medical support for their children. CBO estimated savings from section 7307 would accrue beginning in FY 2007. Additionally, the DRA, in section 7302, implemented our recommendation to increase periodic reviews by requiring States to adjust child support orders of families on the Temporary Assistance for Needy Families program every 3 years. CBO estimated net savings resulting from section 7302 to begin in FY 2009.</p> | <p>\$1</p>                |



## Appendix B: Notes to Tables 1 and 2

### Table 1

<sup>1</sup> The opening balance was adjusted upward \$22.9 million.

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

CIN: A-02-03-01020 NATIONAL GOVERNMENT SERVICES/EMPIRE—CMS subsequently determined that some previously disallowed costs were allowable reducing the disallowance by \$4,665,946.

CIN: A-02-01-00225 STATE OF VIRGINIA DEPARTEMT OF MEDICAL ASSISTANCE SERVICES—CMS disallowed additional costs totaling \$1,700,092.

CIN: A-04-97-01168 STATE OF FLORIDA—Based on the State’s analysis of actual claims data, CMS reduced the disallowance by \$8,051,359.

CIN: A-04-02-68936 STATE OF TENNESSEE—CMS subsequently determined that the State was not liable for eligibility determination errors, reducing the disallowance by \$9,347,100.

CIN: A-05-05-00040 STATE OF MINNESOTA—As a result of negotiations with the State during the appeals process, CMS reduced the original disallowance by \$1,353,542.

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

<sup>3</sup> Included are management decisions to disallow \$29.1 million that was identified in non-Federal audit reports.

<sup>4</sup> Due to administrative delays, many of which are beyond management control, resolution of the following 77 audits was not completed within 6 months of issuance; however, based upon discussions with management, resolution is expected before the end of the next semiannual reporting period:

|                    |  |
|--------------------|--|
| CIN: A-06-07-00041 | REVIEW OF AMP CALCULATION - MFR A, MAR 2008, \$268,000,000   |
| CIN: A-02-03-01029 | REVIEW OF RETROACTIVE SCHOOL HEALTH CLAIMS - NEW YORK CITY DEPT. OF EDUCATION, OCT 2006, \$259,433,325 |
| CIN: A-06-07-00039 | REVIEW OF AMP CALCULATION - MFR C, MAR 2008, \$101,000,000   |

|                    |   |
|--------------------|---|
| CIN: A-04-03-02027 | REVIEW OF MEDICIAD UPPER PAYMENT LIMIT CALCULATIONS IN ALABAMA, DEC 2005, \$73,432,381                    |
| CIN: A-02-04-01021 | REVIEW OF RETROACTIVE SCHOOL HEALTH CLAIMS - REST OF NEW YORK STATE, 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-06-07-00040 | REVIEW OF AMP CALCULATION - MFR B, MAR 2008, \$27,700,000   |
| 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-03-06-00564 | PA FOSTER CARE MAINTENANCE PAYMENT PHILADELPHIA OVER \$300/DAY, DEC 2007, \$11,693,989                    |
| CIN: A-03-05-00550 | AUDIT OF PA FOSTER CARE MAINTENANCE PAYMENTS - CASTILLE SAMPLE, SEP 2007, \$11,611,822                    |
| CIN: A-06-02-00034 | REV OF COST REPORTS & MEDICARE FEE-FOR-SERVICE PYMTS - SCOTT & WHITE, MAY 2003, \$8,229,574               |
| CIN: A-01-06-00007 | REVIEW OF RHODE ISLAND'S MEDICAID ADMINISTRATIVE COST CLAIMS - FY 2004 - FY 2005, MAR 2008, \$5,092,735   |
| CIN: A-04-04-02003 | MEDICARE OUTLIER PAYMENTS TO COMMUNITY MENTAL HEALTH CENTERS, APR 2006, \$4,762,036                       |
| CIN: A-09-01-00085 | AUDIT OF UCSDMC DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR SFYE 1998, SEP 2002, \$3,776,054             |
| 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-03-06-00565 | MD UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS, JAN 2008, \$2,162,248                                       |
| CIN: A-02-06-02011 | FOLLOW-UP REVIEW OF AFDC OVERPAYMENTS - NEW YORK CITY, OCT 2007, \$896,711                                |

|                    |   |
|--------------------|---|
| 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 | REVIEW OF UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS IN INDIANA, 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-02-07-02004 | FOLLOW-UP REVIEW OF AFDC OVERPAYMENTS - UPSTATE NEW YORK, OCT 2007, \$347,375   |
| 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-04-06-03509 | REVIEW OF REFUGEE RESETTLEMENT MEDICAL ASSISTANCE PAYMENTS IN FLORIDA, OCT 2007, \$285,402                                |
| CIN: A-05-05-00033 | MI - UNDISTRIBUTED CHILD SUPPORT COLLECTIONS, AUG 2006, \$257,859   |
| CIN: A-05-01-00094 | PAYMENTS TO KAISER OF OAKLAND FOR INSTITUTIONAL BENEFICIARIES, OCT 2002, \$229,656  |
| CIN: A-07-06-01035 | AUDIT OF QUALITY IMPROVEMENT ORGANIZATION - IOWA, OCT 2007, \$208,974   |
| CIN: A-01-04-01501 | NORTHEASTERN UNIVERSITY DHHS GRANT COSTS GRANT NOS. 9274, 4000 AND 4111, JAN 2005, \$194,890                              |
| CIN: A-02-06-02005 | UNDISTRIBUTABLE CHILD SUPPORT PAYMENTS - NEW JERSEY, FEB 2008, \$186,113  |

|                    |   |
|--------------------|---|
| 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 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-02-06-01023 | AUDIT OF QUALITY IMPROVEMENT ORGANIZATION - NEW YORK, MAR 2008, \$77,358  |
| CIN: A-05-01-00089 | ADDITIONAL BENEFITS REVIEW ON MANAGED CARE ORGANIZATION, OCT 2002, \$77,000   |
| CIN: A-09-06-00039 | MEDICARE INTEGRITY - AUDIT OF QUALITY IMPROVEMENT ORGANIZATION - WASHINGTON STATE, FEB 2008, \$73,636   |



|                    |   |
|--------------------|---|
| CIN: A-06-07-00009 | REVIEW OF CAREFLITE CONTRACT, JUN 2007,<br>\$68,841   |
| CIN: A-04-06-03510 | REVIEW OF REFUGEE RESETTLEMENT CASH<br>ASSISTANCE PAYMENTS IN FLORIDA, OCT 2007,<br>\$65,450  |
| CIN: A-04-05-02000 | AUDIT OF HHA THERAPY BILLINGS, SEP 2005,<br>\$63,425  |
| CIN: A-05-01-00086 | PAYMENTS TO HMO OF NE PA FOR<br>INSTITUTIONAL BENEFICIARIES, MAY 2002,<br>\$62,432  |
| CIN: A-03-02-00373 | REVIEW OF US HELPING US, DEC 2003, \$45,558   |
| CIN: A-01-03-01500 | REVIEW OF CDC HIV PROGRAMS AT GREATER<br>BRIDGEPORT ADOLESCENT PREGNANCY<br>PROGRAM, JUL 2003, \$41,088   |
| CIN: A-08-03-73541 | SOUTH DAKOTA FOUNDATION FOR MEDICAL<br>CARE, JAN 2003, \$28,573   |
| CIN: A-07-02-00150 | PAYMENTS TO COVENTRY-PITTSBURG FOR<br>INSTITUTIONAL BENEFICIARIES, JUN 2003,<br>\$26,000  |
| CIN: A-05-01-00078 | PAYMENTS TO HEALTH NET-TUCSON, AZ.- FOR<br>INSTITUTIONAL BENEFICIARIES, APR 2002,<br>\$21,233   |
| CIN: A-08-04-76779 | COLORADO FOUNDATION FOR MEDICAL CARE,<br>DEC 2003, \$18,925   |
| CIN: A-05-01-00100 | PAYMENTS TO FALLON HEALTH FOR<br>INSTITUTIONALIZED BENEFICIARIES, MAY 2002,<br>\$18,842   |
| CIN: A-05-01-00095 | PAYMENTS TO HUMANA OF ARIZONA FOR<br>INSTITUTIONAL BENEFICIARIES, JUN 2002,<br>\$18,645   |
| CIN: A-07-03-00151 | REVIEW OF MEDICARE PAYMENTS FOR<br>BENEFICIARIES WITH INSTITUTIONAL STATUS,<br>JUN 2003, \$18,400   |
| CIN: A-01-02-01504 | REVIEW OF CDC'S HIV PROGRAMS AT FENWAY<br>COMMUNITY HEALTH CENTER, JUN 2003, \$18,028   |
| CIN: A-07-04-01011 | PAYMENTS FOR UNITED HEALTHCARE FOR<br>INSTITUTIONAL BENEFICIARIES, MAR 2005,<br>\$13,128  |
| CIN: A-01-07-00603 | REVIEW OF RETIREE DRUG SUBSIDY PLAN<br>SPONSOR BLUE CROSS BLUE SHIELD OF<br>MASSACHUSETTS, INC., FOR PLAN YEAR ENDED<br>DECEMBER 31, 2006, JAN 2008, \$12,798 |
| CIN: A-05-06-00043 | REVIEW OF OHIO KEPRO, FEB 2008, \$11,874  |
| CIN: A-05-01-00070 | PAYMENTS TO GHP MCO/ST LOUIS FOR<br>INSTITUTIONAL BENEFICIARIES, JAN 2002,<br>\$11,089  |

|                    |   |
|--------------------|---|
| CIN: A-06-06-00014 | MEDICARE PRESCRIPTION DRUG CARD<br>PROGRAM: ACCLAIM, SEP 2006, \$8,800                          |
| CIN: A-07-07-04106 | COLORADO UNDISTRIBUTABLE CHILD SUPPORT<br>PAYMENTS, NOV 2007, \$8,336                           |
| CIN: A-03-03-00393 | AUDIT OF CDC HIV/AIDS GRANT TO SEXUAL<br>MINORITY YOUTH ASSISTANCE LEAGUE, OCT<br>2003, \$1,155 |

**TOTAL CINS: 77**

**TOTAL AMOUNT: \$999,528,707**

## Table 2

<sup>1</sup> The opening balance was adjusted downward by \$65.5 million.

<sup>2</sup> Management decision has not been made within 6 months on 12 reports.

Discussions with management are ongoing and it is expected that the following audits will be resolved by the next semiannual reporting period:

|                    |  |
|--------------------|--|
| CIN: A-06-07-00042 | INDEXING THE REBATE FOR GENERIC DRUGS, OCT 2007, \$966,000,000                   |
| CIN: A-09-04-00038 | WEDGE: LA COUNTY 1115 WAIVER, OCT 2006, \$285,200,000                            |
| CIN: A-04-01-02006 | MEDICAID DISPROPORTIONATE SHARE PAYMENTS IN ALABAMA, JUN 2004, \$45,763,327      |
| CIN: A-04-06-03508 | UNDISTRIBUTABLE CHILD SUPPORT COLLECTIONS - FLORIDA, JAN 2008, \$7,881,447       |
| CIN: A-05-02-00077 | MICHIGAN MEDICAID/SCHIP REVIEW, NOV 2003, \$5,908,350                            |
| CIN: A-03-02-00203 | VIRGINIA - SCHIP/TITLE IV - D 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-05-01-00070 | 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               |

**TOTAL CINS: 12**

**TOTAL AMOUNT: \$1,327,437,062**



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

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

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

| Section of the Act | Requirement   | Location   |
|--------------------|---|--|
| Section 4(a)(2)    | Review of legislation and regulations   | p. 64  |
| 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 <a href="http://www.oig.hhs.gov/publications.html">http://www.oig.hhs.gov/publications.html</a> |
| (a)(4)             | Matters referred to prosecutive authorities   | p. 36  |
| (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. 62  |
| (a)(9)             | Statistical Table 2 – Funds Recommended To Be Put to Better Use                     | p. 63  |
| (a)(10)            | Summary of previous audit reports without management decisions                      | Appendix B   |
| (a)(11)            | Description and explanation of revised management decisions                         | Appendix B   |
| (a)(12)            | Management decisions with which the Inspector General is in disagreement            | None   |



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

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

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

In response to the 2007 annual solicitation, OIG received the following proposals related to safe harbors:

| Proposal  | OIG Response   |
|---|--|
| New safe harbor for any arrangement that satisfies a physician self-referral statute exception.   | OIG is not adopting this suggestion at this time. The physician self-referral and anti-kickback statutes are different in nature and scope, and it may not be appropriate to adopt a safe harbor that effectively conforms the safe harbors to self-referral exceptions. |
| New safe harbor for compensation paid to physicians providing on-call coverage services in hospital emergency departments.  | OIG is not adopting this suggestion. On-call arrangements vary greatly and should be addressed on a case-by-case basis, such as under the advisory opinion procedures. OIG has addressed this topic in a recent advisory opinion (Ad. Op. No. 07-10).                    |
| Revocation of the group purchasing organization (GPO) safe harbor.  | OIG is not adopting this suggestion. The GPO safe harbor is statutory.   |
| New safe harbor to protect discounts, rebates, and other price concessions on prescription drugs given to Medicare Part D drug plan sponsors, retiree prescription drug plans, or their pharmacy benefit managers (PBM) by pharmaceutical manufacturers, subject to certain safeguards. | OIG is not adopting this suggestion at this time. This suggestion addresses a wide variety of arrangements and requires further study as OIG gains additional experience with the Part D program.  |
| New safe harbor for compensation arrangements between members of the same corporate family.   | OIG is not adopting this suggestion at this time. Arrangements within a corporate family can vary greatly and should be evaluated on a case-by-case basis, such as under the advisory opinion procedures.  |
| Clarification of the specialty referral safe harbor for certain collaborative relationships between advance practice nurses and physicians.   | OIG is not adopting this suggestion. The need for changes to the specialty referral safe harbor is not clear; the fact-specific circumstances described  |

| <b>Proposal</b>  | <b>OIG Response</b>   |
|--|---|
|  | should be evaluated on a case-by-case basis, such as under the advisory opinion procedures.   |
| New safe harbor for gainsharing arrangements between hospitals and medical staff physicians. | OIG is not adopting this suggestion at this time. The Centers for Medicare & Medicaid Services has developed a similar proposal under the physician self-referral statute. OIG may develop an anti-kickback statute safe harbor for similar arrangements in the future. |

In addition to the proposals in the preceding table (some of which are similar to proposals from past years), OIG has had under consideration a number of suggestions reported in past years. The following table updates the status of those suggestions:

| <b>Proposal</b>  | <b>OIG Response</b>  |
|--|--|
| New safe harbors for various types of patient assistance programs for financially needy beneficiaries, including charity models, pharmaceutical company models, Part B wraparound assistance, medication therapy management programs, and others.  | OIG is not adopting this suggestion at this time because it may be impracticable to develop an appropriate safe harbor given the variety of arrangements and the need for adequate safeguards and flexibility. OIG has issued guidance on this topic through a Special Advisory Bulletin (70 Fed. Reg. 70623) and numerous advisory opinions.  |
| Modification of the safe harbor for electronic health records (EHR) arrangements to (1) exclude commercial laboratories and laboratory operators from the category of protected EHR software donors, and (2) provide that donors cannot tie the donation of qualifying software to the acceptance and use of donor-specific interfaces, upgrades, or modifications.  | OIG is not adopting these suggestions at this time, as they require further study and experience with EHR arrangements. With respect to the first suggestion, in the preamble to the final rule, OIG expressed concern about potential abuses by laboratories and indicated that OIG would revisit protection for laboratory donors if abuses occurred. With respect to the second suggestion, OIG notes that the regulations already require interoperability and restrict donors from inhibiting the use, compatibility, or interoperability of donated items and services with other EHR systems. |
| Modification of the GPO safe harbor to clarify (1) the scope and nature of protected payments, (2) the application of the safe harbor to PBMs, (3) the application of the “wholly owned” standard, and (4) the treatment of administrative fees distributed by a GPO to its members.   | OIG is not adopting these suggestions at this time. The suggestions require further study and some of them may be impracticable given the statutory language of the GPO safe harbor.   |
| A new safe harbor protecting certain programs under which beneficiaries may receive a coupon for a limited quantity of a manufacturer’s product for free, as well as clarification of the treatment of patient coupons under the existing discount safe harbor.  | OIG is not adopting these suggestions. Manufacturer coupon arrangements are potentially subject to abuse and should be evaluated on a case-by-case basis, such as under the advisory opinion procedures.   |
| Modification of the discount safe harbor with respect to Medicare Part D plans to (1) incorporate documentation and disclosure standards for manufacturers, Part D plans, and certain other business relationships; and (2) clarify its application to the additional entities with which manufacturers may contract under the Medicare Prescription Drug Improvement, and Modernization Act of 2003 (e.g., pharmacy benefits managers, retail pharmacies, and | OIG is not adopting this suggestion at this time. This suggestion addresses a wide variety of arrangements and requires further study as OIG gains experience with the Part D Program.   |



| Proposal  | OIG Response  |
|---|---|
| Part D drug plan sponsors).   |   |
| New safe harbor for implementation of a communitywide health information network.   | OIG is not adopting this suggestion at this time, as it requires further study and experience with EHR arrangements.  |
| Modification of the existing safe harbor for obstetrical malpractice insurance subsidies to include (1) additional types of malpractice insurance and (2) subsidies for which there is documented need and the amounts are limited in scope and duration.   | OIG is not adopting this suggestion at this time, as it requires further study. OIG has addressed some of the issues raised in other guidance (e.g., Ad. Op. 04-19).  |
| A new safe harbor to cover (1) coinsurance waivers for inpatient services negotiated between a hospital and an Employee Retirement Income Security Act employee welfare benefit plan that covers retirees, and (2) Part B waivers for employer group plans.   | OIG is not adopting this suggestion. The need for a new safe harbor is not clear and the arrangements described are best addressed on a case-by-case basis, such as under the advisory opinion procedures. OIG has addressed a similar topic in a recent advisory opinion (Ad. Op. No. 07-15).                    |
| New safe harbor for inducements offered to beneficiaries that fit in an exception to the beneficiary inducements civil monetary penalties statute at 42 U.S.C. § 1320a-7a(a)(5).  | OIG is not adopting this suggestion at this time. The need generally for such a safe harbor is unclear, and the advisory opinion process is available for specific situations.  |
| Modification of the existing shared risk exception to cover (1) second-tier contractors of federally qualified health centers (FQHC), and (2) the TRICARE program.  | OIG is not adopting this suggestion. OIG previously adopted a safe harbor for FQHC arrangements (72 Fed Reg. 56632). The suggestion as it relates to TRICARE would require further study.   |
| Modification of the discount safe harbor to (1) include a discount that is both obtained by a commercial health plan that does not file claims with the Federal health care programs and otherwise meets the safe harbor conditions, (2) clarify its application to discounts applied to a manufacturer's full product line, (3) modify the reporting and disclosure requirements, and (4) standardize the requirements for offerors and sellers.   | OIG is not adopting these suggestions. The suggestions relate to a wide variety of arrangements that are potentially subject to abuse, and some of the modifications may be impracticable. Some of the suggestions require further study.   |
| Modification of existing safe harbors to conform them to the final regulations under the physician self-referral statute published by CMS and new safe harbors analogous to new self-referral exceptions created by the CMS regulations.  | OIG is not adopting these suggestions at this time. The self-referral and anti-kickback statutes are different in nature and scope, and it may not be appropriate to conform the safe harbors to the self-referral exceptions.  |
| Modification of the ambulatory surgical centers (ASC) safe harbor to (1) address protection of startup multispecialty ASCs that otherwise comply with the current safe harbor conditions, (2) add conditions under which hospitals would not be in positions to make or influence referrals to jointly owned ASCs, (3) specify whether an ASC can require investors to comply with safe harbor conditions, and (4) clarify (a) the use of "pass-through" entities to hold ownership interests and (b) the treatment of physician investors who invest at different times. | OIG is not adopting these suggestions at this time. ASC arrangements vary greatly, and the suggestions require further study in light of the many variations. OIG has issued a number of advisory opinions addressing ASC arrangements and issues raised by the suggestions (e.g., Ad. Op. Nos. 07-05 and 08-08). |

**Proposal****OIG Response**

|  |  |
|--|--|
| New safe harbor for rural health networks operating pursuant to the Medicare Rural Hospital Flexibility Program.   | OIG is not adopting this suggestion. The variety of arrangements potentially encompassed is not amenable to a single safe harbor and should be addressed on a case-by-case basis, such as under the advisory opinion procedures. |
| New safe harbor for arrangements that comply with section 513 of the Internal Revenue Service Code pertaining to the provision of certain supporting goods and services by tax-exempt hospitals to other tax-exempt hospitals. | OIG is not adopting this suggestion. The arrangements described vary and should be addressed on a case-by-case basis, such as under the advisory opinion procedures.   |

## **Appendix E: Summary of Sanction Authorities**

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

### **Program Exclusions**

Section 1128 of the Social Security Act (42 U.S.C. § 1320a–7) provides several grounds for excluding individuals and entities from participation in Medicare, Medicaid, and other Federal health care programs. Exclusions are required for individuals and entities convicted of the following types of criminal offenses: (1) Medicare or Medicaid fraud; (2) patient abuse or neglect; (3) felonies for other health care fraud; and (4) felonies for illegal manufacture, distribution, prescription, or dispensing of controlled substances. The Office of Inspector General (OIG) has the discretion to exclude individuals and entities on several other grounds, including misdemeanors for other health care fraud (other than Medicare or Medicaid) or for illegal manufacture, distribution, prescription, or dispensing of controlled substances; suspension or revocation of a license to provide health care for reasons bearing on professional competence, professional performance, or financial integrity; provision of unnecessary or substandard services; submission of false or fraudulent claims to a Federal health care program; or engaging in unlawful kickback arrangements.

Providers subject to exclusion are granted due process rights (including a hearing before an administrative law judge and appeals to the Department of Health and Human Services Departmental Appeals Board and Federal district and appellate courts) regarding whether the basis for the exclusion exists and the length of the exclusion is reasonable.

### **Patient Dumping**

Section 1867 of the Social Security Act (42 U.S.C. § 1395dd) provides that when an individual presents to the emergency room of a Medicare-participating hospital, the hospital must provide an appropriate medical screening examination to determine whether that individual has an emergency medical condition. If an individual has such a condition, the hospital must provide either treatment to stabilize the condition or an appropriate transfer to another medical facility.

If a transfer is ordered, the transferring hospital must provide stabilizing treatment to minimize the risks of transfer and ensure that the receiving hospital agrees to the transfer and has available space and qualified personnel to treat the individual. In addition, the transferring hospital must effect the transfer through qualified personnel and transportation equipment. Further, a participating hospital with specialized capabilities or facilities may not refuse to accept an appropriate transfer of an individual who needs services if the hospital has the capacity to treat the individual.

OIG is authorized to collect civil monetary penalties (CMP) of up to \$25,000 against small hospitals (fewer than 100 beds) and up to \$50,000 against larger hospitals (100 beds or more) for each instance in which the hospital negligently violated any of the section 1867 requirements. In addition, OIG may collect a penalty of up to \$50,000 from a responsible physician for each negligent violation of any of the section 1867 requirements and, in some circumstances, may exclude a responsible physician.

### **Civil Monetary Penalties Law**

Under the Civil Monetary Penalties Law (CMPL), section 1128A of the Social Security Act (42 U.S.C. § 1320a–7a), a person is subject to penalties, assessments, and exclusion from participation in Federal health care programs for engaging in certain activities. For example, a person who submits or causes to be submitted to a Federal health care program a claim for items and services that the person knows or should know is false or fraudulent is subject to a penalty of up to \$10,000 for each item or service falsely or fraudulently claimed, an assessment of up to three times the amount falsely or fraudulently claimed, and exclusion.

For the purposes of the CMPL, “should know” is defined to mean that the person acted in reckless disregard or deliberate ignorance of the truth or falsity of the claim. The CMPL 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 entity for the furnishing, or arranging for the furnishing, of any item or service payable under the Federal health care programs; or (2) purchasing, leasing or ordering, or arranging for or recommending the purchasing, leasing, or ordering of any good, facility, service, or item payable under the Federal health care programs (section 1128B(b) of the Social Security Act, 42 U.S.C. § 1320a–7b(b)).

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

■ **False Claims Amendments Act of 1986** – Under the Federal civil False Claims Amendments Act of 1986 (FCA) (31 U.S.C. §§ 3729–3733), a person or entity is liable for up to treble damages and a penalty between \$5,500 and \$11,000 for each false claim

it knowingly submits or causes to be submitted to a Federal program. Similarly, a person or entity is liable under the FCA if it knowingly makes or uses, or causes to be made or used, a false record or statement to have a false claim paid.

The FCA defines “knowing” to include not only the traditional definition but also instances in which the person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information. Under the FCA, no specific intent to defraud is required. Further, the FCA contains a qui tam, or whistleblower, provision that allows a private individual to file a lawsuit on behalf of the United States and entitles that whistleblower to a percentage of any fraud recoveries.



## Appendix F: Acronyms and Abbreviations

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

|      |  |
|------|--|
| ACF  | Administration for Children and Families   |
| ALJ  | Administrative Law Judge                   |
| AMP  | average manufacturer price                 |
| ANDA | Abbreviated New Drug Application           |
| ASC  | ambulatory surgical center                 |
| ASP  | average sales price                        |
| AWP  | average wholesale price                    |
| BBA  | Balanced Budget Act of 1997                |
| BBRA | Balanced Budget Refinement Act of 1999     |
| CBO  | Congressional Budget Office                |
| CCA  | certification of compliance agreement      |
| CCDF | Child Care and Development Fund            |
| CDC  | Centers for Disease Control and Prevention |
| CERT | Comprehensive Error Rate Testing           |
| CIA  | corporate integrity agreement              |
| CIN  | Central Identification Number              |
| CMP  | civil monetary penalty                     |
| CMPL | Civil Monetary Penalties Law               |
| CMS  | Centers for Medicare & Medicaid Services   |
| CoP  | conditions of participation                |
| CPG  | compliance program guidance                |
| CY   | calendar year                              |
| DME  | durable medical equipment                  |
| DOJ  | Department of Justice                      |
| DOL  | Department of Labor                        |
| DPM  | Division of Payment Management             |
| DPNA | denial of payment for new admissions       |
| DRA  | Deficit Reduction Act of 2005              |
| DSH  | disproportionate share hospital            |
| EHR  | electronic health record                   |
| EQRO | external quality review organization       |
| ERC  | Ethics Resource Center                     |
| ESRD | end stage renal disease                    |
| FBI  | Federal Bureau of Investigation            |
| FCA  | False Claims Act                           |
| FDA  | Food and Drug Administration               |
| FI   | fiscal intermediary                        |
| FQHC | federally qualified health center          |
| FR   | Federal Register                           |
| FUL  | Federal upper limit                        |
| FY   | fiscal year                                |

|         |  |
|---------|--|
| GPO     | group purchasing organization  |
| GSA     | General Services Administration  |
| HCFAC   | Health Care Fraud and Abuse Control Program                            |
| HCPCS   | Healthcare Common Procedure Coding System                              |
| HEAL    | Health Education Assistance Loan                                       |
| HHA     | home health agency   |
| HHS     | Department of Health and Human Services                                |
| HIPAA   | Health Insurance Portability and Accountability Act                    |
| HMO     | health maintenance organization  |
| HRSA    | Health Resources and Services Administration                           |
| IG      | Inspector General  |
| IMD     | institution for mental disease   |
| IPF     | inpatient psychiatric facility   |
| IT      | information technology   |
| LTC-DRG | long term care diagnosis-related group                                 |
| LTCH    | long term care hospital  |
| LTCP    | long term care pharmacy  |
| MA      | Medicare Advantage   |
| MAC     | maximum allowable costs  |
| MCO     | managed care organizations   |
| MFCU    | Medicaid Fraud Control Unit  |
| MFUOD   | Medicaid Fraud Unit Oversight Division                                 |
| MIP     | Medicaid Integrity Program   |
| MMA     | Medicare Prescription Drug, Improvement, and Modernization Act of 2003 |
| MSP     | Medicare secondary payer   |
| NCI     | National Cancer Institute  |
| NIEHS   | National Institute of Environmental Health Sciences                    |
| NIH     | National Institutes of Health  |
| OBRA    | Omnibus Budget Reconciliation Act of 1990, 1993                        |
| OCSE    | Office of Child Support Enforcement                                    |
| OGD     | Office of Generic Drugs  |
| OIG     | Office of Inspector General  |
| OMB     | Office of Management and Budget  |
| OMHA    | Office of Medicare Hearings and Appeals                                |
| OS      | Office of the Secretary  |
| PBM     | pharmacy benefit manager   |
| PCIE    | President's Council on Integrity and Efficiency                        |
| PCS     | personal care service  |
| PDIG    | Principal Deputy Inspector General                                     |
| PDP     | prescription drug plan   |
| P.L.    | Public Law   |
| PPS     | prospective payment system   |
| PSAO    | pharmacy services administrative organization                          |
| PSC     | Program Support Center   |
| QIC     | qualified independent contractor                                       |



|        |   |
|--------|---|
| QIO    | Quality Improvement Organization          |
| RO     | responsible official                      |
| SAUSA  | Special Assistant United States Attorney  |
| SCHIP  | State Children's Health Insurance Program |
| SFY    | State fiscal year                         |
| SNF    | skilled nursing facility                  |
| SSA    | Social Security Administration            |
| SSI    | Supplemental Security Income              |
| TANF   | Temporary Assistance for Needy Families   |
| UPIN   | unique physician identification number    |
| UPL    | upper payment limit                       |
| U.S.C. | United States Code                        |
| WAMP   | widely available market price             |

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